IDERA PHARMACEUTICALS, INC.
Form 10-K
March 12, 2015
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the Fiscal Year Ended December 31, 2014**

**OR**

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

**Commission File Number: 001-31918**

# IDERA PHARMACEUTICALS, INC.

**(Exact name of Registrant as specified in its charter)**

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

**(617) 679-5500**

**(Registrant s telephone number, including area code)**

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

| Title of Class: | Name of Each Exchange on Which Registered |
|---|---|
| **Common Stock, $.001 par value** | **Nasdaq Capital 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 þ

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to the filing requirements for the past 90 days. Yes þ No ¨

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $195,698,189 based on the last sale price of the registrant s common stock as reported on the Nasdaq Capital Market on June 30, 2014. As of February 19, 2015, the registrant had 117,836,092 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 8, 2015 are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this Form 10-K.

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## FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the documents we incorporate by reference contain 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, cash resources, 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, potentia continue, will, 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 I, Item 1A Risk Factors. These factors and the other cautionary statements made in this Annual Report on Form 10-K and the documents we incorporate by reference should be read as being applicable to all related forward-looking statements whenever they appear in this Annual Report on Form 10-K and the documents we incorporate by reference. In addition, any forward-looking statements represent our estimates only as of the date that this Annual Report on Form 10-K is filed with the Securities and Exchange Commission and should not be relied upon as representing our estimates as of any subsequent date. We do not assume any obligation to update any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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**PART I.**

**Item 1.** ***Business.***

**Overview**

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for oncology and rare diseases. We use two distinct proprietary drug discovery technology platforms to design and develop drug candidates. We developed these platforms based on our scientific expertise and pioneering work with synthetic oligonucleotides as therapeutic agents. Using our Toll-like receptor, or TLR, targeting technology, we design synthetic oligonucleotide-based drug candidates to act by modulating the activity of specific TLRs. In addition, using our gene silencing oligonucleotide, or GSO, technology, we are developing GSOs to turn off the messenger RNA, or mRNA, associated with disease causing genes. We consider our GSO technology to be a third generation antisense technology that can potentially reduce the immunotoxicity and increase the potency of earlier generation antisense and RNA interference, or RNAi, technologies.

Our business strategy focuses on the development of drug candidates for oncology and rare diseases, as we believe we can develop and commercialize targeted therapies on our own in disease indications characterized by small, well-defined patient populations with serious unmet medical needs. To the extent we seek to develop drug candidates for broader disease indications, we plan to execute early-stage development through proof-of-concept clinical trials and explore potential collaborative alliances to support late-stage development and commercialization.

***RESEARCH AND DEVELOPMENT PROGRAMS***

| Drug Candidate(s) | Indication / Application | Development Status |
|---|---|---|
| *Programs for the Modulation of Specific Toll-like Receptors* | | |
| *Oncology* | | |
| *B-cell Lymphomas with MYD88 L265P oncogenic mutation* | | |
| IMO-8400 | Waldenström s Macroglobulinemia | Phase 1/2 clinical trial Anticipated completion and data in the fourth quarter of 2015 |
| IMO-8400 | Diffuse Large B-Cell Lymphoma | Phase 1/2 clinical trial Currently screening patients for enrollment |
| *Immuno-oncology* | | |
| IMO-2055/IMO-2125 | Intratumoral Combination with Checkpoint Inhibitors | Two Phase 1/2 clinical trials Planned initiation of first trial in the second half of 2015 |
| *Rare Diseases* | | |
| IMO-8400 | Dermatomyositis | Phase 2 clinical trial Planned initiation by the end of 2015 |
| IMO-8400 | Duchenne Muscular Dystrophy | Phase 1/2 clinical trial Planned initiation in early 2016 |
| *Autoimmune Diseases* | | |
| IMO-9200 | Selected Autoimmune Disease | Preclinical studies and Phase 1 |

| | | |
|---|---|---|
| | | clinical trial in healthy subjects<br>ongoing |
| *Gene Silencing Oligonucleotides* | | |
| Discovery Candidates | Inhibition of Gene Expression by Targeting RNA | Research |

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*TLR Modulation Technology Platform*

TLRs play a central role in the innate immune system by regulating signaling cascades that stimulate inflammation. As a result, we believe TLRs are potential therapeutic targets for the treatment of a broad range of diseases. Using our chemistry-based platform, we have designed TLR antagonists and agonists to act by modulating the activity of targeted TLRs. A TLR antagonist is a compound that inhibits an immune response by downregulating the targeted TLR. A TLR agonist is a compound that stimulates an immune response through the targeted TLR.

Our TLR antagonist lead drug candidates are IMO-8400 and IMO-9200, which are both antagonists of TLR7, TLR8 and TLR9. We also have created compounds that are agonists of TLR3, TLR7, TLR8 and TLR9. Our TLR agonist lead drug candidates are IMO-2055 and IMO-2125, which are both agonists of TLR9.

Our lead drug candidate is IMO-8400, a novel synthetic oligonucleotide antagonist of TLR7, TLR8, and TLR9. Currently, we are developing IMO-8400 for the treatment of certain genetically defined forms of B-cell lymphoma and for the treatment of rare diseases. We also are conducting a Phase 1 clinical trial of IMO-9200 in healthy subjects, as well as additional preclinical studies of IMO-9200 for a selected autoimmune disease. In addition, we are planning to advance at least one of our TLR9 agonists, IMO-2055 or IMO-2125, into clinical development for intratumoral injection in combination with checkpoint inhibitors for selected oncology targets.

*IMO-8400 Development Program in Genetically Defined Forms of B-cell Lymphoma*

We are developing IMO-8400 for the treatment of certain B-cell lymphomas in which the MYD88 L265P oncogenic mutation is present. Oncogenic mutations are changes in the DNA of tumor cells that promote the survival and proliferation of tumor cells. MYD88 is an adaptor protein in the TLR signaling pathway that mediates TLR signaling. The MYD88 L265P oncogenic mutation has been reported to lead to increased TLR signaling and malignant proliferation in certain B-cell lymphomas, including Waldenström s macroglobulinemia, diffuse large B-cell lymphoma, or DLBCL, and other forms of B-cell malignancies, including Burkitt s lymphoma, cutaneous diffuse large B-cell lymphoma (leg type), chronic lymphocytic leukemia, gastric mucosa-associated lymphoid tissue lymphoma, marginal zone lymphoma, and splenic marginal zone lymphoma. Waldenström s macroglobulinemia is classified as a non-Hodgkin lymphoma of malignant lymphoplasmacytic B-cells that commonly involves the blood and bone marrow and may spread to almost any organ in the body. The cells typically produce immunoglobulin M, or IgM, resulting in high serum levels of the protein and, potentially, hyperviscosity syndrome, with thickening of the blood, decrease in circulation and oxygen delivery, and ultimately impaired function of almost any organ in the body. DLBCL is the most common form of non-Hodgkin lymphoma. It is fast growing and can arise in lymph nodes or outside of the lymphatic system. The diagnosis of DLBCL is based on microscopic evaluation of biopsy samples of a suspected tumor. Subtypes of DLBCL are often defined during the microscopic evaluation of the biopsy samples. Additional subtypes of DLBCL may be differentiated by further analysis, including gene expression.

We believe, based on independent research and our own preclinical research, that the inhibition of specific TLRs may be a useful approach in the treatment of certain B-cell lymphomas in which the MYD88 L265P oncogenic mutation is present. In independent research reported by investigators from the National Cancer Institute at the American Association for Cancer Research Annual Meeting in 2013, it was shown that the MYD88 L265P oncogenic mutation over-activated TLR7 and TLR9-mediated signaling and that inhibition of TLR7 and TLR9 promoted tumor cell death in preclinical models.

In addition, in preclinical studies of IMO-8400 that we presented in April 2014 at the American Association for Cancer Research Annual Meeting, and in August 2014 at both the 18th International Workshop on Waldenström s Macroglobulinemia and at the American Society of Hematology Meeting on Lymphoma Biology, IMO-8400 induced cell death in human Waldenström s macroglobulinemia tumor cells and in DLBCL tumor cells harboring the MYD88 L265P oncogenic mutation. These results were observed in preclinical studies evaluating IMO-8400 as a monotherapy and in combination with rituximab. Consistent with its proposed mechanism of action, IMO-8400 treatment in these studies inhibited cell signaling pathways that promote tumor cell survival and proliferation including those referred to scientifically as IRAK1/4, NF-KB, STAT3, p38, and

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BTK. Further, in these studies, IMO-8400 suppressed tumor cell production of cytokines, such as interleukin-10, or IL-10, that create a favorable microenvironment for tumor cell survival and proliferation. In addition, in preclinical studies in xenograft models, IMO-8400 decreased tumor burden in mice, even where treatment was initiated after tumors had become well established. In these same studies, tumor cells that did not harbor the MYD88 L265P oncogenic mutation were not affected by IMO-8400 treatment, demonstrating the specificity of the treatment effect in these cells.

Based on independent research, we believe that approximately 90% of patients with Waldenström s macroglobulinemia and approximately 10% of patients with DLBCL have the MYD88 L265P oncogenic mutation. We believe that this prevalence data, together with preclinical data generated by us with IMO-8400, supports our plans to develop IMO-8400 in Waldenström s macroglobulinemia and in DLBCL.

In December 2014, we announced that the U.S. Food and Drug Administration, or the FDA, had granted orphan drug designation for IMO-8400 for the treatment of Waldenström s macroglobulinemia. Orphan drug designation is granted by the FDA Office of Orphan Products Development to drugs intended to treat a rare disease or condition that affects fewer than 200,000 people in the United States. This designation provides certain incentives, including eligibility for federal grants, research and development tax credits, a waiver of Prescription Drug User Fee Act filing fees and a seven-year marketing exclusivity period, once the product is approved and as long as orphan drug designation is maintained.

Prior to commencing our ongoing clinical trials of IMO-8400, we conducted a Phase 1 clinical trial of IMO-8400 in healthy subjects and a Phase 2 clinical trial of IMO-8400 in patients with moderate to severe psoriasis. To date, we have administered more than 550 doses of IMO-8400 to more than 85 healthy subjects and patients.

*Phase 1/2 Clinical Trial of IMO-8400 in Waldenström s Macroglobulinemia.* In 2014, we initiated patient treatment in our ongoing open-label, dose-escalation Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia who have relapsed or were refractory to prior therapy. Objectives of the trial include evaluation of safety and tolerability of escalating IMO-8400 dose levels and assessment of IMO-8400 clinical activity using disease-specific international guidelines for classifying clinical response. In this trial, we are evaluating doses of 0.6, 1.2 and 2.4 mg/kg per week administered as subcutaneous injections for 24 weeks. For the 2.4 mg/kg dose level, we are administering IMO-8400 in two doses of 1.2 mg/kg per week. We expect to enroll up to approximately 30 patients in this trial.

As of January 31, 2015, we had enrolled patients at each of the three dose levels. In each case, we advanced dosing to the higher dose level upon the recommendation of an independent committee following its review of safety data from the trial. We plan to complete this trial and have the full data available during the fourth quarter of 2015.

*Phase 1/2 Trial of IMO-8400 in Diffuse Large B-cell Lymphoma.* We are also conducting an open-label, dose-escalation Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL who have relapsed or were refractory to prior therapy. With the concurrence of the FDA Center for Devices and Radiological Health, we plan to enroll in this trial only patients who are positive for the presence of the MYD88 L265P oncogenic mutation. Objectives of the trial include evaluation of safety and tolerability of escalating IMO-8400 dose levels and assessment of IMO-8400 clinical activity using disease-specific international guidelines for classifying clinical response. In this trial, we plan to evaluate escalating doses of 0.6, 1.2 and 2.4 mg/kg per week, administered as subcutaneous injections for 24 weeks. For each dose level, we are administering IMO-8400 subcutaneously in equally divided doses given twice per week. We expect to enroll up to approximately 30 patients in this trial. As of January 31, 2015, we had activated multiple clinical sites and initiated screening of potential study participants for the MYD88 L265P oncogenic mutation. We plan to complete this trial and have the full data available during 2016.

We believe that Waldenström s macroglobulinemia and DLBCL in patients with the MYD88 L265P oncogenic mutation are rare diseases with serious unmet medical needs, based on prevalence of the indications and our understanding of the current treatment paradigms. If we observe sufficient tolerability and a therapeutic effect in either or both of our Phase 1/2 clinical trials, we plan to meet with regulatory authorities to discuss the

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possibility of an accelerated clinical development and regulatory path for the applicable program. We cannot predict whether or when any of our drug candidates will prove effective or safe in humans, if we will be able to participate in FDA expedited review and approval programs, including breakthrough and fast track designation, or if they will receive regulatory approval.

*Companion Diagnostic for MYD88 L265P.* In May 2014, we entered into a collaboration with Abbott Molecular, Inc., or Abbott Molecular, for the development of a companion diagnostic that can be used to identify patients with the MYD88 L265P oncogenic mutation. Under the agreement, Abbott Molecular is primarily responsible for developing and obtaining regulatory approvals for the companion diagnostic test in accordance with an agreed development plan and regulatory plan and for making the companion diagnostic test commercially available in accordance with an agreed commercialization plan.

In November 2014, Abbott Molecular completed initial development of the prototype companion diagnostic for the MYD88 L265P oncogenic mutation. We have incorporated the prototype companion diagnostic into our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL.

*Application of TLR Agonists in Immuno-Oncology*

Our pipeline of drug candidates includes IMO-2055 and IMO-2125, two TLR9 agonists that may have potential applications as immune therapies for the treatment of cancer. Recent advancements in cancer immunotherapy have included the approval and late-stage development of multiple checkpoint inhibitors, which are therapies that target mechanisms by which tumor cells evade detection by the immune system. Because TLR9 agonists stimulate the immune system, we believe that there is a scientific rationale to evaluate the combination of our TLR9 agonists with checkpoint inhibitors. In independent research in preclinical cancer models, intratumoral injection of TLR9 agonists has potentiated the anti-tumor activity of checkpoint inhibitors. We believe that intratumoral injection of our TLR9 agonists activates a local immune response at the tumor which complements the systemic effect of the checkpoint inhibitors. We believe that these data support evaluation of combination regimens including a TLR9 agonist and a checkpoint inhibitor for the treatment of cancer.

We and our collaborators have previously conducted clinical trials of IMO-2055 and IMO-2125. In these clinical trials, IMO-2055 was evaluated as a monotherapy and in combination with other oncology therapeutics in more than 300 patients with various types of cancers, and IMO-2125 was evaluated in more than 95 patients with hepatitis C. To support future potential development in cancer, we have conducted preclinical studies in which our TLR9 agonists have demonstrated anti-tumor activity in combination with the checkpoint inhibitor ipilimumab, an anti-CTLA4 antibody marketed as Yervoy® by Bristol-Myers Squibb Company. In December 2014, we presented data at the American Association for Cancer Research (AACR) Tumor Immunology and Immunotherapy Meeting from a preclinical study in which IMO-2055 delivered intratumorally in combination with ipilimumab demonstrated potent and systemic anti-tumor activity in multiple preclinical cancer models, including increased and sustained inhibition of treated and distant tumor growth in preclinical models of lung, colon and bladder cancer compared to treatment with either agent alone. We are conducting preclinical studies to characterize potential combination regiments with various checkpoint inhibitors. We intend to initiate clinical development of either IMO-2055 or IMO-2125 in combination with these checkpoint inhibitors by submitting an investigational new drug application, or IND, for, and initiating, the first of two planned Phase 1/2 clinical trials in the second half of 2015.

*Program in Rare Diseases*

We are planning to initiate clinical development of IMO-8400 for the treatment of rare diseases. We have selected dermatomyositis and Duchenne muscular dystrophy, or DMD, as the first non-cancer rare diseases for which we plan to develop IMO-8400. We selected these indications for development based on the reported increase in TLR expression in these disease states, expression of cytokines indicative of key TLR-mediated pathways, the identification of prospective biomarkers for evaluation in early clinical trials and, with respect to dermatomyositis, the presence of auto-antibodies that can induce TLR-mediated immune responses. We

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anticipate commencing clinical development in these two indications by initiating a Phase 2 clinical trial in dermatomyositis by the end of 2015 and a Phase 1/2 clinical trial in DMD in early 2016.

In determining whether to proceed in these two rare diseases, we considered that multiple independent research studies across a broad range of autoimmune diseases, including both dermatomyositis and psoriasis, have demonstrated that the over-activation of TLRs plays a critical role in disease maintenance and progression. In autoimmune diseases, endogenous nucleic acids released from damaged or dying cells initiate signaling cascades through TLRs, leading to the induction of multiple pro-inflammatory cytokines. This inflammation causes further damage to the body s own tissues and organs and the release of more self-nucleic acids, creating a self-sustaining autoinflammatory cycle that contributes to chronic inflammation in the affected tissue, promoting disease progression. Research studies have shown a similar pathological amplification cycle in DMD, where endogenous nucleic acids are released from leaky dystrophin-deficient skeletal muscle cells. We believe that TLR antagonism has the potential to improve patient outcomes by disrupting these disease processes.

We believe that we demonstrated proof of concept for our approach of using TLRs to inhibit the over-activation of specific TLRs for the treatment of psoriasis and potentially other autoimmune diseases in a randomized, double-blind, placebo-controlled Phase 2 clinical trial of IMO-8400 that we conducted in patients with moderate to severe plaque psoriasis, a well-characterized autoimmune disease. In this trial, we evaluated IMO-8400 at four subcutaneous dose levels of 0.075, 0.15, 0.3, and 0.6 mg/kg, versus placebo, administered once weekly for 12 weeks in 44 patients. The trial met its primary objective as IMO-8400 was well tolerated at all dose levels with no treatment-related discontinuations, treatment-related serious adverse events or dose reductions. The trial also met its secondary objective of demonstrating clinical activity in psoriasis patients, as assessed by the Psoriasis Area Severity Index. We plan to present additional results from this Phase 2 clinical trial at a future medical congress. With our focus on rare diseases, like dermatomyositis and DMD, we do not currently plan to conduct further clinical development of IMO-8400 for the treatment of psoriasis.

*IMO-8400 Development Program for Dermatomyositis.* Myositis is a group of rare chronic inflammatory muscle disorders that cause muscle destruction and includes dermatomyositis. Major symptoms of dermatomyositis include muscle tissue loss, muscle weakness, joint pain and difficulty swallowing, with skin involvement resulting in rash and/or calcinosis. Potential complications of dermatomyositis include severe disability, interstitial lung disease and cancer. In this form of myositis, over-activated TLRs stimulate a pro-inflammatory response leading to further damage of muscle, skin and other tissue. Current treatments, including corticosteroids and immunosuppressive agents, often provide limited benefit or have unfavorable safety profiles, and there is a significant unmet medical need for new therapies to treat dermatomyositis.

In August 2014, we initiated a collaboration with The Myositis Association, or TMA, a leading U.S. patient advocacy organization focused on myositis, to advance the clinical development of IMO-8400 for the treatment of myositis. Under the collaboration, we and TMA agreed to develop educational programs for patients and healthcare providers on TLR antagonism and opportunities to participate in clinical research. In addition, we formed an advisory committee of leading independent experts in the treatment of myositis to advise us on the development of IMO-8400 in myositis. Based on these ongoing efforts, we have focused our development strategy on dermatomyositis, a form of the disease in which there is muscle and skin involvement. We are finalizing our clinical trial plan for a Phase 2 clinical trial of IMO-8400 in dermatomyositis and anticipate initiating this trial by the end of 2015. If this clinical trial is successful, we may evaluate the potential of IMO-8400 to treat additional forms of myositis.

*IMO-8400 Development Program for Duchenne Muscular Dystrophy*. DMD is an X-linked genetic disorder characterized by progressive muscle weakness leading to severe disability, pulmonary and cardiac dysfunction and death in affected males, typically before age 30. Patients with DMD lack dystrophin, a critical muscle protein, resulting in excessive muscle damage following normal exercise. Damaged muscle cells release endogenous nucleic acids that stimulate TLRs, thereby activating a pro-inflammatory response that propagates a cycle of further muscle cell damage and destruction. In a research article published in Human Molecular Genetics in January 2014, we and scientists from Children s National Medical Center, Washington, DC, reported

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that, in preclinical studies, over-expression of TLR7 exacerbated inflammation and caused muscle degeneration in an *mdx* mouse model of DMD. In addition, in studies with the *mdx* mouse model of DMD, an antagonist of TLR7 and TLR9 significantly reduced muscle inflammation and increased muscle force, providing support for TLR antagonism as a potential treatment approach for DMD.

Current pharmacologic treatment of DMD is generally limited to corticosteroids, which have been shown to have side effects in children including behavioral changes, short stature from slow growth rate, weight gain, facial puffiness known as Cushingoid appearance, and cataracts. The most advanced investigational therapies in development are designed to correct for certain genetic mutations, representing small percentages of the total affected DMD population, enabling production of new dystrophin protein. We believe TLR antagonism is a potential non-steroid-based anti-inflammatory treatment approach for all DMD patients regardless of their genetic mutation.

We are conducting additional preclinical studies of TLR antagonist drug candidates in DMD models and are working in collaboration with Parent Project Muscular Dystrophy, a leading U.S. patient advocacy organization, on the design of a clinical development program for IMO-8400 in DMD. We anticipate initiating a Phase 1/2 clinical trial of IMO-8400 in DMD in early 2016.

*Program in Autoimmune Diseases*

*IMO-9200 for Autoimmune Disease.* We have developed a second novel synthetic oligonucleotide antagonist of TLR7, TLR8, and TLR9, IMO-9200, as a drug candidate in clinical development for potential use in selected autoimmune disease indications. In October 2014, we initiated subcutaneous dosing in a Phase 1 clinical trial of IMO-9200 in healthy subjects. We have also initiated additional preclinical studies of IMO-9200 for a selected autoimmune disease.

*Gene Silencing Oligonucleotide Technology to Target RNA*

We are developing our GSOs to turn off the mRNA associated with disease causing genes. We have designed our GSOs to specifically address challenges associated with earlier generation antisense and RNAi technologies. Although currently used technologies to silence RNA have demonstrated the ability to inhibit the expression of disease-associated proteins, we believe that to reach their full therapeutic potential, gene silencing technologies need to achieve an improved therapeutic index with efficient systemic delivery without using a delivery technology, reduced immunotoxicity and increased potency. We have designed our GSOs to provide these attributes. For example, in preclinical studies, our GSOs have exerted gene-silencing activity in animals following systemic administration. Preclinical data also have shown that systemic delivery of GSOs targeted to the mRNA of apolipoprotein B and proprotein convertase subtilisin/kexin type 9 (PCSK9), which are proteins associated with cardiovascular diseases, resulted in reduced serum total cholesterol and low-density-lipoprotein cholesterol, in addition to reduced levels of the targeted mRNA and associated proteins. Additionally, in mouse models, systemic administration of GSOs showed significant specific gene-silencing activity with minimized induction of immune responses.

We are currently undertaking an analysis of oncology and rare disease indications for development of drug candidates from our GSO technology. Our key considerations in identifying disease indications in our GSO program include: strong evidence that the disease is caused by a specific protein; clear criteria to identify a target patient population; biomarkers for early assessment of clinical proof of concept; a targeted therapeutic mechanism for action; and unmet medical need to allow for a rapid development path to approval. We are planning to conduct disease model studies and begin IND-enabling development programs in each of the first two disease indications selected for further development in our GSO program in the second half of 2015.

*Collaboration Program in Vaccine Adjuvants.*

Vaccines are composed of one or more antigens and one or more adjuvants in an appropriate formulation. Antigens are substances that are capable of stimulating the production of specific antibodies or sensitized immune cells and reacting to those antibodies or sensitized immune cells. 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.

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In preclinical animal models, our TLR7, TLR8, and TLR9 agonists have shown adjuvant activity when combined with various types of antigens. Preclinical studies that we conducted with our TLR7, TLR8, and TLR9 agonists and various antigens have shown improvements in several measures of antigen recognition, such as achievement of higher antibody levels, higher ratios of specific to nonspecific antibodies, and a reduction in the number of doses required to achieve effective antibody levels. Based in part on these results, we believe that agonists of TLR7, TLR8, and TLR9 have the potential to be used as adjuvants in vaccines.

In December 2006, we entered into an exclusive license and research collaboration agreement with Merck Sharp & Dohme Corp. (formerly Merck & Co., Inc.), or Merck & Co., and granted Merck & Co. an exclusive license to develop and commercialize our TLR7, TLR8, and TLR9 agonists by incorporating them in therapeutic and prophylactic vaccines being developed by Merck & Co. for cancer, infectious diseases, and Alzheimer s disease. The original term of the research collaboration was two years, and Merck & Co. extended the research collaboration for two additional years to December 2010. During the four-year research collaboration period, multiple TLR agonists were created by us and evaluated by Merck & Co. against the criteria established in the collaboration agreement. In January 2012, in accordance with the research collaboration, Merck & Co. selected multiple novel TLR7, TLR8, and TLR9 agonists for Merck & Co. s exclusive evaluation and use as vaccine adjuvants under the current license agreement. In April 2014, we entered into an amendment to the agreement. As a result of this amendment, Merck & Co. s rights under the agreement were limited to specified TLR7, TLR8, and TLR9 agonists that Merck & Co. selected in January 2012, and we regained the rights to pursue our other independently discovered TLR7, TLR8, and TLR9 agonists for use as vaccine adjuvants in the fields of cancer, infectious diseases and Alzheimer s disease so that we now have the right to pursue our TLR7, TLR8, and TLR9 agonists for use as vaccine adjuvants in all fields.

**Other Collaborative Alliances**

To the extent we seek to develop drug candidates for broader disease indications, we plan to execute early-stage development through proof-of-concept clinical trials and explore potential collaborative alliances to support late-stage development and commercialization. We may also seek to enter into collaborative alliances with pharmaceutical companies with respect to applications of our GSO program. We are currently party to a collaboration with Merck & Co. and with Abbott Molecular.

*Merck & Co.*

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, TLR8, and TLR9 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, TLR8, and TLR9 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 under the agreement to the number of vaccines to which Merck & Co. could 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. s and our chemistry for use in vaccines in the defined fields. Under the terms of the agreement, Merck & Co. extended the research collaboration for two additional years to December 2010. Under the terms of the agreement:

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

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

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

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;

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

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

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

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

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

In January 2012, in accordance with the agreement, Merck & Co. selected multiple novel TLR7, TLR8, and TLR9 agonists for Merck & Co. s exclusive evaluation and use as vaccine adjuvants.

In April 2014, we entered into an amendment to the agreement. As a result of this amendment, Merck & Co. s rights under the agreement were limited to specified TLR7, TLR8, and TLR9 agonists that Merck & Co. selected in January 2012, and we regained the rights to pursue our other independently discovered TLR7, TLR8, and TLR9 agonists for use as vaccine adjuvants in the fields of cancer, infectious diseases and Alzheimer s disease so that we now have the right to pursue our TLR7, TLR8, and TLR9 agonists for use as vaccine adjuvants in all fields. Merck & Co. s obligations under the agreement to pay us milestone payments and royalties continue in effect with respect to the specified TLR7, TLR8, and TLR9 agonists. However, in connection with this amendment, we agreed that, to the extent that we license to third parties any TLR7, TLR8, and TLR9 agonists for use as vaccine adjuvants in the fields of cancer, infectious diseases and Alzheimer s disease and receive income under such licenses, Merck & Co. may credit against any milestone payments and royalties it owes to us an amount equal to 15% of the license income received by us under the third-party licenses, up to a maximum of $60.0 million in credits.

*Abbott Molecular*

In May 2014, we entered into a development and commercialization agreement with Abbott Molecular for the development of an in vitro companion diagnostic for use in our clinical development programs to treat certain genetically defined forms of B-cell lymphoma with IMO-8400. The agreement provides for the development and subsequent commercialization by Abbott Molecular of a companion diagnostic test utilizing polymerase chain reaction technology to identify with high sensitivity and specificity the presence in tumor biopsy samples of the oncogenic mutation referred to scientifically as MYD88 L265P. Under the agreement, Abbott Molecular is

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primarily responsible for developing and obtaining regulatory approvals for the companion diagnostic in accordance an agreed development plan and regulatory plan and for making the companion diagnostic test commercially available in accordance with an agreed commercialization plan. Abbott Molecular will retain all proceeds from commercialization of the companion diagnostic test. Subject to the terms of the agreement, we are required to pay Abbott Molecular fees and fund Abbott Molecular s development of the companion diagnostic test in an approximate aggregate amount of $6.7 million over an approximately five year development period, which includes clinical trial site costs and Abbott Molecular s costs of preparation and filing fees for regulatory submissions for the companion diagnostic with the FDA. This amount is subject to increase if Abbott Molecular incurs additional expenses in order to meet unexpected material requirements or obligations not included in the agreement or if we are required to conduct additional or different clinical trials which result in Abbott Molecular incurring additional costs.

The parties activities pursuant to the agreed development, regulatory and commercialization plans is governed by a joint steering committee, with Abbott Molecular retaining final decision making authority, subject to its obligations under the agreement, for development, manufacture and marketing of the companion diagnostic and our retaining final decision making authority, subject to our obligations under the agreement, for the development, manufacture and marketing of IMO-8400.

Under the agreement, each party grants the other party specified intellectual property licenses to enable the other party to perform its obligations and exercise its rights under the agreement, including license grants enabling Abbott Molecular to develop and commercialize the companion diagnostic test for use with IMO-8400 and enabling us to develop and commercialize IMO-8400 with Abbott Molecular s companion diagnostic test. The licenses granted by the parties to one another generally survive termination of the agreement. Abbott Molecular remains free to develop its companion diagnostic test for use with third party therapeutic products, and we remain free to engage third party diagnostics companies to develop other companion diagnostic tests for use with IMO-8400.

We are permitted to terminate the agreement for convenience upon 90 days written notice to Abbott Molecular and, under circumstances specified in the agreement, payment of a termination fee and wind-down costs. The parties also may terminate the agreement based on uncured material breaches by or the bankruptcy or insolvency of the other party, and each party has the right to terminate the agreement in the event of specified permanent injunctions based on infringement of third party intellectual property rights.

**Licensing Agreements**

We have not licensed any rights to our TLR technology to any third party other than in connection with the strategic alliance which we have entered into with Merck & Co., and have not in-licensed any technology for our TLR program. Similarly, we have not licensed any rights to our GSO technology to any third party. We have licensed specified rights related to antisense technology to certain parties. We also have in-licensed certain rights related to antisense technology.

*Licensing Agreement with Isis.* In 2001 we entered into an agreement with Isis Pharmaceuticals, Inc., or Isis, under which we granted Isis a license (with the right to sublicense) to our antisense chemistry and delivery patents and patent applications, but we retained the right to use these patents and applications in our own drug discovery and development efforts and in collaborations with third parties. Isis paid us $15.0 million in cash and issued 857,143 shares of its common stock having an aggregate fair market value on the dates on which title to the shares was received of $17.3 million and agreed to pay us a mid double-digit percentage of specified sublicense income it receives from some types of sublicenses of our patents and patent applications. As of December 31, 2014, we have received $0.3 million in sublicense income from Isis. Also under the agreement, we licensed from Isis specified antisense patents and patent applications, principally Isis suite of RNase H patents and patent applications. We paid to Isis $0.7 million and issued 1,005,499 shares of our common stock having a fair market value of approximately $1.2 million on the date of issuance for this license and are obligated to pay

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Isis an annual patent maintenance fee and low single-digit royalties on net sales of antisense products sold that are covered by Isis s patent rights. We have the right to use these patents and patent applications in our drug discovery and development efforts and in some types of third-party collaborations. As of December 31, 2014, we have only paid Isis annual maintenance fees and have not paid any royalties. The agreement may be terminated for an uncured material breach by either party. The licenses granted under the Isis agreement terminate upon the last to expire of the patents and patent applications licensed under the agreement. We may terminate at any time the sublicense by Isis to us of the patents and patent applications.

In addition, we are party to two other license agreements involving the license of our antisense patents and patent applications for antisense chemistry and delivery and for specific gene targets, under which we generally are entitled to receive license fees, sublicensing income, research payments, payments upon achievement of developmental milestones, and royalties on product sales. As of December 31, 2014, we had received a total of $1.5 million under these agreements.

**Academic and Research Collaborations**

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

**Research and Development Expenses**

For the years ended December 31, 2014, 2013 and 2012, we spent approximately $27.5 million, $10.5 million, and $13.7 million on research and development activities.

**Patents, Proprietary Rights and Trade Secrets**

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

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

Novel chemical entities that function as agonists of TLR3, TLR7, TLR8 or TLR9;

Novel chemical entities that function as antagonists of TLR7, TLR8 or TLR9;

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

Composition and use of our GSO compounds to treat and prevent a variety of diseases.

As of February 19, 2015, we owned more than 45 U.S. patents and patent applications and more than 80 patents and patent applications throughout the rest of the world for our TLR-targeted immune modulation

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technologies. These patents and patent applications include claims covering the chemical compositions of matter and methods of use of our IMO compounds, such as IMO-8400, IMO-9200, IMO-2055 and IMO-2125, as well as other compounds. As of February 19, 2015, all of our intellectual property covering immune modulatory compositions and methods of their use is based on discoveries made solely by us. These patents expire at various dates ranging from 2017 to 2031. With respect to IMO-8400, we have an issued U.S. patent that covers the chemical composition of matter of IMO-8400 and certain methods of its use that has a statutory expiration date in 2031. With respect to IMO-9200, we have a U.S. patent application that covers the chemical composition for IMO-9200 and methods of its use, which we would expect to expire, if issued, at the earliest in 2034. With respect to IMO-2055, we have issued patents that cover the chemical composition of matter of IMO-2055 and certain methods of its use, including in combination with marketed cancer products, with the composition claims expiring in 2023. With respect to IMO-2125, we have an issued U.S. patent that covers the chemical composition of matter of IMO-2125 and methods of its use that will expire in 2026.

As of February 19, 2015, we owned two issued U.S. patents, two pending U.S. patent applications and seven foreign patent applications related to our GSO compounds and methods of their use. The issued patents covering our GSO technologies have a statutory expiration date in 2030.

In addition to our TLR-targeted and GSO patent portfolios, we are the owner of or hold licenses to patents related to antisense technology. As of February 19, 2015, our antisense patent portfolio included more than 30 U.S. patents and more than 60 patents throughout the rest of the world. These antisense patents include novel compositions of matter, the use of these compositions for various genes, sequences and therapeutic targets, and oral and other routes of administration. Some of the patents and patent applications in our antisense portfolio were in-licensed. These in-licensed patents expire at various dates through 2021.

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.

Litigation may be necessary to defend against or assert claims of infringement, to enforce patents issued to us, to protect trade secrets or know-how owned by us, or to determine the scope and validity of the proprietary rights of others or to determine the appropriate term for an issued patent. In addition, the United States Patent and Trademark Office, or USPTO, may declare interference proceedings to determine the priority of inventions with respect to our patent applications or reexamination or reissue proceedings to determine if the scope of a patent should be narrowed. Litigation or any of these other proceedings could result in substantial costs to and diversion of effort by us, even if the eventual outcome is favorable to 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.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug, biological product or medical device approved pursuant to a pre-market approval may also be eligible for patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug is under regulatory review while the patent is in force. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date set for the patent. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be granted an extension and only those claims reading on the approved drug are extended. Similar

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provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug.

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.

**Manufacturing**

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

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

**Competition**

We are developing our TLR-targeted drug candidates for use in the treatment of certain genetically defined forms of B-cell lymphoma and rare diseases and in our immuno-oncology program. One of our drug candidates, IMO-8400, is in clinical development for the treatment of certain B-cell lymphomas in which the MYD88 L265P oncogenic mutation is present. We plan to initiate clinical trials of IMO-8400 in dermatomyositis and DMD. We are also planning to conduct Phase 1/2 clinical trials of either IMO-2055 or IMO-2125 in combination with a checkpoint inhibitor for selected oncology targets in our immuno-oncology program. Finally, we may seek to enter into collaborative alliances with pharmaceutical companies to advance our TLR antagonist candidates in broader autoimmune disease indications. For all of these disease areas, there are many other companies, public and private, that are actively engaged in discovery, development, and commercializing products and technologies that may compete with our drug candidates and programs, including TLR-targeted compounds as well as non-TLR-targeted therapeutics.

We are developing IMO-8400 for the treatment of certain genetically defined forms of B-cell lymphoma. There are currently no drugs specifically approved for the treatment of Waldenström s macroglobulinemia or DLBCL with the MYD88 L265P oncogenic mutation other than ibrutinib, which is marketed as Imbruvica® by Pharmacyclics, Inc. and was approved in January 2015 for the treatment of Waldenström s macroglobulinemia in the United States. Currently, patients with any form of non-Hodgkin lymphoma are most often treated with the monoclonal antibody rituximab and/or with one or more chemotherapeutic agents. Rituximab is co-marketed in the United States by Biogen Idec Inc. and Genentech Inc. and F. Hoffmann-La Roche AG, or Hoffmann-La Roche, and Chugai Pharmaceutical Co., Ltd. in territories outside the United States. We are aware of additional compounds in development for the treatment of genetically defined forms of B-cell lymphoma, including an inhibitor of interleukin-1 receptor-associated kinase 4, which is being developed by Nimbus Discovery, Inc.

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Our principal competitor developing TLR antagonist targeted compounds for rare diseases is Dynavax Technologies Corporation, or Dynavax. In addition, we are aware that other companies including Dynavax, InDex Pharmaceuticals AB, Mologen AG, BioLineRx Ltd., Innate Immunotherapeutics Ltd., VentiRx Pharmaceuticals Inc., Telormedix S.A., Gilead Sciences Inc., GlaxoSmithKline plc, AstraZeneca plc and Hoffmann-La Roche are developing TLR agonists for various indications, some of which are in the field of oncology.

Many of the drug development programs in dermatomyositis are focusing on expanding the use of drugs approved in different indications through investigator sponsored studies such as the ongoing studies of the monoclonal antibodies, belimumab and tocilizumab. In addition, Novartis is developing a competitive anti-inflammatory approach with its new investigational drug, BAF312, a sphingosine-1-phosphate receptor modulator aimed at inhibiting the migration of lymphocytes to the location of inflammation. We are not aware of other new chemical or molecular entities being developed for the treatment of dermatomyositis.

Competitors with respect to our DMD program include ReveraGen BioPharma, Inc., or ReveraGen, and Catabasis Pharmaceuticals, Inc., or Catabasis, both whom are pursuing novel anti-inflammatory approaches for the treatment of DMD. ReveraGen is conducting a Phase 1 healthy volunteer study and Catabasis has announced its plans to conduct a Phase 2 clinical trial in DMD patients in the first half of 2015. In addition, Sarepta Therapeutics Inc. and BioMarin Pharmaceuticals Inc. (following its acquisition of Prosensa Holding N.V.) each have RNA-based drug candidates targeted at treating genetically defined subsets of DMD in late stage development. PTC Therapeutics, Inc. also has a drug candidate targeted at treating a genetically defined subset of DMD that is conditionally approved for the treatment of DMD in Europe, and is currently being evaluated in a Phase 3 clinical trial. We believe that these dystrophin replacement therapeutic approaches, as well as other therapeutic approaches being pursued for the treatment of DMD, including anti-inflammatory, muscle blood flow, reducing fibrosis, increasing muscle mass, supporting muscle integrity and cardioprotective approaches being pursued by multiple companies, have the potential to be complementary to our TLR antagonist approach.

Immuno-oncology, which utilizes a patient s own immune system to combat cancer, is currently an active area of research for biotechnology and pharmaceutical companies. Interest in immuno-oncology is driven by recent efficacy data in cancers with historically bleak outcomes and the potential to achieve a cure or functional cure for some patients. As such, our efforts in this field will be competitive with a wide variety of different approaches. Any one of these competitive approaches may result in the development of novel technologies that are more effective, safer or less costly than any that we are developing. In addition, Dynavax is conducting a Phase 1/2 clinical trial of an investigational TLR9 agonist in combination with checkpoint inhibitors.

We are also developing GSOs that we have created using our proprietary technology, to inhibit the production of disease-associated proteins by targeting RNA. We also face competition from other companies working to develop novel drugs using technologies that may compete with our GSO technology. We are aware of multiple companies that are developing technologies that use oligonucleotide-based compounds to inhibit the production of disease associated proteins. These technologies include, but are not limited to, antisense technology as well as RNAi. In the field of antisense technologies, we compete with multiple companies, including Isis Pharmaceuticals, or Isis, and its partners. Isis is currently marketing an antisense drug, Kynamro, and has several antisense drug candidates in clinical trials. In the field of RNAi, our primary competition is with Alnylam Pharmaceuticals, Inc., or Alnylam, and its partners. Alnylam is currently developing multiple RNAi-based technologies and has several drug candidates in clinical trials. Any of the competing companies may develop gene-silencing technologies more rapidly and more effectively than us, and antisense technology and RNAi may become the preferred technology for drugs that target RNA in order to inhibit the production of disease-associated proteins.

Some of these potentially competitive products have been in development or commercialized for years, in some cases by large, well established pharmaceutical companies. Many of the marketed products have been accepted by the medical community, patients, and third-party payors. Our ability to compete may be affected by

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the previous adoption of such products by the medical community, patients, and third-party payors. Additionally, in some instances, insurers and other third-party payors seek to encourage the use of generic products, which makes branded products, such as our drug candidates, potentially less attractive, from a cost perspective, to buyers.

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

We anticipate that the competition with our drug candidates and technologies will be based on a number of factors including product efficacy, safety, availability, and price. The timing of market introduction of our drug candidates 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, protect our intellectual property, and to secure sufficient capital resources for the period between technological conception and commercial sales.

**Government Regulation**

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

*Review and Approval of Drugs in the United States*

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

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA s good laboratory practice, or GLP, regulations;

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submission to the FDA of an IND, which must take effect before human clinical trials may begin in the United States;

approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;

performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;

preparation and submission to the FDA of a new drug application, or NDA;

review of the product by an FDA advisory committee, where appropriate or if applicable;

satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product s identity, strength, quality and purity;

satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;

payment of user fees and securing FDA approval of the NDA; and

compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, where applicable, and post-approval studies required by the FDA.

*Preclinical Studies*

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, are submitted to the FDA as part of an IND. Additional preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

*Human Clinical Studies in Support of an NDA*

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

Typically, the FDA will require one IND for early development studies where the sponsor is uncertain of the indication or dosage form of the proposed product, where the drug is being developed for closely related indications within a single review division at FDA, or where there are multiple closely-related routes of administration using the same dosage formulation. On the other hand, multiple INDs may be required where there are two or more unrelated conditions being developed or where multiple dosage forms are being extensively investigated or where multiple routes of administration are being evaluated.

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In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

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

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

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

*Phase 3:* The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB s requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

*Section 505(b)(2) NDAs*

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA s previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

Thus, Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the Section 505(b)(2) applicant can establish that reliance on the FDA s previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or

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measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

*Submission of an NDA to the FDA*

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical and clinical studies, together with detailed information relating to the product s chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee, currently exceeding $2.1 million, and the sponsor of an approved NDA is also subject to annual product and establishment user fees, currently exceeding $104,000 per product and $554,000 per establishment. These fees are typically increased annually.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA s receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for priority review products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections cover all facilities associated with an NDA submission, including drug component manufacturing (such as Active Pharmaceutical Ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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*Fast Track, Breakthrough Therapy and Priority Review Designations*

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product s NDA before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA s time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as breakthrough therapies. A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA s goal for taking action on a marketing application from ten to six months.

*Accelerated Approval Pathway*

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

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For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor s agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug s clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

*The FDA s Decision on an NDA*

On the basis of the FDA s evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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

*Post-Approval Requirements*

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the

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product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

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

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

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

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

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

*Abbreviated New Drug Applications for Generic Drugs*

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD.

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Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is bioequivalent to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug.

Upon approval of an ANDA, the FDA indicates whether the generic product is therapeutically equivalent to the RLD in its publication Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the Orange Book. Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA s designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

*Hatch-Waxman Patent Certification and the 30-Month Stay*

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant s product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

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

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

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for

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

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

*Pediatric Studies and Exclusivity*

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the FDASIA in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA s internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in the FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA s request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

*Orphan Drug Designation and Exclusivity*

Under the Orphan Drug Act, the FDA may designate a drug product as an orphan drug if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product

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designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation, the product generally will receive orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

*Patent Term Restoration and Extension*

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Amendments, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product s approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

*Review and Approval of Drug Products in the European Union*

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

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. Clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a drug under European Union regulatory systems, an applicant must submit a marketing authorization application, or MAA, either under a centralized or decentralized procedure.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. The centralized procedure is compulsory for

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specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the European Medicines Agency, or EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various European Union member states where such product has not received marketing approval in any European Union member states before. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state s assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

*Orphan Drug Designation and Exclusivity*

Regulation 141/2000 provides that a drug shall be designated as an orphan drug if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Community when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Community and that without incentives it is unlikely that the marketing of the drug in the European Community would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Community or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Regulation 847/2000 sets out criteria and procedures governing designation of orphan drugs in the EU. Specifically, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities

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of the product, demonstration of clinically relevant superiority by a similar medicinal product, or, after a review by the Committee for Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs pursuant to Regulation 141/2000 shall be eligible for incentives made available by the European Community and by the member states to support research into, and the development and availability of, orphan drugs.

*Pharmaceutical Coverage, Pricing and Reimbursement*

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

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

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

*Healthcare Law and Regulation*

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

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the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

the federal transparency requirements under the Health Care Reform Law require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; and

analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

**Employees**

As of February 19, 2015, we employed 45 individuals, 25 of whom are engaged in research and development and 14 of whom 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.

**Corporate Information**

We were incorporated in Delaware in 1989 and our offices are located at 167 Sidney Street, Cambridge, Massachusetts 02139 and 760 Constitution Drive, Suite 14, Exton, Pennsylvania 19341.

**Information Available on the Internet**

Our internet address is www.iderapharma.com. The contents of our website are not part of this Annual Report on Form 10-K and our internet address is included in this document as an inactive textual reference. We make available free of charge through our web site our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission, or the SEC.

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

**RISK FACTORS**

*Investing in our securities 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. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks or uncertainties. In that case, the market price of our common stock could decline, and you may lose all or part of your investment in our securities.*

## Risks Relating to Our Financial Results and Need for Financing

***We will need additional financing, which may be difficult to obtain. Our failure to obtain necessary financing or doing so on unattractive terms could result in the termination of our operations and the sale and license of our assets or otherwise adversely affect our research and development programs and other operations.***

We had cash, cash equivalents and investments of approximately $48.6 million at December 31, 2014. In February 2015, we received net proceeds of approximately $80.6 million from a follow on public offering. We believe that our existing cash, cash equivalents and investments, including the estimated net proceeds from the offering, will enable us to fund our operations into the first quarter of 2017. Specifically, we believe that our available funds will be sufficient to enable us to:

- complete our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia and our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL harboring the MYD88 L265P oncogenic mutation;
- initiate two Phase 1/2 clinical trials involving either IMO-2055 or IMO-2125 in combination with a checkpoint inhibitor for selected oncology targets and complete at least one of these trials;
- initiate a Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis and a Phase 1/2 clinical trial of IMO-8400 in patients with DMD;
- complete our ongoing Phase 1 clinical trial of IMO-9200 in healthy subjects; and
- conduct disease model studies and begin IND-enabling development programs in each of the first two disease indications selected for further development in our GSO program.

We expect that we will require substantial additional funds to conduct any additional research and development of our TLR drug candidates or GSO technology, including preclinical testing and clinical trials of our drug candidates, and to fund our operations. We are seeking and expect to continue to seek additional funding through collaborations, the sale or license of assets or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain funding are:

- the results of our clinical and preclinical development activities in our genetically defined forms of B-cell lymphoma and rare disease programs, our immuno-oncology program, and our GSO program and our ability to advance our drug candidates and GSO technology on the timelines anticipated;
- the cost, timing, and outcome of regulatory reviews;

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

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

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

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In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require additional funds or further cost reductions.

Financing may not be available to us when we need it or may not be available to us on favorable or acceptable terms or at all. 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. An equity financing that involves existing stockholders may cause a concentration of ownership. 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 or equity financing may contain terms which are not favorable to us or to our stockholders, such as liquidation and other preferences, or liens or other restrictions on our assets. As discussed in Note 10 to the financial statements appearing elsewhere in this Annual Report on Form 10-K, additional equity financings may also result in cumulative changes in ownership over a three-year period in excess of 50% which would limit the amount of net operating loss and tax credit carryforwards that we may utilize in any one year.

If we are unable to obtain adequate funding on a timely basis or at all, we will be required to terminate, modify or delay preclinical or clinical trials of one or more of our drug candidates, significantly curtail or terminate discovery or development programs for new drug candidates or relinquish rights to portions of our technology, drug candidates and/or products.

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

We have incurred losses in every year since our inception, except for 2002, 2008, and 2009 when our recognition of revenues under license and collaboration agreements resulted in our reporting net income for those years. As of December 31, 2014, we had an accumulated deficit of $451.5 million. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 to December 31, 2014, we incurred losses of $191.3 million. We incurred losses of $260.2 million prior to December 31, 2000, during which time we were primarily involved in the development of non-TLR-targeted antisense technology. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, total assets, and working capital.

We have never had any products of our own available for commercial sale and have received no revenues from the sale of drugs. As of December 31, 2014, substantially 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 have not completed development of any drug candidates. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our drug candidates will become commercially available, or when we will become profitable, if at all. We expect to incur substantial operating losses in future periods.

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**Risks Relating to Our Business, Strategy and Industry**

***We are depending heavily on the development of TLR-targeted drug candidates for the treatment of certain genetically defined forms of B-cell lymphoma and rare diseases and in our immuno-oncology program and on the development of our GSO technology. If we terminate the development of any of our programs or any of our drug candidates in such programs, are unable to successfully develop and commercialize any of our drug candidates, or experience significant delays in doing so, our business may be materially harmed.***

We have invested a significant portion of our time and financial resources in the development of TLR-targeted clinical stage lead drug candidates as part of our rare disease program. In the future, we intend to invest a significant portion of our time and financial resources in the development of our TLR-targeted candidates for the treatment of certain genetically defined forms of B-cell lymphoma and rare diseases and in our immuno-oncology program. We also plan to invest substantial time and resources to further advance the development of our GSOs under our GSO program. For instance:

- we initiated a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia and a Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL harboring the MYD88 L265P oncogenic mutation;
- we are planning to conduct two Phase 1/2 clinical trials involving either IMO-2055 or IMO-2125 in combination with a checkpoint inhibitor for selected oncology targets;
- we are planning to conduct a Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis and a Phase 1/2 clinical trial of IMO-8400 in patients with DMD;
- we initiated a Phase 1 clinical trial of IMO-9200 in healthy subjects; and
- we are planning to conduct disease model studies and begin IND-enabling development programs in each of the first two disease indications selected for further development in our GSO program.

We anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of our TLR drug candidates in our genetically defined forms of B-cell lymphoma, rare disease and immuno-oncology programs, and the successful identification, development and commercialization of drug candidates in our GSO program.

Our ability to generate product revenues under our collaboration with Merck & Co. and under any other collaboration that we enter into with respect to our other programs, will depend on the development and commercialization of the drug candidates being developed.

Our efforts, and the efforts of Merck & Co., to develop and commercialize these compounds are at an early stage and are subject to many challenges. We have experienced setbacks with respect to our programs for IMO-3100, a TLR7 and TLR9 antagonist, IMO-2125, and IMO-2055, including:

- In July 2011, the FDA placed a clinical hold on the protocol that we had submitted for a phase 2 clinical trial of IMO-3100 that we planned to conduct in patients with psoriasis in light of some reversible immune responses that were observed in 13-week nonclinical toxicology studies of IMO 3100 that were inconsistent with observations made in our other nonclinical studies of IMO-3100.
- In April 2011, we chose to delay initiation of our planned 12-week Phase 2 randomized clinical trial of IMO-2125 plus ribavirin in treatment-naïve, genotype 1 hepatitis C virus, or HCV, patients based on observations of lymphoproliferative malignancies in an ongoing 26-week chronic nonclinical toxicology study of IMO-2125 in rodents. We subsequently completed a 39-week chronic nonclinical toxicology study of IMO-2125 in non-human primates in which there were no similar observations.

In July 2011, Merck KGaA, Darmstadt, Germany, or Merck KGaA, a former collaborator, informed us that, based on increased incidence of neutropenia and electrolyte imbalances reported in its Phase 1 clinical trial of IMO-2055 in combination with cisplatin/5-FU and cetuximab in patients with first-line

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squamous cell carcinoma of the head and neck, or SCCHN, and subsequent re-evaluation of its clinical development program, Merck KGaA had determined that it would not conduct further clinical development of IMO-2055. In May 2012, we announced that in a Phase 2 clinical trial of IMO-2055 in combination with cetuximab in patients with second-line SCCHN, the combination of IMO-2055 and cetuximab did not meet the primary endpoint of the trial.

We are conducting multiple clinical trials of IMO-8400 in different indications. If patients in any of these trials experience adverse safety events, we may be required to delay, discontinue or modify all of our clinical trials of IMO-8400.

We may seek to enter into collaborative alliances with pharmaceutical companies to advance our TLR antagonist candidates in broader autoimmune disease indications and with respect to applications of our GSO technology program. Our previous setbacks with respect to our programs for IMO-3100, IMO-2125, and IMO-2055 could negatively impact our ability to license any of such compounds to a third party.

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

- the drug candidates demonstrating activity in clinical trials;
- the drug candidates demonstrating an acceptable safety profile in nonclinical toxicology studies and during clinical trials;
- timely enrollment in clinical trials of IMO-8400 and other drug candidates, which may be slower than anticipated, potentially resulting in significant delays;
- satisfying conditions imposed on us and/or our collaborators by the FDA or equivalent foreign regulatory authorities regarding the scope or design of clinical trials;
- the ability to demonstrate to the satisfaction of the FDA, or equivalent foreign regulatory authorities, the safety and efficacy of the drug candidates through current and future clinical trials;
- timely receipt of necessary marketing approvals from the FDA and equivalent foreign regulatory authorities;
- the ability to combine our drug candidates and the drug candidates being developed by Merck & Co. and any other collaborators safely and successfully with other therapeutic agents;
- achieving and maintaining compliance with all regulatory requirements applicable to the products;
- establishment of commercial manufacturing arrangements with third-party manufacturers;
- the successful commercial launch of the drug candidates, assuming FDA approval is obtained, whether alone or in combination with other products;
- acceptance of the products as safe and effective by patients, the medical community, and third-party payors;

competition from other companies and their therapies;

changes in treatment regimens;

the strength of our intellectual property portfolio in the United States and abroad; and

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

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***We have recently begun to focus our efforts on the research and development of drug candidates for use in the treatment of certain genetically defined forms of B-cell lymphoma, and our approach for the treatment of these genetically defined B-cell lymphomas is novel and may not result in any approved and marketable products.***

We are in the early stages of developing our program in genetically defined forms of B-cell lymphoma, an area in which we have little experience. In connection with this program, we are focusing our efforts on the research and development of TLR antagonist drug candidates for use in the treatment of certain genetically defined forms of B-cell lymphoma. The scientific evidence to support the feasibility of developing drug candidates for this use is both preliminary and limited. We have conducted preclinical studies in human lymphoma cell lines that carry the MYD88 L265P oncogenic mutation to evaluate our TLR antagonists as a potential approach to the treatment of certain genetically defined forms of B-cell lymphoma. Although the preliminary results of our preclinical studies have been promising, it is unknown whether these results are indicative of results that may be obtained in our clinical trials. Therefore, we do not know if our approach of inhibiting TLRs to treat patients with genetically defined forms of B-cell lymphoma will be successful or if we will ever succeed in obtaining regulatory approval to market any product for this purpose. In addition, in the event that our development efforts for such a drug candidate progress towards commercialization, we likely will need to develop companion diagnostics for such drug candidate. We have no experience in developing companion diagnostics and will be dependent on the efforts of third-party collaborators to successfully develop and commercialize these companion diagnostics on our behalf. In May 2014, we entered into an agreement with Abbott Molecular to develop a companion diagnostic for identification of patients with B-cell lymphomas harboring the MYD88 L265P oncogenic mutation. We cannot assume that the program under this agreement will be successful.

***We are in the early stages of developing our GSO program, which is a novel technology, and our efforts may not be successful or result in any approved and marketable products.***

We are in the early stages of developing our GSO technology program, and the scientific evidence to support the feasibility of developing drugs based on this technology is preliminary. Further, neither we nor any other company has received regulatory approval to market therapeutics utilizing GSOs.

The future success of our GSO technology program depends on our success in identifying and developing marketable products based on such technology. Although the results of our preclinical studies to date have been supportive of the viability of this technology, it is unknown whether these results are indicative of results that may be obtained in any future clinical trials that we may conduct. We are currently undertaking an analysis of priority oncology and rare disease indications and development strategies to determine next steps in developing our GSO technology, and are planning to conduct disease model studies and begin IND-enabling development programs in each of the first two disease indications selected for further development in our GSO program in the second half of 2015. However, many steps must be successfully achieved prior to the declaration of a GSO-based drug candidate and the initiation of clinical development. Given the level of uncertainty of our ability to successfully achieve these many steps and the uncertainty of the drug discovery and clinical development processes in general, there can be no assurance that we will succeed in developing any marketable product as a result of our efforts with respect to our GSO technology program.

***If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In particular, because there are a limited number of patients with Waldenström s macroglobulinemia or patients with DLBCL harboring the MYD88 L265P oncogenic mutation, and a limited number of patients with dermatomyositis, DMD, or other rare diseases having indications for which we may determine to develop our TLR antagonists, our ability to enroll eligible patients in any clinical trials for

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these indications may be limited or may result in slower enrollment than we anticipate. In addition, the relapsed or refractory DLBCL patients that we are seeking to enroll in our Phase 1/2 clinical trial of IMO-8400, typically have progressed disease with a severe prognosis. As a result, some patients for which we have initiated screening may not survive to complete screening for the MYD88 L265P oncogenic mutation. If enrolled, the disease in these patients may be too progressed for them to receive any benefit from treatment or for their treatment to contribute meaningful data to the clinical trial. In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors drug candidates.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the TLR antagonist drug candidates under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the availability of competing clinical trials or other therapies;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

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

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

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

clinical trials. Numerous unforeseen events may occur during, or as a result of, preclinical testing, nonclinical testing or the clinical trial process that could delay or inhibit the ability to receive regulatory approval or to commercialize drug products.

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Only one TLR-targeted drug, imiquimod, which is marketed as Aldara® and Zyclara® by Meda AB, Graceway Pharmaceuticals LLC, and iNova Pharmaceuticals (Australia) Pty Limited has been approved by the FDA. Other companies developing drugs targeted to TLRs have experienced setbacks in clinical trials. For example in 2007, Coley Pharmaceutical Group, which since has been acquired by Pfizer, Inc., discontinued four clinical trials for PF-3512676, its investigational TLR9 agonist compound, in combination with cytotoxic chemotherapy in cancer, and suspended its development of Actilon®, a TLR9 agonist, for HCV infection. In July 2007, Anadys Pharmaceuticals, Inc. and its partner Novartis discontinued the development of ANA975, the investigational TLR7 agonist compound for HCV infection. Dynavax announced in May 2008 discontinuation of the clinical development program for TOLAMBA®, an investigational vaccine which contained a TLR9 agonist adjuvant, and in February 2013 Dynavax announced receipt of a Complete Response Letter from FDA regarding its Biological License Application for HEPLISAV®, which is an investigational hepatitis B vaccine that contains a TLR9 agonist adjuvant. These setbacks may result in enhanced scrutiny by regulators or institutional review boards, or IRBs, of clinical trials of our drug candidates, including our TLR-targeted drug candidates, which could result in regulators or IRBs prohibiting the commencement of clinical trials, requiring additional nonclinical studies as a precondition to commencing clinical trials or imposing restrictions on the design or scope of clinical trials that could slow enrollment of trials, increase the costs of trials or limit the significance of the results of trials. Such setbacks could also adversely impact the desire of investigators to enroll patients in, and the desire of patients to enroll in, clinical trials of our drug candidates.

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

- regulators or IRBs may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- nonclinical or clinical data may not be readily interpreted, which may lead to delays and/or misinterpretation;
- our nonclinical tests, including toxicology studies, or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical testing or clinical trials or we may abandon projects that we expect may not be promising;
- the rate of enrollment or retention of patients in our clinical trials may be lower than we expect;
- we might have to suspend or terminate our clinical trials if the participating subjects experience serious adverse events or undesirable side effects or are exposed to unacceptable health risks;
- regulators or IRBs may hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements, issues identified through inspections of manufacturing or clinical trial operations or clinical trial sites, or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;
- regulators may hold or suspend our clinical trials while collecting supplemental information on, or clarification of, our clinical trials or other clinical trials, including trials conducted in other countries or trials conducted by other companies;
- we, along with our collaborators and subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA s Application Integrity Policy, or similar policy under foreign regulatory authorities. Employment of such debarred persons, even if inadvertent, may result in delays in the FDA s or foreign equivalent s review or approval of our drug candidates, or the rejection of data developed with the involvement of such person(s);
- we or our contract manufacturers may be unable to manufacture sufficient quantities of our drug candidates for use in clinical trials;

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

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

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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 drug candidates.

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

Our drug candidates and our collaborators drug candidates will require preclinical and other nonclinical testing and extensive clinical trials prior to submission of any regulatory application for commercial sales. In conducting clinical trials, we cannot be certain that any planned clinical trial will begin on time, if at all. Delays in commencing clinical trials of potential products could increase our drug candidate 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 or proposed clinical trial design;
- obtaining IRB approval for conducting a clinical trial at a prospective site; and
- enrolling patients in order to commence the clinical trial.

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

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

Moreover, only one oligonucleotide drug, Kynamro®, has been approved by the FDA for marketing in the United States since 1998. As such, oligonucleotides as a chemical class of drug candidates have limited precedence for successful late-stage development and regulatory approval. As we progress our oligonucleotide drug candidates into Phase 2 clinical trials involving patients with severe disease and as we conduct long-term nonclinical toxicology studies, we expect to encounter an increased risk of generating clinical adverse events and nonclinical toxicology study results that will require careful interpretation. In animal toxicology studies, we have observed adverse treatment-related effects on serum complement as well as evidence of adverse kidney, vascular, and heart pathology in longer term dosing of animals with our oligonucleotide compounds, which we believe are consistent with data previously generated with other third party oligonucleotides. Given the limited experience in assessing the relevance of oligonucleotide-related adverse animal toxicology findings to humans, the clinical and

regulatory context for interpreting the significance of such events and results is not well established.

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

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

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

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

We are developing our TLR-targeted drug candidates for use in the treatment of certain genetically defined forms of B-cell lymphoma and rare diseases and in our immuno-oncology program. One of our drug candidates, IMO-8400, is in clinical development for the treatment of certain genetically defined forms of B-cell lymphoma, including Waldenström s macroglobulinemia and DLBCL with the MYD88 L265P oncogenic mutation present. We plan to initiate clinical trials of IMO-8400 in dermatomyositis and DMD. We are also planning to conduct Phase 1/2 clinical trials of either IMO-2055 or IMO-2125 in combination with a checkpoint inhibitor for selected oncology targets in our immuno-oncology program. Finally, we may seek to enter into collaborative alliances with pharmaceutical companies to advance our TLR antagonist candidates in broader autoimmune disease indications. For all of these disease areas, there are many other companies, public and private, that are actively engaged in discovery, development, and commercializing products and technologies that may compete with our drug candidates and programs, including TLR-targeted compounds as well as non-TLR-targeted therapeutics.

We are developing IMO-8400 for the treatment of certain genetically defined forms of B-cell lymphoma. There are currently no drugs specifically approved for the treatment of Waldenström s macroglobulinemia or DLBCL with the MYD88 L265P oncogenic mutation other than ibrutinib, which is marketed as Imbruvica® by Pharmacyclics, Inc. and was approved in January 2015 for the treatment of Waldenström s macroglobulinemia in the United States. Currently, patients with any form of non-Hodgkin lymphoma are most often treated with the monoclonal antibody rituximab and/or with one or more chemotherapeutic agents. Rituximab is co-marketed in the United States by Biogen Idec Inc. and Genentech Inc. and Hoffmann-La Roche, and Chugai Pharmaceutical Co., Ltd. in territories outside the United States. We are aware of additional compounds in development for the treatment of genetically defined forms of B-cell lymphoma, including an inhibitor of interleukin-1 receptor-associated kinase 4, which is being developed by Nimbus Discovery, Inc.

Our principal competitor developing TLR antagonist targeted compounds for rare diseases is Dynavax. In addition, we are aware that other companies including Dynavax, InDex Pharmaceuticals AB, Mologen AG, BioLineRx Ltd., Innate Immunotherapeutics Ltd., VentiRx Pharmaceuticals Inc., Telormedix S.A., Gilead Sciences Inc., GlaxoSmithKline plc, AstraZeneca plc and Hoffmann-La Roche are developing TLR agonists for various indications, some of which are in the field of oncology.

Many of the drug development programs in dermatomyositis are focusing on expanding the use of drugs approved in different indications through investigator sponsored studies such as the ongoing studies of the

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monoclonal antibodies, belimumab and tocilizumab. In addition, Novartis is developing a competitive anti-inflammatory approach with its new investigational drug, BAF312, a sphingosine-1-phosphate receptor modulator aimed at inhibiting the migration of lymphocytes to the location of inflammation. We are not aware of other new chemical or molecular entities being developed for the treatment of dermatomyositis.

Competitors with respect to our DMD program include ReveraGen and Catabasis, both whom are pursuing novel anti-inflammatory approaches for the treatment of DMD. ReveraGen is conducting a Phase 1 healthy volunteer study and Catabasis has announced its plans to conduct a Phase 2 clinical trial in DMD patients in the first half of 2015. In addition, Sarepta Therapeutics Inc. and BioMarin Pharmaceuticals Inc. (following its acquisition of Prosensa Holding N.V.), each have RNA-based drug candidates targeted at treating genetically defined subsets of DMD in late stage development. PTC Therapeutics, Inc. also has a drug candidate targeted at treating a genetically defined subset of DMD that is conditionally approved for the treatment of DMD in Europe, and is currently being evaluated in a Phase 3 clinical trial. We believe that these dystrophin replacement therapeutic approaches, as well as other therapeutic approaches being pursued for the treatment of DMD, including anti-inflammatory, muscle blood flow, reducing fibrosis, increasing muscle mass, supporting muscle integrity and cardioprotective approaches being pursued by multiple companies, have the potential to be complementary to our TLR antagonist approach.

Immuno-oncology, which utilizes a patient s own immune system to combat cancer, is currently an active area of research for biotechnology and pharmaceutical companies. Interest in immuno-oncology is driven by recent efficacy data in cancers with historically bleak outcomes and the potential to achieve a cure or functional cure for some patients. As such, our efforts in this field will be competitive with a wide variety of different approaches. Any one of these competitive approaches may result in the development of novel technologies that are more effective, safer or less costly than any that we are developing. In addition, Dynavax is conducting a Phase 1/2 clinical trial of an investigational TLR9 agonist in combination with checkpoint inhibitors.

We are also developing GSOs that we have created using our proprietary technology, to inhibit the production of disease-associated proteins by targeting RNA. We also face competition from other companies working to develop novel drugs using technologies that may compete with our GSO technology. We are aware of multiple companies that are developing technologies that use oligonucleotide-based compounds to inhibit the production of disease associated proteins. These technologies include, but are not limited to, antisense technology as well as RNAi. In the field of antisense technologies, we compete with multiple companies, including Isis and its partners. Isis is currently marketing an antisense drug, Kynamro, and has several antisense drug candidates in clinical trials. In the field of RNAi, our primary competition is with Alnylam and its partners. Alnylam is currently developing multiple RNAi-based technologies and has several drug candidates in clinical trials. Any of the competing companies may develop gene-silencing technologies more rapidly and more effectively than us, and antisense technology and RNAi may become the preferred technology for drugs that target RNA in order to inhibit the production of disease-associated proteins.

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

We recognize that other companies, including large pharmaceutical companies, may be developing or have plans to develop products and technologies that may compete with ours. Many of our competitors have substantially greater financial, technical, and human resources than we have. In addition, many of our competitors have significantly greater experience than we have in undertaking preclinical studies and human clinical trials of new pharmaceutical products, obtaining FDA and other regulatory approvals of products for use

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in health care and manufacturing, and marketing and selling approved products. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than any that we are developing. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

We anticipate that the competition with our drug candidates and technologies will be based on a number of factors including product efficacy, safety, availability, and price. The timing of market introduction of our drug candidates 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, 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 Mr. Vincent Milano and Dr. Sudhir Agrawal. Mr. Milano serves as our President and Chief Executive Officer, and Dr. Agrawal serves as our President of Research.

We are a party to employment agreements with Mr. Milano and Dr. Agrawal. Mr. Milano s employment agreement is terminable upon 15 days prior written notice at the election of either party and immediately in the event of a termination for cause. Dr. Agrawal s employment agreement expires on October 19, 2017, but automatically extends annually for additional one-year periods. 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 Mr. Milano or 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 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 drug candidates are subject to extensive regulation by governmental authorities in Europe, the United States, and elsewhere throughout the world.

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

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Even if we obtain regulatory approval for any of our drug candidates, we will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians, advertising and promotion, and recordkeeping. Even if marketing approval of a drug candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a risk evaluation and mitigation strategy. If any of our drug candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the product. For example, new cancer drugs frequently are indicated only for patient populations that have not responded to an existing therapy or have relapsed.

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

- the regulatory agency s delay in approving, or refusal to approve, an application for marketing of a product or a supplement to an approved application;
- total or partial suspension of any ongoing clinical trials;
- restrictions on our drug candidates or the marketing or manufacturing of our drug candidates;
- withdrawal of our drug candidates from the market;
- warning letters;
- voluntary or mandatory product recalls;
- fines;
- suspension or withdrawal of regulatory approvals;
- product seizure or detention;
- refusal to permit the import or export of our drug candidates;
- injunctions or the imposition of civil penalties; and
- criminal penalties.

The regulatory requirements and policies may change and additional government regulations may be enacted for which we may also be required to comply. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we or any current or future collaborator are not able to maintain regulatory compliance,

we or such collaborator, as applicable, will not be permitted to market our future products and our business will suffer.

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

All of the drug candidates that we are developing, or may develop in the future, will require additional research and development, extensive preclinical studies, nonclinical testing, clinical trials, and regulatory approval prior to any commercial sales. This process is lengthy, often taking a number of years, is uncertain, and is expensive. Since our inception, we have conducted clinical trials of a number of compounds and are planning to initiate clinical trials for a number of additional disease indications. Specifically, we are currently:

- conducting a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia and a Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL harboring the MYD88 L265P oncogenic mutation;

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planning to conduct two Phase 1/2 clinical trials involving either IMO-2055 or IMO-2125 in combination with a checkpoint inhibitor for selected oncology targets;

planning to conduct a Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis and a Phase 1/2 clinical trial of IMO-8400 in patients with DMD;

conducting a Phase 1 clinical trial of IMO-9200 in healthy subjects; and

planning to conduct disease model studies and begin IND-enabling development programs in each of the first two disease indications selected for further development in our GSO program.

The FDA and other regulatory authorities may not approve any of our potential products for any indication.

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

***We may not be able to obtain orphan drug exclusivity for applications of our TLR antagonist drug candidates.***

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

The FDA has granted us orphan drug designation for IMO-8400 for the treatment of Waldenström s macroglobulinemia. However, there can be no assurance that we will obtain orphan drug exclusivity for Waldenström s macroglobulinemia or any other disease indications for which we develop IMO-8400 or our other drug candidates. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

***A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.***

We intend to seek fast track designation for some applications of our drug candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular drug candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to

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conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

***A breakthrough therapy designation by the FDA for any application of our drug candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that those drug candidates will receive marketing approval.***

We may seek a breakthrough therapy designation for some applications of our drug candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe an application of one of our drug candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a drug candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our drug candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

***If we are unable to successfully develop companion diagnostics for our drug candidates intended for the treatment of genetically defined forms of B-cell lymphoma, or experience significant delays in doing so, we may not achieve marketing approval or realize the full commercial potential of these drug candidates.***

We plan to develop companion diagnostics for our TLR antagonist drug candidates in our genetically defined forms of B-cell lymphoma program. We expect that, at least in some cases, the FDA and similar regulatory authorities outside the United States may require the development and regulatory approval of a companion diagnostic as a condition to approving our TLR antagonist drug candidates specifically for the treatment of patients with a genetically defined form of B-cell lymphoma. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely on third parties or collaborators to perform these functions. In May 2014, we entered into an agreement with Abbott Molecular for the development and potential commercialization of a companion diagnostic for use with IMO-8400 with respect to our identification of patients with B-cell lymphomas harboring the MYD88 L265P oncogenic mutation in our genetically defined forms of B-cell lymphoma program. We may enter into similar agreements for our other drug candidates and possible expansion indications for IMO-8400. Companion diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval prior to commercialization.

If we, any third parties that we engage to assist us or any of our collaborators are unable to successfully develop companion diagnostics for our TLR antagonist drug candidates, or experience delays in doing so:

- the development of our TLR antagonist drug candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials;

- our TLR antagonist drug candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and

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we may not realize the full commercial potential of any TLR antagonist drug candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients with the specific oncogenic mutation targeted by our TLR antagonist drug candidates.

If any of these events were to occur, our business would be harmed, possibly materially.

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

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

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

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

**Risks Relating to Collaborators**

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

Historically, an important element of our business strategy has included 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 2006, we entered into an exclusive license and research collaboration with Merck & Co. to research, develop, and commercialize vaccine products containing our TLR7, TLR8 and TLR9 agonists in the fields of cancer, infectious diseases, and Alzheimer s disease. 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. Additionally, in May 2014, we entered into a development and commercialization agreement with Abbott Molecular for the development of an in vitro companion diagnostic for use in our clinical development programs to treat certain genetically defined forms of B-cell lymphoma with IMO-8400.

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

our collaborators may control the development of the drug candidates being developed with our technologies and compounds including the timing of development;

our collaborators may control the development of the companion diagnostic to be developed for use in conjunction with our drug candidates including the timing of development;

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

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

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

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

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

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

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

Collaborators provide the necessary resources and drug development experience to advance our compounds in their programs. We may seek to enter into collaborative alliances with pharmaceutical companies to advance our TLR antagonist candidates in broader autoimmune disease indications. We may seek to enter into collaborative alliances with pharmaceutical companies with respect to applications of our GSO technology program.

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 certain genetically defined forms of B-cell lymphoma and autoimmune diseases and on GSOs. We believe that additional resources will be required to advance compounds in all of these areas. If we do not reach agreements with additional collaborators in the future, we may not be able to obtain the expertise and resources necessary to achieve our business objectives, our ability to advance our compounds will be jeopardized and we may fail to meet our business objectives.

We may have difficulty establishing additional collaborative alliances, particularly with respect to our TLR-targeted drug candidates and technology and our GSO technology. For example, potential partners may note that our TLR collaborations with Novartis and with Merck KGaA have been terminated. Potential partners may also be reluctant to establish collaborations with respect to IMO-2125, IMO-3100, IMO-2055, and our other TLR-targeted drug candidates, given our setbacks with respect to these drug candidates. Additionally, in the event we seek collaborations for our GSO program, any potential collaborators may not be willing to enter into a collaboration with us due to the early stage of this technology. We also face, and expect to continue to face, significant competition in seeking appropriate collaborators.

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

**Risks Relating to Intellectual Property**

***If we are unable to obtain and maintain 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 and maintain valid and enforceable patents;

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

operate without infringing upon the proprietary rights of others;

prevent others from infringing on our proprietary rights; and

protect our trade secrets.

We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may be issued in the future, or those licensed to us, may be challenged, invalidated, held unenforceable, narrowed in the course of a post-issuance proceeding or circumvented, and the rights granted thereunder may not provide us proprietary protection or competitive advantages against competitors with similar technology. Moreover, intellectual property laws may

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change and negatively impact our ability to obtain issued patents covering our technologies or to enforce any patents that issue. Because of the extensive time required for development, testing, and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thus reducing any advantage provided by the patent.

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

As of February 19, 2015, we owned more than 45 U.S. patents and patent applications and more than 80 patents and patent applications throughout the rest of the world for our TLR-targeted immune modulation technologies. These patents and patent applications include claims covering the chemical compositions of matter and methods of use of our IMO compounds, such as IMO-8400, IMO-9200, IMO-2055 and IMO-2125, as well as other compounds. As of February 19, 2015, all of our intellectual property covering immune modulatory compositions and methods of their use is based on discoveries made solely by us. These patents expire at various dates ranging from 2017 to 2031. With respect to IMO-8400, we have an issued U.S. patent that covers the chemical composition of matter of IMO-8400 and certain methods of its use that has a statutory expiration date in 2031. With respect to IMO-9200, we have a U.S. patent application that covers the chemical composition for IMO-9200 and methods of its use, which we would expect to expire, if issued, at the earliest in 2034. With respect to IMO-2055, we have issued patents that cover the chemical composition of matter of IMO-2055 and certain methods of its use, including in combination with marketed cancer products, with the composition claims expiring in 2023. With respect to IMO-2125, we have an issued U.S. patent that covers the chemical composition of matter of IMO-2125 and methods of its use that will expire in 2026.

As of February 19, 2015, we owned two issued U.S. patents, two pending U.S. patent applications and seven foreign patent applications related to our GSO compounds and methods of their use. The issued patents covering our GSO technologies have a statutory expiration date in 2030.

In addition to our TLR-targeted and GSO patent portfolios, we are the owner of or hold licenses to patents and patent applications related to antisense technology. As of February 19, 2015, our antisense patent portfolio included more than 30 U.S. patents and more than 60 patents throughout the rest of the world. These antisense patents and patent applications include novel compositions of matter, the use of these compositions for various genes, sequences and therapeutic targets, and oral and other routes of administration. Some of the patents and patent applications in our antisense portfolio were in-licensed. These in-licensed patents expire at various dates through 2021.

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

Although we have many issued patents and pending patent applications in the United States and other countries, we may not have rights under certain third-party patents or patent applications related to our products. Third parties may own or control these patents and patent applications in the United States and abroad. In particular, we are aware of certain third-party U.S. patents that contain claims related to immunostimulatory polynucleotides and their use to stimulate an immune response. Although we do not believe any of our TLR9 agonists infringe any valid claim of these patents, we cannot be assured that the holder of such patents would not seek to assert such patents against us or, if the holder did, that the courts would not interpret the claims of such patents more broadly than we believe appropriate and determine that we are in infringement of such patents. In addition, there may be other patents and patent applications related to our products of which we are not aware. Therefore, in some cases, in order to develop, manufacture, sell or import some of our products, we or our

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collaborators may choose to seek, or be required to seek, licenses under third-party patents issued in the United States and abroad or under third-party patents that might issue from U.S. 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 become involved in expensive patent litigation or other proceedings, which could result in our incurring substantial costs and expenses or substantial liability for damages, require us to stop our development and commercialization efforts or result in our patents being invalidated, interpreted narrowly or limited.***

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 U.S. Patent and Trademark Office for some of our antisense and ribozyme patents. All of these interferences have since been resolved. We are neither practicing nor intending to practice the intellectual property that is associated with any of these interference proceedings.

Other patent office proceedings include oppositions, reexaminations, supplemental examinations and *inter partes* reviews involving our patents or the patents of third parties. We may initiate such proceedings or have such proceedings brought against us. An adverse determination in any such proceeding, or in litigation, could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates. An adverse determination in a proceeding involving a patent in our portfolio could result in the loss of protection or a narrowing in the scope of protection provided by that patent.

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. In a patent office proceeding, such as an opposition, reexamination or *inter partes* review, our patents may be narrowed or invalidated.

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

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

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

We have limited manufacturing experience and no manufacturing facilities, infrastructure or clinical or commercial scale manufacturing capabilities. In order to continue to develop our drug candidates, apply for

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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 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 drug candidates, if approved. Our current and anticipated future dependence upon others for the manufacture of our drug candidates may adversely affect our future profit margins and our ability to develop drug candidates and commercialize any drug candidates on a timely and competitive basis. We currently do not have any long term supply contracts.

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

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

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

Any contract manufacturers with which we enter into manufacturing arrangements will be subject to ongoing periodic, unannounced inspections by the FDA, or foreign equivalent, and corresponding state and foreign agencies or their designees to ensure compliance with cGMP requirements and other governmental regulations and corresponding foreign standards. For example, one of our contract manufacturers notified us that it had received a cGMP warning letter from the FDA in February 2011. This contract manufacturer no longer manufactures drug product for us. Any failure by our third-party manufacturers to comply with such requirements, regulations or standards could lead to a delay in the conduct of our clinical trials, or a delay in, or failure to obtain, regulatory approval of any of our drug candidates. Such failure could also result in sanctions being imposed, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, product seizures or recalls, imposition of operating restrictions, total or partial suspension of production or distribution, or criminal prosecution.

Additionally, contract manufacturers may not be able to manufacture our drug candidates at a cost or in quantities necessary to make them commercially viable. As of February 19, 2015, our third-party manufacturers have met our manufacturing requirements, but we cannot be assured that they will continue to do so. Furthermore, changes in the manufacturing process or procedure, including a change in the location where the drug substance or drug product is manufactured or a change of a third-party manufacturer, may require prior FDA review and approval in accordance with the FDA s cGMP and New Drug Application/biologics license application regulations. Contract manufacturers may also be subject to comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a drug candidate. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their

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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 drug candidates, we will face competition with respect to commercial sales, marketing, and distribution. These are areas in which we have no experience. To market any of our drug candidates directly, we would need to develop a marketing and sales force with technical expertise and with supporting distribution capability. In particular, we would need to recruit 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 drug candidates and our business may suffer.***

We do not have the ability to independently conduct the clinical trials required to obtain regulatory approval for our drug candidates. We depend on independent clinical investigators, contract research organizations, and other third-party service providers in the conduct of the clinical trials of our drug candidates and expect to continue to do so. We have contracted with contract research organizations to manage our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia and our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL and the MYD88 L265P oncogenic mutation, and expect to contract with such organizations for future clinical trials. We rely heavily on these parties for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and foreign regulatory agencies require us to comply with certain standards, commonly referred to as good clinical practices, and applicable regulatory requirements, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or at all, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. If these third parties fail to carry out their obligations, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated, and we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable drug candidate, or to commercialize such drug candidate being tested in such studies or trials. 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 research, clinical, quality and corporate infrastructure.

***Failure of our third-party collaborators to successfully commercialize companion diagnostics developed for use with any TLR antagonist drug candidates that we develop with respect to our genetically defined forms of B-cell lymphoma program could harm our ability to commercialize these TLR antagonist drug candidates.***

Some of the TLR antagonist drug candidates that we develop with respect to our genetically defined forms of B-cell lymphoma program will necessitate the use of companion diagnostics. We do not plan to develop

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companion diagnostics internally and, as a result, we will be dependent on the efforts of our third-party collaborators to successfully commercialize these companion diagnostics. Our collaborators:

- may not perform their obligations as expected;
- may encounter production difficulties that could constrain the supply of the companion diagnostics;
- may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community;
- may not pursue commercialization of any companion diagnostics that achieve regulatory approval;
- may elect not to continue or renew commercialization programs based on changes in the collaborators strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- may not commit sufficient resources to the marketing and distribution of such companion diagnostics; and
- may terminate their relationship with us.

If companion diagnostics for use with our genetically defined forms of B-cell lymphoma TLR antagonist drug candidates fail to gain market acceptance, our ability to derive revenues from sales of these TLR antagonist drug candidates could be harmed. If our collaborators fail to commercialize these companion diagnostics, we may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with genetically defined forms of B-cell lymphoma TLR antagonist drug candidates or do so on commercially reasonable terms, which could adversely affect and delay the development or commercialization of these TLR antagonist drug candidates.

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

Any products that we ultimately bring to the market, if they receive marketing approval, may not gain market acceptance by physicians, patients, third-party payors or others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments. If our products do not achieve an adequate level of acceptance, we may not generate product revenue and we may not become profitable. The degree of market acceptance of our products, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects, including any limitations or warnings contained in the product s approved labeling;
- the efficacy and potential advantages over alternative treatments;
- the ability to offer our drug candidates for sale at competitive prices;

relative convenience and ease of administration;

the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

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

publicity concerning our products or competing products and treatments.

Even if a potential product displays a favorable efficacy and safety profile, market acceptance of the product will not be known until after it is launched. Our efforts to educate patients, the medical community, and third-

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party payors on the benefits of our drug candidates may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by conventional technologies marketed by our competitors.

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

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

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 drug candidates. These further clinical trials would require additional time, resources, and expenses. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our prospects for generating revenue, if any, could be adversely affected and our business may suffer.

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

Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. These third-party payors may base their coverage and reimbursement on the coverage and reimbursement rate paid by carriers for Medicare beneficiaries. Furthermore, many such payors are investigating or implementing methods for reducing health care costs, such as the establishment of capitated or prospective payment systems. Cost containment pressures have led to an increased emphasis on the use of cost-effective products by health care providers. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could limit the price we might establish for products that we or our current or future collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

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***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 Ownership of Our Common Stock**

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

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

a classified board of directors;

limitations on the removal of directors;

limitations on stockholder proposals at meetings of stockholders;

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

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

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

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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.

***We have two significant securityholders. If these securityholders choose to act together, they could exert substantial influence over our business. In addition, in connection with any merger, consolidation or sale of all or substantially all of our assets, they would be entitled to receive consideration in excess of their reported beneficial ownership of our common stock.***

As of February 19, 2015, Baker Bros. Advisors LP, and certain of its affiliated funds, which we refer to collectively as Baker Brothers, held 6,965,432 shares of our common stock, warrants to purchase up to 20,316,327 shares of our common stock at an exercise price of $0.47 per share and pre-funded warrants to purchase up to 22,151,052 shares of our common stock at an exercise price of $0.01 per share. In addition, two members of our board of directors are affiliates of Baker Brothers. Under the terms of the warrants and pre-funded warrants issued to Baker Brothers, Baker Brothers is not permitted to exercise such warrants to the extent that such exercise would result in Baker Brothers (and its affiliates) beneficially owning more than 4.999% of the number of shares of our common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such warrants. Baker Brothers has the right to increase this beneficial ownership limitation in its discretion on 61 days prior written notice to us, provided that in no event is Baker Brothers permitted to exercise such warrants to the extent that such exercise would result in Baker Brothers (and its affiliates) beneficially owning more than 19.99% of the number of shares of our common stock outstanding or the combined voting power of our securities outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such warrants. After giving effect to the 4.99% beneficial ownership limitation currently in effect with respect to the warrants and pre-funded warrants held by Baker Brothers, as of February 19, 2015, and based on the securities held by Baker Brothers as of February 19, 2015, Baker Brothers beneficially owned 6.0% of our outstanding common stock. If the warrants and pre-funded warrants held by Baker Brothers could be exercised without this limitation, then as of February 19, 2015, and based on the securities held by Baker Brothers as of February 19, 2015, Baker Brothers would have beneficially owned 30.9% of our common stock. On February 9, 2015, we entered into a registration rights agreement with Baker Brothers, pursuant to which we are obligated to file a registration statement to register for resale the shares of our common stock (including shares issuable upon the exercise of warrants) held by Baker Brothers.

As of February 19, 2015, entities affiliated with Pillar Invest Corporation, which we refer to collectively as the Pillar Investment Entities, held 18,675,405 shares of our common stock and warrants to purchase up to 14,795,490 shares of our common stock at exercise prices ranging from $0.47 per share to $1.46 per share. In addition, one member of our board of directors is an affiliate of the Pillar Investment Entities. The Pillar Investment Entities are subject to contractual limitations that limit their ability to exercise any securities held by them that are exercisable into shares of our common stock to the extent that such exercise would result in the Pillar Investment Entities (and their affiliates) beneficially owning more than 19.99% of the number of shares of our common stock outstanding or the combined voting power of our securities outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such securities. After giving effect to the 19.99% beneficial ownership limitation currently in effect with respect to the securities held by the Pillar Investment Entities, as of February 19, 2015, the Pillar Investment Entities beneficially owned 19.99% of our outstanding common stock. If the warrants held by the Pillar Investment Entities could be exercised without these limitations, then as of February 19, 2015, the Pillar Investment Entities would have beneficially owned 25.3% of our common stock.

Although there are contractual limitations on the beneficial ownership of Baker Brothers and the Pillar Investment Entities, which we refer to collectively as our significant securityholders, if our significant securityholders were to exercise their warrants for common stock and were to choose to act together, they could be able to exert substantial influence over our business. This concentration of voting power could delay, defer or prevent a change of control, entrench our management and the board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire.

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In addition, conflicts of interest could arise in the future between us, on the one hand, and either or both of our significant securityholders on the other hand, concerning potential competitive business activities, business opportunities, the issuance of additional securities and other matters. Furthermore in the event of a sale of our company, whether by merger, sale of all or substantially all of our assets or otherwise, our significant securityholders would be entitled to receive, with respect to each share of common stock issuable upon exercise of the warrants then held by them and without regard to the beneficial ownership limitations imposed on the conversion or exercise of such securities, the same amount and kind of securities, cash or property as they would have been entitled to receive if such securities had been converted into or exercised for shares of our common stock immediately prior to such sale of our company. Because the significant securityholders would receive this sale consideration with respect to warrants not included in their reported beneficial ownership of our common stock, in the event of a sale of our company, they would be entitled to receive a significantly larger portion of the total proceeds distributable to the holders of our securities than is represented by their reported beneficial ownership of our common stock.

***Our stock price has been and may in the future be extremely volatile. In addition, because our common stock has historically been traded at low volume levels, 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, 2013 to February 19, 2015, the closing sales price of our common stock ranged from a high of $6.59 per share to a low of $0.46 per share. The stock market has also experienced periods of significant price and volume fluctuations 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:

our cash resources;

timing and results of nonclinical studies and clinical trials of our drug candidates or those of our competitors;

the regulatory status of our drug candidates;

failure of any of our drug candidates, if approved, to achieve commercial success

the success of competitive products or technologies;

regulatory developments in the United States and foreign countries;

our success in entering into collaborative agreements;

developments or disputes concerning patents or other proprietary rights;

the departure of key personnel;

our ability to maintain the listing of our common stock on The Nasdaq Capital Market or an alternative national securities exchange;

variations in our financial results or those of companies that are perceived to be similar to us;

the terms of any financing consummated 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

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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.

***Because we do not intend to pay dividends on our common stock, investor returns will be limited to any increase in the value of our stock.***

We have never declared or paid any cash dividends on our common stock. In addition, under the terms of our loan and security agreement with Oxford Finance LLC, we are required to obtain the prior written consent of Oxford Finance LLC in order to declare or pay a cash dividend on our common stock in an amount in excess of $500,000 in any fiscal year. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business and do not anticipate declaring or paying any cash dividends on our common stock for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, if any.

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

None.

**Item 2.** ***Properties.***

We lease approximately 27,000 square feet of laboratory and office space located in Cambridge, Massachusetts. The lease expires on August 31, 2017 subject to a three-year renewal option exercisable by us. We have specified rights to sublease this facility.

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

None.

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

Not applicable.

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**PART II.**

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

**Market Information**

Our common stock has been listed under the symbol IDRA on the Nasdaq Capital Market since February 7, 2013 when it was transferred from the Nasdaq Global Market.

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 and the Nasdaq Capital Market. These prices reflect inter-dealer prices without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

| | High | Low |
|---|---|---|
| **2013** | | |
| First Quarter | $ .92 | $ .19 |
| Second Quarter | .83 | .43 |
| Third Quarter | 2.34 | .67 |
| Fourth Quarter | 4.75 | 1.55 |
| **2014** | | |
| First Quarter | $ 6.87 | $ 3.56 |
| Second Quarter | 4.50 | 2.29 |
| Third Quarter | 3.01 | 2.28 |
| Fourth Quarter | 4.78 | 1.94 |

**Holders**

As of February 19, 2015, we had approximately 105 common stockholders of record registered on our books, excluding shares held through banks and brokers.

**Dividends**

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

**Comparative Stock Performance**

*The information included under the heading Comparative Stock Performance in Item 5 of this Annual Report on Form 10-K is furnished and not filed and shall not be deemed to be soliciting material or subject to Regulation 14A, shall not be deemed filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act.*

The comparative stock performance graph shown below compares cumulative stockholder return on our common stock from December 31, 2009 through December 31, 2014, with the cumulative total return of the Nasdaq Biotechnology Index and the Russell 2000 Index. This graph assumes an investment of $100 on December 31, 2009 in our common stock and in each of the indices and assumes that dividends are reinvested.

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| | 12/31/09 | 12/31/10 | 12/31/11 | 12/31/12 | 12/31/13 | 12/31/14 |
|---|---|---|---|---|---|---|
| IDERA PHARMACEUTICALS, INC. | $ 100.00 | $ 55.90 | $ 20.31 | $ 17.21 | $ 89.56 | $ 85.30 |
| RUSSELL 2000 INDEX | $ 100.00 | $ 126.86 | $ 121.56 | $ 141.43 | $ 196.34 | $ 205.95 |
| NASDAQ BIOTECHNOLOGY INDEX | $ 100.00 | $ 106.62 | $ 122.01 | $ 166.55 | $ 286.43 | $ 378.29 |

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

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

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2014 | 2013 | 2012 | 2011 | 2010 |
| | (In thousands, except per share data) | | | | |
| **Statement of Operations and Comprehensive (Loss) Income Data:** | | | | | |
| Alliance revenue | $ 73 | $ 47 | $ 51 | $ 53 | $ 16,110 |
| Operating expenses: | | | | | |
| Research and development | 27,493 | 10,475 | 13,673 | 17,969 | 24,226 |
| General and administrative | 11,332 | 7,741 | 6,279 | 7,939 | 9,867 |
| Total operating expenses | 38,825 | 18,216 | 19,952 | 25,908 | 34,093 |
| Loss from operations | (38,752) | (18,169) | (19,901) | (25,855) | (17,983) |
| Other income (expense): | | | | | |
| Decrease in fair value of warrant liability | | | 675 | 1,974 | |
| Investment income, net | 39 | 11 | 9 | 30 | 114 |
| Foreign currency exchange gain (loss) | 71 | (68) | (23) | 75 | (94) |
| Net loss | $ (38,642) | $ (18,226) | $ (19,240) | $ (23,776) | $ (17,963) |
| Loss on extinguishment of convertible preferred stock, and preferred stock accretion and dividends | 519 | 2,866 | 3,210 | 4,548 | |
| Net loss applicable to common stockholders | $ (39,161) | $ (21,092) | $ (22,450) | $ (28,324) | $ (17,963) |
| Basic and diluted net loss per share applicable to common stockholders | $ (0.47) | $ (0.48) | $ (0.81) | $ (1.03) | $ (0.71) |
| Shares used in computing basic and diluted net loss per common share applicable to common stockholders (1) | 82,827 | 43,906 | 27,639 | 27,623 | 25,139 |
| Net loss | (38,642) | (18,226) | (19,240) | (23,776) | (17,963) |
| Other comprehensive (loss) income: | | | | | |
| Unrealized (loss) gain on available-for-sale securities | (10) | (7) | | (13) | 32 |
| Other comprehensive (loss) income | (10) | (7) | | (13) | 32 |
| Comprehensive loss | $ (38,652) | $ (18,233) | $ (19,240) | $ (23,789) | $ (17,931) |
| **Balance Sheet Data:** | | | | | |
| Cash, cash equivalents and investments | $ 48,571 | $ 35,592 | $ 10,096 | $ 24,571 | $ 34,643 |
| Working capital | 35,384 | 25,867 | 6,163 | 18,741 | 32,100 |
| Total assets | 51,426 | 36,867 | 10,823 | 25,595 | 36,881 |
| Capital lease obligations | 21 | 9 | 12 | | 8 |
| Note payable | 870 | | | | |
| Redeemable preferred stock | | | 5,921 | 5,921 | |
| Accumulated deficit | (451,526) | (412,884) | (394,658) | (375,418) | (351,642) |
| Total stockholders equity | 43,402 | 32,452 | 706 | 12,024 | 33,101 |

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

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

**Overview**

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for oncology and rare diseases. We use two distinct proprietary drug discovery technology platforms to design and develop drug candidates. We developed these platforms based on our scientific expertise and pioneering work with synthetic oligonucleotides as therapeutic agents. Using our Toll-like receptor, or TLR, targeting technology, we design synthetic oligonucleotide-based drug candidates to act by modulating the activity of specific TLRs. In addition, using our gene silencing oligonucleotide, or GSO, technology, we are developing GSOs to turn off the messenger RNA, or mRNA, associated with disease causing genes. We consider our GSO technology to be a third generation antisense technology that can potentially reduce the immunotoxicity and increase the potency of earlier generation antisense and RNAi technologies.

We are currently conducting a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia and Phase 1/2 clinical trial of IMO-8400 in patients with diffuse large B-cell lymphoma, or DLBCL, who harbor the MYD88 L265P oncogenic mutation. We are planning to initiate clinical development of IMO-8400 for the treatment of rare diseases and have selected dermatomyositis and Duchenne muscular dystrophy, or DMD, as the first non-cancer rare diseases for which we plan to develop IMO-8400. We believe that we can develop and commercialize therapies on our own in these disease indications, which are characterized by small, well-defined patient populations with serious unmet medical needs.

We are also advancing a second novel synthetic oligonucleotide antagonist of TLR7, TLR8 and TLR9, IMO-9200, as a drug candidate for potential use in selected autoimmune disease indications. We are conducting a Phase 1 clinical trial of IMO-9200 in healthy volunteers.

We are also developing our GSOs to specifically address challenges associated with earlier generation antisense and RNAi technologies. Although currently used technologies to silence RNA have demonstrated the ability to inhibit the expression of disease-associated proteins, we believe that to reach their full therapeutic potential, gene silencing technologies need to achieve an improved therapeutic index with efficient systemic delivery without using a delivery technology, reduced immunotoxicity and increased potency. We are currently undertaking an analysis of oncology and rare disease indications for development of drug candidates from our GSO technology. We are planning to conduct disease model studies and begin IND-enabling development programs in each of the first two disease indications selected for further development in our GSO program in the second half of 2015.

At December 31, 2014, we had an accumulated deficit of $451.5 million. We expect to incur substantial operating losses in future periods. We do not expect to generate product revenue, sales-based milestones or royalties until we successfully complete development and obtain marketing approval for drug candidates, either alone or in collaborations with third parties, which we expect will take a number of years. In order to commercialize our drug candidates, we need to complete clinical development and to comply with comprehensive regulatory requirements.

**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. In preparing our financial statements, management evaluates its estimates and judgments, including those related to stock-based compensation and our convertible preferred stock and related common stock warrants. Management bases its estimates and judgments on historical experience and on various other

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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 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 stock-based compensation and convertible preferred stock and related common stock warrants fit the description of critical accounting estimates and judgments.

*Stock-Based Compensation*

We recognize all share-based payments to employees and directors as expense in our statements of operations and comprehensive loss based on their fair values. We record compensation expense over an award s requisite service period, or 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, adjusted for forfeitures, on a straight-line basis over the vesting period, which is generally four years for employees and three years for directors.

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

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

We recorded charges of $4.3 million, $1.4 million, and $2.1 million in our statements of operations and comprehensive loss for the years ended December 31, 2014, 2013 and 2012, respectively, for stock compensation expense attributable to share-based payments made to employees and directors.

*Convertible Preferred Stock and Warrants*

*Series D Redeemable Convertible Preferred Stock and Warrants*

On November 4, 2011, we received net proceeds of $9.1 million from the sale and issuance of shares of our Series D redeemable convertible preferred stock, or Series D preferred stock, and related warrants to purchase

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shares of our common stock, or Series D warrants. We first assessed these financial instruments under Accounting Standards Codification, or ASC, 480, Distinguishing Liabilities from Equity , and determined that neither financial instrument was within the scope of ASC 480. We then assessed these financial instruments under ASC 815, Derivatives and Hedging as follows:

*Series D Warrants.* We determined that the Series D warrants when issued were a derivative instrument as they contained a price protection feature that caused the Series D warrants to not be considered indexed to the company s own stock and to therefore not be qualified for the exemption requirements in ASC 815-40. We recorded the Series D warrants as a liability at fair value as of the November 4, 2011 transaction date and marked the recorded amount to fair value through earnings each quarter. The fair value of the Series D warrants was determined to be $3.2 million on the November 4, 2011 transaction date and $1.2 million at December 31, 2011. The $2.0 million decrease in the fair value between November 4, 2011 and December 31, 2011 was recorded as non-operating income in 2011. The fair value of the Series D warrant liability decreased from $1.2 million at December 31, 2011 to $0.5 million at November 9, 2012, the date on which we sold shares of our Series E convertible preferred stock, or Series E preferred stock, and related warrants to purchase shares of our common stock, or Series E warrants, in a financing transaction, resulting in the recognition of $0.7 million in non-operating income in 2012. The sale of shares of Series E preferred stock and Series E warrants in our November 2012 Series E financing triggered an anti-dilution adjustment under the terms of the Series D warrants, resulting in the exercise price of the Series D warrants being reduced and fixed at the minimum price of $1.46 per share. As a result, beginning on November 9, 2012, the Series D warrants were no longer subject to any anti-dilution adjustments and met the exception under ASC 815-40 as they were then considered indexed to the company s own stock and met certain criteria for equity classification. Accordingly, we marked the Series D warrants to fair value through earnings as of November 9, 2012, and reclassified the remaining $0.5 million balance of the Series D warrant liability to stockholders equity at that time.

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

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

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

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

As the Series D preferred stock contained a contingent put feature that was outside of our control, it was considered redeemable and we initially recorded it in temporary equity. The initial carrying value of the Series D

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preferred stock was $1.5 million, after discounts for the portion of the financing proceeds allocated to the warrant liability, the BCF and the financing transaction costs. Since the Series D preferred stock was immediately convertible, the $4.4 million discount related to the BCF was immediately accreted to preferred dividends in 2011, resulting in an increase in the carrying value of the Series D preferred stock to $5.9 million. The sale of shares of Series E preferred stock and Series E warrants in our November 2012 Series E financing triggered an anti-dilution adjustment under the terms of the Series D preferred stock, resulting in the conversion price of the Series D preferred stock being reduced and fixed at $1.46 per share, and such shares no longer being subject to any anti-dilution adjustments. The anti-dilution adjustment to the conversion price of the Series D preferred stock resulted in an additional $1.2 million discount on the purchase price of the Series D preferred stock and resulted in an additional BCF. The $1.2 million additional BCF was immediately accreted to preferred dividends in November 2012 which resulted in the carrying value of the Series D preferred stock remaining at $5.9 million. The holders of shares of Series D preferred stock then outstanding were entitled to require us to purchase such shares of Series D preferred stock for $9.1 million plus any accrued but unpaid dividends upon the occurrence of a fundamental change of the Company. Since we determined that a fundamental change of the Company was not probable, the remaining discount of $3.2 million was not accreted to preferred stock dividends in our statements of operations and comprehensive loss. Such amount would only be accreted to preferred dividends in our statements of operations and comprehensive loss at the time that the redemption becomes probable, if ever.

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

Effective May 7, 2013, Pillar Pharmaceuticals I, L.P., or Pillar I, the holder of all 1,124,260 shares of our authorized, issued and outstanding Series D preferred stock, waived the redemption rights and liquidation preference with respect to the Series D preferred stock. This waiver generally and the effect of this waiver on our financial statements specifically are discussed below under the caption *Series D and Series E Waivers*. On February 6, 2014, Pillar I converted such shares into 6,266,175 shares of our common stock in accordance with the terms of the Series D Certificate of Designations. As a result of this conversion, no shares of our Series D preferred stock remain outstanding.

*Series E Convertible Preferred Stock*

On November 9, 2012, we received net proceeds of $6.0 million from the sale and issuance of shares of our Series E preferred stock and Series E warrants to purchase shares of our common stock. We first considered the Series E preferred stock under ASC 480 and determined that it was not mandatorily redeemable. We then identified the following three embedded features within the Series E preferred stock: (1) optional conversion by the holder; (2) optional redemption by the company; and (3) an alternative redemption by the company. We determined that the Series E preferred stock was equity like. We assessed the optional conversion by the holder to be clearly and closely related to the Series E preferred stock and thus not subject to bifurcation under ASC 815. The optional redemption by us and the alternative redemption by us were both indexed to our own stock and met the criteria for equity classification under ASC 815-40 and thus were not required to be bifurcated.

We issued the Series E preferred stock together with Series E warrants to purchase up to 8,484,840 shares of common stock. Since the Series E preferred stock and the Series E warrants were classified in stockholders equity, the gross proceeds from the financing were allocated between the Series E preferred stock and the Series E warrants based on their relative fair values at the time of the November 9, 2012 Series E financing. We computed the fair value of the warrants using the Black-Scholes option pricing model and determined it to be $2.9 million. We recorded the $2.3 million prorated value of the warrants as additional paid-in capital.

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We then considered the Series E preferred stock under ASC 470-20 to determine if a BCF existed. As of the transaction date, we computed a BCF of $1.3 million using the initial stated conversion rate. Since the conversion feature is immediately exercisable, we accreted the $1.3 million BCF immediately to preferred dividends.

Effective May 7, 2013, the holders of our Series E preferred stock waived the liquidation preference with respect to the Series E preferred stock. This waiver generally and the effect of this waiver on our financial statements specifically are discussed below under the caption *Series D and Series E Waivers*.

In December 2014, the holders of our Series E preferred stock converted such shares into 8,484,840 shares of our common stock in accordance with the terms of the Series E Certificate of Designations. As a result of this conversion, no shares of our Series E preferred stock remain outstanding.

*Series D and Series E Waivers*

As a result of the irrevocable waiver by the holders of the Series D preferred stock and the Series E preferred stock of the Series D preferred stock redemption rights and the Series D preferred stock and Series E preferred stock liquidation preferences, which became effective when we completed a qualified financing on May 7, 2013, we determined to reassess our accounting in May 2013 for our Series D preferred stock and our Series E preferred stock.

Prior to our reassessment, the Series D preferred stock had been classified as temporary equity in our condensed balance sheet because the Series D redemption rights represented a contingent put feature that was outside our control. Since the Series D stockholder irrevocably waived its Series D redemption rights, the contingent put feature ceased to exist at the time that the Series D stockholder s waiver of the Series D redemption rights became effective. In addition, the Series D and Series E stockholders irrevocably waived the liquidation preferences of both the Series D preferred stock and the Series E preferred stock. We concluded that these irrevocable waivers of the Series D redemption rights and the Series D and Series E liquidation preferences, which became effective when we consummated a follow-on underwritten public offering of our common stock on May 7, 2013, represented changes to the fundamental terms of both the Series D preferred stock and the Series E preferred stock. As a result, we accounted for these irrevocable waivers as an extinguishment of the Series D preferred stock and the Series E preferred stock and changed the classification of the Series D preferred stock from temporary equity to permanent equity. We compared (1) the sum of the fair values of the Series D preferred stock, the Series E preferred stock and the warrants issued in connection with the waivers immediately after the effectiveness of the waivers to (2) the sum of the carrying values of the Series D preferred stock and Series E preferred stock immediately prior to the effectiveness of the waivers on May 7, 2013. We recorded the excess of the aggregate fair value of the preferred stock plus the warrants issued in connection with the waivers immediately after the effectiveness of the waivers over the aggregate carrying value of the preferred stock immediately prior to May 7, 2013 as a loss on extinguishment and classified the fair values, immediately after the effectiveness of the waivers, of the Series D preferred stock, the Series E preferred stock and the warrants issued in connection with the waivers within permanent equity on our condensed balance sheet.

The effect of this extinguishment accounting on our financial statements as of May 7, 2013 was to:

remove the $5.9 million carrying value of the Series D preferred stock immediately prior to the extinguishment from temporary equity;

record the $5.5 million fair value of the Series D preferred stock immediately after the extinguishment in permanent equity, or equity;

remove the $3.7 million carrying value of the Series E preferred stock immediately prior to the extinguishment from equity;

record the $5.5 million fair value of the Series E preferred stock immediately after the extinguishment in equity;

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record the $0.4 million fair value of the warrants issued in connection with the waivers in equity; and

record a $1.8 million extinguishment loss to net loss applicable to common stockholders.

These accounting entries resulted in a $5.9 million net increase in stockholders equity on our balance sheet in 2013.

**Results of Operations**

***Years ended December 31, 2014, 2013 and 2012***

*Research and Development Expenses*

Research and development expenses increased by approximately $17.0 million, or 162%, from $10.5 million in 2013 to $27.5 million in 2014, and decreased by approximately $3.2 million, or 23%, from $13.7 million in 2012 to $10.5 million in 2013. In the following table, research and development expense is set forth in four categories which are discussed beneath the table:

| | Year Ended December 31, | | | Annual Percentage Change | |
|---|---|---|---|---|---|
| | 2014 | 2013 | 2012 | 2014/2013 | 2013/2012 |
| | | (In millions) | | | |
| IMO-8400 external development expense | $ 7.4 | $ 3.5 | $ 0.5 | 111% | 600% |
| IMO-9200 external development expense | 1.7 | | | | |
| Companion diagnostic external development expense | 2.2 | | | | |
| Other drug development expense | 9.1 | 3.6 | 7.8 | 153% | (54)% |
| Basic discovery expense | 7.1 | 3.4 | 5.4 | 109% | (37)% |
| | $ 27.5 | $ 10.5 | $ 13.7 | 162% | (23)% |

*IMO-8400 External Development Expenses.* These expenses include external expenses that we have incurred in connection with IMO-8400 since October 2012, when we commenced clinical development of IMO-8400. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-8400 clinical development but exclude internal costs such as payroll and overhead expenses. Since October 2012, we have incurred approximately $11.3 million in external development expenses through December 31, 2014, including costs associated with our Phase 1 clinical trial in healthy subjects, preparation for and conduct of our Phase 2 clinical trial in patients with psoriasis, preparation for and conduct of our ongoing Phase 1/2 clinical trial in patients with Waldenström s macroglobulinemia and our ongoing Phase 1/2 clinical trial in patients with DLBCL, as well as additional nonclinical studies. We classified the IMO-8400 external development expenses incurred prior to October 2012 in other drug development expenses.

The increase in our IMO-8400 external development expenses in 2014, as compared to 2013, was primarily attributable to costs incurred in 2014 in connection with preparation for and conduct of our Phase 1/2 clinical trial in patients with Waldenström s macroglobulinemia and our Phase 1/2 clinical trial in patients with DLBCL harboring the MYD88 L265P oncogenic mutation, the conduct of long-term nonclinical safety studies and the manufacture of additional drug substance for use in our ongoing and planned clinical trials. These increases were partially offset by 2013 costs associated with our Phase 1 clinical trial of IMO-8400 in healthy subjects and with our Phase 2 clinical trial of IMO-8400 in patients with psoriasis.

The increase in our IMO-8400 external development expenses in 2013, as compared to 2012, was primarily attributable to increases in costs of our Phase 1 clinical trial in healthy subjects and nonclinical studies during 2013 and costs associated with the preparation for and conduct of our Phase 2 clinical trial in patients with psoriasis and preparation for our Phase 1/2 clinical trial in patients with Waldenström s macroglobulinemia that were incurred during 2013.

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We expect our IMO-8400 external development expenses to increase in 2015 as we plan to continue our clinical trial in patients with Waldenström s macroglobulinemia, initiate patient treatment in our DLBCL clinical trial, initiate a clinical trial in patients with dermatomyositis, or DM, prepare for the initiation of a clinical trial in patients with DMD, and continue manufacturing activities and nonclinical safety studies.

*IMO-9200 External Development Expenses.* These expenses include external expenses that we have incurred in connection with IMO-9200 since October 2014, when we commenced clinical development of IMO-9200. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-9200 clinical development but exclude internal costs such as payroll and overhead expenses. We have incurred approximately $1.7 million in external development expenses from October 2014 through December 31, 2014, including costs associated with our Phase 1 clinical trial in healthy subjects and additional nonclinical studies. We classified the IMO-9200 external development expenses incurred prior to October 2014 in other drug development expenses.

We expect our IMO-9200 external development expenses to increase in 2015 as we complete our Phase 1 clinical trial in healthy subjects and conduct additional preclinical studies of IMO-9200 for a selected autoimmune disease.

In addition to the expected increases in IMO-8400 and IMO-9200 external development expenses in 2015, we expect additional external development expenses as a result of our planned initiation of a clinical trial in IMO-2055 or IMO-2125 during the second half of 2015.

*Companion Diagnostic External Development Expenses.* These expenses include external expenses associated with our collaboration with Abbott Molecular for the development of a companion diagnostic for identification of patients with B-cell lymphoma harboring the MYD88 L265P oncogenic mutation incurred since January 2014, when development of the companion diagnostic commenced. During 2014, we incurred $2.2 million in companion diagnostic external development expenses, reflecting costs associated with start-up activities, the development of an assay as the prototype of the companion diagnostic, introduction of the assay for use in our ongoing clinical trial in patients with DLBCL harboring the MYD88 L265P oncogenic mutation, and the expected submission by Abbott Molecular of an Investigational Device Exemption with the FDA Center for Devices and Radiological Health in 2015. We will not receive any revenues from future sales of the companion diagnostic, if any.

*Other Drug Development Expenses.* These expenses include external expenses associated with preclinical development of identified compounds in anticipation of advancing these compounds into clinical development. In addition, these expenses include internal costs, such as payroll and overhead expenses, associated with preclinical development and products in clinical development. The external expenses associated with preclinical compounds include payments to contract vendors for manufacturing and the related stability studies, preclinical studies, including animal toxicology and pharmacology studies, and professional fees. Other drug development expenses also include costs associated with compounds that were previously being developed but are not currently being developed.

The increase in other drug development expenses in 2014, as compared to 2013, was primarily due to costs of preclinical studies and manufacturing activities to support the initiation of the Phase 1 clinical trial of IMO-9200, increasing payroll costs, including from the addition of a Chief Medical Officer in January 2014 and additional headcount associated with our expanded drug development programs, higher stock-based compensation costs attributable to options granted after the third quarter 2013 and the cost of preclinical studies in our GSO technology program. Costs associated with the clinical development of IMO-9200 since October 2014 are included in IMO-9200 external development expenses. The increase in other drug development expenses in 2014 was partially offset by a decrease in development expenses associated with IMO-3100, a TLR7 and TLR9 antagonist we were developing for psoriasis, reflecting our decision in the second quarter of 2013 to focus our resources on the development of IMO-8400.

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The decrease in other drug development expenses in 2013, as compared to 2012, was primarily due to costs incurred during 2012 for nonclinical safety studies and manufacture of drug supply to support the IND for IMO-8400 that we submitted during the third quarter of 2012 and a decrease in IMO-3100 development expenses in 2013. The decrease in IMO-3100 development expenses during 2013, as compared to 2012, was attributable to a decrease in costs associated with our Phase 2 clinical trial to evaluate IMO-3100 in patients with psoriasis as we completed patient activities in the trial in December 2012. Costs associated with the clinical development of IMO-8400 since October 2012 are included in IMO-8400 external development expenses. The decrease in other drug development expenses in 2013, as compared to 2012, was partially offset by costs incurred in 2013 in connection with preclinical studies and manufacturing activities to support the IND submission for IMO-9200 in the second half of 2014.

*Basic Discovery Expenses.* These expenses include our internal and external expenses relating to our discovery efforts with respect to our TLR-targeted programs, including agonists and antagonists of TLR3, TLR7, TLR8 and TLR9, TLR antisense, and our GSO program. These expenses reflect payments for laboratory supplies, external research, and professional fees, as well as payroll and overhead expenses. The increase in basic discovery expenses in 2014, as compared to 2013, was primarily due to increases in the cost of employee compensation and laboratory supplies reflecting increased activity and headcount associated with our GSO program. The decrease in basic discovery expenses in 2013, as compared to 2012, was primarily due to decreases in the cost of employee compensation reflecting reduced activity and reduced headcount and decreases in the cost of laboratory supplies resulting from our re-assessment and prioritization of our drug development programs in September 2011.

We do not know if we will be successful in developing any drug candidate from our research and development programs. At this time, and without knowing the results from our ongoing and planned clinical trials of IMO-8400 and IMO-9200, our planned clinical trial in IMO-2055 or IMO-2125 and our planned IND-enabling development programs in each of the first two disease indications selected for further development in our GSO program, 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 $3.6 million, or 47%, from $7.7 million in 2013 to $11.3 million in 2014. General and administrative expenses consist primarily of salary expense, stock compensation expense, consulting fees and professional legal fees associated with our patent applications and maintenance, our corporate regulatory filing requirements, our corporate legal matters, and our business development initiatives.

The increase in general and administrative expenses in 2014, as compared to 2013, was primarily due to higher stock-based compensation costs primarily attributable to options granted after September 30, 2013 and the recognition of amortization associated with options subject to accelerated vesting, higher cash compensation costs, including additional headcount associated with our strategic focus on our rare disease and oncology programs, the addition of a new Chief Executive Officer in December 2014, and the accrual of incentive compensation, and increases in corporate communications, investor relations, recruiting expenses, higher legal costs associated with patent matters, and accounting and auditing fees, including the cost of Sarbanes-Oxley compliance and the related internal control audit. The increase in general and administrative expenses during 2014 was partially offset by a decrease in consulting fees associated with business and strategic initiatives and lower corporate legal expenses as compared to 2013. We expect general and administrative expenses to increase in 2015, as compared to 2014, due to additional headcount to support our drug development programs.

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General and administrative expenses increased by $1.4 million, or 22%, from $6.3 million in 2012, to $7.7 million in 2013 primarily due to consulting fees associated with business and strategic initiatives during 2013. Corporate legal expenses associated with our corporate regulatory filing requirements also increased during 2013. The increase in general and administrative expenses was partially offset by lower legal costs associated with patent matters and lower stock compensation cost during 2013.

*Decrease in Fair Value of Warrant Liability*

During November 2011 we recorded a warrant liability of $3.2 million reflecting the fair value of the Series D warrants issued in our November 2011 Series D financing. We determined the Series D warrants to be a derivative instrument because they contained a specified anti-dilution provision that did not meet the indexed to the company s own stock exemption requirements in ASC 815-40, Derivatives and Hedging Contracts in an Entity s own Stock, ASC 815-40. As a result, we classified the Series D warrants as a liability and recorded them at fair value as of the transaction date. We marked these warrants to fair value through earnings each quarter. The fair value of the Series D warrants decreased to $1.2 million at December 31, 2011 primarily due to a decrease in the price of our common stock.

The fair value of the Series D warrant liability decreased from $1.2 million at December 31, 2011 to $0.5 million at November 9, 2012 primarily due to decreases in the market price of our common stock and the remaining term of the Series D warrants resulting in the recognition of $0.7 million in non-operating income in 2012. The sale of shares of Series E preferred stock and Series E warrants in our November 2012 Series E financing triggered an anti-dilution adjustment under the terms of the Series D warrants, resulting in the exercise price of the Series D warrants being reduced and fixed at the minimum $1.46 per share and the Series D warrants no longer being subject to any anti-dilution adjustments. Once the exercise price of the Series D warrants became fixed, the Series D warrants then met the exception under ASC 815-40 as they were indexed to the company s own stock and met certain criteria for equity classification. As a result, we marked the Series D warrants to fair value through earnings as of November 9, 2012 and reclassified the remaining $0.5 million Series D warrant liability to stockholders equity at that time. Consequently, we did not record any non-operating income or expense related to the Series D warrants during 2014 and 2013.

*Investment Income, net*

Investment income, net increased in 2014, as compared to 2013, primarily due to an increase in investment balances, including corporate debt securities, in 2014 resulting from our follow-on underwritten public offerings in September 2013 and February 2014 and warrant and option exercises. Investment income, net was a negligible amount in 2013 and 2012 because most of our invested funds were deposited in a money market fund, which paid minimal interest, during those years.

*Foreign Currency Exchange Gain (Loss)*

Our foreign currency exchange gain was $0.1 million in 2014, and we had losses of $0.1 million in 2013 and a negligible amount in 2012. The foreign currency exchange gain during 2014 was primarily due to the impact that the strengthening value of the U.S. dollar had on our Euro-denominated accrued liabilities. The foreign currency exchange losses during 2013 and 2012 were primarily due to the impact that the weakening value of the U.S. dollar had on our Euro-denominated accrued liabilities.

*Loss on Extinguishment of Convertible Preferred Stock and Preferred Stock Accretion and Dividends*

The $0.5 million in preferred stock dividends in 2014 reflects $0.1 million in dividends accrued on shares of our Series D preferred stock and $0.4 million in dividends accrued on shares of our Series E preferred stock. Our Series D preferred stock was converted into common stock in February 2014 at which time dividends on our Series D preferred stock ceased to accrue. Our Series E preferred stock was converted into common stock in December 2014 at which time dividends on our Series E preferred stock ceased to accrue.

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The $2.9 million in preferred stock dividends in 2013 consists of $1.8 million related to the loss on extinguishment of the Series D preferred stock and the Series E preferred stock that we have charged to net loss applicable to common stockholders as a preferred stock dividend, as described under Critical Accounting Policies and Estimates, $0.7 million in dividends accrued on shares of our Series D preferred stock and $0.4 million in dividends accrued on shares of our Series E preferred stock. The dividends accrued on shares of Series D preferred stock increased in 2013, as compared to 2012 because the terms of the Series D preferred stock required that dividends that we accrued, up to July 26, 2013, on the Series E preferred stock also be accrued on the Series D preferred stock on an as-converted to common stock basis. As a result of the approval of amendments to the dividend provisions of the Series D Certificate of Designations at our 2013 annual meeting of stockholders, effective July 26, 2013, dividends accrued on the Series E preferred stock are no longer required to be accrued on the Series D preferred stock.

The $3.2 million in preferred stock accretion and dividends in 2012 consists of $1.3 million related to the BCF of the Series E preferred stock and $1.2 million related to the additional BCF of the Series D preferred stock that we have accreted to preferred dividends, as described under Critical Accounting Policies and Estimates, $0.7 million in dividends payable on shares of our Series D preferred stock and a negligible amount of dividends accrued on shares of our Series E preferred stock.

*Net Loss Applicable to Common Stockholders*

As a result of the factors discussed above, our net loss applicable to common stockholders was $39.2 million, $21.1 million and $22.4 million for the years ended December 31, 2014, 2013 and 2012, respectively. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through December 31, 2014, we incurred losses of $191.3 million. We also incurred net losses of $260.2 million prior to December 31, 2000 during which time we were primarily involved in the development of non-TLR-targeted antisense technology. Since our inception, we had an accumulated deficit of $451.5 million through December 31, 2014. We expect to continue to incur substantial operating losses in the future.

*Net Operating Loss Carryforwards*

The Tax Reform Act of 1986 contains provisions that limit the amount of net operating loss carryforwards, or NOLs, and tax 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, 2014, have resulted in ownership changes in excess of 50% that will significantly limit our ability to utilize our NOL and tax credit carryforwards. In December 2014, we completed a study which determined that a cumulative three-year ownership change in excess of 50% had occurred in November 2012.

After adjusting our federal and state NOLs to reflect the ownership change limitations that resulted from this study, as of December 31, 2014, we had cumulative NOLs of approximately $79,112,000 and $75,395,000, respectively, available to reduce federal and state taxable income. These NOLs expire through 2034. In addition, after adjusting our federal and state tax credit carryforwards to reflect the ownership change limitations that were identified during this study, as of December 31, 2014, we had cumulative federal and state tax credit carryforwards of $1,680,000 and $749,000, respectively, available to reduce federal and state income taxes which expire through 2034 and 2029, respectively. Additional ownership change limitations may result from ownership changes that occur after November 2012.

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**Liquidity and Capital Resources**

*Sources of Liquidity*

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

- sale of common stock, preferred stock and warrants and warrant exercises;
- debt financing, including capital leases;
- license fees, research funding and milestone payments under collaborative and license agreements; and
- interest income.

*February 19, 2015 Follow-on Underwritten Public Offering*

On February 19, 2015, we closed a follow-on underwritten public offering, in which we sold 23,000,000 shares of common stock at a price to the public of $3.75 per share for aggregate gross proceeds of $86.3 million. The estimated net proceeds to us from the offering, after deducting underwriters discounts and commissions and other estimated offering costs and expenses were approximately $80.6 million.

*Loan and Security Agreement*

On September 30, 2014, we executed a loan and security agreement with Oxford Finance LLC, or Oxford. Under the agreement, Oxford committed to lend us up to an aggregate principal amount of $3,000,000 in one or more advances each of which is to be evidenced by a promissory note. Our obligations to Oxford will be secured by the specific laboratory, manufacturing, office or computer equipment financed under the agreement. Each equipment advance will bear interest at a fixed interest rate equal to the greater of 7.5% per annum and 7.27% plus the three-month U.S. Libor Rate per annum, set at the time of funding. Each equipment advance will be repaid in 36 monthly installments commencing on the applicable amortization date, which is July 1, 2015, for any equipment advance made on or before June 30, 2015, and is the first monthly payment date, for any equipment advance made on or after July 1, 2015. Monthly installments payable prior to July 1, 2015 will consist of accrued interest only and monthly installments payable on or after July 1, 2015 will consist of principal and accrued interest.

We are required to pay a final payment in an amount equal to 5.7% of the aggregate advanced amount under each equipment advance at the time that the final monthly installment is due or such earlier date as specified in the loan and security agreement. The weighted average annual effective interest rate on the notes payable based on the amount advanced through December 31, 2014, including the amortization of the facility fee and accrual of the final payment, is 11.1%. If we prepay all or a portion of the loan prior to maturity, we will pay the lender a prepayment fee of between 1% and 3% of the principal amount of such equipment advance.

As of December 31, 2014, we had received approximately $893,000 in advances under the loan and security agreement and had an additional $2,107,000 available under the agreement.

*February 10, 2014 Follow-on Underwritten Public Offering*

On February 10, 2014, we closed a follow-on underwritten public offering, in which we sold 7,867,438 shares of common stock at a price to the public of $4.00 per share and pre-funded warrants to purchase up to 2,158,750 shares of common stock at a price to the public of $3.99 per share for aggregate gross proceeds of $40.1 million. The pre-funded warrants have an exercise price of $0.01 per share and will expire if not exercised by February 10, 2021. The net proceeds to us from the offering, after deducting underwriters discounts and commissions and other offering costs and expenses and excluding the proceeds of the exercise of the warrants, if any, were approximately $37.2 million.

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*Warrant Exercises*

Warrants to purchase 5,543,802 shares of our common stock were exercised during 2014. We received proceeds of $7.5 million from the exercise of these warrants.

*Cash Flows*

As of December 31, 2014, we had approximately $48.6 million in cash, cash equivalents and investments, a net increase of approximately $13.0 million from December 31, 2013. Net cash used in operating activities totaled $31.3 million during 2014, reflecting our $38.6 million net loss, as adjusted for non-cash income and expenses, including stock-based compensation, depreciation and amortization. Net cash used in operating activities also reflects changes in our prepaid expenses and accounts payable, accrued expenses and other liabilities.

The net cash used in investing activities during 2014 reflects the purchase of $23.6 million of available-for-sale securities, which are investments that we do not have the positive intent to hold to maturity at the time of purchase, the maturity of $4.1 million of available-for-sale securities, and payments for the purchase of $1.1 million in property and equipment.

The $45.6 million net cash provided by financing activities during 2014 primarily reflects $37.2 million in net proceeds from our follow-on underwritten public offering of our securities in February 2014, which were partially offset by $0.1 million in costs related to our 2013 financings, $8.5 million in net proceeds from employee stock purchases under our 1995 Employee Stock Purchase Plan, or ESPP, and the exercise of common stock options and warrants and $0.8 million in net proceeds from the issuance of the promissory note under the loan and security agreement with Oxford which were partially offset by dividends paid on our Series D preferred stock and our Series E preferred stock.

As of December 31, 2013, we had approximately $35.6 million in cash, cash equivalents and investments, a net increase of approximately $25.5 million from December 31, 2012. Net cash used in operating activities totaled $17.1 million during 2013, reflecting an $18.2 million net loss in 2013, as adjusted for non-cash income and expenses, including stock-based compensation and depreciation. Net cash used in operating activities also reflects changes in our prepaid expenses and accounts payable, accrued expenses and other liabilities.

The net cash used in investing activities during 2013 of $9.3 million reflects the purchase of $9.3 million in investments that we do not have the positive intent to hold to maturity at the time of purchase, which are referred to as available-for-sale securities.

The $42.7 million net cash provided by financing activities during 2013 primarily reflects $40.2 million in net proceeds from our equity financings, including our follow-on underwritten public offerings of our securities in May 2013 and September, 2013, and $3.5 million in net proceeds from the exercise of common stock options and warrants and employee stock purchases under our ESPP which were partially offset by $0.1 million in costs related to the November 2012 Series E financing that were paid in 2013 and dividends paid on our Series D preferred stock and our Series E preferred stock.

As of December 31, 2012, we had approximately $10.1 million in cash and cash equivalents, a net decrease of approximately $14.5 million from December 31, 2011. Net cash used in operating activities totaled $19.9 million during 2012, reflecting a $19.2 million net loss for 2012, as adjusted for non-cash income and expenses, including stock-based compensation, depreciation and the $0.7 million decrease in the warrant liability that was credited to operations through November 9, 2012. It also reflects changes in our prepaid expenses and accounts payable, accrued expenses and other liabilities.

The $5.4 million net cash provided by financing activities during 2012 primarily reflects the $6.0 million in net proceeds from the sale of Series E preferred stock and Series E warrants in November 2012 and the proceeds received from employee stock purchases in 2012, offset, in part, by dividends paid on our Series D preferred stock and payments on our capital lease.

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*Funding Requirements*

We have incurred operating losses in all fiscal years since our inception except 2002, 2008 and 2009, and we had an accumulated deficit of $451.5 million at December 31, 2014. We expect to incur substantial operating losses in future periods. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, total assets and working capital. We have received no revenues from the sale of drugs. As of February 19, 2015, substantially all of our revenues have been from collaboration and license agreements. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any drugs. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our products will become commercially available or when we will become profitable, if at all.

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

We had cash, cash equivalents and investments of approximately $48.6 million at December 31, 2014. We believe that our existing cash, cash equivalents and investments, including the estimated net proceeds of $80.6 million from the follow-on public offering that we closed in February 2015, will enable us to fund our operations into the first quarter of 2017. Specifically, we believe that our available funds will be sufficient to enable us to:

- complete our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia and our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL harboring the MYD88 L265P oncogenic mutation;
- initiate two Phase 1/2 clinical trials involving either IMO-2055 or IMO-2125 in combination with a checkpoint inhibitor for selected oncology targets and complete at least one of these trials;
- initiate a Phase 2 clinical trial of IMO-8400 in patients with dermatomyositis and a Phase 1/2 clinical trial of IMO-8400 in patients with DMD;
- complete our ongoing Phase 1 clinical trial of IMO-9200 in healthy subjects; and
- conduct disease model studies and begin IND-enabling development programs in each of the first two disease indications selected for further development in our GSO program.

We expect that we will require substantial additional funds to conduct any additional research and development of our TLR drug candidates or GSO technology, including preclinical testing and clinical trials of our drug candidates, and to fund our operations. We are seeking and expect to continue to seek additional funding through collaborations, the sale or license of assets or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain funding are:

- the results of our clinical and preclinical development activities in our genetically defined forms of B-cell lymphoma and rare disease programs, our immuno-oncology program, and our GSO program and our ability to advance our drug candidates and GSO technology on the timelines anticipated;
- the cost, timing, and outcome of regulatory reviews;

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

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

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

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In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require additional funds or further cost reductions.

Financing may not be available to us when we need it or may not be available to us on favorable or acceptable terms or at all. 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. An equity financing that involves existing stockholders may cause a concentration of ownership. 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 or equity financing may contain terms which are not favorable to us or to our stockholders, such as liquidation and other preferences, or liens or other restrictions on our assets. As discussed in note 10 to the financial statements appearing elsewhere in this Annual Report on Form 10-K, additional equity financings may also result in cumulative changes in ownership over a three-year period in excess of 50% which would limit the amount of net operating loss and tax credit carryforwards that we may utilize in any one year.

If we are unable to obtain adequate funding on a timely basis or at all, we will be required to terminate, modify or delay preclinical or clinical trials of one or more of our drug candidates, significantly curtail or terminate discovery or development programs for new drug candidates or relinquish rights to portions of our technology, drug candidates and/or products.

*Contractual Obligations*

As of December 31, 2014, our contractual commitments were as follows:

| | | Payments Due by Period | | | |
|---|---|---|---|---|---|
| **Contractual Commitment** | **Total** | **Less than 1 year** | **1-3 years** | **3-5 years** | **More than 5 years** |
| | | | **(In thousands)** | | |
| Operating lease | $ 4,117 | $ 1,521 | $ 2,596 | $ | $ |
| Loan and security agreement | 1,085 | 200 | 666 | 219 | |
| License agreement | 20 | 10 | 10 | | |
| Total | $ 5,222 | $ 1,731 | $ 3,272 | $ 219 | $ |

Our only material lease commitment relates to our facility in Cambridge, Massachusetts, which expires on August 31, 2017 subject to a three-year renewal option exercisable by us. The license agreement commitment relates to minimum amounts due under a license related to our earlier antisense technology. Since we developed all of our TLR technology internally, there are no TLR technology in-license agreements.

As of December 31, 2014, we had no off-balance sheet arrangements.

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

Foreign currency exchange gains and losses may result from amounts to be paid under our clinical trial agreements that are denominated in Euros. As of December 31, 2014, we had net accrued obligations of 0.3 million ($0.4 million using a December 31, 2014 exchange rate). All other material assets and liabilities are in U.S. dollars, which is our functional currency.

We maintain investments in accordance with our investment policy. The primary objectives of our investment activities are to preserve principal, maintain proper liquidity to meet operating needs and maximize

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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. At December 31, 2014, all of our invested funds were invested in two money market funds, classified in cash and cash equivalents on the accompanying balance sheet, corporate bonds and commercial paper classified in short-term investments.

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

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

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

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**Quarterly Operating Results (Unaudited)**

The following table presents the unaudited statement of operations and comprehensive loss data for each of the eight quarters in the period ended December 31, 2014. 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, 2014 | Sep. 30, 2014 | Jun. 30, 2014 | Mar. 31, 2014 | Dec. 31, 2013 | Sep. 30, 2013 | Jun. 30, 2013 | Mar. 31, 2013 |
| | (In thousands, except per share data) | | | | | | | |
| **Statement of Operations and Comprehensive Loss Data:** | | | | | | | | |
| Alliance revenue | $ 2 | $ 30 | $ 38 | $ 3 | $ 4 | $ 7 | $ 29 | $ 7 |
| Operating expenses: | | | | | | | | |
| Research and development | 8,245 | 6,678 | 5,637 | 6,933 | 3,640 | 2,510 | 1,997 | 2,328 |
| General and administrative | 3,686 | 2,873 | 2,730 | 2,043 | 2,436 | 2,179 | 1,599 | 1,527 |
| Total operating expenses | 11,931 | 9,551 | 8,367 | 8,976 | 6,076 | 4,689 | 3,596 | 3,855 |
| Loss from operations | (11,929) | (9,521) | (8,329) | (8,973) | (6,072) | (4,682) | (3,567) | (3,848) |
| Investment income, net | (6) | 14 | 16 | 15 | 5 | 2 | 2 | 2 |
| Foreign currency exchange gain (loss) | 17 | 52 | 5 | (3) | (23) | (58) | (26) | 39 |
| Net loss | $ (11,918) | $ (9,455) | $ (8,308) | $ (8,961) | $ (6,090) | $ (4,738) | $ (3,591) | $ (3,807) |
| Loss on extinguishment of convertible preferred stock and preferred stock accretion and dividends | 97 | 119 | 118 | 185 | 279 | 278 | 2,030 | 279 |
| Net loss applicable to common stockholders | $ (12,015) | $ (9,574) | $ (8,426) | $ (9,146) | $ (6,369) | $ (5,016) | $ (5,621) | $ (4,086) |
| Basic and diluted net loss per common share applicable to common stockholders (1) | $ (0.14) | $ (0.11) | $ (0.10) | $ (0.12) | $ (0.10) | $ (0.11) | $ (0.15) | $ (0.15) |
| Shares used in computing basic and diluted net loss per common share applicable to common stockholders (1) | 87,657 | 84,527 | 82,961 | 76,018 | 63,795 | 45,720 | 38,048 | 27,644 |
| Net loss | $ (11,918) | $ (9,455) | $ (8,308) | $ (8,961) | $ (6,090) | $ (4,738) | $ (3,591) | $ (3,807) |
| Other comprehensive loss: | | | | | | | | |
| Unrealized (loss) gain on available-for-sale securities | (15) | (5) | (1) | 11 | (7) | | | |
| Other comprehensive loss | (15) | (5) | (1) | 11 | (7) | | | |
| Comprehensive loss | $ (11,933) | $ (9,460) | $ (8,309) | $ (8,950) | $ (6,097) | $ (4,738) | $ (3,591) | $ (3,807) |

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

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**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 Exchange Act) as of December 31, 2014. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving 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 principal executive officer and principal financial officer concluded that as of December 31, 2014, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others, particularly during the period in which this report was prepared, and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms.

**Internal Control over Financial Reporting**

**a) Management s Annual Report on Internal Control over Financial Reporting**
Our management, with the participation of our principal executive officer and principal financial officer, 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, 2014. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control Integrated Framework* (2013).

Based on this assessment, management believes that, as of December 31, 2014, the Company s internal control over financial reporting is effective based on those criteria.

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Ernst & Young LLP, our independent registered public accounting firm, has issued a report on the effectiveness of our internal control over financial reporting as of December 31, 2014. This report appears immediately below.

**b) Attestation Report of the Registered Public Accounting Firm**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Idera Pharmaceuticals, Inc.

We have audited Idera Pharmaceuticals Inc. s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (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 Annual 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, 2014, 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, 2014 and 2013, and the related statements of operations and comprehensive loss, shareholders equity, and cash flows for each of the three years in the period ended December 31, 2014 of Idera Pharmaceuticals Inc. and our report dated March 12, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 12, 2015

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**c) Changes in Internal Controls over Financial Reporting.**
No change in our internal control over financial reporting occurred during the fourth quarter of the fiscal year ended December 31, 2014 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 8, 2015.

**Item 10.** ***Directors, Executive Officers, and Corporate Governance.***
We have adopted a written code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We have posted a current copy of the Code of Business Conduct and Ethics in the Investors Corporate Governance section of our website, which is located at www.iderapharma.com. We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of our code of business conduct and ethics by posting such information on our website at www.iderapharma.com.

The remainder of the response to this item will be contained in the 2015 Proxy Statement under the captions Proposal One Election of Directors, Section 16(a) Beneficial Ownership Reporting Compliance and Corporate Governance Information, which sections are incorporated herein by reference.

**Item 11.** ***Executive Compensation.***
The response to this item will be contained in the 2015 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 will be contained in the 2015 Proxy Statement under the caption Security Ownership of Certain Beneficial Owners and Management, which section is incorporated herein by reference.

The disclosures required for securities authorized for issuance under equity compensation plans are contained in the 2015 Proxy Statement under the caption Equity Compensation Plan Information, which section is incorporated herein by reference.

**Item 13.** ***Certain Relationships and Related Transactions, and Director Independence.***
The response to this item will be contained in the 2015 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 will be contained in the 2015 Proxy Statement under the caption Accounting Matters Independent Registered Public Accounting Firm Fees, which section is incorporated herein by reference.

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**PART IV.**

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

(a) (1) *Financial Statements.*



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

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

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

(c) None.

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this 12th day of March 2015.

Idera Pharmaceuticals, Inc.

By: /s/ Vincent J. Milano
Vincent J. Milano
*President and*

*Chief Executive Officer*

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

| Signature | Title | Date |
|---|---|---|
| /s/ Vincent J. Milano<br>Vincent J. Milano | President, Chief Executive Officer and Director (Principal Executive Officer) | March 12, 2015 |
| /s/ Louis J. Arcudi III<br>Louis J. Arcudi, III | Chief Financial Officer and Treasurer (Principal Financial and<br>Accounting Officer) | March 12, 2015 |
| /s/ James A. Geraghty<br>James A. Geraghty | Chairman of the Board of Directors | March 12, 2015 |
| /s/ Sudhir Agrawal<br>Sudhir Agrawal, D. Phil. | Director | March 12, 2015 |
| /s/ Julian C. Baker<br>Julian C. Baker | Director | March 12, 2015 |
| /s/ Youssef El Zein<br>Youssef El Zein | Director | March 12, 2015 |
| /s/ Mark Goldberg<br>Mark Goldberg, M.D. | Director | March 12, 2015 |
| /s/ Robert W. Karr<br>Robert W. Karr, M.D. | Director | March 12, 2015 |

| | | |
|---|---|---|
| /s/ Malcolm MacCoss | Director | March 12, 2015 |
| Malcolm MacCoss, Ph.D. | | |
| /s/ Kelvin M. Neu | Director | March 12, 2015 |
| Kelvin M. Neu, M.D. | | |

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| Signature | Title | Date |
|---|---|---|
| /s/ William S. Reardon<br>William S. Reardon, C.P.A. | Director | March 12, 2015 |
| /s/ Eve E. Slater<br>Eve E. Slater, M.D., F.A.C.C. | Director | March 12, 2015 |

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**IDERA PHARMACEUTICALS, INC.**

**INDEX TO FINANCIAL STATEMENTS**

**December 31, 2014**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the accompanying balance sheets of Idera Pharmaceuticals, Inc. (the Company) as of December 31, 2014 and 2013, and the related statements of operations and comprehensive loss, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2014. 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, 2014 and 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Idera Pharmaceuticals, Inc. s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 12, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 12, 2015

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**IDERA PHARMACEUTICALS, INC.**

**BALANCE SHEETS**

| (In thousands, except per share amounts) | December 31, 2014 | December 31, 2013 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 19,971 | $ 26,278 |
| Short-term investments | 21,256 | 3,125 |
| Prepaid expenses and other current assets | 1,203 | 874 |
| Total current assets | 42,430 | 30,277 |
| Long-term investments | 7,344 | 6,189 |
| Property and equipment, net | 1,306 | 90 |
| Restricted cash and other assets | 346 | 311 |
| Total assets | $ 51,426 | $ 36,867 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,458 | $ 904 |
| Accrued expenses | 4,460 | 3,506 |
| Current portion of note payable | 128 | |
| Total current liabilities | 7,046 | 4,410 |
| Note payable, net of current portion | 742 | |
| Other liabilities | 236 | 5 |
| Total liabilities | 8,024 | 4,415 |
| Commitments and contingencies (Note 9) | | |
| Stockholders equity: | | |
| Preferred stock, $0.01 par value, Authorized 5,000 shares: | | |
| Series E convertible preferred stock, Designated 424 shares; Issued and outstanding zero shares and 424 shares at December 31, 2014 and December 31, 2013, respectively | | 5,528 |
| Series D convertible preferred stock, Designated zero shares and 1,124 shares at December 31, 2014 and December 31, 2013, respectively; Issued and outstanding zero shares and 1,124 shares at December 31, 2014 and December 31, 2013, respectively | | 5,464 |
| Series A convertible preferred stock; Designated 1,500 shares, Issued and outstanding 1 share at December 31, 2014 and December 31, 2013 | | |
| Common stock, $0.001 par value, Authorized 280,000 shares; Issued and outstanding 94,829 and 66,252 shares at December 31, 2014 and 2013, respectively | 95 | 66 |
| Additional paid-in capital | 494,850 | 434,285 |
| Accumulated deficit | (451,526) | (412,884) |
| Accumulated other comprehensive loss | (17) | (7) |
| Total stockholders equity | 43,402 | 32,452 |
| Total liabilities and stockholders equity | $ 51,426 | $ 36,867 |

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

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**IDERA PHARMACEUTICALS, INC.**

**STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

| (In thousands, except per share amounts) | Years Ended December 31, 2014 | 2013 | 2012 |
|---|---|---|---|
| Alliance revenue | $ 73 | $ 47 | $ 51 |
| Operating expenses: | | | |
| Research and development | 27,493 | 10,475 | 13,673 |
| General and administrative | 11,332 | 7,741 | 6,279 |
| Total operating expenses | 38,825 | 18,216 | 19,952 |
| Loss from operations | (38,752) | (18,169) | (19,901) |
| Other income (expense): | | | |
| Decrease in fair value of warrant liability | | | 675 |
| Investment income, net | 39 | 11 | 9 |
| Foreign currency exchange gain (loss) | 71 | (68) | (23) |
| Net loss | (38,642) | (18,226) | (19,240) |
| Loss on extinguishment of convertible preferred stock, preferred stock accretion and dividends | 519 | 2,866 | 3,210 |
| Net loss applicable to common stockholders | $ (39,161) | $ (21,092) | $ (22,450) |
| Basic and diluted net loss per common share applicable to common stockholders (Note 12) | $ (0.47) | $ (0.48) | $ (0.81) |
| Shares used in computing basic and diluted net loss per common share applicable to common stockholders | 82,827 | 43,906 | 27,639 |
| Net loss | $ (38,642) | $ (18,226) | $ (19,240) |
| Other comprehensive loss: | | | |
| Increase in unrealized loss and decrease in unrealized gain on available-for-sale securities | (10) | (7) | |
| Other comprehensive loss | (10) | (7) | |
| Comprehensive loss | $ (38,652) | $ (18,233) | $ (19,240) |

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

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**IDERA PHARMACEUTICALS, INC.**

**STATEMENTS OF STOCKHOLDERS EQUITY**

| (In thousands) | Series E Convertible Preferred Stock Number of Shares | Series E Convertible Preferred Stock Amount | Series D Convertible Preferred Stock Number of Shares | Series D Convertible Preferred Stock Amount | Common Stock Number of Shares | Common Stock $0.001 Par Value | Additional Paid-In Capital | Accumulated Deficit | Accumulated Other Comprehensive (Loss)/Income | Total Stockholders Equity |
|---|---|---|---|---|---|---|---|---|---|---|
| **Balance, December 31, 2011** | | | | | 27,637 | $ 28 | $ 387,414 | $ (375,418) | $ | $ 12,024 |
| Exercise of common stock options, warrants and employee stock purchases | | | | | 5 | | 4 | | | 4 |
| Issuance of common stock for services | | | | | 1 | | 1 | | | 1 |
| Non-employee stock option expense | | | | | | | 5 | | | 5 |
| Stock-based compensation | | | | | | | 2,096 | | | 2,096 |
| Series D redeemable preferred stock beneficial conversion feature | | | | | | | 1,238 | | | 1,238 |
| Series D redeemable preferred stock accretion and dividends | | | | | | | (1,908) | | | (1,908) |
| Transfer of Series D warrant to equity | | | | | | | 503 | | | 503 |
| Sale of Series E preferred stock and warrants, net of issuance costs | 424 | $ 3,701 | | | | | 2,322 | | | 6,023 |
| Series E preferred stock beneficial conversion feature | | (1,262) | | | | | 1,262 | | | |
| Series E preferred stock accretion and dividends | | 1,262 | | | | | (1,302) | | | (40) |
| Net loss | | | | | | | | (19,240) | | (19,240) |
| **Balance, December 31, 2012** | 424 | $ 3,701 | | | 27,643 | $ 28 | $ 391,635 | $ (394,658) | $ | $ 706 |
| Sale of common stock and warrants, net of issuance costs | | | | | 31,227 | 31 | 40,071 | | | 40,102 |
| Exercise of common stock options, warrants and employee stock purchases | | | | | 7,346 | 7 | 3,520 | | | 3,527 |
| Issuance of common stock for services | | | | | 36 | | 26 | | | 26 |
| Non-employee stock option expense | | | | | | | 121 | | | 121 |
| Stock-based compensation | | | | | | | 1,398 | | | 1,398 |
| Extinguishment of convertible preferred stock & recognition of warrants issued | (424) | (3,701) | | | | | (1,370) | | | (5,071) |
| Recognition of convertible preferred stock | 424 | 5,528 | 1,124 | $ 5,464 | | | | | | 10,992 |
| Series D convertible preferred stock dividends | | | | | | | (756) | | | (756) |
| Series E convertible preferred stock dividends | | | | | | | (360) | | | (360) |
| Unrealized loss on marketable securities | | | | | | | | | (7) | (7) |
| Net loss | | | | | | | | (18,226) | | (18,226) |
| **Balance, December 31, 2013** | 424 | $ 5,528 | 1,124 | $ 5,464 | 66,252 | $ 66 | $ 434,285 | $ (412,884) | $ (7) | $ 32,452 |
| Sale of common stock and warrants, net of issuance costs | | | | | 7,867 | 8 | 37,229 | | | 37,237 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Exercise of common stock options, warrants and employee stock purchases | | | | | 5,932 | 6 | 8,450 | | | | 8,456 |
| Issuance of common stock for services | | | | | 27 | | 82 | | | | 82 |
| Non-employee stock option expense | | | | | | | 24 | | | | 24 |
| Stock-based compensation | | | | | | | 4,322 | | | | 4,322 |
| Series D convertible preferred stock dividends | | | | | | | (66) | | | | (66) |
| Series E convertible preferred stock dividends | | | | | | | (453) | | | | (453) |
| Unrealized loss on marketable securities | | | | | | | | | | (10) | (10) |
| Conversion of Series D preferred stock to common | | | (1,124) | (5,464) | 6,266 | 6 | 5,458 | | | | 0 |
| Conversion of Series E preferred stock to common | (424) | (5,528) | | | 8,485 | 9 | 5,519 | | | | 0 |
| Net loss | | | | | | | | (38,642) | | | (38,642) |
| **Balance, December 31, 2014** | | | | | 94,829 | $ 95 | $ 494,850 | $ (451,526) | $ | (17) | $ 43,402 |

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

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**IDERA PHARMACEUTICALS, INC.**

**STATEMENTS OF CASH FLOWS**

| (In thousands) | Years Ended December 31, 2014 | 2013 | 2012 |
|---|---|---|---|
| **Cash Flows from Operating Activities:** | | | |
| Net loss | $ (38,642) | $ (18,226) | $ (19,240) |
| Adjustments to reconcile net loss to net cash used in operating activities | | | |
| Loss from disposition of assets | 1 | | 4 |
| Non-employee stock option expense | 24 | 121 | 5 |
| Stock-based compensation | 4,322 | 1,398 | 2,096 |
| Decrease in fair value of warrant liability | | | (675) |
| Issuance of common stock for services rendered | 82 | 26 | 1 |
| Amortization of investment premiums | 213 | 9 | |
| Depreciation and amortization expense | 206 | 137 | 251 |
| Changes in operating assets and liabilities | | | |
| Prepaid expenses and other current assets | (329) | (676) | 57 |
| Accounts payable, accrued expenses, and other liabilities | 2,802 | 74 | (2,415) |
| Net cash used in operating activities | (31,321) | (17,137) | (19,916) |
| **Cash Flows from Investing Activities:** | | | |
| Purchases of available-for-sale securities | (23,623) | (9,331) | |
| Proceeds from maturity of available-for-sale securities | 4,115 | | |
| Purchases of property and equipment | (1,093) | (9) | |
| Net cash (used in) provided by investing activities | (20,601) | (9,340) | |
| **Cash Flows from Financing Activities:** | | | |
| Sale of common stock and warrants, net of issuance costs | 37,137 | 40,202 | |
| Sale of Series E convertible preferred stock and warrants, net of issuance costs | | | 6,023 |
| Proceeds from issuance of note payable | 825 | | |
| Proceeds from exercise of common stock warrants and options and employee stock purchases | 8,456 | 3,527 | 4 |
| Dividends paid | (798) | (1,066) | (583) |
| Payments on capital lease | (5) | (4) | (3) |
| Net cash provided by financing activities | 45,615 | 42,659 | 5,441 |
| Net (decrease) increase in cash and cash equivalents | (6,307) | 16,182 | (14,475) |
| Cash and cash equivalents, beginning of year | 26,278 | 10,096 | 24,571 |
| Cash and cash equivalents, end of year | $ 19,971 | $ 26,278 | $ 10,096 |

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

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS**

**December 31, 2014**

**1. Organization**

Idera Pharmaceuticals, Inc. ( Idera or the Company ) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for oncology and rare diseases. The Company uses two distinct proprietary drug discovery technology platforms to design and develop drug candidates. The Company developed these platforms based on its scientific expertise and pioneering work with synthetic oligonucleotides as therapeutic agents. Using its Toll-like receptor ( TLR ) targeting technology, the Company designs synthetic oligonucleotide-based drug candidates to act by modulating the activity of specific TLRs. In addition, using its gene silencing oligonucleotide ( GSO ) technology, the Company is developing GSOs to turn off the messenger RNA ( mRNA ) associated with disease causing genes. The Company considers its GSO technology to be a third generation antisense technology that can potentially reduce the immunotoxicity and increase the potency of earlier generation antisense and RNA interference ( RNAi ) technologies.

Idera is currently conducting a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia and Phase 1/2 clinical trial of IMO-8400 in patients with diffuse large B-cell lymphoma ( DLBCL ) who harbor the MYD88 L265P oncogenic mutation. The Company is planning to initiate clinical development of IMO-8400 for the treatment of rare diseases and has selected dermatomyositis and Duchenne muscular dystrophy ( DMD ) as the first non-cancer rare diseases for which it plans to develop IMO-8400. The Company believes it can develop and commercialize therapies on its own in these disease indications, which are characterized by small, well-defined patient populations with serious unmet medical needs.

The Company is also advancing a second novel synthetic oligonucleotide antagonist of TLR7, TLR8 and TLR9, IMO-9200, as a drug candidate for potential use in selected autoimmune disease indications. The Company is conducting a Phase 1 clinical trial of IMO-9200 in healthy volunteers.

The Company is also developing its GSOs to specifically address challenges associated with earlier generation antisense and RNAi technologies. Although currently used technologies to silence RNA have demonstrated the ability to inhibit the expression of disease-associated proteins, the Company believes that to reach their full therapeutic potential, gene silencing technologies need to achieve an improved therapeutic index with efficient systemic delivery without using a delivery technology, reduced immunotoxicity and increased potency. The Company is currently undertaking an analysis of oncology and rare disease indications for development of drug candidates from its GSO technology. The Company is planning to conduct disease model studies and begin IND-enabling development programs in each of the first two disease indications selected for further development in its GSO program in the second half of 2015.

At December 31, 2014, the Company had an accumulated deficit of $451,526,000. The Company expects to incur substantial operating losses in future periods. The Company does not expect to generate significant product revenue, sales-based milestones or royalties until the Company successfully completes development and obtains marketing approval for drug candidates, either alone or in collaborations with third parties, which the Company expects will take a number of years. In order to commercialize its drug candidates, the Company needs to complete clinical development and 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.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**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) Cash, Cash Equivalents and 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, 2014 and 2013 consisted of cash and money market funds.

Management determines the appropriate classification of marketable securities at the time of purchase. Investments that the Company does not have the positive intent to hold to maturity are classified as available-for-sale and reported at fair market value. Available-for-sale investments are classified as long-term if their contractual maturity is greater than one year at the balance sheet date and the Company does not have the intent to sell them in order to fund current operations. Unrealized gains and losses associated with available-for-sale investments are recorded in Accumulated other comprehensive income on the accompanying balance sheets. The amortization of premiums and accretion of discounts, and any realized gains and losses and declines in value judged to be other-than-temporary, and interest and dividends for all available-for-sale securities are included in Investment income, net on the accompanying statements of operations. Investments that the Company intends to hold to maturity are classified as held-to-maturity investments. The Company had no held-to-maturity investments at either December 31, 2014 or 2013. 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 2014, 2013 or 2012. There were no losses or other-than-temporary declines in value included in Investment income, net for any securities for the three years ended December 31, 2014. The Company had no auction rate securities as of December 31, 2014 and 2013.

*(c) Restricted Cash*

As part of the Company s lease arrangement for its office and laboratory facility, the Company is required to restrict cash held in a certificate of deposit securing a line of credit for the lessor. As of December 31, 2014 and 2013, the restricted cash amounted to $311,000 held in certificates of deposit securing a line of credit for the lessor.

*(d) Depreciation and Amortization*

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

*(e) Revenue Recognition*

For the years ended December 31, 2014, 2013 and 2012, alliance revenue consisted primarily of revenue from the reimbursement by licensees of costs associated with patent maintenance. The Company recognizes the reimbursement revenue during the period in which the related expenses are incurred.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

*(f) Financial Instruments*

The fair value of the Company s financial instruments is determined and disclosed in accordance with the three-tier fair value hierarchy specified in Note 2(m). The Company is required to disclose the estimated fair values of its financial instruments. The Company s financial instruments consist of cash, cash equivalents, available-for-sale investments, receivables and a note payable. The estimated fair values of these financial instruments approximate their carrying values as of December 31, 2014 and 2013. As of December 31, 2014, the Company did not have any derivatives, hedging instruments or other similar financial instruments except for the note issued under the Company s loan and security agreement, which is discussed in Note 5(a), including put and call features which the Company determined are clearly and closely associated with the debt host and do not require bifurcation as a derivative liability, or the fair value of the feature is immaterial. As of December 31, 2013, the Company did not have any derivatives, hedging instruments or other similar financial instruments except for the Series D convertible preferred stock (the Series D preferred stock ) embedded features discussed in Note 7(a) and the Series E convertible preferred stock (the Series E preferred stock ) embedded features discussed in Note 8(g).

*(g) Comprehensive Income (Loss)*

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive income (loss) for the years ended December 31, 2014, 2013 and 2012 is comprised of reported net income (loss) and any change in net unrealized gains and losses on investments during each year, which is included in Accumulated other comprehensive income on the accompanying balance sheets. The Company applies Accounting Standards Update ( ASU ) No. 2011-05, Comprehensive Income by presenting the components of net income and other comprehensive income as one continuous statement.

The following table includes the changes in the accumulated balance of the component of other comprehensive (loss) gain for the years ended December 31, 2014 and 2013:

| (In thousands) | Year ended December 31, 2014 | 2013 |
|---|---|---|
| Accumulated unrealized loss on available-for-sale securities at beginning of period | $ (7) | $ |
| Change during the period | (10) | (7) |
| Accumulated unrealized loss on available-for-sale securities at end of period | $ (17) | $ (7) |

There was no accumulated unrealized gain or loss on available-for-sale securities during 2012.

*(h) Net Income (Loss) per Common Share applicable to Common Stockholders*

Basic and diluted net loss per common share applicable to common stockholders is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net loss per common share applicable to common stockholders is the same as basic net loss per common share applicable to common stockholders for each of the three years ended December 31, 2014 as the effects of the Company s potential common stock equivalents are antidilutive (see Note 12).

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

*(i) Segment Reporting*

The Company views its operations and manages its business as one operating segment. Accordingly, the Company operates in one segment, which is the business of discovering and developing novel therapeutics that modulate immune responses through TLRs. As a result, the financial information disclosed herein represents all of the material financial information related to the Company s principal operating segment. For all of the periods presented, all of the Company s revenues were generated in the United States. As of December 31, 2014 and 2013, all assets were located in the United States.

*(j) Stock-Based Compensation*

The Company recognizes all share-based payments to employees and directors as expense in the statements of operations and comprehensive loss based on their fair values. The Company records compensation expense over an award s requisite service period, or vesting period, based on the award s fair value at the date of grant. The Company s policy is to charge the fair value of stock options as an expense, adjusted for forfeitures, on a straight-line basis over the vesting period, which is generally four years for employees and three years for directors.

The Company recorded charges of $4,322,000, $1,398,000, and $2,096,000 for the years ended December 31, 2014, 2013 and 2012, respectively, for stock-based compensation expense attributable to share-based payments made to employees and directors. The 2014 charge includes approximately $1,293,000 for the recognition of amortization associated with an employee s options that were subject to accelerated vesting as a result of a modification. The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model. The following assumptions apply to the options to purchase 8,232,424, 5,072,583, and 187,500 shares of common stock granted to employees and directors during the years ended December 31, 2014, 2013 and 2012, respectively:

| | 2014 | 2013 | 2012 |
|---|---|---|---|
| Average risk free interest rate | 1.4% | 1.3% | 0.8% |
| Expected dividend yield | | | |
| Expected lives (years) | 4.4 | 5.0 | 5.6 |
| Expected volatility | 86% | 67% | 62% |
| Weighted average grant date fair value of options granted during the period (per share) | $ 2.36 | $ 0.89 | $ 0.51 |
| Weighted average exercise price of options granted during the period (per share) | $ 3.69 | $ 1.55 | $ 0.92 |

The expected lives of the options and the expected volatility are based on historical experience. All options granted during the three years ended December 31, 2014 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant**.**

The fair value of options that vested during 2014, 2013 and 2012 amounted to $4,208,000, $1,429,000 and $2,123,000, respectively. The intrinsic value of options exercised amounted to $573,000 and $150,000 during 2014 and 2013, respectively. There were no option exercises in 2012. As of December 31, 2014, there was $18,669,000 of unrecognized compensation cost related to nonvested stock-based compensation arrangements, which the Company expects to recognize over a weighted average period of 3.6 years.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

*(k) 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.

*(l) Concentration of Credit Risk*

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents and available-for-sale 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, 2014, all of the Company s cash, cash equivalents and investments are held at two financial institutions.

*(m) Fair Value of Assets and Liabilities*

The Company measures fair value at the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date using assumptions that market participants would use in pricing the asset or liability (the inputs ) into a three-tier fair value hierarchy. This fair value hierarchy gives the highest priority (Level 1) to quoted prices in active markets for identical assets or liabilities and the lowest priority (Level 3) to unobservable inputs in which little or no market data exists, requiring companies to develop their own assumptions. Observable inputs that do not meet the criteria of Level 1, and include quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets and liabilities in markets that are not active, are categorized as Level 2. Level 3 inputs are those that reflect the Company s estimates about the assumptions market participants would use in pricing the asset or liability, based on the best information available in the circumstances. Valuation techniques for assets and liabilities measured using Level 3 inputs may include unobservable inputs such as projections, estimates and management s interpretation of current market data. These unobservable Level 3 inputs are only utilized to the extent that observable inputs are not available or cost-effective to obtain. The Company applies ASU No. 2011-04, Fair Value Measurement (Topic 820), in its fair value measurements and disclosures.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

The table below presents the assets and liabilities measured and recorded in the financial statements at fair value on a recurring basis at December 31, 2014 and 2013 categorized by the level of inputs used in the valuation of each asset and liability.

| (In thousands) | | Total | Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
|---|---|---|---|---|---|
| **December 31, 2014** | | | | | |
| Assets | | | | | |
| Money market funds | | $ 17,156 | $ 17,156 | $ | $ |
| Other cash equivalents | commercial paper | 2,500 | | 2,500 | |
| Short-term investments | commercial paper | 4,494 | | 4,494 | |
| Short-tem investments | certificate of deposit | 500 | | 500 | |
| Short-term investments | corporate bonds | 14,357 | | 14,357 | |
| Short-term investments | municipal bonds | 1,905 | | 1,905 | |
| Long-term investments | | 7,344 | | 7,344 | |
| Total Assets | | $ 48,256 | $ 17,156 | $ 31,100 | $ |
| Total Liabilities | | $ | $ | $ | $ |
| **December 31, 2013** | | | | | |
| Assets | | | | | |
| Money market funds | | $ 25,201 | $ 25,201 | $ | $ |
| Short-term investments | commercial paper | 1,997 | | 1,997 | |
| Short-term investments | corporate bonds | 1,128 | | 1,128 | |
| Long-term investments | | 6,189 | | 6,189 | |
| Total Assets | | $ 34,515 | $ 25,201 | $ 9,314 | $ |
| Total Liabilities | | $ | $ | $ | $ |

The Level 1 assets consist of money market funds, which are actively traded daily. The Level 2 assets consist of corporate bond, commercial paper, certificate of deposit and municipal bond investments whose fair value may not represent actual transactions of identical securities. The fair value of corporate bonds 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. The fair value of commercial paper is generally determined based on the relationship between the investment s discount rate and the discount rates of the same issuer s commercial paper available in the market which may not be actively traded daily. The fair value of certificates of deposits approximates carrying value. Since these fair values may not be based upon actual transactions of identical securities, they are classified as Level 2. Since any investments are classified as available-for-sale securities, any unrealized gains or losses are recorded in accumulated other comprehensive income or loss within stockholders equity on the balance sheet. The Company did not elect to measure any other financial assets or liabilities at fair value at December 31, 2014 or 2013.

In connection with the sale of its Series D preferred stock in November 2011, the Company issued warrants which contained provisions for anti-dilution protection in the event that the Company issued other equity securities

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

at a price below $1.46 per common share. Because of the potential adjustment to the warrant exercise price that could result from this anti-dilution protection, the warrants did not meet the criteria set forth in ASC 815-40, Derivatives and Hedging Contracts in Entity s own Stock and the Company recorded the fair value of these warrants as a Level 3 liability at the issuance date using the Black-Scholes option pricing model based, in part, on the Company s assumptions and significant inputs not observed in the market. The Company revalued the warrants at the end of each quarter using the Black-Scholes option pricing model and recognized the change in the fair value of the warrants in the statements of operations and comprehensive loss as other income (expense).

The sale of shares of Series E preferred stock and Series E warrants in the Company s November 2012 Series E financing triggered an anti-dilution adjustment under the terms of the Series D warrants, resulting in the exercise price of the Series D warrants being reduced and fixed at the minimum $1.46 per share and the Series D warrants no longer being subject to any anti-dilution adjustments. Since the exercise price of the Series D warrants became fixed, the Series D warrants then met the exception under ASC 815-40 as they were indexed to the company s own stock and met certain criteria for equity classification, thus the Series D warrants were marked to fair value resulting in the recognition of $675,000 of non-operating income during the period ended November 9, 2012 at which time the $503,000 fair value of the warrant liability was transferred to stockholders equity. As of December 31, 2012, there was no warrant liability.

*(n) New Accounting Pronouncements Recently Issued*

In April 2014, the Financial Accounting Standards Board ( FASB ) issued ASU No. 2014-08 Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity. The amendments in this ASU require that a disposal representing a strategic shift that has (or will have) a major effect on an entity s operations and financial results or a business activity classified as held for sale should be reported as discontinued operations. The amendments also expand the disclosure requirements for discontinued operations and add new disclosure requirements for individually significant components that do not qualify as discontinued operations. This ASU will be effective prospectively for fiscal years beginning on or after December 15, 2014. Early adoption is permitted, but only for disposals that have not been previously reported in financial statements previously issued. The Company does not expect the adoption of this ASU to have a material effect on its financial statements.

In May 2014, the FASB issued ASU No. 2014-09 Revenue from Contracts with Customers (Topic 606). This ASU requires an entity to recognize revenue from the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In particular, this ASU addresses contracts with more than one performance obligation, as well as the accounting for some costs to obtain or fulfill a contract with a customer, and provides for additional disclosures with respect to revenues and cash flows arising from contracts with customers. This ASU will be effective for fiscal years beginning after December 15, 2016. Early adoption of this ASU is not permitted. The Company is currently evaluating the effect that the adoption of this ASU will have on its financial statements.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**3. Investments**

The Company s available-for-sale investments at fair value consisted of the following at December 31, 2014 and 2013:

| | December 31, 2014 | | | |
|---|---|---|---|---|
| | Cost | Gross Unrealized (Losses) | Gross Unrealized Gains | Estimated Fair Value |
| | (In thousands) | | | |
| Commercial paper due in one year or less | $ 4,493 | $ | $ 1 | $ 4,494 |
| Certificate of deposit due in one year or less | 500 | | | 500 |
| Corporate bonds due in one year or less | 14,364 | (7) | | 14,357 |
| Municipal bonds due in one year or less | 1,906 | (1) | | 1,905 |
| Total short-term investments | 21,263 | (8) | 1 | 21,256 |
| Corporate bonds due in one year or more | 7,354 | (10) | | 7,344 |
| Total long-term investments | 7,354 | (10) | | 7,344 |
| Total investments | $ 28,617 | $ (18) | $ 1 | $ 28,600 |

| | December 31, 2013 | | | |
|---|---|---|---|---|
| | Cost | Gross Unrealized (Losses) | Gross Unrealized Gains | Estimated Fair Value |
| | (In thousands) | | | |
| Commercial paper due in one year or less | $ 1,997 | $ | $ | $ 1,997 |
| Corporate bonds due in one year or less | 1,128 | | | 1,128 |
| Total short-term investments | 3,125 | | | 3,125 |
| Corporate bonds due in one year or more | 6,196 | (7) | | 6,189 |
| Total long-term investments | 6,196 | (7) | | 6,189 |
| Total investments | $ 9,321 | $ (7) | $ | $ 9,314 |

The Company had no realized gains or losses from available-for-sale securities in 2014, 2013 or 2012. There were no losses or other-than-temporary declines in value included in Investment income, net for any securities for the three years ended December 31, 2014. The Company had no auction rate securities as of December 31, 2014 and 2013. See Notes 2(f) and 2(m).

**4. Property and Equipment**

At December 31, 2014 and 2013, net property and equipment at cost consisted of the following:

| | December 31, | |
|---|---|---|
| | 2014 | 2013 |
| | (In thousands) | |
| Leasehold improvements | $ 525 | $ 525 |
| Laboratory equipment and other | 3,884 | 2,854 |
| Total property and equipment, at cost | 4,409 | 3,379 |
| Less: Accumulated depreciation and amortization | 3,103 | 3,289 |
| Property and equipment, net | $ 1,306 | $ 90 |

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

Depreciation and amortization expense on property and equipment was approximately $200,000, $137,000 and $251,000 in 2014, 2013 and 2012, respectively.

**5. Note Payable and Accrued Expenses**

*(a) Note Payable*

On September 30, 2014, the Company executed a loan and security agreement with Oxford Finance LLC ( Oxford ). Under the agreement, Oxford committed to lend the Company up to an aggregate principal amount of $3,000,000 in one or more advances each of which is to be evidenced by a promissory note. The Company s obligations to Oxford will be secured by the specific laboratory, manufacturing, office or computer equipment financed under the agreement. Each equipment advance will include interest at a fixed interest rate equal to the greater of 7.5% per annum and 7.27% plus the three-month U.S. Libor Rate per annum, set at the time of funding. The principal amount of each equipment advance will be repaid in 36 monthly installments commencing on the applicable amortization date, which is July 1, 2015 for any equipment advance made on or before June 30, 2015, and is the first monthly payment date for any equipment advance made on or after July 1, 2015. Monthly installments payable prior to July 1, 2015 will consist of accrued interest only and monthly installments payable on or after July 1, 2015 will consist of principal and accrued interest.

The Company is required to pay a final payment in an amount equal to 5.7% of the aggregate advanced amount under each equipment advance at the time that the final monthly installment is due or such earlier date as specified in the loan and security agreement. The final payments will be accrued as interest expense over the term of each equipment advance using the effective interest method. The weighted average annual effective interest rate on the notes payable based on the amount advanced through December 31, 2014, including accrual of the final payment, is 11.1%. If the Company prepays all or a portion of the principal amount of any equipment advance prior to maturity, it will be required to pay Oxford a prepayment fee of between 1% and 3% of the principal amount of such equipment advance.

As of December 31, 2014, the Company had received approximately $893,000 in advances under the loan and security agreement and an additional $2,107,000 remained available under the agreement. Aggregate future minimum payments, reflecting payments on outstanding principal plus interest, due under the loan and security agreement as of December 31, 2014, were as follows (in thousands):

| **Year ending December 31,** | |
|---|---|
| 2015 | $ 200 |
| 2016 | 333 |
| 2017 | 333 |
| 2018 | 219 |
| Total minimum payments | 1,085 |
| Less amount representing interest | (192) |
| Notes payable, gross | 893 |
| Unamortized facility fee | (27) |
| Accrual of final payment | 4 |
| Notes payable, balance | 870 |
| Less current portion of notes payable | (128) |
| Non-current portion of notes payable | $ 742 |

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

The loan and security agreement includes standard affirmative and restrictive covenants, but does not include any covenants to attain or maintain any financial metrics, and also includes standard events of default, including payment defaults, breaches of covenants following any applicable cure period, a material impairment in the perfection or priority of Oxford s security interest or in the value of the collateral, a material impairment of the prospect of repayment of the loans and a material adverse change in the business, operations or conditions of the Company. Upon the occurrence of an event of default and following any applicable cure periods, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and Oxford may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the loan and security agreement.

The Company assessed all terms and features of the note that the Company issued under its loan and security agreement in order to identify any potential embedded features that would require bifurcation. As part of this analysis, the Company assessed the economic characteristics and risks of the note, including put and call features. The Company determined that all features of the note are clearly and closely associated with a debt host and do not require bifurcation as a derivative liability, or the fair value of the feature is immaterial. The Company will continue to reassess the features to determine if they require separate accounting on a quarterly basis.

*(b) Accrued Expenses*

At December 31, 2014 and 2013, accrued expenses consisted of the following:

| | December 31, | |
|---|---|---|
| | 2014 | 2013 |
| | (In thousands) | |
| Payroll and related costs | $ 1,453 | $ 817 |
| Clinical and nonclinical trial expenses | 2,068 | 1,277 |
| Cost of regaining rights to cancer program | 251 | 966 |
| Professional and consulting fees | 530 | 337 |
| Other | 158 | 109 |
| | $ 4,460 | $ 3,506 |

**6. Collaboration and License Agreements**

*(a) Collaboration with Abbott Molecular Inc.*

In May 2014, the Company entered into a development and commercialization agreement with Abbott Molecular, Inc. ( Abbott Molecular ) for the development of an in vitro companion diagnostic for use in the Company s clinical development programs to treat certain genetically defined forms of B-cell lymphoma with IMO-8400, the Company s lead drug candidate. The agreement provides for the development and subsequent commercialization by Abbott Molecular of a companion diagnostic test utilizing polymerase chain reaction technology to identify with high sensitivity and specificity the presence in tumor biopsy samples of the oncogenic mutation referred to scientifically as MYD88 L265P. Under the agreement, Abbott Molecular is primarily responsible for developing and obtaining regulatory approvals for the companion diagnostic in accordance an agreed development plan and regulatory plan and for making the companion diagnostic test commercially available in accordance with an agreed commercialization plan. Abbott Molecular will retain all proceeds from commercialization of the companion diagnostic test. Subject to the terms of the agreement, the Company will pay Abbott Molecular fees and fund Abbott Molecular s development of the companion diagnostic test in an approximate aggregate amount of $6.7 million over an approximately five year development

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

period, which includes clinical trial site costs and Abbott Molecular s costs of preparation and filing fees for regulatory submissions for the companion diagnostic with the U.S. Food and Drug Administration ( FDA ). This amount is subject to increase if Abbott Molecular incurs additional expenses in order to meet unexpected material requirements or obligations not included in the agreement or if the Company is required to conduct additional or different clinical trials which result in Abbott Molecular incurring additional costs. The Company incurred $2.2 million in expenses under the Abbott Molecular agreement through December 31, 2014.

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

In December 2006, the Company entered into an exclusive, worldwide license and research collaboration agreement with Merck & Co. to research, develop, and commercialize vaccine products containing the Company s TLR7, TLR8, and TLR9 agonists in the fields of cancer, infectious diseases, and Alzheimer s disease. Under the terms of the agreement, the Company granted Merck & Co. exclusive rights to a number of the Company s TLR7, TLR8, and TLR9 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 under the agreement to the number of vaccines to which Merck & Co. can apply the Company s agonists within these fields. The Company also agreed with Merck & Co. to engage in a two-year research collaboration to generate novel agonists targeting TLR7 and TLR8 incorporating both Merck & Co. and the Company s chemistry for use in vaccines in the defined fields. Under the terms of the agreement, Merck & Co. extended the research collaboration for two additional years to December 2010. 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;

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

Merck & Co. 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, the Company would be entitled to receive additional milestone payments; and

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

The Company recognized the $20.0 million upfront payment as revenue over four years, including the initial two-year research term and the two-year extension period that ended in December 2010, which was the Company s period of continuing involvement under the research collaboration. The Company has recognized a total of $1.0 million of milestone revenue under the license and collaboration agreement, which related to the achievement of a preclinical milestone with one of its TLR9 agonists used as an adjuvant in cancer vaccines.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

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 such stock 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 aggregate gross proceeds of $10.0 million.

In April 2014, the Company entered into an amendment to the license and research collaboration agreement with Merck & Co. As a result of this amendment, Merck & Co. s rights under the agreement have been limited to specified TLR7, TLR8, and TLR9 agonists that Merck & Co. selected in January 2012, and the Company regained the rights to pursue its other independently discovered TLR7, TLR8, and TLR9 agonists for use as vaccine adjuvants in the fields of cancer, infectious diseases and Alzheimer s disease so that it now has the right to pursue its TLR7, TLR8, and TLR9 agonists for use as vaccine adjuvants in all fields. Merck & Co. s obligations under the agreement to pay the Company milestone payments and royalties continue in effect with respect to the specified TLR7, TLR8, and TLR9 agonists. However, in connection with this amendment, the Company agreed that, to the extent that the Company licenses to third parties any TLR7, TLR8, and TLR9 agonists for use as vaccine adjuvants in the fields of cancer, infectious diseases and Alzheimer s disease and receives income under such licenses, Merck & Co. may credit against any milestone payments and royalties it owes to the Company an amount equal to 15% of the license income received by the Company under the third-party licenses, up to a maximum of $60.0 million in credits.

*(c) Other License Agreements*

The Company has out-licensed and in-licensed therapies related to antisense technology.

In 2001, the Company entered into an agreement with Isis Pharmaceuticals, Inc. ( Isis ), under which it granted Isis a license, with the right to sublicense, to its antisense chemistry and delivery patents and patent applications; and it retained the right to use these patents and applications in its own drug discovery and development efforts and in collaborations with third parties. During 2001, Isis paid the Company $15.0 million in cash and issued 857,143 shares of its common stock having an aggregate fair market value on the dates on which title to the shares was received of $17.3 million and is required to pay the Company a low to mid double-digit percentage of specified sublicense income it receives from some types of sublicenses of its patents. As of December 31, 2014, the Company has received $0.3 million in sublicense income from Isis. Also under the agreement, the Company licensed from Isis specified antisense patents and patent applications, principally Isis suite of RNase H patents and patent applications. The Company also paid to Isis $0.7 million and issued 1,005,499 shares of common stock having a fair market value of approximately $1.2 million on the date of issuance for this license and is obligated to pay Isis an annual maintenance fee and low single-digit royalties on net sales of antisense products sold that are covered by Isis s patent rights. The Company has the right to use these patents and patent applications in its drug discovery and development efforts and in some types of third-party collaborations. As of December 31, 2014, the Company has only paid Isis annual maintenance fees and has not paid any royalties. The agreement may be terminated for an uncured material breach by either party. The licenses granted under the Isis agreement terminate upon the last to expire of the patents and patent applications licensed under the agreement. The Company may terminate at any time the sublicense by Isis to it of the patents and patent applications.

In addition, the Company is a party to other license agreements involving the license of its antisense patents for oligonucleotide chemistry and delivery and for specific gene targets, under which the Company typically is entitled to receive license fees, sublicensing income, research payments, payments upon achievement of developmental milestones, and royalties on product sales. As of December 31, 2014, the Company had received a total of $1.5 million under these agreements.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**7. Series D Convertible Preferred Stock and Warrants**

The following securities were issued in connection with the Company s November 4, 2011 financing. As discussed below, on February 6, 2014, all of the shares of Series D preferred stock were converted into 6,266,175 shares of the Company s common stock.

*(a) Convertible Preferred Stock*

The Series D preferred stock had the rights and preferences set forth in the Certificate of Designations, Preferences and Rights of Series D preferred stock of the Company, as amended (the Series D Certificate of Designations ), as summarized below.

*Dividends* The holders of the Series D preferred stock were entitled to receive dividends payable quarterly in arrears at the rate of 7% per annum. Such dividends were required to be paid in cash through September 30, 2013 and thereafter could have been paid in cash or with shares of common stock or with shares of a to-be-created new series of non-voting preferred stock in the event that payment of such dividends could not be made in shares of its common stock as a result of the application of the beneficial ownership and voting power limitations set forth the Series D Certificate of Designations, as determined by the Company in its sole discretion, except that the Company could not pay any dividends to a holder of Series D preferred stock in shares of common stock to the extent the issuance of such shares would result in the holder of Series D preferred stock and its affiliates beneficially owning more than 19.99% of (i) the common stock outstanding or (ii) the combined voting power of the securities of the Company outstanding immediately after giving effect to the issuance of such shares of common. Dividends payable on the Series D preferred stock amounted to $160,000 at December 31, 2013. There were no dividends payable on the Series D preferred stock at December 31, 2014. Under the original terms of the Series D preferred stock, the 4.6% dividends that the Company originally paid to the Series E preferred stockholders under the terms of the Series E preferred stock were also be paid to the Series D preferred stockholders on an as-converted to common stock basis, which resulted in Series D preferred stockholders being entitled to an additional 2.2% per annum cash dividend payable quarterly in arrears. At the Company s 2013 annual meeting of stockholders (the 2013 Annual Meeting ), an amendment to the Series D Certificate of Designations to, among other things, modify the terms of the Series D preferred stock requiring payment of dividends to Series D preferred stockholders upon payment of dividends to Series E stockholders was approved by the Company s stockholders. As a result, the Series E preferred stockholders became entitled to receive dividends payable in cash quarterly in arrears at the rate of 8% per annum and the Series D preferred stockholders ceased to be entitled to corresponding dividends effective July 26, 2013.

*Liquidation and Other Events* In the event of a liquidation, dissolution or winding up of the Company (a Liquidation ), whether voluntary or involuntary, after payment or provision for payment of debts and other liabilities of the Company, the holders of the Series D preferred stock then outstanding were entitled to be paid out of the assets of the Company available for distribution to its stockholders an amount per share of Series D preferred stock equal to the amount that would be payable with respect to such share had all shares of Series D preferred stock been converted into shares of common stock immediately prior to such Liquidation and not any amount greater than that amount in preference to the Company s common stock. Such amount would have been paid before any cash distribution could be made or any other assets distributed in respect of junior securities to the holders of any junior securities including, without limitation, common stock and Series A preferred stock of the Company. In the event of a sale of the corporation, after payment to the holders of the Series A preferred stock and any other class of capital stock of the Company ranking senior to the Series D preferred stock, the remaining assets of the

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

Company available for distribution to its stockholders will be distributed among the holders of shares of Series E preferred stock, Series D preferred stock and common stock on a pro rata (and as converted to common stock) basis based on the number of shares held by each such holder.

*Conversion* Each share of Series D preferred stock was convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and nonassessable shares of common stock as is determined by dividing the Series D preferred stock original issue price by the Series D preferred stock conversion price in effect at the time of conversion. The Series D preferred stock conversion price was initially equal to $1.63 and the Series D preferred stock issue price was initially equal to the $8.1375 original purchase price of the Series D preferred stock. Accordingly, each share of Series D preferred stock was initially convertible at the option of the holder into five fully paid and nonassessable shares of the common stock. As a result of the Company s Series E financing in November 2012, the Series D preferred stock conversion price was adjusted to the $1.46 per share minimum resulting in each share of Series D preferred stock becoming convertible at the option of the holder into 5.5736 fully paid and nonassessable shares of the common stock. No holder could convert its shares to the extent such conversion would result in the holder and its affiliates beneficially owning more than 19.99% of the common stock outstanding. The Series D preferred stock conversion price, and the rate at which shares of Series D preferred stock could have been converted into shares of common stock, was subject to adjustment for stock dividends, stock splits and other events, as provided in the Series D Certificate of Designations.

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

The effects of the extinguishment of the Series D preferred stock during 2013 are discussed in Note 14.

On January 10, 2014, the Company notified Pillar Pharmaceuticals I, L.P. ( Pillar I ), an investment partnership managed by one of the Company s directors and significant stockholders and the holder of all 1,124,260 shares of the Company s issued and outstanding Series D preferred stock, of its intention to redeem the Series D preferred stock on February 10, 2014 in accordance with the terms of the Series D Certificate of Designations. Following this notice, Pillar I had the right to convert its Series D preferred stock into shares of the Company s common stock at any time prior to the close of business on February 9, 2014. On February 6, 2014, Pillar I converted such shares into 6,266,175 shares of the Company s common stock in accordance with the terms of the Series D Certificate of Designations. As a result of the conversion, no shares of the Company s Series D preferred stock remain outstanding.

On March 28, 2014, the Company filed a Certificate of Elimination of Number of Shares of Preferred Stock Designated as Series D Convertible Preferred Stock with the State of Delaware Secretary of State which eliminated the designation of the shares of Series D preferred stock.

At the time of its issuance and prior to being amended, the Series D preferred stock was first assessed under ASC 480, Distinguishing Liabilities from Equity and it was determined that it was not within the scope of ASC 480 so the preferred stock was not considered a liability under ASC 480. The preferred stock was then assessed under ASC 815, Derivatives and Hedging.

The Series D preferred stock contained three embedded features: (1) optional redemption by the Company; (2) optional redemption by the holders; and (3) optional conversion by the holders. Each embedded feature met

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**NOTES TO FINANCIAL STATEMENTS (Continued)**

the definition of a derivative. The Company believed that the Series D preferred stock was an equity host for the purposes of assessing the embedded derivatives for potential bifurcation. The Company noted the following regarding these embedded features:

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

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

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

The following is a summary of the changes in the Series D preferred stock during 2012 and 2011 (in thousands):

| | |
|---|---|
| Gross proceeds from November 4, 2011 Series D financing (including $351 paid for the warrants) | $ 9,500 |
| Less allocation of proceeds to: | |
| Fair value of warrants | (3,152) |
| Beneficial conversion feature | (4,445) |
| Transaction costs | (427) |
| Net proceeds allocated to Series D preferred stock | 1,476 |
| Accretion of beneficial conversion feature | 4,445 |
| Fair value of Series D preferred stock November 4, 2011 | $ 5,921 |
| Fair value of Series D preferred stock December 31, 2011 | $ 5,921 |
| Beneficial conversion feature related to Series E financing | (1,238) |
| Accretion of beneficial conversion feature | 1,238 |
| Fair value of Series D preferred stock December 31, 2012 | $ 5,921 |

Because the Series D preferred stock was redeemable upon events outside the control of the Company, the Company initially recorded it in temporary equity. The sale of shares and warrants in the Company s November 2012 Series E financing triggered an anti-dilution adjustment under the terms of the Series D preferred stock, resulting in the conversion price of the Series D preferred stock being reduced and fixed at the minimum $1.46 per share and the Series D preferred stock no longer being subject to any anti-dilution adjustments which resulted in an additional $1,238,000 discount related to the additional BCF. The additional BCF was immediately accreted to preferred dividends in 2012 which resulted in the carrying value of the Series D preferred stock remaining at $5,921,000. The Series D preferred stock was redeemable by the holder for the original $9,149,000 purchase price plus unpaid accrued dividends upon a fundamental change, as described above. The Company has determined that the occurrence of a fundamental change was not probable and did not accrete the difference

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

between the $5,921,000 fair value of the Series D preferred stock and the redemption value of $9,149,000 purchase price plus unpaid accrued dividends. If the occurrence of a fundamental change became probable, the Company would have accreted this $3,228,000 difference at that time.

The Series D Convertible Preferred Stock and Warrant Purchase Agreement was amended in connection with the Series E financing. The amendments consisted of changes to voting rights limitations and restrictions on the transferability of securities issued in the November 2011 Series D financing. There is no specific guidance on accounting for amendments to preferred stock agreements. However it is generally accepted that such changes should be analyzed to determine if they represent a modification or an extinguishment of the preferred stock. The Company has adopted a qualitative approach to assessing whether amendments are accounted for as modifications or extinguishments. The Company considers the nature of the changes to the preferred stock agreement, including whether the amendments significantly change a substantial contractual term or fundamentally change the nature of the stock; and whether the amendment of the terms would have changed the initial accounting for the stock. If the amendments significantly change a substantial term; fundamentally change the nature of the preferred shares; or change the accounting for the stock, then the change is accounted for as an extinguishment. Otherwise the amendments are accounted for as modifications.

The Company has considered the nature of these amendments and whether the amendments significantly change any substantial terms that affect the initial accounting for the Series D preferred stock. The Company determined that these Series D amendments related to the November 2012 Series E financing were not to substantial terms of the agreement and did not fundamentally change the nature of the Series D preferred stock. In addition, the Company assessed the original accounting for the Series D preferred stock and determined that the accounting did not change as a result of the amendments. Thus, the changes were considered a modification and not an extinguishment. The Company then considered the appropriate model for accounting for the modification of the Series D preferred stock. The Company considered the debt and the share based payment modification guidance and determined that the share based modification rules included in ASC 718-20-35 were more appropriate. The model under ASC 718-20-35 requires the measurement of the fair value of the Series D preferred stock immediately before and after the modification. The Company determined that the change in fair value resulting from the modification was de minimis, as the Series D amendments related to the Series E financing did not affect substantial terms of the agreement and did not affect the Company s financial statements.

*(b) Warrants*

The Series D warrants had an initial exercise price of $1.63 per common share (subject to adjustment as provided therein) and may be exercised at the holder s option at any time on or before November 4, 2016. The sale of shares of Series E preferred stock and Series E warrants in the Company s November 2012 Series E financing triggered an anti-dilution adjustment under the terms of the Series D warrants, resulting in the conversion price of the Series D warrants being reduced and fixed at the minimum $1.46 per share and the Series D warrants no longer being subject to any anti-dilution adjustments. The Series D warrants provide that the Company shall not effect any exercise of the Series D warrants, and the Series D warrants may not be exercised with respect to any portion of the Series D warrants, to the extent that such exercise would result in the holder and its affiliates beneficially owning more than 19.99% of (i) the number of shares of common stock outstanding or (ii) the combined voting power of the securities of the Company outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of the Series D warrants. After November 4, 2013, the Company may redeem the Series D warrants for $0.01 per share of common stock issuable on exercise of the Series D warrants following notice to the holder if the closing price of the common stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to $6.51 (subject to adjustment for stock splits, stock dividends, combinations, recapitalizations, reclassifications, and similar transactions affecting the common stock).

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

The Series D warrants were first assessed under ASC 480 and it was determined that they were not within its scope so the warrants were not considered a liability under ASC 480. The Series D warrants were then assessed under ASC 815 and were determined to be derivative instruments since the price protection features do not meet the indexed to the company s own stock exemption requirements in ASC 815-40. The Series D warrants were recorded at fair value as of the transaction date and were being marked to fair value through earnings each quarter. The sale of shares of Series E preferred stock and Series E warrants in the Company s November 2012 Series E financing triggered an anti-dilution adjustment under the terms of the Series D warrants, resulting in the exercise price of the Series D warrants being reduced and fixed at the minimum $1.46 per share and the Series D warrants no longer being subject to any anti-dilution adjustments. Since the exercise price of the Series D warrants became fixed, the Series D warrants then met the exception under ASC 815-40 as they were indexed to the company s own stock and met certain criteria for equity classification. Accordingly, the Series D warrants were marked to fair value through earnings as of November 9, 2012 and the remaining $503,000 was reclassified to stockholders equity at that time. See Note 2(m).

The Series D warrants were also amended in connection with the November 2012 Series E financing. The amendments consisted of changes in limitations on the Company s right to redeem the Series D warrants and the Series D warrant holder s right to exercise the Series D warrants. There is no specific guidance on accounting for amendments to warrant agreements. However it is generally accepted that such changes should be analyzed to determine if they represent a modification or an extinguishment of the warrant. The Company has adopted a qualitative approach to assessing whether amendments are accounted for as modifications or extinguishments. The Company considers the nature of the changes to the warrant agreement, including whether the amendments significantly change a substantial contractual term or fundamentally change the nature of the warrant; and whether the amendment of the terms would have changed the initial accounting for the Series D warrant. If the amendments significantly change a substantial term; fundamentally change the nature of the Series D warrant; or change the accounting for the Series D warrant, then the change is accounted for as an extinguishment. Otherwise the amendments are accounted for as modifications.

The Company has considered the nature of these amendments and whether the amendments significantly change any substantial terms that affect the initial accounting for the Series D warrants. The Company determined that these amendments were not to substantial terms of the agreement and did not fundamentally change the nature of the Series D warrants. In addition, the Company assessed the original accounting for the Series D warrants and determined that the accounting did not change as a result of the amendments. Thus, the changes were considered a modification and not an extinguishment.

The Company then considered the appropriate model for accounting for the modification of the Series D warrants. The Company considered the debt and the share based payment modification guidance and determined that the share based modification rules included in ASC 718-20-35 were more appropriate. The model under ASC 718-20-35 requires the measurement of the fair value of the Series D warrants immediately before and after the modification. The Company determined that the change in fair value resulting from the modification was de minimis, as the amendments did not affect substantial terms of the agreement and did not affect the Company s financial statements.

**8. 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

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**NOTES TO FINANCIAL STATEMENTS (Continued)**

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

As of December 31, 2014, the Company has repurchased or received documentation of the transfer of 399,950 Put Shares and 35,780 of the Put Shares continued to be held in the name of Put Holders. The Company cannot determine at this time what portion of the Put Rights of the remaining 763,954 Put Shares have terminated.

*(b) Warrants*

The Company has the following warrants outstanding and exercisable for the purchase of common stock at December 31, 2014:

| Expiration Date | Shares | Weighted Average Exercise Price Per share |
|---|---|---|
| August 5, 2015 | 334,600 | $ 3.71 |
| November 4, 2016 | 2,810,650 | 1.46 |
| November 9, 2017 | 7,484,840 | 0.70 |
| May 7, 2018 | 24,906,327 | 0.47 |
| May 7, 2020 | 15,816,327 | 0.01 |
| September 30, 2020 | 4,175,975 | 0.01 |
| February 10, 2021 | 2,158,750 | 0.01 |
| Total | 57,687,469 | 0.39 |

See Note 7(b).

*(c) Stock Options*

Under the Company s 2013 Stock Incentive Plan (the 2013 Stock Incentive Plan ), the Company may grant options to purchase common stock, stock appreciation rights, restricted stock awards and other forms of stock-based compensation. Stock options generally vest over three to four years, and expire no later than 10 years from the date of grant. A total of 10,224,460 shares of common stock, plus such additional number of shares of common stock (up to 5,720,540) as is equal to the sum of (i) the number of shares of common stock reserved for issuance under the Company s 2008 Stock Incentive Plan (the 2008 Stock Incentive Plan ) that are available for grant under the 2008 Stock Incentive Plan immediately prior to the date the 2013 Stock Incentive Plan is

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

approved by its stockholders and (ii) the number of shares of common stock subject to awards granted under the 2008 Stock Incentive Plan which awards expire, terminate or are otherwise surrendered, cancelled, or forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right (subject, however, in the case of incentive stock options to any limitations of the Internal Revenue Code of 1986, as amended (the Code )), may be issued pursuant to awards granted under the 2013 Stock Incentive Plan subject to reduction in the event that there are any full-value awards, as defined in the plan. The maximum number of shares of common stock with respect to which awards may be granted to any participant under the plan is 1,500,000 per calendar year. The compensation committee of the board of directors has the authority to select the employees to whom options are granted and determine the terms of each option, including (i) the number of shares of common stock subject to the option; (ii) when the option becomes exercisable; (iii) the option exercise price, which must be at least 100% of the fair market value of the common stock as of the date of grant; and (iv) the duration of the option, which may not exceed 10 years. Stock options may not be re-priced without shareholder approval. Discretionary awards to non-employee directors are granted and administered by a committee comprised of independent directors. As of December 31, 2014, options to purchase a total of 7,944,549 shares of common stock were outstanding under the 2013 Stock Incentive Plan. As of December 31, 2014, 2,516,500 shares of common stock remain available for grant under the 2013 Stock Incentive Plan.

The Company is no longer granting stock options or other awards pursuant to the share-based compensation plans that were utilized prior to the approval of the 2013 Stock Incentive Plan. Under these earlier plans, stock options generally vested over three to four years and expired no later than 10 years from the date of grant. As of December 31, 2014, options to purchase a total of 6,406,439 shares of common stock were outstanding under these earlier plans. During 2014, the Company also granted as inducement grants non-statutory stock options to purchase an aggregate of 2,600,000 shares of common stock. The inducement grant awards were made outside of the 2013 Stock Incentive Plan pursuant to the NASDAQ inducement grant exception as a material component of new hires employment compensation. All of the inducement grants remained outstanding at December 31, 2014.

The following table summarizes information related to the outstanding and exercisable options during 2014 (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, 2013 | 10,148 | $ 3.38 | | |
| Granted | 8,232 | 3.69 | | |
| Exercised | (374) | 2.37 | | |
| Forfeited | (825) | 2.18 | | |
| Expired | (230) | 6.81 | | |
| Outstanding at December 31, 2014 | 16,951 | 3.56 | 8.06 | $ 23,512 |
| Exercisable at December 31, 2014 | 7,393 | 3.95 | 6.15 | 11,950 |
| Total exercisable or expected to vest | 16,320 | 3.57 | 8.00 | 22,749 |

*(d) Employee Stock Purchase Plan*

The Company s 1995 Employee Stock Purchase Plan (the Stock Purchase Plan ), as amended, provides for the issuance of up to 500,000 shares of common stock to participating employees of the Company or its subsidiaries. Participation is limited to employees that would not own 5% or more of the total combined voting power or value of the stock of the Company after the grant.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

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

Offering periods are three months in duration and commence on March 1, June 1, September 1, and December 1. In 2014, 2013, and 2012, the Company issued 13,844, 14,716, and 4,746 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. As of December 31, 2014, the Company has designated 1,500,000 shares as Series A convertible preferred stock and 424,242 shares of Series E preferred stock (see Note 8(g)). On March 28, 2014, the Company filed a Certificate of Elimination of Number of Shares of Preferred Stock Designated as Series D Convertible Preferred Stock with the State of Delaware Secretary of State which eliminated the designation of the shares of Series D preferred stock.

*(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 designated, fully paid and nonassessable shares of Series A preferred stock. The Company paid dividends in stock until 2004 when it elected to pay further dividends 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. As of December 31, 2014 and 2013, there were 655 shares of Series A convertible preferred stock outstanding.

*(g) Series E Convertible Preferred Stock*

The Series E convertible preferred stock was issued in connection with the Company s November 9, 2012 financing discussed in Note 15. As discussed below, in December 2014, all of the shares of Series E preferred stock were converted into 8,484,840 shares of the Company s common stock.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

On November 9, 2012, the board of directors of the Company designated 424,242 shares as Series E preferred stock, having the rights and preferences set forth in the Certificate of Designations, Preferences and Rights of Series E Preferred Stock (the Series E Certificate of Designations ). The rights and preferences of Series E preferred stock of the Company set forth in the Series E Certificate of Designations, as amended, are summarized below.

*Dividends* The holders of Series E preferred stock were entitled to receive cash dividends payable quarterly in arrears at the Initial Dividend Rate (as defined below) with the first payment date being March 31, 2013. The Company proposed at the 2013 Annual Meeting an amendment to the Series D Certificate of Designations to, among other things, modify the terms of the Series D preferred stock that require payment of dividends to Series D preferred stockholders upon payment of dividends to Series E stockholders. Since the stockholders of the Company approved the amendment to the Series D Certificate of Designations, the dividend rate with respect to the Series E preferred dividends increased from the Initial Dividend Rate to the rate of 8% per annum. The term Initial Dividend Rate means 4.6% per annum or such other percentage per annum as may be approved by the Company and by the holders of at least a majority of the then outstanding shares of Series E preferred stock. Dividends payable on the Series E preferred stock amounted to $119,000 at December 31, 2013. There were no dividends payable on the Series E preferred stock at December 31, 2014.

*Liquidation and Other Events* In the event of a liquidation, dissolution or winding up of the Company (other than a Sale of the Corporation as defined in the Series E Certificate of Designations) (a Liquidation ), whether voluntary or involuntary, after payment or provision for payment of debts and other liabilities of the Company, the holders of the Series E preferred stock then outstanding would have been entitled to be paid out of the assets of the Company available for distribution to its stockholders an amount per share of Series E preferred stock equal to the amount that would be payable with respect to such share had all shares of Series E preferred stock been converted into shares of common stock immediately prior to such Liquidation and not any amount greater than that amount in preference to the Company s common stock. Such amount would have been paid before any cash distribution may be made or any other assets distributed in respect of the holders of common stock, Series A convertible preferred stock, Series D preferred stock or any other class of capital stock of the Company ranking junior to the Series E preferred stock as to liquidation. In the event of a sale of the corporation, after payment to the holders of the Series A preferred stock and any other class of capital stock of the Company ranking senior to the Series E preferred stock, the remaining assets of the Company available for distribution to its stockholders would have been distributed among the holders of shares of Series E preferred stock, Series D preferred stock and common stock on a pro rata (and as converted to common stock) basis based on the number of shares held by each such holder.

*Voting* The Series E preferred stock has no voting rights.

*Protective Provisions* For so long as at least 84,849 shares of Series E preferred stock, subject to adjustment, remain outstanding, the Company has agreed that it will not, directly or indirectly, (a) amend the Certificate of Incorporation or bylaws of the Company in a manner that adversely and uniquely affects the Series E preferred stock, (b) except as expressly permitted by the Series E Certificate of Designations, purchase or redeem or pay or declare any dividend or make any distribution on, any shares of capital stock of the Company, or (c) recapitalize or reclassify any of the common stock, without in each case the written consent or affirmative vote of the holders of at least 51% of the then outstanding shares of Series E preferred stock.

*Conversion* Each share of Series E preferred stock was convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

thereof, into such number of fully paid and nonassessable shares of common stock as is determined by dividing the Series E preferred stock original issue price by the Series E preferred stock conversion price in effect at the time of conversion. The Series E preferred stock conversion price is initially equal to $0.70 and the Series E preferred stock issue price is initially equal to the $14.00 original purchase price of the Series E preferred stock. Accordingly, each share of Series E preferred stock is initially convertible at the option of the holder into 20 fully paid and nonassessable shares of the common stock. No holder could convert its shares to the extent such conversion would result in the holder and its affiliates beneficially owning more than 19.99% of the outstanding common stock or outstanding voting power of the Company (including shares of common stock issuable upon conversion of the Series E preferred stock). The initial Series E preferred stock conversion price, and the rate at which shares of Series E preferred stock may be converted into shares of common stock, was subject to adjustment for stock dividends, stock splits and other similar events, as provided in the Series E Certificate of Designations.

*Redemption by Company* After the later of November 9, 2014 and the date that no shares of Series D preferred stock remain outstanding, the Company could have redeemed all or a portion of the Series E preferred stock for a cash payment equal to the original Series E preferred stock issue price per share plus any accrued or declared but unpaid dividends thereon following notice to the holders of the Series E preferred stock if the closing price of the common stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to 400% of the Series E preferred stock conversion price. The Company could not redeem any shares of Series E preferred stock from a holder that could not convert such shares of Series E preferred stock into common stock as a result of the beneficial ownership limitations described above under Conversion. In such event, the Company could have redeemed such nonredeemable shares pursuant to alternative redemption provisions set forth in the Series E Certificate of Designations following notice to the holders of the nonredeemable shares, for a cash payment equal to the greater of the 20 consecutive trading day average closing price per share of the common stock ending on the trading day immediately prior to redemption date plus any dividends accrued or declared but unpaid thereon and the Series E conversion price plus any dividends accrued or declared but unpaid thereon.

The Series E preferred stock was first considered under ASC 480 and it was determined that it was not mandatorily redeemable. The Company identified the following three embedded features within the Series E preferred stock: (1) optional conversion by the holder; (2) optional redemption by the company; and (3) an alternative redemption by the company. The Series E preferred stock was determined to be an equity host. The optional conversion by the holder was assessed to be clearly and closely related to the Series E preferred stock and thus not subject to bifurcation under ASC 815. The optional redemption by the company and the alternative redemption by the company were both indexed to the Company s own stock and met the criteria for equity classification under ASC 815-40 and thus were not required to be bifurcated. The Series E preferred stock is redeemable only at the Company s option. In addition, the Series E preferred stock only has preferences in the event of a final liquidation or termination of the Company. In the event of a deemed liquidation, the Series E preferred stock has no preferences and ranks together with the common stockholders. Thus, the Series E preferred stock is not within the scope of ASC 480-10-S99 and will be classified in stockholders equity.

The Series E preferred stock was issued together with warrants to purchase 8,484,840 shares of common stock (the Series E warrants ). Since the Series E preferred stock and the Series E warrants were classified in stockholders equity, the gross proceeds from the financing were allocated between the Series E preferred stock and the Series E warrants based on their relative fair values at the time of the November 9, 2012 Series E financing. The fair value of the Series E warrants was computed using the Black-Scholes option pricing model and was determined to be $2,949,000. The $2,322,000 prorated value of the Series E warrants was recorded as additional paid-in capital.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

The Series E preferred stock was then considered under ASC 470-20 to determine if a BCF existed. As of the transaction date, a BCF of $1,262,000 was computed using the initial stated conversion rate. Since the conversion feature is immediately exercisable, the $1,262,000 BCF was accreted immediately to preferred dividends.

The following is a summary of the changes in the Series E preferred stock during 2012 (in thousands):

| | |
|---|---|
| Gross proceeds from November 9, 2012 Series E financing (including $1,061 paid for the warrants) | $ 7,000 |
| Less allocation of proceeds to: | |
| Fair value allocated to warrants | (2,322) |
| Beneficial conversion feature | (1,262) |
| Transaction costs | (977) |
| Net proceeds allocated to Series E preferred stock | 2,439 |
| Accretion of beneficial conversion feature | 1,262 |
| Carrying Value of Series E preferred stock November 9, 2012 | $ 3,701 |
| Carrying Value of Series E preferred stock December 31, 2012 | $ 3,701 |

The effects of the extinguishment of the Series E preferred stock during 2013 are discussed in Note 14.

In December 2014, the holders of Series E preferred stock converted such shares into 8,484,840 shares of common stock in accordance with the terms of the Series E Certificate of Designations. As a result of this conversion, no shares of Series E preferred stock remain outstanding.

**9. Commitments and Contingencies**

*(a) Lease Commitments*

During 2014, 2013 and 2012, rent expense, including real estate taxes, was $1,672,000, $1,601,000 and $1,596,000, respectively. As part of the lease, the Company is required to restrict approximately $311,000 of cash for a security deposit as of December 31, 2014. The lease is classified as an operating lease. Future minimum commitments as of December 31, 2014 under the Company s lease agreement are approximately:

| December 31, | Operating Lease (In thousands) |
|---|---|
| 2015 | $ 1,521 |
| 2016 | 1,550 |
| 2017 | 1,046 |
| | $ 4,117 |

The operating lease was amended on February 21, 2014 to, among other things, extend the expiration date to August 31, 2017 subject to a three-year renewal option exercisable by the Company.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

*(b) External Collaborations*

The Company is a party to 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 minimum payments due under one of these agreements of $10,000 in each of 2015 and 2016.

*(c) Contract Obligations*

The Company has employment agreements with its executive officers that include future minimum commitments of approximately $2,246,000 per year.

*(d) Related-Party Transactions*

In November 2011, the Company issued and sold shares of Series D preferred stock and Series D warrants pursuant to a Convertible Preferred Stock and Warrant Purchase Agreement with Pillar I, an investment partnership managed by one of the Company s directors and significant shareholders, which is described in Note 15. As discussed in Note 7(a), all shares of Series D preferred stock were converted to common stock in February, 2014. In November 2012, the Company issued and sold shares of Series E preferred stock and Series E warrants pursuant to a Convertible Preferred Stock and Warrant Purchase Agreement with Pillar II, an investment partnership managed by two of the Company s directors and one of its significant shareholders, which is described in Note 15. As discussed in Note 8(g), all shares of Series E preferred stock were converted to common stock in December 2014.

In connection with the Company s follow-on underwritten public offering on May 7, 2013, the Company sold 5,000,000 shares of common stock and warrants to purchase 5,000,000 shares of common stock at $0.47 per share for an aggregate purchase price of $2,500,000 to Pillar Pharmaceuticals III, L.P. ( Pillar III ) and an entity affiliated with Pillar III (together with Pillar III, the Pillar III Entities ), which is described in Note 15. In connection with the Company s follow-on underwritten public offering on September 30, 2013, the Company sold 1,774,193 shares of common stock for an aggregate purchase price of $2,750,000 to Pillar Pharmaceuticals IV, L.P. ( Pillar IV ) and an entity affiliated with Pillar IV (together with Pillar IV, the Pillar IV Entities ), which is described in Note 15.

Youssef El Zein, a member of the Company s board of directors, is a director and controlling stockholder of Pillar Invest Corporation ( Pillar Invest ), which is the general partner of Pillar I, Pillar II, Pillar III and Pillar IV. Mr. El Zein has voting and investment control over the securities beneficially owned by the Pillar III Entities and the Pillar IV Entities. In addition, Abdul-Wahab Umari, who was also a member of the Company s board of directors until June 2014, is a managing partner of Pillar Invest.

The Company paid a director consulting fees of approximately $1,000 in 2012 for services performed in 2011. The Company did not pay any consulting fees to directors in 2014 or 2013. The Company issued common stock in lieu of director board and committee fees of approximately $82,000, $26,000, and $1,000 during 2014, 2013 and 2012, respectively.

Additional information on related party transactions associated with the April 2013 agreements between the Company and the Pillar Entities (as defined in Note 14) is included in Note 14.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**10. Income Taxes**

The Tax Reform Act of 1986 contains provisions that limit the amount of net operating loss carryforwards ( NOLs ) and tax 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, 2014, have resulted in ownership changes in excess of 50% that will significantly limit the Company s ability to utilize its NOL and tax credit carryforwards. In December, 2014, the Company completed a study which determined that a cumulative three-year ownership change in excess of 50% had occurred in November, 2012. The 2014 federal and state NOLs, tax credit carryforwards and related deferred tax assets shown below have been adjusted to reflect the ownership change limitations that resulted from this study. The corresponding 2013 amounts have not been adjusted. Additional ownership change limitations may result from ownership changes that occur after November 2012.

As of December 31, 2014, the Company had cumulative NOLs of approximately $79,112,000 and $75,395,000 available to reduce federal and state taxable income. These NOLs expire through 2034. In addition, at December 31, 2014, the Company had cumulative federal and state tax credit carryforwards of $1,680,000 and $749,000, respectively, available to reduce federal and state income taxes which expire through 2034 and 2029, respectively. The federal and state NOLs include approximately $670,000 and $349,000, respectively, of deductions related to the exercise of stock options subsequent to the adoption of ASC 718, Stock Compensation. These amounts represent excess tax benefits as defined under ASC 718 and have not been included in the gross deferred tax asset reflected for NOLs.

As of December 31, 2014 and 2013, the components of the deferred tax assets are approximately as follows:

| | 2014 | 2013 |
|---|---|---|
| | (In thousands) | |
| Operating loss carryforwards | $ 30,632 | $ 68,500 |
| Tax credit carryforwards | 2,174 | 9,376 |
| Other | 5,625 | 5,078 |
| | 38,431 | 82,954 |
| Valuation allowance | (38,431) | (82,954) |
| | $ | $ |

The Company has provided a valuation allowance for its deferred tax asset due to the uncertainty surrounding the ability to realize this asset. The decreases in the operating loss and tax credit carryforward deferred tax assets and the valuation allowance in the current year are primarily attributable to the ownership change limitations discussed above.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

The difference between the 34% U.S. federal corporate tax rate and the Company s effective tax rate is as follows for the years ended December 31, 2014, 2013 and 2012:

| | 2014 | 2013 | 2012 |
|---|---|---|---|
| Expected federal income tax rate | (34.0)% | (34.0)% | (34.0)% |
| Expiring credits and NOLs | | 0.2 | 116.3 |
| Change in valuation allowance | (115.3) | 43.1 | (76.6) |
| Federal and state credits | (4.0) | (5.0) | (0.6) |
| State income taxes, net of federal benefit | (5.1) | (5.1) | (5.2) |
| Permanent differences | 0.8 | 0.9 | 0.1 |
| Section 382 Limitation | 157.5 | | |
| Other | 0.1 | (0.1) | |
| Effective tax rate | 0.0% | 0.0% | 0.0% |

The Company applies ASC 740-10, Accounting for Uncertainty in Income Taxes, an interpretation of ASC 740. ASC 740-10 clarifies the accounting for uncertainty in income taxes recognized in financial statements and requires the impact of a tax position to be recognized in the financial statements if that position is more likely than not of being sustained by the taxing authority. The Company had no unrecognized tax benefits resulting from uncertain tax positions at December 31, 2014 and 2013.

The Company has not, as of yet, conducted a study of its research and development credit carryforwards. Such a study might result in an adjustment to the Company s research and development credit carryforwards, however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position under ASC 740-10. A full valuation allowance has been provided against the Company s research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the statements of operations and comprehensive loss 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 2011, except to the extent that it utilizes NOLs or tax credit carryforwards that originated before 2011. 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 statements of operations and comprehensive loss as general and administrative expense.

**11. Employee Benefit Plan**

The Company has an employee benefit plan under Section 401(k) of the 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 $139,000, $83,000, and $106,000 of 401(k) benefits were charged to operating expenses during 2014, 2013 and 2012, respectively.

**12. Net Loss per Common Share Applicable to Common Stockholders**

For the years ended December 31, 2014 and 2013, basic and diluted net loss per common share applicable to common stockholders is computed using the weighted average number of shares of common stock outstanding

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

during the period. Diluted net loss per common share applicable to common stockholders is the same as basic net loss per common share applicable to common stockholders as the effects of the Company s potential common stock equivalents are antidilutive. Total antidilutive securities were 74,640,383 and 85,973,681 at December 31, 2014 and 2013, respectively, and consisted of stock options, preferred stock and warrants.

For the year ended December 31, 2014, net loss per common share applicable to common stockholders reflects $66,000 and $453,000, respectively, in dividends accrued on shares of Series D preferred stock and Series E preferred stock. For the year ended December 31, 2013, net loss per common share applicable to common stockholders reflects $1,750,000 related to the loss on extinguishment of the Series D preferred stock and the Series E preferred stock that the Company issued in November 2011 and November 2012, respectively, that has been charged to net loss applicable to common stockholders as a preferred stock dividend and $756,000 and $360,000, respectively, in dividends accrued on shares of Series D preferred stock and Series E preferred stock.

**13. Supplemental Disclosure of Cash Flow Information**

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| | | (In thousands) | |
| Supplemental disclosure of cash flow information: | | | |
| Cash paid for interest | $ 21 | $ | $ |
| Supplemental disclosure of non-cash financing and investing activities: | | | |
| Conversion of Series D preferred stock to common stock | $ 5,464 | $ | $ |
| Conversion of Series E preferred stock to common stock | $ 5,528 | $ | $ |
| Extinguishment of Series D and Series E preferred stock and issuance of related warrants | $ | $ 5,921 | $ |
| Accrued 2013 financing transaction costs paid in 2014 | $ | $ 100 | $ |
| Accretion of Series D redeemable preferred stock beneficial conversion feature | $ | $ | $ 1,238 |
| Accretion of Series E preferred stock beneficial conversion feature | $ | $ | $ 1,262 |
| Reclassification of Series D warrants from liabilities to stockholders equity | $ | $ | $ 503 |

**14. April 2013 Pillar Agreements**

In April 2013, the Company entered into two agreements (the Pillar Agreements ) with Pillar I, Pillar II and an entity affiliated with Pillar I and Pillar II (together with Pillar I and Pillar II, the Pillar Entities ). The agreements, including the Company s obligations to issue the warrants under the Pillar Agreements, became effective upon the consummation of the follow-on underwritten public offering of the Company s securities on May 7, 2013. Mr. El Zein, a member of the Company s board of directors, is a director and controlling stockholder of Pillar Invest, which is the general partner of Pillar I and Pillar II, and is a limited partner of Pillar I and Pillar II. Mr. El Zein has voting and investment control over the securities beneficially owned by the Pillar Entities. In addition, Abdul-Wahab Umari, who was also a member of the Company s board of directors until June 2014, is a managing partner of Pillar Invest.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

Under the first agreement entered into with Pillar I and Pillar II (the April 22, 2013 Pillar Agreement ), Pillar I, as the sole holder of the Company s Series D preferred stock, irrevocably waived and agreed to not exercise the rights, powers, preferences and other terms of the Series D preferred stock under Section 6 of the Series D Certificate of Designations, including without limitation the right to require the Company to purchase all or any portion of the shares of its Series D preferred stock at a price equal to the original Series D preferred stock purchase price per share plus all accrued or declared but unpaid dividends thereon upon the occurrence of specified fundamental changes such as mergers, consolidations, business combinations, stock purchases or similar transactions resulting in a person or group unaffiliated with any holder of Series D preferred stock owning 66.67% or more of the outstanding voting securities of the Company or successor entity (the Series D Redemption Rights ).

Under the April 22, 2013 Pillar Agreement, the Company agreed to seek approval and each of Pillar I and Pillar II agreed to vote in favor, of the following proposals at the Company s 2013 Annual Meeting:

amendments to the Series D Certificate of Designations for the Series D preferred stock to:

modify the dividend provisions of the Series D Certificate of Designations to change the date after which the Company may elect to pay dividends in shares of its common stock from December 31, 2014 to October 1, 2013, and to allow for the payment of such dividends in shares of a to-be-created new series of non-voting preferred stock in the event that payment of such dividends may not be made in shares of its common stock as a result of the application of the beneficial ownership and voting power limitations set forth the Series D Certificate of Designations; and

modify the Series D Certificate of Designations to provide, in the event of a sale of the Company, for the distribution of any assets that remain available for distribution to its stockholders, after payment to the holders of its Series A convertible preferred stock and any other class of its capital stock that ranks senior to its Series D preferred stock, to the holders of the Company s Series D preferred stock on a pro rata basis with the holders of its common stock, Series E preferred stock and such new series of non-voting preferred stock; and

amendments to the Series E Certificate of Designations to:

modify the dividend provisions of the Series E Certificate of Designations to allow for the payment of dividends in shares of its common stock commencing October 1, 2013; and

allow for the payment of dividends in shares of a to-be-created new series of non-voting preferred stock in the event that payment of such dividends may not be made in shares of its common stock as a result of the application of the beneficial ownership and voting power limitations set forth in the Series E Certificate of Designations.

Under the second agreement with the Pillar Entities (the April 30, 2013 Pillar Agreement ), Pillar I irrevocably waived the right of the holders of the Series D preferred stock under Section 2.1 of the Series D Certificate of Designations to receive, in the event of a voluntary or involuntary liquidation, dissolution or winding up of the Company (a Liquidation ), an amount per share of Series D preferred stock equal to the original issue price of such share of Series D preferred stock plus any dividends accrued or declared but unpaid thereon to the extent such amount is greater than the amount that would have been payable with respect to such share had all shares of Series D preferred stock been converted into shares of the Company s common stock immediately prior to such Liquidation, and that upon a Liquidation the holders of the Series D preferred stock will receive an amount per share of Series D preferred stock equal to the amount that would be payable with respect to such share had all shares of Series D preferred stock been converted into shares of common stock immediately prior to such Liquidation.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

In addition, under the April 30, 2013 Pillar Agreement, Pillar II and the entity affiliated with Pillar I and Pillar II, as the holders of 100% of the Company s Series E preferred stock, irrevocably waived the right of the holders of the Series E preferred stock under Section 2.1.1 of the Series E Certificate of Designations to receive, in the event of a Liquidation, an amount per share of Series E preferred stock equal to the original issue price of such share of Series E preferred stock plus any dividends accrued or declared but unpaid thereon to the extent such amount is greater than the amount that would have been payable with respect to such share had all shares of Series E preferred stock been converted into shares of common stock immediately prior to such Liquidation, and that upon a Liquidation the holders of the Series E preferred stock will receive under Section 2.1 of the Series E Certificate of Designations an amount per share of Series E preferred stock equal to the amount that would be payable with respect to such share had all shares of Series E preferred stock been converted into shares of common stock immediately prior to such Liquidation.

In accordance with the terms of the Pillar Agreements, the Company sought approval from its stockholders of amendments to the Series D Certificate of Designations and Series E Certificate of Designations to effect the changes described above to the dividend and liquidation provisions of the Company s Series D preferred stock and Series E preferred stock, the redemption rights of the holders of its Series D preferred stock and the rights of the holders of its Series D preferred stock to distributions in the event of a sale of the Company. These matters were approved at the 2013 Annual Meeting that took place on July 26, 2013.

Under the April 22, 2013 Pillar Agreement, in consideration of the agreements of Pillar I and II under the April 22, 2013 Pillar Agreement and the delivery of the waiver by Pillar I, and for no additional cash consideration, the Company issued to Pillar I warrants, the Pillar I Warrants, to purchase up to 1,000,000 shares of the Company s common stock at an exercise price of $0.61 per share.

In addition, under the April 30, 2013 Pillar Agreement, in consideration of the agreements of the Pillar Entities under the April 30, 2013 Pillar Agreement and the delivery of the waivers by the Pillar Entities, and for no additional cash consideration, the Company issued to the Pillar Entities warrants (the Additional Pillar Warrants, and together with the Pillar I Warrants, the Pillar Warrants ), to purchase up to an aggregate of 1,000,000 shares of the Company s common stock at an exercise price of $0.79 per share.

The Pillar Warrants became exercisable immediately upon issuance. The Pillar I Warrants will expire if not exercised on or prior to the fifth anniversary from the date of issuance and the Additional Pillar Warrants will expire if not exercised on or prior to June 1, 2014. The Pillar I Warrants provide that, after the second anniversary of the date of issuance, the Company may redeem such Pillar I Warrants for $0.01 per share of common stock issuable on exercise of such Pillar I Warrants following notice to the holder thereof if the closing price of its common stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to $2.80 per share.

In connection with the Pillar Agreements, the Company filed a registration statement that became effective on July 10, 2013, registering the resale of the shares of common stock issuable upon exercise of the Pillar Warrants. All of the Pillar I Warrants and the Additional Pillar Warrants were exercised during 2014.

The amendments to the Series D Certificate of Designations and Series E Certificate of Designations did not become effective until the amendments were approved by the Company s stockholders at the 2013 Annual Meeting, which occurred during the Company s fiscal quarter that began on July 1, 2013. As discussed in Note 7(a), all shares of Series D preferred stock were converted to common stock in February, 2014. As discussed in Note 8(g), all shares of Series E preferred stock were converted to common stock in December 2014.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

Since Pillar I irrevocably waived and agreed to not exercise the Series D Redemption Rights, the Company reassessed its accounting in May 2013 for the Series D preferred stock, which had been classified as temporary equity in the Company s condensed balance sheet because the Series D Redemption Rights represented a contingent put feature that was outside the Company s control. Upon effectiveness of this waiver, the contingent put feature ceased to exist.

In addition, the Pillar Entities irrevocably waived the liquidation preferences of both the Series D preferred stock and the Series E preferred stock. The Company concluded that these irrevocable waivers of the Series D Redemption Rights and the Series D and Series E liquidation preferences, which became effective on May 7, 2013, represented changes to the fundamental terms of both the Series D preferred stock and the Series E preferred stock. As a result, the Company has accounted for these irrevocable waivers as an extinguishment of the Series D preferred stock and the Series E preferred stock and changed the classification of the Series D preferred stock from temporary equity to permanent equity. The Company compared (1) the sum of the fair values of the Series D preferred stock, the Series E preferred stock and the Pillar Warrants immediately after the effectiveness of the waivers to (2) the sum of the carrying values of the Series D preferred stock and Series E preferred stock immediately prior to the effectiveness of the waivers on May 7, 2013. The Company recorded the excess of the aggregate fair value of the preferred stock plus the Pillar Warrants immediately after the effectiveness of the waivers over the aggregate carrying value of the preferred stock immediately prior to May 7, 2013 as a loss on extinguishment and classified the fair values, immediately after the effectiveness of the waivers, of the Series D preferred stock, the Series E preferred stock and the Pillar Warrants within permanent equity on its balance sheet.

The effect of this extinguishment accounting on the Company s financial statements was to (1) remove the $5,921,000 carrying value of the Series D preferred stock immediately prior to the extinguishment from temporary equity; (2) record the $5,464,000 fair value of the Series D preferred stock immediately after the extinguishment in permanent equity ( equity ); (3) remove the $3,701,000 carrying value of the Series E preferred stock immediately prior to the extinguishment from equity; (4) record the $5,528,000 fair value of the Series E preferred stock immediately after the extinguishment in equity; (5) record the $380,000 fair value of the Pillar Warrants in equity; and (6) record a $1,750,000 extinguishment loss to net loss applicable to common stockholders. These accounting entries resulted in a $5,921,000 net increase in stockholders equity on its balance sheet.

The Company determined the fair value of the Series D preferred stock and the Series E preferred stock as of May 7, 2013, the date the above described waivers became effective, based on the Option Pricing Method ( OPM ) which is a market based approach to imply the aggregate equity value of the Company by using the closing price of the Company s publicly traded common stock as of the May 7, 2013 valuation date. Under the OPM, the fair value of preferred stock and common stock are determined based on the net value of a series of call options representing the present value of the expected future returns to each shareholder class. Essentially, the rights of the common stock are equivalent to a call option on any value of the Company above any cumulative preferred stock liquidation preference. The analysis involves calculating the equity value breakeven points at which the various equity classes would participate, or convert in the case of preferred stock, or exercise in the case of stock options and warrants.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

The Company used the Black-Scholes option pricing model to compute the fair value of the Pillar Warrants as of the May 7, 2013 effective date on which the Pillar Warrants were issued based on the following assumptions and other inputs:

| | Pillar I Warrants | Additional Pillar Warrants |
|---|---|---|
| Common stock price | $ 0.57 | $ 0.57 |
| Warrant exercise price | $ 0.61 | $ 0.79 |
| Term of warrant (years) | 5.0 | 1.1 |
| Expected volatility | 62% | 67% |
| Average risk free interest rate | 0.8% | 0.1% |
| Expected dividend yield | | |
| Expected percentage of warrants to be exercised | 100% | 100% |

The closing price of the Company s common stock is readily determinable since it is publicly traded. The warrant exercise prices and the warrant terms are readily determinable from the warrant agreements. The expected volatility is based on the actual stock-price volatility over a period equal to the greater of the term of the warrant or three years. The assumed risk-free interest rate is based on the U.S. Treasury security rate with a term equal to the term of the warrant. The assumed dividend yield of zero is based on the fact that the Company has never paid cash dividends to common stockholders and has no present intention to pay cash dividends to common stockholders. The Company assumed that future financings would dilute the warrant holder s ownership in the Company such that the 19.99% ownership limitation would not prevent the warrant holder from exercising all of the warrants during the term of the warrants.

**15. Financings**

*February 10, 2014 Follow-on Underwritten Public Offering*

On February 10, 2014, the Company closed a follow-on underwritten public offering, in which it sold 7,867,438 shares of common stock at a price to the public of $4.00 per share and pre-funded warrants to purchase up to 2,158,750 shares of common stock at a price to the public of $3.99 per share for aggregate gross proceeds of $40.1 million. The pre-funded warrants have an exercise price of $0.01 per share and will expire if not exercised by February 10, 2021. The net proceeds to the Company from the offering, after deducting underwriters discounts and commissions and other offering costs and expenses and excluding the proceeds of the exercise of the warrants, if any, were approximately $37.2 million.

*September 30, 2013 Follow-on Underwritten Public Offering*

On September 30, 2013, the Company closed a follow-on underwritten public offering, in which it sold 13,727,251 shares of common stock at a price to the public of $1.55 per share and pre-funded warrants to purchase up to 4,175,975 shares of common stock at a price to the public of $1.54 per share for aggregate gross proceeds of $27.7 million. The pre-funded warrants have an exercise price of $0.01 per share and will expire if not exercised by September 30, 2020. The net proceeds to the Company from the offering, after deducting underwriters discounts and commissions and offering costs and expenses and excluding the proceeds of the exercise of the warrants, if any, were approximately $25.7 million.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

*May 7, 2013 Follow-on Underwritten Public Offering*

On May 7, 2013, the Company closed a follow-on underwritten public offering, in which it sold 17,500,000 shares of common stock, together with matching warrants to purchase up to 17,500,000 shares of common stock, and pre-funded warrants to purchase up to 15,816,327 shares of common stock, together with matching warrants to purchase up to 15,816,327 shares of common stock, for aggregate gross proceeds of $16.5 million as follows:

| | Combined Price to the Public (per share of Common Stock) | Common Stock | Pre-funded Warrants | Matching Warrants |
|---|---|---|---|---|
| Common stock and matching warrants sold (shares) | $ 0.50 | 17,500,000 | | 17,500,000 |
| Pre-funded warrants and matching warrants sold (shares) | $ 0.49 | | 15,816,327 | 15,816,327 |
| Total (shares) | | 17,500,000 | 15,816,327 | 33,316,327 |
| Warrant exercise price (per share) | | | $ 0.01 | $ 0.47 |
| Term of warrant (years) | | | 7.0 | 5.0 |

The net proceeds to the Company from the offering, after deducting underwriters discounts and commissions and offering costs and expenses and excluding the proceeds of the exercise of the warrants, if any, were approximately $14.5 million.

The warrants and the pre-funded warrants each provide that, after the second anniversary of the date of issuance, the Company may redeem the warrants for $0.01 per share of common stock issuable on exercise of the warrants following 30 days prior written notice to the holder if the closing price of the common stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to $2.80.

*Warrant Exercises*

Warrants to purchase 5,543,802 shares of common stock were exercised during 2014. The Company received $7,534,000 in proceeds from the exercise of these warrants.

Warrants to purchase 7,160,000 shares of common stock were exercised during 2013. The Company received $3,365,000 in proceeds from the exercise of these warrants.

There were no warrant exercises during 2012.

*Series E Preferred Stock and Warrant Financing*

In November 2012, the Company entered into a Convertible Preferred Stock and Warrant Purchase Agreement (the Series E Purchase Agreement ) with Pillar II and the other purchaser named therein (together, the Series E Purchasers ). Pursuant to the Series E Purchase Agreement, the Company issued and sold to the Series E Purchasers, for an aggregate purchase price of approximately $7.0 million, 424,242 shares of its Series E preferred stock and Series E warrants to purchase up to 8,484,840 shares of its common stock. The shares of Series E preferred stock are convertible, subject to limitations, into an aggregate of 8,484,840 shares of common stock at a conversion price of $0.70 per share. The initial exercise price of the Series E warrants is $0.70 per share. The Series E warrants are exercisable immediately, and will expire if not exercised on or prior to November 9, 2017. The Company has agreed to pay to the holders of the Series E preferred stock quarterly

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

dividends payable in cash in arrears at the rate of 4.6% per annum with the first dividend payment being due on March 31, 2013. Under the terms of the Series D preferred stock, any dividends paid to the holders of Series E preferred stock would also be paid to the holders of the Series D preferred stock on an as-converted to common stock basis. The Company agreed that, at the 2013 Annual Meeting, it would, among other things, propose an amendment to the Series D Certificate of Designations to, among other things, modify the terms of the Series D preferred stock that require payment of dividends to Series D preferred stockholders upon payment of dividends to Series E stockholders. Since the stockholders of the Company approved the amendment to the Series D Certificate of Designations, the dividend rate with respect to the Series E preferred dividends increased from the 4.6% to the rate of 8% per annum. The net proceeds to the Company, excluding the proceeds of any exercise of the warrants, were approximately $6.0 million. The Company intends to use these funds for research and clinical development activities, the manufacturing of its drug candidates, working capital and general corporate purposes, including the advancement of the Company s autoimmune disease program in at least two indications.

The securities offered by the Company in the private placement were not registered under the Securities Act of 1933, as amended (the Securities Act ), and cannot be offered or sold in the United States absent registration or an applicable exemption from registration requirements. In January 2013, the Company filed a registration statement with the Securities and Exchange Commission that became effective on January 17, 2013, registering the resale of the shares of common stock issuable upon conversion of the Series E preferred stock and the shares of common stock issuable upon exercise of the Series E warrants issued in the private placement.

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

*Series D Preferred Stock and Warrant Financing*

In November 2011, the Company entered into a Convertible Preferred Stock and Warrant Purchase Agreement (the Series D Purchase Agreement ) with Pillar I. Pursuant to the Series D Purchase Agreement, the Company issued and sold to Pillar I, for an aggregate purchase price of $9.5 million, 1,124,260 shares of its Series D preferred stock initially convertible into 5,621,300 shares of its common stock, and Series D warrants to purchase 2,810,650 shares of its common stock. Each share of Series D preferred stock was initially convertible, subject to limitations, at a conversion price of $1.63 per share. The initial exercise price of the Series D warrants was $1.63 per share.

The sale of shares of Series E preferred stock and Series E warrants in the Company s November 2012 Series E financing triggered anti-dilution adjustments under the terms of the Series D preferred stock and the Series D warrants. The anti-dilution adjustment under the Series D preferred stock resulted in the conversion price of the Series D preferred stock being reduced and fixed at $1.46 per share, and such shares no longer being subject to any anti-dilution adjustments. Each share of Series D preferred stock became convertible into 5.5736 shares of the Company s common stock and, as a result, the 1,124,260 shares of Series D preferred stock became convertible, subject to limitations, into 6,266,175 shares of the Company s common stock. The anti-dilution adjustment under the Series D warrants resulted in the exercise price of the Series D warrants being reduced and fixed at the minimum $1.46 per share and the Series D warrants no longer being subject to any anti-dilution adjustments.

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

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

The securities offered by the Company in the private placement were not registered under the Securities Act and cannot be offered or sold in the United States absent registration or an applicable exemption from registration requirements. In December 2011, the Company filed a registration statement with the Securities and Exchange Commission that became effective on December 21, 2011, registering the resale of the shares of common stock issuable upon conversion of the Series D preferred stock and the shares of common stock issuable upon exercise of the warrants issued in the private placement. In February 2013, the Company filed a registration statement with the Securities and Exchange Commission that became effective on February 8, 2013, covering the resale of additional shares of common stock issuable upon conversion of the Series D preferred stock.

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

**16. Subsequent Event**

*February 19, 2015 Follow-on Underwritten Public Offering*

On February 19, 2015, the Company closed a follow-on underwritten public offering, in which it sold 23,000,000 shares of common stock at a price to the public of $3.75 per share for aggregate gross proceeds of $86.3 million. The estimated net proceeds to the Company from the offering, after deducting underwriters discounts and commissions and other offering costs and expenses were approximately $80.6 million. Investment funds affiliated with Baker Bros. Advisors LP and two members of the Company s board of directors purchased 5,333,333 shares in this offering at $3.75 per share.

As of February 19, 2015, Baker Bros. Advisors LP and certain of its affiliated funds (which include the Selling Stockholders) (collectively, Baker Brothers ), held 6,965,432 shares of the Company s common stock, warrants to purchase up to 20,316,327 shares of the Company s common stock at an exercise price of $0.47 per share and pre-funded warrants to purchase up to 22,151,052 shares of the Company s common stock at an exercise price of $0.01 per share.

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**Exhibit Index**

| Exhibit Number | Description | Filed Herewith | Incorporated by Reference to Form | Filing Date | SEC File No. |
|---|---|---|---|---|---|
| 3.1 | Restated Certificate of Incorporation of Idera Pharmaceuticals, Inc., as amended. | | 8-K | February 5, 2014 | 001-31918 |
| 3.2 | Amended and Restated Bylaws of Idera Pharmaceuticals, Inc. | | S-1 | November 6, 1995 | 33-99024 |
| 3.3 | Certificate of Elimination of Number of Shares of Preferred Stock Designated as Series D Convertible Preferred. | | 10-Q | May 12, 2014 | 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 |
| 10.1 | 2008 Stock Incentive Plan, as amended | | 8-K | June 17, 2011 | 001-31918 |
| 10.2 | 2005 Stock Incentive Plan, as amended | | 10-Q | August 14, 2006 | 001-31918 |
| 10.3 | Amended and Restated 1997 Stock Incentive Plan. | | 10-Q | May 15, 2001 | 000-27352 |
| 10.4 | 1995 Director Stock Option Plan. | | 8-K | June 10, 2008 | 001-31918 |
| 10.5 | 1995 Employee Stock Purchase Plan, as amended | | 8-K | June 17, 2011 | 001-31918 |
| 10.6 | Non-Employee Director Nonstatutory Stock Option Agreement Granted under 1997 Stock Incentive Plan. | | 10-K | March 25, 2005 | 001-31918 |
| 10.7 | Form of Incentive Stock Option Agreement Granted Under the 2005 Stock Incentive Plan. | | 8-K | June 21, 2005 | 001-31918 |
| 10.8 | Form of Nonstatutory Stock Option Agreement Granted Under the 2005 Stock Incentive Plan. | | 8-K | June 21, 2005 | 001-31918 |
| 10.9 | Form of Incentive Stock Option Agreement Granted Under the 2008 Stock Incentive Plan. | | 8-K | June 10, 2008 | 001-31918 |
| 10.10 | Form of Nonstatutory Stock Option Agreement Granted Under the 2008 Stock Incentive Plan. | | 8-K | June 10, 2008 | 001-31918 |
| 10.11 | Form of Nonstatutory Stock Option Agreement (Non-Employee Directors) Granted Under the 2008 Stock Incentive Plan. | | 8-K | June 10, 2008 | 001-31918 |
| 10.12 | Form of Restricted Stock Agreement Under the 2008 Stock Incentive Plan. | | 8-K | June 10, 2008 | 001-31918 |
| 10.13 | Policy on Treatment of Stock Options in the Event of Retirement, approved April 28, 2014. | | 10-Q | August 12, 2014 | 001-31918 |
| 10.14 | Employment Agreement dated October 19, 2005 between Idera Pharmaceuticals, Inc. and Dr. Sudhir Agrawal | | 10-Q | November 9, 2005 | 001-31918 |
| 10.15 | Amendment dated December 17, 2008 to Employment Agreement by and between Idera Pharmaceuticals, Inc. and Dr. Sudhir Agrawal dated October 19, 2005. | | 8-K | December 18, 2008 | 001-31918 |

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| Exhibit Number | Description | Filed Herewith | Incorporated by Reference to Form | Filing Date | SEC File No. |
|---|---|---|---|---|---|
| 10.16 | Amended and Restated Employment Letter Agreement by and between Idera Pharmaceuticals, Inc. and Louis J. Arcudi, III, Dated December 2, 2011. | | 10-K | March 14, 2012 | 001-31918 |
| 10.17 | Director Compensation Program | | 10-Q | May 12, 2014 | 001-31918 |
| 10.18 | First Amendment dated February 21, 2014 to Lease Agreement dated October 31, 2006 between Idera Pharmaceuticals, Inc. and ARE-MA-Region No. 23, LLC. | | 10-Q | May 12, 2014 | 001-31918 |
| 10.19 | Development and Commercialization Agreement, dated May 1, 2014, by and between Abbott Molecular Inc. and Idera Pharmaceuticals, Inc. | | 10-Q | August 12, 2014 | 001-31918 |
| 10.20 | 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 |
| 10.21 | 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 |
| 10.22 | 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 |
| 10.23 | Exclusive License and Research Collaboration Agreement by and between Merck, Inc. and Idera Pharmaceuticals, Inc., dated December 8, 2006. | | 8-K | March 6, 2007 | 001-31918 |
| 10.24 | Employment Letter Agreement, dated December 1, 2014, by and between Idera Pharmaceuticals, Inc. and Vincent Milano. | X | | | |
| 10.25 | 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 |
| 10.26 | 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 |
| 10.27 | Registration Rights Agreement, dated March 24, 2006, by and among Idera Pharmaceuticals, Inc. and the Investors named therein. | | 8-K | March 29, 2006 | 001-31918 |
| 10.28 | Registration Rights Agreement, dated March 24, 2006, by and among Idera Pharmaceuticals, Inc., Biotech Shares Ltd. and Youssef El Zein. | | 8-K | March 29, 2006 | 001-31918 |
| 10.29 | Amendment No. 1 to the Registration Rights Agreement dated March 24, 2006, by and among Idera Pharmaceuticals, Inc. and Biotech Shares Ltd. | | 10-Q | August 14, 2006 | 001-31918 |

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| Exhibit Number | Description | Filed Herewith | Incorporated by Reference to Form | Filing Date | SEC File No. |
|---|---|---|---|---|---|
| 10.30 | Form of Warrant issued to Investors in Idera Pharmaceuticals, Inc. s August 5, 2010 Financing. | | 10-Q | November 4, 2010 | 001-31918 |
| 10.31 | Second Amendment dated December 1, 2014 to Employment Agreement by and between Idera Pharmaceuticals, Inc. and Dr. Sudhir Agrawal dated October 19, 2005. | X | | | |
| 10.32 | Employment Letter, dated December 12, 2014, by and between Idera Pharmaceuticals, Inc. and J. Peter Wolf, III | X | | | |
| 10.33 | Form of Pre-Funded Warrant issued to purchasers in Idera Pharmaceuticals, Inc. s registered public offering on Idera Pharmaceuticals, Inc. s registration statement on Form S-3 (File No. 333-191073). | | 8-K | September 26, 2013 | 001-31918 |
| 10.34 | Form of Pre-Funded Warrant issued to purchasers in Idera Pharmaceuticals, Inc. s registered public offering on Idera Pharmaceuticals, Inc. s registration statement on Form S-3 (File No. 333-191073). | | 8-K | February 5, 2014 | 001-31918 |
| 10.35 | Convertible Preferred Stock and Warrant Purchase Agreement, dated November 4, 2011, between Idera Pharmaceuticals, Inc. and the Purchaser named therein. | | 8-K | November 10, 2011 | 001-31918 |
| 10.36 | Amendment No. 1, dated November 9, 2012, to Convertible Preferred Stock and Warrant Purchase Agreement, dated November 4, 2011, between Idera Pharmaceuticals, Inc. and the Purchaser named therein | | 8-K | November 14, 2012 | 001-31918 |
| 10.37 | Registration Rights Agreement, November 4, 2011, between Idera Pharmaceuticals, Inc. and the Purchaser named therein. | | 8-K | November 10, 2011 | 001-31918 |
| 10.38 | Form of Warrant issued to Purchaser pursuant to Convertible Preferred Stock and Warrant Purchase Agreement, dated November 4, 2011, between Idera Pharmaceuticals, Inc. and the Purchaser named therein. | | 8-K | November 10, 2011 | 001-31918 |
| 10.39 | Amendment No. 1, dated November 9, 2012, to Warrant, dated November 4, 2011, between Idera Pharmaceuticals, Inc. and the Registered Holder named therein | | 8-K | November 14, 2012 | 001-31918 |
| 10.40 | Convertible Preferred Stock and Warrant Purchase Agreement, dated November 9, 2012, among Idera Pharmaceuticals, Inc. and the Purchasers named therein. | | 8-K | November 14, 2012 | 001-31918 |

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| Exhibit Number | Description | Filed Herewith | Incorporated by Reference to Form | Filing Date | SEC File No. |
|---|---|---|---|---|---|
| 10.41 | Registration Rights Agreement, November 9, 2012, among Idera Pharmaceuticals, Inc. and the Purchasers named therein. | | 8-K | November 14, 2012 | 001-31918 |
| 10.42 | Form of Warrant issued to each Purchaser pursuant to Convertible Preferred Stock and Warrant Purchase Agreement, dated November 9, 2012, among Idera Pharmaceuticals, Inc. and the Purchasers named therein. | | 8-K | November 14, 2012 | 001-31918 |
| 10.43 | Employment Letter Agreement by and between Idera Pharmaceuticals, Inc. and Louis Brenner, dated January 3, 2014. | | 10-K | March 13, 2014 | 001-31918 |
| 10.44 | Lease Agreement dated October 31, 2006 between Idera Pharmaceuticals, Inc. and ARE-MA-Region No. 23, LLC. | | 10-K/A | May 8, 2007 | 001-31918 |
| 10.45 | Agreement, dated April 22, 2013, among Idera Pharmaceuticals, Inc., Pillar Pharmaceuticals I, L.P. and Pillar Pharmaceuticals II, L.P. | | 8-K | April 23, 2013 | 001-31918 |
| 10.46 | Agreement, dated April 30, 2013, among Idera Pharmaceuticals, Inc., Pillar Pharmaceuticals I, L.P., Pillar Pharmaceuticals II, L.P. and Participations Besancon. | | S-1/A | May 1, 2013 | 333-187155 |
| 10.47 | Form of Warrant issued to purchasers in Idera Pharmaceuticals, Inc. s registered public offering on Idera Pharmaceuticals, Inc. s registration statement on Form S-1 (File No. 333-187155). | | 10-Q | May 15, 2013 | 001-31918 |
| 10.48 | Form of Warrant issued to entities affiliated with Pillar Invest Corporation in Idera Pharmaceuticals, Inc. s registered public offering on Idera Pharmaceuticals, Inc. s registration statement on Form S-1 (File No. 333-187155). | | 10-Q | May 15, 2013 | 001-31918 |
| 10.49 | Form of Pre-Funded Warrant issued to purchasers in Idera Pharmaceuticals, Inc. s registered public offering on Idera Pharmaceuticals, Inc. s registration statement on Form S-1 (File No. 333-187155). | | 10-Q | May 15, 2013 | 001-31918 |
| 10.50 | 2013 Stock Incentive Plan. | | 8-K | June 13, 2014 | 001-31918 |
| 10.51 | Form of Incentive Stock Option Agreement granted under the 2013 Stock Incentive Plan. | | 10-Q | July 29, 2013 | 001-31918 |
| 10.52 | Form of Nonstatutory Stock Option Agreement granted under the 2013 Stock Incentive Plan. | | 10-Q | July 29, 2013 | 001-31918 |

**Table of Contents**

| Exhibit Number | Description | Filed Herewith | Incorporated by Reference to Form | Filing Date | SEC File No. |
|---|---|---|---|---|---|
| 10.53 | Form of Nonstatutory Stock Option Agreement (Non-Employee Directors) granted under the 2013 Stock Incentive Plan. | | 10-Q | July 29, 2013 | 001-31918 |
| 23.1 | Consent of Independent Registered Public Accounting Firm. | X | | | |
| 31.1 | Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002. | X | | | |
| 31.2 | Certification of Chief Financial Officer 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 | | | |
| 101.INS | XBRL Instance Document | X | | | |
| 101.SCH | XBRL Taxonomy Extension Schema | X | | | |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document | X | | | |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document | X | | | |
| 101.LAB | XBRL Taxonomy Extension Labels Linkbase Document | X | | | |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document | X | | | |

Confidential treatment granted as to certain portions, which 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.