# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, DC 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d)**
**of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): September 24, 2013**

# Idera Pharmaceuticals, Inc.
**(Exact Name of Registrant as Specified in Charter)**

| **Delaware** | **001-31918** | **04-3072298** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| **167 Sidney Street**<br>**Cambridge, Massachusetts** | **02139** |
|---|---|
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (617) 679-5500**

**(Former Name or Former Address, if Changed Since Last Report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 8.01. Other Events.**

Idera Pharmaceuticals, Inc. (the "Company") is filing this Current Report on Form 8-K to provide certain information as an update to the information provided in the Company's previous periodic filings with the Securities and Exchange Commission in order to reflect recent business developments. Updated risk factors and a summary description of the Company's business are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference. This Current Report on Form 8-K, including the exhibits hereto, should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2012, the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2013 and June 30, 2013 and the Company's Current Reports on Form 8-K.

On September 24, 2013, the Company issued a press release announcing its intention to offer and sell shares of its common stock and pre-funded warrants in an underwritten public offering, subject to market conditions and other factors, pursuant to the Company's effective Registration Statement on Form S-3 (File No. 333-191073). The full text of the press release issued in connection with the announcement is attached to this Current Report on Form 8-K as Exhibit 99.3 and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

See attached Exhibit Index.

**SIGNATURE**

Pursuant to the requirements 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 hereunto duly authorized.

**Idera Pharmaceuticals, Inc.**

Date: September 24, 2013

By: /s/ Sudhir Agrawal

Sudhir Agrawal, D. Phil.

*President and Chief Executive Officer*

**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| 99.1 | Updated Risk Factors |
| 99.2 | Updated Summary Business Description |
| 99.3 | Press Release dated September 24, 2013 |

**Exhibit 99.1**

## RISK FACTORS

*Investing in our securities involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included or incorporated by reference in this Current Report on Form 8-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 and cash equivalents of approximately $16.3 million at June 30, 2013. We believe that our existing cash and cash equivalents would be sufficient to fund our operations at least through the fourth quarter of 2014, based on an operating plan that includes the completion of our ongoing Phase 2 clinical trial of IMO-8400 in patients with psoriasis and planning with respect to further clinical development of IMO-8400. We believe that our available funds will enable us to complete our ongoing Phase 2 clinical trial in patients with psoriasis. We will need to raise additional funds in order to conduct any other clinical development of IMO-8400 or IMO-9200, including to conduct any other development of our other drug candidates or technologies.

We expect that we will require substantial additional funds to conduct additional research and development, 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 programs, including the results of our ongoing Phase 2 clinical trial of IMO-8400 in patients with moderate to severe plaque psoriasis that we initiated in June 2013 and the results of the dose escalation phase of our planned Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia and our planned Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL;
- 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.

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 financing or equity that we raise may contain terms, such as liquidation and other preferences, or liens or other restrictions on our assets, which are not favorable to us or our stockholders.

If we are unable to obtain adequate funding on a timely basis or at all, we 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 June 30, 2013, we had an accumulated deficit of $402.1 million. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 to June 30, 2013, we incurred losses of $141.9 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 June 30, 2013, almost all of our revenues have been from collaborative and license agreements. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any drug candidates. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our drug candidates will become commercially available, or when we will become profitable, if at all. We expect to incur substantial operating losses in future periods.

***Our independent auditors have expressed substantial doubt about our ability to continue as a going concern.***

We have received a report dated March 11, 2013 from Ernst & Young LLP, our independent registered public accounting firm, regarding our financial statements as of December 31, 2012 and for the fiscal year then ended, which included an explanatory paragraph stating that the financial statements were prepared assuming we will continue as a going concern. The report also stated that our recurring losses and negative cash flows from operations will require us to raise additional capital or obtain alternative means of financial support, or both, prior to December 31, 2013 in order to continue to fund our operations. These factors raise substantial doubt about our ability to continue as a going concern. The going concern explanatory paragraph included in our auditor's report on our financial statements could inhibit our ability to finance our operations. On May 7, 2013, we raised $16.5 million in gross proceeds from a follow-on underwritten public offering of our securities, increasing our cash resources sufficiently to fund our operations at least through the fourth quarter of 2014. We will need to raise substantial additional funds in order to conduct research and development, including preclinical testing and clinical trials of our drug candidates, and to fund our operations beyond such time. 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 must continue to meet the Nasdaq Capital Market continued listing requirements or we risk delisting. If our common stock were to be delisted, our stock price may decline and it would likely make it more difficult for us to sell securities in a financing and for our stockholders to trade our stock.***

Our common stock trades on the Nasdaq Capital Market. In order to continue the listing of our common stock on the Nasdaq Capital Market, we are required to meet the continued listing requirements of the Nasdaq Capital Market. We recently faced the delisting of our common stock from the Nasdaq Capital Market as a result of our failure to satisfy the minimum stockholders' equity requirement pursuant to Nasdaq Listing Rule 5450(b)(2), and the minimum bid price requirement in accordance with Nasdaq Listing Rule 5450(a)(1). Nasdaq notified us that we had regained compliance with the minimum stockholders' equity requirement on May 8, 2013 and with the minimum bid price requirement on August 12, 2013. If we do not continue to meet the continued listing requirements of the Nasdaq Capital Market, our common stock will be delisted. If our common stock were to be delisted from the Nasdaq Capital Market, it might be eligible to trade on the Over-The-Counter Bulletin Board, which may be a less liquid market, or on the pink sheets. In such case, our stockholders' ability to trade, or obtain quotations of the market value of, shares of our common stock would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our securities. There can be no assurance that our common stock, if in the future it were to be delisted from the Nasdaq Capital Market, would be listed on a national securities exchange, a national quotation service, the Over-The-Counter Bulletin Board or the pink sheets. Delisting from the Nasdaq Capital Market, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, adversely affect the market liquidity of our common stock, reduce security analysts' coverage of us and diminish investor, supplier and employee confidence.

## Risks Relating to Our Business, Strategy and Industry

***We are depending heavily on the development of TLR-targeted drug candidates for the treatment of autoimmune and inflammatory diseases and certain genetically defined B-cell lymphomas. 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 clinical stage lead drug candidates as part of our autoimmune and inflammatory disease program. In June 2013, we initiated a Phase 2 clinical trial in patients with psoriasis to, among other things, evaluate the clinical activity of IMO-8400 with a treatment period of up to 12 weeks. We expect to have top-line data from this Phase 2 trial during the first quarter of 2014. In the future, we also intend to invest a significant portion of our time and financial resources in the development of IMO-8400 as part of our genetically defined B-cell lymphoma program.

We are planning to initiate 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 in the first quarter of 2014, and are also planning to initiate a Phase 1 clinical trial of IMO-9200 in the third quarter of 2014. However, our plans to conduct these trials are subject to our ability to fund the conduct of these trials with additional financing. We expect to seek such additional funding through public or private equity offerings, debt financings, collaborations and licensing arrangements, and other sources.

We anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of our drug candidates in our autoimmune and inflammatory disease and genetically defined B-cell lymphoma programs.

Our ability to generate product revenues under our collaboration with Merck Sharp & Dohme Corp. (formerly Merck & Co., Inc.), or Merck & Co., and under any other collaboration that we enter into with respect to our autoimmune disease program, 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, IMO-2125, and IMO-2055, including:

- During the fourth quarter of 2010, we commenced additional nonclinical studies of IMO-3100 in light of some reversible immune responses that were observed in the 13-week nonclinical toxicology studies and that were inconsistent with observations made in our other nonclinical studies of IMO-3100. In June 2011, we submitted a Phase 2 protocol to the United States Food and Drug Administration, or FDA, to conduct a 12-week clinical trial of IMO-3100 in patients with psoriasis. In July 2011, the FDA placed a clinical hold on the protocol that we had submitted. In October 2011, we submitted to FDA a new Phase 2 protocol to evaluate IMO-3100 in adult patients with moderate to severe plaque psoriasis, over a four-week treatment period. In December 2011, the FDA removed the clinical hold. We subsequently initiated in the second quarter of 2012 the four-week Phase 2 clinical trial that we completed in the fourth quarter of 2012. We cannot be certain that the FDA will allow us to conduct further clinical trials of IMO-3100 for treatment periods of more than four weeks or at all without additional clinical or preclinical data.
- 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 preliminary observations in an ongoing 26-week chronic nonclinical toxicology study of IMO-2125 in rodents. We subsequently completed a 39-week chronic nonclinical toxicology study of IMO-2125 in non-human primates in which there were no similar observations. During the third quarter of 2011, we re-assessed and prioritized our drug development programs, and determined to discontinue further investment of internal resources on the development of IMO-2125 for the treatment of HCV.
- In July 2011, Merck KGaA, Darmstadt, Germany, or Merck KGaA, informed us that, based on increased incidence of neutropenia and electrolyte imbalances reported in its Phase 1 trial of IMO-2055 in combination with cisplatin/5-FU and cetuximab in patients with first-line 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 November 2011, as part of an agreed-upon termination of our collaboration with Merck KGaA, we regained global rights to IMO-2055 and our other TLR9 agonists, including preclinical lead drug candidates selected for further evaluation under the collaboration, for the treatment of cancer. In May 2012, we announced that in the Phase 2 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 intend to seek to enter into collaborations with pharmaceutical companies to advance the use of our TLR antagonist product candidates. Our 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;
- successful protection of our intellectual property rights from competing products in the United States and abroad; and
- a continued acceptable safety and efficacy profile of the drug candidates following marketing approval.

***We have recently begun to focus our efforts on the research and development of product candidates for use in the treatment of certain genetically defined B-cell lymphomas, 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 B-cell lymphomas, 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 product candidates for use in the treatment of certain genetically defined B-cell lymphomas. The scientific evidence to support the feasibility of developing product candidates for this use is both preliminary and limited. We have conducted preclinical studies in human lymphoma cell lines that carry the specific genetic mutation and have also entered into a M-CRADA with NCI to evaluate our TLR antagonists as a potential approach to the treatment of certain genetically defined B-cell lymphomas. 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 planned clinical trials. Therefore, we do not know if our approach of inhibiting TLRs to treat patients with genetically defined B-cell lymphomas 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 product candidate progress towards commercialization, we will need to develop companion diagnostics for such product 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.

***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 TLR antagonist product 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 the Waldenström's macroglobulinemia or DLBCL and the specific genetic mutation, our ability to enroll eligible patients in any clinical trials for these indications may be limited or may result in slower enrollment than we anticipate. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our TLR antagonist product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product 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 product candidates under study;
- the efforts to facilitate timely enrollment in clinical trials;
- 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 TLR antagonist product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

With respect to our genetically defined B-cell lymphoma programs, we expect to design future clinical trials to include some patients with a particular genetic mutation that causes the disease with a view to assessing possible early evidence of potential therapeutic effect. If we are unable to include patients with the applicable genetic mutation, this could compromise our ability to seek participation in FDA expedited review and approval programs, including breakthrough therapy and fast track designation, or otherwise to seek to accelerate clinical development and regulatory timelines.

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

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

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

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., or Pfizer, 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 Pharmaceuticals, Ltd., or Novartis, discontinued the development of ANA975, the investigational TLR7 agonist compound for HCV infection. Dynavax

Technologies Corporation, or 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 with respect to TLR-targeted drug candidates may result in enhanced scrutiny by regulators or institutional review boards, or IRBs, of clinical trials of TLR-targeted drug candidates, including our TLR-targeted drug candidates, which could result in regulators or IRBs prohibiting the commencement of clinical trials, requiring additional nonclinical studies as a precondition to commencing clinical trials or imposing restrictions on the design or scope of clinical trials that could slow enrollment of trials, increase the costs of trials or limit the significance of the results of trials. Such setbacks could also adversely impact the desire of investigators to enroll patients in, and the desire of patients to enroll in, clinical trials of TLR-targeted drug candidates.

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

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

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

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

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

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

- manufacturing sufficient quantities of drug candidate that satisfy the required quality standards for use in clinical trials;
- demonstrating sufficient safety to obtain regulatory approval for conducting a clinical trial;
- reaching an agreement with any collaborators on all aspects of the clinical trial;
- reaching agreement with contract research organizations, if any, and clinical trial sites on all aspects of the clinical trial;
- resolving any objections from the FDA or any regulatory authority on an Investigational New Drug application, or 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 targeted to TLRs and on GSOs. Neither we nor any other company have obtained regulatory approval to market such compounds as therapeutic drugs, and no such products currently are being marketed. It is unknown whether the results of preclinical studies with TLR-targeted compounds will be indicative of results that may be obtained in clinical trials, and results we have obtained in the clinical trials we have conducted to date may not be predictive of results in subsequent large-scale clinical trials. Further, the chemical and pharmacological properties of RNA- and DNA-based compounds targeted to TLRs or of GSOs may not be fully recognized in preclinical studies and small-scale clinical trials, and such compounds may interact with human biological systems in unforeseen, ineffective or harmful ways that we have not yet identified.

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

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

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

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

We are developing our TLR-targeted drug candidates for use in the treatment of autoimmune and inflammatory diseases and genetically defined B-cell lymphomas and for use as vaccine adjuvants. We have one drug candidate, IMO-8400, in clinical development in our autoimmune and inflammatory disease program. With respect to our genetically defined B-cell lymphoma program we have conducted preclinical studies on and entered into a M-CRADA with NCI to evaluate our TLR antagonists as a potential approach to the treatment of certain genetically defined B-cell lymphomas, and plan to initiate 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 during the first quarter of 2014. We are also collaborating with Merck & Co. for the use of agonists of TLR7, TLR8, and TLR9 as vaccine adjuvants for cancer, infectious diseases and Alzheimer's disease. Finally, we are seeking to enter into collaborative alliances with pharmaceutical companies to advance our TLR-targeted programs in broader autoimmune disease indications, such as psoriasis, lupus and arthritis, as well as applications of our GSO technology platform. 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 therapies.

Our principal competitor developing TLR-targeted compounds for autoimmune and inflammatory diseases is Dynavax, with its collaborator, GlaxoSmithKline plc., or GlaxoSmithKline. Merck & Co.'s vaccines using our TLR7, TLR8 or TLR9 agonists as adjuvants may compete with vaccines using TLR agonists as adjuvants being developed or marketed by GlaxoSmithKline, Novartis, Dynavax, VaxInnate, Inc., Intercell AG, and Cytos Biotechnology AG.

We are developing drug candidates for the treatment of moderate to severe plaque psoriasis. There are a number of well-known immune suppressors and biologics that are currently being widely used for the treatment of moderate to severe plaque psoriasis, including methotrexate and cyclosporine, which are both immune suppressors, and biologics like Enbrel, which is marketed by Amgen Inc., or Amgen, Pfizer, and Takeda Pharmaceutical Company Limited, Remicade, which is marketed by Janssen Biotech, Merck & Co., and Mitsubishi Tanabe Pharma, Humira, which is marketed by Abbott Laboratories, and Stelara, which is marketed by Janssen Biotech. In addition to existing treatments, we are also aware of additional compounds for the treatment of moderate to severe plaque psoriasis that are currently in late stage development, including apremilast, which is being developed by Celgene Corporation, tofacitinib, which is being developed by Pfizer, secukinumab, which is being developed by Novartis, ixekizumab, which is being developed by Eli Lilly and Company, and brodalumab, which is being developed by Amgen, AstraZeneca PLC, and Kyowa Hakko Kirin Co., Ltd.

We are planning to develop drug candidates for the treatment of genetically defined B-cell lymphoma. There are currently no drugs specifically approved for the treatment of Waldenström's macroglobulinemia or DLBCL. Currently, patients with any form of non-Hodgkin lymphoma are most often treated with monoclonal antibody rituximab and/or with one or more chemotherapeutic agents. Rituximab is co-marketed in the United States by Biogen Idec and Genentech and Hoffmann-La Roche and Chugai Pharmaceuticals in territories outside the United States. We are aware of additional compounds in development for the treatment of genetically defined B-cell lymphoma, including Ibrutinib, which is being developed by Pharmacyclics, Inc., and an inhibitor of interleukin-1 receptor-associated kinase 4, or IRAK4, which is being developed by Nimbus Discovery, Inc.

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

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

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

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

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

Our success is highly dependent on the retention of principal members of our technical and management staff, including Dr. Sudhir Agrawal. Dr. Agrawal serves as our President and Chief Executive Officer. Dr. Agrawal has made significant contributions to the field of oligonucleotide-based drug candidates, and has led the discovery and development of our compounds targeted to TLRs.

He is named as an inventor on over 400 patents and patent applications in countries around the world. Dr. Agrawal provides us with leadership for our management team and research and development activities. The loss of Dr. Agrawal's services would be detrimental to our ongoing scientific progress and the execution of our business plan.

We are a party to an employment agreement with Dr. Agrawal that expires on October 19, 2015, 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 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 products are subject to extensive regulation by governmental authorities in Europe, the United States, and elsewhere throughout the world.

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

Even if we obtain regulatory approval for any of our product candidates, we will be subject to 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, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product 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 product 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;
- restrictions on our products or the marketing or manufacturing of our products;
- withdrawal of our products from the market;
- warning letters;
- voluntary or mandatory product recalls;
- fines;
- suspension or withdrawal of regulatory approvals;
- product seizure or detention;
- refusal to permit the import or export of our products;
- injunctions or the imposition of civil penalties; and
- criminal penalties.

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

All of the drug candidates that we are developing, or may develop in the future, will require additional research and development, extensive preclinical studies, nonclinical testing, clinical trials, and regulatory approval prior to any commercial sales. This process is lengthy, often taking a number of years, is uncertain, and is expensive. Since our inception, we have conducted clinical trials of a number of compounds. Currently we are conducting a Phase 2 clinical trial of IMO-8400. The FDA and other regulatory authorities may not approve any of our potential products for any indication.

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

***We may not be able to obtain orphan drug exclusivity for applications of our TLR antagonist product 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 European Medicines Agency, or 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.

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 TLR antagonist product 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 TLR antagonist product 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 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 TLR antagonist product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that those TLR antagonist product candidates will receive marketing approval.***

We may seek a breakthrough therapy designation for some applications of our TLR antagonist product 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 TLR antagonist product 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 TLR antagonist product 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 TLR antagonist product 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 product candidates intended for the treatment of genetically defined B-cell lymphoma, or experience significant delays in doing so, we may not achieve marketing approval or realize the full commercial potential of these product candidates.***

We plan to develop companion diagnostics for our TLR antagonist product candidates in our genetically defined B-cell lymphoma programs. 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 product candidates specifically for the treatment of patients with a genetically defined 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. To date, we have not entered into any agreements for the development or commercialization of companion diagnostics for use with any of our product candidates. However, we expect to enter into such agreements in the future with respect to our TLR antagonist product candidates in our genetically defined B-cell lymphoma programs. 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 product candidates, or experience delays in doing so:

- the development of our TLR antagonist product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials;
- our TLR antagonist product candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and
- we may not realize the full commercial potential of any TLR antagonist product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients with the specific genetic mutation targeted by our TLR antagonist product 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 products are based on new technologies; these factors may affect our ability or the time we require to obtain necessary regulatory approvals.***

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

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

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

authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all.

## Risks Relating to Collaborators

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

Collaborators provide the necessary resources and drug development experience to advance our compounds in their programs. We are seeking to enter into collaborative alliances with pharmaceutical companies to advance our TLR-targeted programs in broader autoimmune disease indications, such as psoriasis, lupus and arthritis, as well as applications of our GSO technology platform

Upfront payments and milestone payments received from collaborations help to provide us with the financial resources for our internal research and development programs. Our internal programs are focused on developing TLR-targeted drug candidates for the potential treatment of autoimmune and inflammatory diseases and certain genetically defined B-cell lymphomas. 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. 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 recent setbacks with respect to these drug candidates. We also face, and expect to continue to face, significant competition in seeking appropriate collaborators.

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

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

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

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

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

- our collaborators may control the public release of information regarding the developments, and we may not be able to make announcements or data presentations on a schedule favorable to us;
- disputes may arise in the future with respect to the ownership of rights to technology developed with our collaborators;
- disagreements with our collaborators could delay or terminate the research, development or commercialization of products, or result in litigation or arbitration;
- we may have difficulty enforcing the contracts if any of our collaborators fail to perform;
- our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect the perception of us in the business or financial communities;
- our collaboration agreements are likely to be for fixed terms and subject to termination by our collaborators in the event of a material breach or lack of scientific progress by us;
- our collaborators may have the first right to maintain or defend our intellectual property rights and, although we would likely have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not, our ability to do so may be compromised by our collaborators' acts or omissions;
- our collaborators may 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, 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 products to reach their potential could be limited if our collaborators decrease or fail to increase spending relating to such products;
- our collaborators may under fund or not commit sufficient resources to the testing, marketing, distribution or development of our products; and
- our collaborators may develop alternative products either on their own or in collaboration with others, or encounter conflicts of interest or changes in business strategy or other business issues, which could adversely affect their willingness or ability to fulfill their obligations to us.

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

## Risks Relating to Intellectual Property

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

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

- obtain patents;
- obtain licenses to the proprietary rights of others on commercially reasonable terms;
- operate without infringing upon the proprietary rights of others;
- prevent others from infringing on our proprietary rights; and
- protect our trade secrets.

We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may be issued in the future, or those licensed to us, may be challenged, invalidated or circumvented, and the rights granted thereunder may not provide us proprietary protection or competitive advantages against competitors with similar technology. Moreover, intellectual property laws may change and negatively impact our ability to obtain issued patents covering our technologies or to enforce any patents that issue. Because of the extensive time required for development, testing, and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thus reducing any advantage provided by the patent.

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

As of September 1, 2013, we owned more than 45 U.S. patents and patent applications and more than 85 patents and patent applications throughout the rest of the world for our TLR-targeted immune modulation technologies. These patents and patent applications include novel chemical compositions of matter and methods of use of our IMO compounds, including IMO-3100, IMO-8400, IMO-9200, and IMO-2055. As of September 1, 2013, all of our intellectual property covering immune modulatory compositions and methods of their use is based on discoveries made solely by us. These patents expire at various dates ranging from 2017 to 2031. With respect to IMO-3100, we have issued U.S. patents that cover the chemical composition of matter of IMO-3100 and methods of its use that will expire at the earliest in 2026. With respect to IMO-8400, we have an issued U.S. patent that covers the chemical composition of matter of IMO-8400 and methods of its use that will expire at the earliest in 2031. With respect to IMO-9200, we have a provisional U.S. patent application that covers the chemical composition for IMO-9200 and methods of its use, which, if issued, would expire at the earliest in 2034. With respect to IMO-2055, we have issued U.S. patents that cover the chemical composition of matter of IMO-2055 and methods of its use, including in combination with marketed cancer products, with the earliest composition claims in the United States expiring in 2023.

As of September 1, 2013, we owned one issued U.S. patent, three U.S. patent applications, one international patent application and five foreign patent applications for our GSO compounds and methods of their use. Patents issuing from these patent applications, if any, would expire at the earliest in 2030.

In addition to our TLR-targeted and GSO patent portfolios, we are the owner or hold licenses of patents and patent applications related to antisense technology. As of September 1, 2013, our antisense patent portfolio included more than 65 U.S. patents, one U.S. patent application 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 ranging from 2013 to 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 third-party U.S. patents that contain broad claims related to the use of certain oligonucleotides for stimulating an immune response, although we do not believe that these claims are valid. In addition, there may be other patents and patent applications related to our products of which we are not aware. Therefore, in some cases, in order to develop, manufacture, sell or import some of our products, we or our collaborators may choose to seek, or be required to seek, licenses under third-party patents issued in the United States and abroad or under third-party patents that might issue from 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 lose our rights to patents, patent applications or technologies of third parties if our licenses from these third parties are terminated. In such an event, we might not be able to develop or commercialize products covered by the licenses.***

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

Our failure to comply with these requirements could result in termination of the licenses. These licenses generally will otherwise remain in effect until the expiration of all valid claims of the patents covered by such licenses or upon earlier termination by the parties. The issued patents covered by these licenses expire at various dates ranging from 2013 to 2021. If one or more of these licenses is terminated, we may be delayed in our efforts, or be unable, to develop and market the products that are covered by the applicable license or licenses.

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

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

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

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

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

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

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

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

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

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

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

Any contract manufacturers with which we enter into manufacturing arrangements will be subject to ongoing periodic, unannounced inspections by the FDA, or foreign equivalent, and corresponding state and foreign agencies or their designees to ensure compliance with cGMP requirements and other governmental regulations and corresponding foreign standards. For example, one of our contract manufacturers notified us that it had received a cGMP warning letter from the FDA in February 2011. 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 September 1, 2013, our third-party manufacturers have met our manufacturing requirements, but we cannot be assured that they will continue to do so. Furthermore, changes in the manufacturing process or procedure, including a change in the location where the drug substance or drug product is manufactured or a change of a third-party manufacturer, may require prior FDA review and approval in accordance with the FDA's cGMP and NDA/BLA regulations. Contract manufacturers may also be subject to comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a drug candidate. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. If we or our contract manufacturers are unable to comply, we or they may be subject to regulatory action, civil actions or penalties.

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

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

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

We do not have the ability to independently conduct the clinical trials required to obtain regulatory approval for our drug candidates. We depend on independent clinical investigators, contract research organizations, and other third-party service providers in the conduct of the clinical trials of our drug candidates and expect to continue to do so. We contracted with contract research organizations to manage our Phase 1 and Phase 2 clinical trials of IMO-3100, our Phase 1 clinical trial of IMO-8400 and our ongoing Phase 2 clinical trial of IMO-8400 in patients with psoriasis, and expect to contract with such organizations for future clinical trials. We rely heavily on these parties for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and foreign regulatory agencies require us to comply with certain standards, commonly referred to as good clinical practices, and applicable regulatory requirements, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or at all, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval, and commercialization of our drug candidates. If we seek to conduct any of these activities ourselves in the future, we will need to recruit appropriately trained personnel and add to our infrastructure.

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

Any TLR antagonist product candidates that we develop with respect to our genetically defined B-cell lymphoma program will necessitate the use of companion diagnostics. We do not plan to develop 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 TLR antagonist product candidates 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 product or products; and
- may terminate their relationship with us.

If companion diagnostics for use with our genetically defined B-cell lymphoma TLR antagonist product candidates fail to gain market acceptance, our ability to derive revenues from sales of these TLR antagonist product 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 B-cell lymphoma TLR antagonist product candidates or do so on commercially reasonable terms, which could adversely affect and delay the development or commercialization of these TLR antagonist product 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 drug candidates, if approved for commercial sale, will depend on a number of factors, including:

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

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and the timing of market introduction of competitive products; and
- publicity concerning our products or competing products and treatments.

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

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

Most patients rely on Medicare, Medicaid, private health insurers, and other third-party payors to pay for their medical needs, including any drugs we may market. If third-party payors do not provide adequate coverage or reimbursement for any products that we may develop, our revenues and prospects for profitability will suffer. Congress enacted a limited prescription drug benefit for Medicare recipients in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. While the program established by this statute may increase demand for our products if we 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 products. These further clinical trials would require additional time, resources, and expenses. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our prospects for generating revenue, if any, could be adversely affected and our business may suffer.

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

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

***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 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.

***The preferred stock and warrants issued to certain affiliates of Pillar Invest Corporation, our largest stockholder group, in connection with our Series D and Series E financing have rights, preferences and privileges that are not held by, and are preferential to the rights of, our common stockholders. As a result, the interests of Pillar and its affiliates may differ from the interests of our common stockholders.***

In connection with our November 2011 Series D redeemable convertible preferred stock financing, which we refer to as our November 2011 Series D financing, we issued to Pillar Pharmaceuticals I, L.P., or Pillar I, 1,124,260 shares of our Series D redeemable convertible preferred stock, or Series D preferred stock, which shares are convertible into 6,266,175 shares of our common stock, and warrants exercisable for up to 2,810,650 shares of our common stock. In connection with our November 2012 Series E convertible preferred stock financing, which we refer to as our November 2012 Series E financing, we issued to Pillar Pharmaceuticals II, L.P., or Pillar II, and an affiliated second purchaser an aggregate of 424,242 shares of our Series E convertible preferred stock, or Series E preferred stock, which shares are convertible into 8,484,840 shares of our common stock, and warrants exercisable for up to 8,484,840 shares of our common stock. In connection with the Pillar Agreements, we issued to the Pillar Entities warrants exercisable for up to 2,000,000 shares of common stock. In connection with our follow-on underwritten public offering in May 2013, we issued to the Pillar Entities and Pillar Pharmaceuticals III, L.P., or Pillar III, and together with the Pillar Entities, the Pillar Investment Entities, 5,000,000 shares of our common stock and warrants exercisable for up to 5,000,000 shares of common stock. As a result, the Pillar Investment Entities are collectively our largest stockholder group. In addition, two members of our board of directors are affiliates of the Pillar Investment Entities. In connection with their ownership of these securities, the Pillar Investment Entities obtained various rights, preferences and privileges that are not held by the holders of our common stock and that in certain instances are preferential to the rights of the holders of our common stock. As a result, the interests of the Pillar Investment Entities may differ from the interests of the holders of our common stock in material respects. Although there are contractual limitations on the beneficial ownership and voting rights of the Pillar Investment Entities, the Pillar Investment Entities may still be able to exert substantial influence over our business.

***The securities issued in our Series D and Series E financings have certain rights with respect to dividends, that may adversely affect our common stockholders and that may adversely affect our ability to obtain financing in the future.***

The rights, preferences and privileges of the Series D preferred stock and Series E preferred stock that we issued and sold in our November 2011 Series D financing and November 2012 Series E financing, respectively, provide the holders of such securities with significant rights, including preferential rights with respect to dividends, which are not provided to the holders of our common stock. The dividend rights of the Series D preferred stock and Series E preferred stock may adversely affect our liquidity. For example, our obligation to pay quarterly cash dividends to the holders of our preferred stock has reduced and will continue to reduce the funds that would otherwise be available to us for working capital and other general corporate purposes. In addition, under certain circumstances, we are entitled to pay dividends on our Series D preferred stock and Series E preferred stock in shares of common stock. If we were to pay such dividends in common stock, our existing stockholders will experience dilution.

The rights, preferences and privileges associated with our Series D preferred stock and Series E preferred stock may adversely affect our ability to obtain financing in the future, including potentially limiting the price that investors might be willing to pay in the future for shares of our common stock or our other securities.

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

Our stock price has been volatile. During the period from January 1, 2011 to September 20, 2013, the closing sales price of our common stock ranged from a high of $3.25 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 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.

**Exhibit 99.2**

**Idera Pharmaceuticals, Inc.**

**Overview**

We are a clinical stage biotechnology company engaged in the discovery and development of novel synthetic DNA- and RNA-based drug candidates that are designed to modulate immune responses mediated through Toll-like Receptors, or TLRs. TLRs are specific receptors present in immune system cells. Using a chemistry-based approach, we have created synthetic DNA- and RNA-based compounds that are targeted to TLR3, TLR7, TLR8, and TLR9. A TLR antagonist is a compound that blocks activation of an immune response through the targeted TLR. A TLR agonist is a compound that stimulates an immune response through the targeted TLR.

We are conducting a Phase 2 clinical trial of our lead drug candidate, IMO-8400, a TLR7, TLR8, and TLR9 antagonist, for the treatment of psoriasis. In 2012, we completed all patient activities in a Phase 2 clinical trial of IMO-3100, a TLR7 and TLR9 antagonist, in patients with moderate to severe plaque psoriasis. We believe that the results of the Phase 2 clinical trial of IMO-3100 provided proof of concept for our approach of inhibiting specific TLRs for the treatment of psoriasis and potentially other autoimmune and inflammatory diseases. We have designed our ongoing Phase 2 clinical trial of IMO-8400 to provide further proof of concept for our approach. Additionally, recently published independent research has suggested that inhibition of specific TLRs may be a useful approach for the treatment of certain genetically defined B-cell lymphomas.

Our business strategy is to develop IMO-8400 and other TLR antagonists for the treatment of autoimmune diseases with orphan indications or other autoimmune diseases with serious unmet medical needs and for the treatment of certain genetically defined B-cell lymphomas. We plan to seek to enter into one or more collaborations for the development of our TLR antagonists in broader autoimmune disease indications, including psoriasis, lupus and arthritis.

***Program in Autoimmune and Inflammatory Disease***. In 2012, we completed all patient activities in a randomized double-blinded, placebo-controlled Phase 2 clinical trial of IMO-3100 in 44 adult patients with moderate to severe plaque psoriasis. In this Phase 2 trial, IMO-3100 showed clinical activity in patients who received subcutaneous doses of IMO-3100 once weekly for four weeks. We believe that the results of this trial provide proof of concept for our approach of targeting specific TLRs for the treatment of psoriasis and potentially other autoimmune and inflammatory diseases.

In 2013, we completed a Phase 1 clinical trial of IMO-8400 in healthy subjects. The objectives of the trial, which was conducted at a single U.S. site, were to evaluate the safety, pharmacokinetics, and pharmacodynamics of IMO-8400 administered by subcutaneous injection. The first portion of the trial involved escalating single doses of IMO-8400 and the second portion of the trial involved four weekly doses of IMO-8400. In this trial, IMO-8400 was well-tolerated at all dose levels, and showed target engagement of TLR7, TLR8, and TLR9 in subjects treated with IMO-8400 compared to treatment with placebo. Based on the clinical activity observed in the four-week Phase 2 clinical trial of IMO-3100 in patients with psoriasis and the data from our Phase 1 clinical trial of IMO-8400, we determined that the next step in our development program was to conduct a Phase 2 clinical trial in patients with moderate to severe plaque psoriasis with a treatment period of up to 12 weeks. Based on our evaluation of the comparative profiles of IMO-3100 and IMO-8400, including the engagement of TLR8 by IMO-8400, we determined to conduct this trial in patients with psoriasis with IMO-8400.

We initiated the Phase 2 clinical trial of IMO-8400 in patients with moderate to severe psoriasis with a 12-week treatment period and a six-week follow-up period during the second quarter of 2013. In the trial, we are evaluating IMO-8400 at three dose levels, 0.075 mg/kg, 0.15 mg/kg and 0.3 mg/kg, and in a placebo cohort. To date, IMO-8400 treatment in this Phase 2 clinical trial has been well-tolerated, with no treatment-related discontinuations. We expect to complete the target enrollment of 32 patients in September 2013 and to have top-line data from this Phase 2 trial during the first quarter of 2014.

We are currently evaluating orphan autoimmune disease indications for which we may develop IMO-8400 or other of our TLR antagonists. We plan to seek to enter into one or more collaborations for broader autoimmune disease indications such as psoriasis, lupus and arthritis.

***Program in Genetically Defined B-cell Lymphomas***. Recent independent research suggests that inhibition of specific TLRs may be a useful approach to the treatment of certain genetically defined B-cell lymphomas. In this research, a specific genetic mutation has been identified which has been shown to engage TLR7 and TLR9 to confer a survival benefit to the tumor cells. In this research, the inhibition of TLR7 and TLR9 led to increased rates of cell death in tumor cells harboring this mutation.

We have conducted preclinical studies of IMO-8400 in human lymphoma cell lines that carry this specific genetic mutation and in human lymphoma cell lines lacking the mutation. In these studies, IMO-8400 increased rates of cell death, inhibited cytokine production, and inhibited key components of signaling pathways. IMO-8400 did not have any significant effects in human lymphoma cell lines that did not carry the mutation. In addition, in a study that we conducted in a mouse tumor model, IMO-8400 monotherapy showed anti-tumor activity using a human lymphoma cell line that carries the mutation. In July 2013, we entered into a materials cooperative research and development agreement, or M-CRADA, with the National Cancer Institute, or NCI, to evaluate our TLR antagonists as a potential approach for the treatment of certain genetically defined B-cell lymphomas.

This specific genetic mutation has been reported in several types of B-cell lymphomas, and is most often associated with non-Hodgkin lymphoma. We initially plan to evaluate IMO-8400 with respect to two forms of non-Hodgkin lymphomas. One is Waldenström's macroglobulinemia, a lymphoma that commonly involves the blood and bone marrow and may spread to almost any organ in the body. Based on published independent reports, we believe that approximately 90% of patients with Waldenström's macroglobulinemia have the specific genetic mutation. Diffuse large B-cell lymphoma, or DLBCL, is another form of non-Hodgkin lymphoma with a high incidence of this specific genetic mutation. Based on published independent reports, we believe that approximately 30% of patients with activated B-cell-like, or ABC, DLBCL carry the specific genetic mutation.

Based on the SEER Cancer Statistics Review, 1975-2001, from the National Cancer Institute's SEER database and published independent reports as to patients with B-cell lymphoma with the specific genetic mutation, and taking into consideration estimated population growth, we estimate that there will be approximately 4,000 patients diagnosed with non-Hodgkin forms of B-cell lymphoma in 2013, including 1,200 patients with Waldenström's macroglobulinemia and 2,000 patients with ABC-DLBCL. Based on this information, we also believe that at least 7,500 patients in the United States currently have B-cell lymphoma with the specific genetic mutation. We believe Waldenström's macroglobulinemia and DLBCL are orphan indications with unmet medical need. There are currently no drugs specifically approved for the treatment of Waldenström's macroglobulinemia or DLBCL. Currently, patients with any form of non-Hodgkin lymphoma are most often treated with monoclonal antibody rituximab and/or with one or more chemotherapeutic agents.

Our planned next step in our B-cell lymphoma program is to conduct two Phase 1/2 clinical trials of IMO-8400 in relapsed or refractory patients. We plan to evaluate patients with Waldenström's macroglobulinemia in one trial and patients with DLBCL in the second trial. We expect that some of the patients in each trial will have the specific genetic mutation, which we believe will provide us with the opportunity to assess the clinical activity of IMO-8400 in patients with the specific genetic mutation. The planned Phase 1/2 clinical trials are designed to evaluate safety and tolerability in dose-escalation cohorts and to evaluate the potential for clinical activity in expansion cohorts at one or more dose levels. In the dose-escalation cohorts, each trial is designed to include approximately 12 to 18 patients. In the expansion cohorts, an additional 12 patients in each trial will be evaluated for safety and for signals of potential clinical activity. Each trial therefore is expected to enroll approximately 30 patients. We currently anticipate submitting an Investigational New Drug application, or IND, with respect to the use of IMO-8400 in B-cell lymphomas to the United States Food and Drug Administration, or FDA, in the fourth quarter of 2013, with the goal of initiating the two Phase 1/2 clinical trials in the first quarter of 2014.

Our strategy for our program in genetically defined B-cell lymphomas is to include in the planned trials patients with the genetically defined cancer that we are seeking to treat. If we see early evidence of a therapeutic effect in either of these trials, we plan to meet with regulatory authorities to discuss the possibility of an accelerated clinical development and regulatory pathway for the applicable program. We cannot predict whether or when any of our product candidates will prove effective or safe in humans, if they will receive regulatory approval or if we will be able to participate in FDA expedited review and approval programs, including breakthrough and fast track designation.

***Expanding Development Pipeline of TLR Antagonist Candidates***. We have selected an additional TLR antagonist candidate, IMO-9200, for development and have completed early stage preclinical studies of this TLR antagonist product candidate. We intend to initiate an IND-enabling development program of IMO-9200 in the fourth quarter of 2013 for one of the diverse disease indications for which TLR antagonists may be applicable. We anticipate submission of an IND for IMO-9200 in the third quarter of 2014, with the goal of initiating the Phase 1 trial in the third quarter of 2014.

***Additional Programs***. We have also created gene silencing oligonucleotides, or GSOs, which are designed to inhibit the production of disease-associated proteins by targeting RNA. We believe our GSO technology provides us with a platform from which drug candidates for multiple disease indications can be developed.

We had cash and cash equivalents of approximately $16.3 million at June 30, 2013. We believe that our existing cash and cash equivalents would be sufficient to fund our operations at least through the fourth quarter of 2014, based on an operating plan that includes the completion of our ongoing Phase 2 clinical trial of IMO-8400 in patients with psoriasis and planning with respect to further clinical development of IMO-8400. We believe that our available funds will enable us to complete our ongoing Phase 2 clinical trial in patients with psoriasis. We will need to raise additional funds in order to conduct any other clinical development of IMO-8400 or IMO-9200, including to conduct any other development of our other drug candidates or technologies.

**Exhibit 99.3**


**Idera Pharmaceuticals Announces Public Offering of Common Stock and Pre-Funded Warrants**

CAMBRIDGE, Mass. –(BUSINESS WIRE)—Sept. 24, 2013—Idera Pharmaceuticals, Inc. (NASDAQ: IDRA) ("Idera" or, the "Company") today announced that it intends to offer and sell shares of its common stock and pre-funded warrants to purchase shares of its common stock in an underwritten public offering. Piper Jaffray & Co. is acting as sole manager for the offering. The offering is subject to market conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

The securities described above are being offered by the Company pursuant to a shelf registration statement previously filed with and declared effective by the Securities and Exchange Commission on September 18, 2013. The offering will be made only by means of the written prospectus and prospectus supplement that form a part of the registration statement. Copies of the preliminary prospectus supplement and the accompanying prospectus relating to the securities being offered may also be obtained from Piper Jaffray & Co., Attention: Prospectus Department, 800 Nicollet Mall, J12S03, Minneapolis, MN 55402, via telephone at 800-747-3924 or email at prospectus@pjc.com.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy the securities being offered, nor shall there be any sale of the securities being offered in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or other jurisdiction.

**About Idera Pharmaceuticals, Inc.**

Idera's technology platform involves creating novel synthetic RNA- and DNA-based compounds to modulate immune responses. Idera has applied this platform to develop proprietary Toll-like receptor (TLR) antagonists as immunomodulatory drug candidates. Toll-like receptor antagonists block the overactivation of immune factors which can cause a range of pathological effects. Idera is conducting clinical development of TLR antagonists in autoimmune and inflammatory diseases, and preclinical development of their use in certain genetically defined forms of B-cell lymphoma. More information on Idera is available at iderapharma.com.

**Forward Looking Statements**

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding the Company's 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," "potential," "likely," "projects," "continue," "will," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Idera cannot guarantee that it will actually achieve the plans, intentions or expectations disclosed in its forward-looking statements and you should not place undue reliance on the Company's forward-looking statements. There are a number of important factors that could cause Idera's actual results to differ materially from those indicated or implied by its forward-looking statements. Factors that may cause such a difference include: whether Idera's cash resources will be sufficient to fund its continuing operations and the further development of the Company's programs; whether results obtained in early research, preclinical studies and clinical trials will be indicative of the results that will be generated in future clinical studies; whether products based on Idera's technology will advance into or through the clinical trial process on a timely basis or at all and receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether, if the Company's products receive approval, they will be successfully distributed and marketed; whether Idera will be able to enter into collaborations that will advance the development of its compounds for autoimmune disease indications; and such other important factors as are set forth under the

caption “Risk Factors” in the Company’s Quarterly Report on Form 10-Q. Although Idera may elect to do so at some point in the future, the Company does not assume any obligation to update any forward-looking statements and it disclaims any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Source: Idera Pharmaceuticals, Inc.

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