IDERA PHARMACEUTICALS, INC.
Form S-3
December 11, 2012

As filed with the Securities and Exchange Commission on December 11, 2012

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

IDERA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**04-3072298**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

167 Sidney Street

Cambridge, Massachusetts 02139

(617) 679-5500

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Sudhir Agrawal, D. Phil.

Chairman of the Board of Directors, President

and Chief Executive Officer

Idera Pharmaceuticals, Inc.

167 Sidney Street

Cambridge, Massachusetts 02139

(617) 679-5500

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:

Stuart M. Falber, Esq.

Wilmer Cutler Pickering Hale and Dorr LLP

60 State Street

Boston, Massachusetts 02109

Telephone: (617) 526-6000

Telecopy: (617) 526-5000

Approximate date of commencement of proposed sale to public: From time to time after the effective date of this registration statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

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

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

CALCULATION OF REGISTRATION FEE

Title of Shares to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, $0.001 par value per share	16,969,680	$0.68	$11,539,383	$1,574

(1) Consists of (a) 8,484,840 shares of common stock issuable upon conversion of the registrant s series E convertible preferred stock, $0.01 par value per share, (b) 8,484,840 shares of common stock issuable upon the exercise of common stock purchase warrants and (c) such indeterminate number of additional shares of common stock as may become issuable upon conversion of the series E convertible preferred stock or exercise of the common stock purchase warrants to prevent dilution resulting from stock splits, stock dividends or similar transactions, which shares are registered hereunder pursuant to Rule 416 under the Securities Act.

(2) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act and based upon the average of the high and low prices on the Nasdaq Global Market on December 7, 2012.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling stockholders named in this prospectus may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and the selling stockholders named in this prospectus are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated December 11, 2012

PROSPECTUS

IDERA PHARMACEUTICALS, INC.

16,969,680 SHARES OF COMMON STOCK

This prospectus relates to the resale from time to time of up to 16,969,680 shares of common stock of Idera Pharmaceuticals, Inc. by the selling stockholders identified in this prospectus. We will not receive any proceeds from the sale of the shares offered by this prospectus.

We have agreed to bear all of the expenses incurred in connection with the registration of these shares. The selling stockholders will pay or assume brokerage commissions and similar charges incurred for the sale of shares of our common stock.

The selling stockholders identified in this prospectus, or their respective pledgees, donees, transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. See Plan of Distribution beginning on page 24.

Our common stock is currently traded on the Nasdaq Global Market under the symbol IDRA. On December 10, 2012, the closing sale price of our common stock on the Nasdaq Global Market was $0.68 per share. You are urged to obtain current market quotations for the common stock.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 3.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2012.

TABLE OF CONTENTS

We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock.

PROSPECTUS SUMMARY

This summary highlights important features of this offering and the information included or incorporated by reference in this prospectus. This summary may not contain all of the information that is important to you. You should read the entire prospectus carefully, including Risk Factors beginning on page 3, before deciding to invest in our common stock.

Idera Pharmaceuticals, Inc.

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

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

We are focusing our internal development efforts on IMO-3100 and IMO-8400, our two TLR-targeted candidates for autoimmune and inflammatory diseases. We are also collaborating with Merck Sharp & Dohme Corp. (formerly Merck & Co., Inc.), which is referred to herein as Merck, for the use of agonists of TLRs 7, 8, and 9 as vaccine adjuvants for cancer, infectious diseases, and Alzheimer s disease. We are seeking to enter into collaborative alliances with pharmaceutical companies to advance our TLR-targeted programs in oncology, infectious diseases, respiratory diseases, and the use of TLR3 agonists as vaccine adjuvants, as well as applications of our GSO technology platform.

Autoimmune and Inflammatory Disease Program. We have two drug candidates in clinical development in our autoimmune and inflammatory disease program. We are conducting a Phase 2 clinical trial of IMO-3100, an antagonist of TLR7 and TLR9 in adult patients with moderate to severe plaque psoriasis. We initiated the trial in the second quarter of 2012 and completed enrollment of the trial in October 2012 with a total enrollment of 44 patients. We anticipate that we will have top-line data for some of the endpoints in this Phase 2 study by the end of 2012 and complete data during the first quarter of 2013.

In addition, we have selected IMO-8400, an antagonist of TLRs 7, 8, and 9, as a second candidate for development in the treatment of autoimmune disease, with lupus as our initial indication. In the fourth quarter of 2012, we initiated a Phase 1 clinical trial of IMO-8400 in healthy subjects.

We have evaluated IMO-3100 and IMO-8400 in preclinical models of several autoimmune diseases including psoriasis, lupus, rheumatoid arthritis, and multiple sclerosis. In these models, treatment with IMO-3100 or IMO-8400 was associated with inhibition of Th1, Th17, and inflammasome pathways and improvement in a number of disease parameters.

Vaccine Adjuvant Collaboration. In January 2012, we announced that Merck had selected several of our novel agonists of TLR7, TLR8 or TLR 9 for evaluation and use as vaccine adjuvant candidates in the fields of cancer, infectious diseases, and Alzheimer s disease.

Cancer Program. In November 2011, we reacquired rights to IMO-2055, an agonist of TLR9 in clinical development for the treatment of cancer, from Merck KGaA, Darmstadt, Germany, our former collaborator. We believe that IMO-2055 can be developed for use as an immune modifier in combination with targeted anticancer agents in certain cancer indications and are seeking to enter into collaborations with pharmaceutical companies to advance the use of IMO-2055 in the treatment of cancer.

Gene Silencing Oligonucleotide Technology Platform. Our GSOs are single-stranded RNA or DNA constructs that are complementary to targeted mRNA sequences of therapeutic interest. In preclinical studies, our GSOs have inhibited in vivo gene expression without requiring a delivery enhancement technology. We are seeking to enter into collaborations with pharmaceutical companies to advance applications of our GSO technology platform.

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

Corporate Information

Our executive offices are located at 167 Sidney Street, Cambridge, MA 02139, our telephone number is (617) 679-5500 and our Internet address is www.iderapharma.com. The information on our website is not incorporated by reference in this prospectus and should not be considered to be part of this prospectus. Our website address is included in this prospectus as an inactive technical reference only. Unless the context otherwise requires, references in this prospectus to Idera Pharmaceuticals, we, us, and our refer to Idera Pharmaceuticals, Inc.

Idera® and IMO® are our trademarks. All other trademarks and service marks appearing in this registration statement are the property of their respective owners.

The Offering

Common stock offered by selling stockholders	16,969,680 shares
Use of proceeds	We will not receive any proceeds from the sale of shares in this offering.
Nasdaq Global Market symbol	IDRA

RISK FACTORS

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

Risks Relating to Our Financial Results and Need for Financing

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

We had cash and cash equivalents of $8.4 million at September 30, 2012. We believe that our existing cash and cash equivalents, together with the proceeds raised from a private placement of our securities in November 2012, will be sufficient to fund our operations at least into the third quarter of 2013 based on our current operating plan, including the completion of our ongoing Phase 2 clinical trial of IMO-3100 in patients with psoriasis that we initiated in April 2012, the completion of our ongoing Phase 1 clinical trial of IMO-8400 in healthy subjects, and preparations for the further advancement of our autoimmune disease program in at least two indications. We will need to raise additional funds in order to conduct any additional clinical development or to operate our business beyond such time. Additional financing may not be available to us in this time frame in the amounts that we need or on terms that are acceptable to us.

We expect that we will require substantial additional funds to conduct 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 the ongoing Phase 2 trial of IMO-3100 and ongoing Phase 1 clinical trial of IMO-8400;
- developments related to our existing strategic collaboration with Merck;
- the cost, timing, and outcome of regulatory reviews;
- competitive and potentially competitive products and technologies and investors receptivity to our drug candidates and the technology underlying them in light of competitive products and technologies;
- the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies such as ours specifically; and
- our ability to enter into additional strategic collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

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. 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 may 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 meet the Nasdaq Global Market continued listing requirements or we risk delisting, which could result in a decrease in our stock price and make it harder for us to sell securities in a financing and for our stockholders to trade our stock.

Our common stock is currently listed on the Nasdaq Global Market. In order to maintain our listing, we are required to meet specified financial requirements, including requirements that we maintain a minimum closing bid price of at least $1.00 per share for our common stock and that we maintain a minimum stockholders equity of $10,000,000 or a minimum market value of $50,000,000.

On June 7, 2012, we received a notification letter from the Nasdaq Listing Qualifications staff of The Nasdaq Stock Market advising us that we were not in compliance with the $50,000,000 minimum market value requirement for continued listing on The Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(b)(2)(A). Nasdaq also noted in its letter that we were no longer in compliance with Nasdaq Listing Rule 5450(b)(1)(A), which requires registrants to maintain a minimum of $10,000,000 in stockholders equity.

Nasdaq stated in its letter that, in accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have been provided a compliance period of 180 calendar days, or until December 4, 2012, to regain compliance with the minimum market value continued listing requirement. The Nasdaq letter stated that if, at any time before December 4, 2012, the minimum market value of our common stock closed at $50,000,000 or more for a minimum of 10 consecutive business days, the Nasdaq staff would provide us with written notification that we have achieved compliance with the minimum market value continued listing requirements and the matter would be closed. We could also regain compliance with Nasdaq s continued listing requirements by reporting stockholders equity of $10 million or more.

On December 5, 2012, we received a letter from Nasdaq Listing Qualifications staff of The Nasdaq Stock Market advising us that we had not regained compliance with the minimum $50,000,000 market value of listed securities requirement set forth in Nasdaq Listing Rule 5450(b)(2)(A) or the minimum $10,000,000 stockholders equity continued listing requirement set forth in Nasdaq Listing Rule 5450(b)(1)(A), and that, unless we request a hearing before Nasdaq Listing Qualifications Hearings Panel, or Panel, trading in our common stock will be suspended at the opening of business on December 14, 2012, and our common stock will be delisted from The Nasdaq Global Market. We intend to request a hearing before the Panel at which we will request continued listing pending our return to compliance. Our hearing request will stay the suspension of trading and delisting of our common stock pending the conclusion of the hearing process. Consequently, our common stock will remain listed on The Nasdaq Global Market at least until the Panel renders a decision following the hearing. There can be no assurance that that our request for a hearing before the Panel will be granted or that, if granted, the Panel will approve our request for continued listing pending our return to compliance.

In addition, on November 26, 2012, we received a letter from Nasdaq Listing Qualifications staff of The Nasdaq Stock Market indicating that based on the closing bid price of our common stock for the 30 consecutive business days prior to November 26, 2012, we no longer satisfied the requirement that our common stock maintain a minimum bid price of $1.00 per share as required by Nasdaq Listing Rule 5450(a)(1). Nasdaq stated in its letter that in accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been provided with 180 calendar days, or until May 28, 2013, to regain compliance with the minimum bid price requirement. The Nasdaq letter stated that if, at any time before May 28, 2013, the closing bid price of our common stock is at or above $1.00 per share for a minimum of 10 consecutive business days, we will regain compliance with the minimum bid price requirement and the matter will be closed. If we do not regain compliance with the minimum bid price requirement by May 28, 2013, Nasdaq will provide us with a written notification that our common stock is subject to delisting. We may be eligible to receive an additional 180 day grace period (for a total of 360 days from November 26, 2012) to regain compliance with the minimum bid price requirement provided that we have applied to transfer our securities to the Nasdaq Capital Market and are then in compliance with the continued listing standard for market value of publicly held shares and all other applicable initial listing standards for the Nasdaq Capital Market, other than the minimum bid price requirement. If we do not meet the applicable requirements to transfer to the Nasdaq Capital Market, or we elect to seek continued listing on the Nasdaq Global Market, we may request a hearing before the Panel at such time as it receives any notification that it has no further grace period, and the Panel would have the discretion to grant us an additional grace period of up to 180 days (for a total of 360 days from November 26, 2012).

If our common stock is delisted from Nasdaq, it may be eligible to trade on the over-the-counter market, which may be a less liquid market, or on the pink sheets. In such case, our stockholders ability to trade, or obtain quotations of the market value of, shares of our common stock would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to

lower prices and larger spreads in the bid and ask prices for our securities. There can be no assurance that our common stock, if delisted from the Nasdaq Global Market, will be listed on a national securities exchange, a national quotation service, the OTC Bulletin Board or the pink sheets. Delisting from Nasdaq, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, adversely affect the market liquidity of our common stock, reduce security analysts coverage of us and diminish investor, supplier and employee confidence.

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 September 30, 2012, we had an accumulated deficit of $390.9 million. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through September 30, 2012, we incurred losses of $130.7 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 (deficit) equity, total assets, and working capital.

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

Risks Relating to Our Business, Strategy and Industry

We are depending heavily on the development of IMO-3100 and IMO-8400 and on our collaborative alliance with Merck. If we or our collaborator decides to terminate the development of any of our drug candidates, are unable to successfully develop and commercialize 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 our clinical stage lead drug candidates, IMO-3100 and IMO-8400, as part of our autoimmune disease program. We expect that the next steps in our autoimmune disease program will be to advance the clinical development of IMO-8400 by completing our ongoing Phase 1 clinical trial in healthy subjects, preparing for the further advancement of our autoimmune disease program in at least two indications, and if the results of the IMO-8400 Phase 1 study are favorable, then subject to obtaining the required funding, initiating a Phase 2 clinical trial in patients with lupus. As such, we anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of IMO-3100 and/or IMO-8400. Our ability to generate product revenues will also depend on the development and commercialization of the drug candidates being developed under our collaboration with Merck. Our efforts, and the efforts of Merck, to develop and commercialize these compounds are at an early stage and are subject to many challenges. 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 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 are currently conducting. The outcome of this trial could negatively impact our ability or willingness to proceed with the further development and commercialization of our TLR candidates for the treatment of autoimmune disease, or our ability to license such compounds to a third party. Moreover, with respect to IMO-3100, we cannot be certain that the FDA will allow us to conduct further clinical trials of IMO-3100 for treatment periods of more than four weeks or at all without additional clinical or preclinical data.

In April 2011, we chose to delay initiation of our planned 12-week Phase 2 randomized clinical trial of IMO-2125 plus ribavirin in treatment-naïve, genotype 1 HCV patients based on preliminary observations in an ongoing 26-week chronic nonclinical toxicology study of IMO-2125 in rodents. We subsequently completed a 39-week chronic nonclinical toxicology study of IMO-2125 in non-human primates in which there were no similar observations. During the third quarter of 2011, we re-assessed and prioritized our drug development programs, and determined to discontinue further investment of internal resources on the development of IMO-2125 for the treatment of HCV.

In July 2011, Merck KGaA informed us that, based on increased incidence of neutropenia and electrolyte imbalances reported in its Phase 1 trial of IMO-2055 in combination with cisplatin/5-FU and cetuximab in patients with first-line SCCHN and subsequent re-evaluation of its clinical development program, Merck KGaA had determined that it would not conduct further clinical development of IMO-2055. In November 2011, we and Merck KGaA entered into a termination agreement terminating our collaboration and we reacquired the rights to IMO-2055 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 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 and any other collaborators safely and successfully with other therapeutic agents;
- achieving and maintaining compliance with all regulatory requirements applicable to the products;
- establishment of commercial manufacturing arrangements with third-party manufacturers;

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

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

competition from other companies and their therapies;

changes in treatment regimes;

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

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

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

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

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

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

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

regulators or IRBs may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

nonclinical or clinical data may not be readily interpreted, which may lead to delays and/or misinterpretation;

our nonclinical tests, including toxicology studies, or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical testing or clinical trials or we may abandon projects that we expect may not be promising;

- the rate of enrollment or retention of patients in our clinical trials may be lower than we expect;
- we might have to suspend or terminate our clinical trials if the participating subjects experience serious adverse events or undesirable side effects or are exposed to unacceptable health risks;
- regulators or IRBs may hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements, issues identified through inspections of manufacturing or clinical trial operations or clinical trial sites, or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;
- regulators may hold or suspend our clinical trials while collecting supplemental information on, or clarification of, our clinical trials or other clinical trials, including trials conducted in other countries or trials conducted by other companies;
- we, along with our collaborators and subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA s Application Integrity Policy, or similar policy under foreign regulatory authorities. Employment of such debarred persons, even if inadvertent, may result in delays in the FDA s or foreign equivalent s review or approval of our products, or the rejection of data developed with the involvement of such person(s);
- the cost of our clinical trials may be greater than we currently anticipate; and
- our products may not cause the desired effects or may cause undesirable side effects or our products may have other unexpected characteristics.

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

- the size of the patient population;
- the proximity of patients to clinical sites;
- the eligibility criteria for the study;
- the nature of the study, including the pattern of patient enrollment;
- the existence of competitive clinical trials; and
- the availability of alternative treatments.

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

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

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

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

- manufacturing sufficient quantities of drug candidate that satisfy the required quality standards for use in clinical trials;
- demonstrating sufficient safety to obtain regulatory approval for conducting a clinical trial;
- reaching an agreement with any collaborators on all aspects of the clinical trial;
- reaching agreement with contract research organizations, if any, and clinical trial sites on all aspects of the clinical trial;
- resolving any objections from the FDA or any regulatory authority on an IND application or proposed clinical trial design;
- obtaining IRB approval for conducting a clinical trial at a prospective site; and
- enrolling patients in order to commence the clinical trial.

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

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

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

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

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

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

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

technologies and drug candidates and technology, including TLR targeted compounds as well as non-TLR targeted therapies.

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

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

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

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

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

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

We are a party to an employment agreement with Dr. Agrawal that expires on October 19, 2015, but automatically extends annually for an additional year. This agreement may be terminated by us or Dr. Agrawal for any reason or no reason at any time upon notice to the other party. We do not carry key man life insurance for Dr. Agrawal.

Furthermore, our future growth will require hiring a number of qualified technical and management personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we are not able to continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or growth.

Regulatory Risks

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

All of the drug candidates that we are developing, or may develop in the future, will require additional research and development, extensive preclinical studies, nonclinical testing, clinical trials, and regulatory approval prior to any commercial sales. This process is

lengthy, often taking a number of years, is uncertain, and is expensive. Since our inception, we have conducted clinical trials of a number of compounds. Currently two of our compounds, IMO-3100 and IMO-8400, are in clinical development. The FDA and other regulatory authorities may not approve any of our potential products for any indication.

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

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

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

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

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

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

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

product seizure or detention;

refusal to permit the import or export of our products;

injunctions or the imposition of civil penalties; and

criminal penalties.

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

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

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

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

Risks Relating to Collaborators

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

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 oncology, infectious diseases, respiratory diseases, and the use of TLR3 agonists as vaccine adjuvants, 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. We are also advancing our GSO technology for potential application as research reagents and as therapeutic agents. We believe that additional resources will be required to advance compounds in all of these areas. If we do not reach agreements with additional collaborators in the future, we may not be able to obtain the expertise and resources necessary to achieve our business objectives, our ability to advance our compounds will be jeopardized and we may fail to meet our business objectives.

We may have difficulty establishing additional 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 candid