IDERA PHARMACEUTICALS, INC.
Form S-3
June 28, 2013
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As filed with the Securities and Exchange Commission on June 28, 2013

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	**(I.R.S. Employer**

incorporation or organization) **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 ¨
Non-accelerated filer x (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	2,000,000	$0.65	$1,300,000	$178

(1) Consists of (a) 2,000,000 shares of common stock issuable upon the exercise of common stock purchase warrants and (b) such indeterminate number of additional shares of common stock as may become issuable upon 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 June 26, 2013.

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.

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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 June 28, 2013

PROSPECTUS

IDERA PHARMACEUTICALS, INC.

2,000,000 SHARES OF COMMON STOCK

This prospectus relates to the resale from time to time of up to 2,000,000 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 28.

Our common stock is currently traded on the Nasdaq Capital Market under the symbol IDRA. On June 27, 2013, the closing sale price of our common stock on the Nasdaq Capital Market was $0.71 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 , 2013.

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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.

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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 that are designed to modulate immune responses mediated through Toll-like Receptors, or TLRs. We are focusing our development efforts on the treatment of autoimmune and inflammatory diseases. 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. We have presented data from 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 this trial provide clinical proof of concept for our approach of targeting specific TLRs for the treatment of psoriasis and potentially other autoimmune and inflammatory diseases.

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 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, including autoimmune and inflammatory diseases, cancer and respiratory diseases, and for use as vaccine adjuvants. We are a party to a collaboration alliance with Merck Sharp & Dohme Corp. (formerly Merck & Co., Inc.), or Merck & Co., for the use of agonists of TLR7, TLR8, and TLR9 as adjuvants in the development of vaccines for cancer, infectious diseases, and Alzheimer s disease. We are seeking to enter into additional collaborative alliances with third parties with respect to our TLR-targeted programs in oncology, hematological malignancies, respiratory diseases, and the use of TLR3 agonists as vaccine adjuvants.

Autoimmune and Inflammatory Disease Program. We are conducting a Phase 2 clinical trial of IMO-8400 in patients with psoriasis with a treatment period of up to 12 weeks. We initiated this Phase 2 trial in June 2013 and expect to have top-line data by the end of 2013. This Phase 2 trial is a randomized, double-blind placebo-controlled trial of IMO-8400 monotherapy in 32 patients with moderate to severe plaque psoriasis. In this Phase 2 trial, patients will receive weekly doses of IMO-8400 or placebo for 12 weeks. This trial is being conducted in the Netherlands.

We have conducted a Phase 1 clinical trial to evaluate the safety and pharmacodynamics of IMO-8400 in healthy subjects. 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 the trial, IMO-8400 was well-tolerated and showed target engagement of TLR7, TLR8, and TLR9 in subjects treated with IMO-8400 compared to placebo. We plan to present data from this trial at a scientific conference in June 2013.

We are also planning to initiate additional clinical trials of IMO-8400 in additional disease indications. However, our plans to conduct these trials are subject to our ability to raise additional funding to fund the conduct of these trials. We expect to seek such additional funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources.

Vaccine Adjuvant Collaboration. In January 2012, we announced that Merck & Co. had selected several of our TLR7, TLR8 or TLR9 agonists for evaluation and use as vaccine adjuvant candidates in the fields of cancer, infectious diseases, and Alzheimer s disease.

Additional Programs. In addition to our TLR program in autoimmune and inflammatory diseases, and our collaboration with Merck & Co. for the use of TLR7, TLR8, and TLR9 agonists as vaccine adjuvants, we have identified TLR drug candidates for applications in the treatment of cancer, hematological malignancies and respiratory diseases, and created TLR3 agonists for use as vaccine adjuvants. 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

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candidates for multiple disease indications can be developed. We are seeking to enter into collaborations with third parties to advance these drug candidates and technology platform. Except in connection with collaborations, we do not plan to expend any additional resources on these programs.

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	2,000,000 shares
Use of proceeds	We will not receive any proceeds from the sale of shares in this offering.
Nasdaq Capital Market symbol	IDRA

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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 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 $6.1 million at March 31, 2013. We believe that the net proceeds of our follow-on public offering of our securities in May 2013, which we refer to as our May 2013 public offering, together with our existing cash and cash equivalents, will enable us to fund our operations at least through the fourth quarter of 2014. We believe that our available funds following the May 2013 public offering will be sufficient to enable us to conduct our planned Phase 2 clinical trial of IMO-8400 in patients with psoriasis and to plan for further clinical development of IMO-8400. We will need to raise additional funds in order to conduct any other clinical development of IMO-8400 or to conduct any other development of our other product candidates or technologies. It is also possible that we will not achieve the progress that we expect with respect to IMO-8400 because the actual costs and timing of clinical development activities are difficult to predict and are subject to substantial risks and delays.

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 our Phase 1 clinical trial of IMO-8400 and the results of the Phase 2 clinical trial of IMO-8400 in patients with moderate to severe plaque psoriasis that we initiated in June 2013;
- developments related to our existing collaboration with Merck & Co.;
- our ability to maintain the listing of our common stock on the Nasdaq Capital Market or an alternative national securities exchange;
- 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

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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.

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 an underwritten public offering, increasing our cash resources sufficiently to fund our operations into 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 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 began trading on the Nasdaq Capital Market on February 7, 2013. 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. If we do not meet these continued listing requirements, our common stock will be delisted.

On November 26, 2012, we received a letter from the Listing Qualifications Staff of the Nasdaq Stock Market, or the Staff, 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). The Staff stated in its letter that in accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days, or until May 28, 2013, to regain compliance with the minimum bid price requirement. We did not evidence compliance with the minimum bid price requirement as of May 28, 2013.

On May 29, 2013, we received a letter from the Staff indicating that although we did not evidence compliance with the minimum bid price requirement, as set forth in Nasdaq Listing Rule 5550(a)(2), within the initial 180 day compliance period ended May 28, 2013, we were granted an additional 180 calendar day period, or until November 25, 2013, to evidence compliance with the minimum bid price requirement.

In its letter, the Staff indicated that if, at any time prior to November 25, 2013, the bid price for our shares closes at or above $1.00 per share for a minimum of 10 consecutive business days (unless the Staff exercises its discretion to extend the minimum 10-day period), the Staff will provide written confirmation to us of our compliance with the minimum bid price requirement. If we do not regain compliance with the minimum bid price requirement by November 25, 2013, the Staff will provide written notification that our shares are subject to delisting based on the deficiency. At that time, we may appeal the delisting determination to the Nasdaq Listing Qualifications Hearings Panel, or the Panel. In the letter, the Staff also indicated that, if we were to appeal such a determination to the Panel, we would be asked to provide a plan to regain compliance and advised us that, historically, the Panel has generally viewed a near term reverse stock split as the only definitive and acceptable plan to resolve a bid price deficiency.

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Prior to February 7, 2013, our common stock was traded on the Nasdaq Global Market where we were required to meet specified financial requirements, including requirements that we maintain a minimum stockholders equity of $10.0 million or a minimum market value of listed securities of $50.0 million. On June 7, 2012, we received a notification letter from the Staff advising us that we were not in compliance with these requirements. Nasdaq also stated in its letter that, in accordance with Nasdaq Listing Rule 5810(c)(3)(C), we had been provided a compliance period of 180 calendar days, or until December 4, 2012, to regain compliance with these requirements.

Because we were not able to regain compliance with these requirements by such date, we requested a hearing before the Panel at which we requested continued listing pending our return to compliance. Our hearing request stayed the suspension of trading and delisting of our common stock pending the conclusion of the hearing process. On February 5, 2013, the Panel granted our request to transfer the listing of our common stock from the Nasdaq Global Market to the Nasdaq Capital Market and to continue the listing of our common stock on the Nasdaq Capital Market, provided that we satisfied the $2.5 million stockholders equity requirement on or before March 31, 2013, and otherwise met the continued listing requirements of the Nasdaq Capital Market. On March 5, 2013, the Panel extended this date to May 22, 2013 and indicated that by such date, in addition to satisfying the $2.5 million stockholders equity requirement for continued listing on that market and otherwise meeting the continued listing requirements of the Nasdaq Capital Market, we were also required to provide the Panel with additional information regarding our projected burn-rate and stockholders equity through May 31, 2014. On May 8, 2013, we received formal notice from the Nasdaq Stock Market LLC that we had evidenced compliance with the minimum stockholders equity requirement for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5450(b)(2) as required by the Panel and that the matter had been closed.

If our common stock were to be delisted from the Nasdaq Capital Market, it may 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.

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 March 31, 2013, we had an accumulated deficit of $398.5 million. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 to March 31, 2013, we incurred losses of $138.3 million. We incurred losses of $260.2 million prior to December 31, 2000 during which time we were primarily involved in the development of non-TLR targeted antisense technology. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, total assets, and working capital.

We have never had any products of our own available for commercial sale and have received no revenues from the sale of drugs. As of April 15, 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.

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. If we terminate the development of the program or any of our drug candidates in the program, 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.

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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 by the end of 2013.

We are also planning to initiate additional clinical trials of IMO-8400 in additional disease indications. 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.

As such, 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 program. 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 & Co. 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 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;

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- 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 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

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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.

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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 trial;
- the nature of the trial, 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 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

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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 for use as vaccine adjuvants. We have two drug candidates in clinical development in our autoimmune and inflammatory disease program. 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 oncology and respiratory diseases, and for the use of TLR3 agonists as vaccine adjuvants, 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.

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.

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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 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 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 have two clinical stage compounds, IMO-3100 and 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.

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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;