IDERA PHARMACEUTICALS, INC.
Form 10-Q
May 12, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2014

or

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

For transition period from _____ to _____.

Commission File Number: 001-31918

IDERA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

(617) 679-5500

(Registrant s telephone number, including area code)

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

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

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

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

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

Common Stock, par value $.001 per share	**82,442,460**
Class	**Outstanding as of April 30, 2014**

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this report regarding our strategy, future operations, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, plans, and objectives of management are forward-looking statements. The words believes, anticipates, estimates, plans, expects, intends, may, could, should, potential, likely, projects, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth below under Part II, Item 1A Risk Factors. These factors and the other cautionary statements made in this Quarterly Report on Form 10-Q should be read as being applicable to all related forward-looking statements whenever they appear in this Quarterly Report on Form 10-Q. In addition, any forward-looking statements represent our estimates only as of the date that this Quarterly Report on Form 10-Q is filed with the Securities and Exchange Commission and should not be relied upon as representing our estimates as of any subsequent date. We do not assume any obligation to update any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

IDERA PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

(UNAUDITED)

(In thousands, except per share amounts)	March 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 60,748	$ 26,278
Short-term investments	9,896	3,125
Prepaid expenses and other current assets	1,160	874
Total current assets	71,804	30,277
Long-term investments		6,189
Property and equipment, net	125	90
Restricted cash	311	311
Total assets	$ 72,240	$ 36,867
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 707	$ 904
Accrued expenses	4,647	3,506
Total current liabilities	5,354	4,410
Other liabilities	4	5
Total liabilities	5,358	4,415
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.01 par value, Authorized 5,000 shares		
Series E convertible preferred stock, Designated, issued and outstanding 424 shares	5,528	5,528
Series D convertible preferred stock, Designated, issued and outstanding zero shares and 1,124 shares at March 31, 2014 and December 31, 2013, respectively		5,464
Series A convertible preferred stock, Designated 1,500 shares, Issued and outstanding 1 share		
Common stock, $0.001 par value, Authorized 280,000 shares ; Issued and outstanding 82,439 and 66,252 shares at March 31, 2014 and December 31, 2013, respectively	82	66

Additional paid-in capital	483,113	434,285
Accumulated deficit	(421,845)	(412,884)
Accumulated other comprehensive gain (loss)	4	(7)
Total stockholders equity	66,882	32,452
Total liabilities and stockholders equity	$ 72,240	$ 36,867

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

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IDERA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

	Three Months Ended March 31	
(In thousands, except per share amounts)	**2014**	**2013**
Alliance revenue	$ 3	$ 7
Operating expenses:		
Research and development	6,933	2,328
General and administrative	2,043	1,527
Total operating expenses	8,976	3,855
Loss from operations	(8,973)	(3,848)
Other income (expense):		
Investment income, net	15	2
Foreign currency exchange (loss) gain	(3)	39
Net loss	(8,961)	(3,807)
Preferred stock dividends	185	279
Net loss applicable to common stockholders	$ (9,146)	$ (4,086)
Basic and diluted net loss per common share applicable to common stockholders (Note 11)	$ (0.12)	$ (0.15)
Shares used in computing basic and diluted net loss per common share applicable to common stockholders	76,018	27,644
Net loss	$ (8,961)	$ (3,807)
Other comprehensive gain:		
Unrealized gain on available-for-sale securities	11	
Comprehensive loss	$ (8,950)	$ (3,807)

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

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IDERA PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(In thousands)	Three Months Ended March 31, 2014	2013
Cash Flows from Operating Activities:		
Net loss	$ (8,961)	$ (3,807)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	535	253
Non-employee stock option expense	11	2
Issuance of common stock for services rendered	14	
Amortization of investment premiums	46	
Depreciation and amortization expense	31	42
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(286)	22
Accounts payable, accrued expenses, and other liabilities	1,008	(211)
Net cash used in operating activities	(7,602)	(3,699)
Cash Flows from Investing Activities:		
Purchases of available-for-sale securities	(616)	
Purchases of property and equipment	(12)	(1)
Net cash used in investing activities	(628)	(1)
Cash Flows from Financing Activities:		
Sale of common stock and warrants, net of issuance costs	37,378	
Dividends paid	(345)	(160)
Prior year financing transaction costs paid in current year	(100)	(87)
Proceeds from exercise of common stock warrants and options and employee stock purchases	5,768	1
Payments on capital lease	(1)	(1)
Net cash provided by (used in) financing activities	42,700	(247)
Net increase (decrease) in cash and cash equivalents	34,470	(3,947)
Cash and cash equivalents, beginning of period	26,278	10,096
Cash and cash equivalents, end of period	$ 60,748	$ 6,149

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

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IDERA PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

March 31, 2014

(UNAUDITED)

(1) Organization

Idera Pharmaceuticals, Inc. (Idera or the Company) is a clinical stage biotechnology company advancing drug candidates for the treatment of certain genetically defined forms of B-cell lymphoma and for the treatment of autoimmune diseases. These drug candidates are designed to inhibit over-activation of specific Toll-like receptors (TLRs). In addition to Idera s TLR program, the Company has initiated a research program employing its gene silencing oligonucleotides (GSOs) to inhibit the production of disease-associated proteins by targeting RNA.

The Company s lead drug candidate in its TLR program is IMO-8400, an antagonist of TLR7, TLR8, and TLR9. IMO-8400 is in development for the treatment of certain genetically defined forms of B-cell lymphoma and for the treatment of selected orphan autoimmune diseases. A TLR antagonist is a compound that blocks activation of an immune response through the targeted TLR. To date, the Company has evaluated IMO-8400 in two clinical trials. The Company also has selected IMO-9200 as a second novel antagonist of TLR7, TLR8, and TLR9 for development as a drug candidate for potential use in selected autoimmune disease indications. The Company has initiated preclinical studies of IMO-9200 to support submission of an Investigational New Drug application to the U.S. Food and Drug Administration (FDA).

Idera s business strategy is to develop IMO-8400 and other TLR antagonist candidates for the treatment of certain genetically defined forms of B-cell lymphoma and for the treatment of orphan autoimmune diseases with unmet medical needs. In addition, the Company may seek to enter into collaborative alliances with pharmaceutical companies to advance its TLR antagonist candidates in broader autoimmune disease indications, such as psoriasis, lupus, and arthritis.

At March 31, 2014, the Company had an accumulated deficit of $421,845,000. The Company expects to incur substantial operating losses in future periods. The Company does not expect to generate significant product revenue, sales-based milestones or royalties until the Company successfully completes development and obtains marketing approval for drug candidates, either alone or in collaborations with third parties, which the Company expects will take a number of years. In order to commercialize its drug candidates, the Company needs to complete clinical development and comply with comprehensive regulatory requirements.

The Company is subject to a number of risks and uncertainties similar to those of other companies of the same size within the biotechnology industry, such as uncertainty of clinical trial outcomes, uncertainty of additional funding, and history of operating losses.

(2) Unaudited Interim Financial Statements

The accompanying unaudited financial statements included herein have been prepared by the Company in accordance with United States Generally Accepted Accounting Principles (U.S. GAAP) for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S.

GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustments, and disclosures considered necessary for a fair presentation of interim period results have been included. Interim results for the three months ended March 31, 2014 are not necessarily indicative of results that may be expected for the year ended December 31, 2014. For further information, refer to the financial statements and footnotes thereto included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2013, which was filed with the SEC on March 13, 2014.

(3) Financial Instruments

The fair value of the Company s financial instruments is determined and disclosed in accordance with the three-tier fair value hierarchy specified in Note 5. The Company is required to disclose the estimated fair values of its financial instruments. The Company s financial instruments consist of cash, cash equivalents, available-for-sale investments and receivables. The estimated fair values of these financial instruments approximate their carrying values as of March 31, 2014 and December 31, 2013. As of March 31, 2014 and December 31, 2013, the Company did not have any derivatives, hedging instruments or other similar financial instruments except for the Series E convertible preferred stock, (the Series E preferred stock), the embedded features of which are discussed in Note 8(g) to the financial statements included in the Company s Form 10-K for the year ended December 31, 2013.

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(4) Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be cash equivalents. Cash and cash equivalents at March 31, 2014 and December 31, 2013 consisted of cash and money market funds.

(5) Fair Value of Assets and Liabilities

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

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

(In thousands)		Total	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
March 31, 2014					
Assets					
Money market funds		$ 60,684	$ 60,684	$	$
Short-term investments	commercial paper	1,999		1,999	
Short-term investments	corporate bonds	7,897		7,897	
Total Assets		$ 70,580	$ 60,684	$ 9,896	$
December 31, 2013					
Assets					
Money market funds		$ 25,201	$ 25,201	$	$

Short-term investments	commercial paper	1,997		1,997	
Short-term investments	corporate bonds	1,128		1,128	
Long-term investments	corporate bonds	6,189		6,189	
Total Assets		$ 34,515	$ 25,201	$ 9,314	$

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

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(6) Investments

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

	March 31, 2014			
	Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Estimated Fair Value
	(In thousands)			
Commercial paper due in one year or less	$ 1,999	$	$	$ 1,999
Corporate bonds due in one year or less	7,893	(1)	5	7,897
Total short-term investments	9,892	(1)	5	9,896
Total long-term investments				
Total investments	$ 9,892	$ (1)	$ 5	$ 9,896

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

The Company had no realized gains or losses from available-for-sale securities in the three months ended March 31, 2014 and 2013. There were no losses or other-than-temporary declines in value included in Investment income, net on the Company s Statements of Operations and Comprehensive Loss for any securities for the three months ended March 31, 2014 and 2013. The Company had no auction rate securities as of March 31, 2014 and December 31, 2013. See Note 3, Financial Instruments, and Note 5, Fair Value of Assets and Liabilities for additional information related to the Company s investments.

(7) Property and Equipment

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

(In thousands)	March 31, 2014	December 31, 2013
Leasehold improvements	$ 525	$ 525
Laboratory equipment and other	2,920	2,854
Total property and equipment, at cost	3,445	3,379
Less: accumulated depreciation	3,320	3,289
Property and equipment, net	$ 125	$ 90

Depreciation and amortization expense was approximately $31,000 and $42,000 in the three months ended March 31, 2014 and 2013, respectively.

(8) Restricted Cash

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

(9) Comprehensive Income (Loss)

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

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The following table includes the changes in the accumulated balance of the component of other comprehensive income (loss) for the three months ended March 31, 2014:

(In thousands)	Three Months ended March 31, 2014
Accumulated unrealized loss on available-for-sale securities at beginning of period	$ (7)
Change during the period	11
Accumulated unrealized gain on available-for-sale securities at end of period	$ 4

There was no accumulated unrealized gain or loss on available-for-sale securities during the three months ended March 31, 2013.

(10) Stock-Based Compensation

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

The Company recorded charges of $535,000 and $253,000 in its statements of operations and comprehensive loss for the three months ended March 31, 2014 and 2013, respectively, for stock-based compensation expense attributable to share-based payments made to employees and directors. The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions apply to the options to purchase 992,500 shares of common stock granted to employees and directors during the three months ended March 31, 2014:

	Three Months Ended March 31, 2014
Average risk free interest rate	1.6%
Expected dividend yield	
Expected lives (years)	5.0
Expected volatility	81.0%
Weighted average grant date fair value of options granted during the period (per share)	$ 3.36
	$ 5.15

Weighted average exercise price of options granted during the period (per share)	

The expected lives and the expected volatility of the options granted during the three months ended March 31, 2014 are based on historical experience. All options granted during the three months ended March 31, 2014 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant. The Company did not grant any stock options during the three months ended March 31, 2013.

(11) Net Loss per Common Share Applicable to Common Stockholders

For the three months ended March 31, 2014 and 2013, basic and diluted net loss per common share applicable to common stockholders is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net loss per common share applicable to common stockholders is the same as basic net loss per common share applicable to common stockholders as the effects of the Company s potential common stock equivalents are antidilutive. Total antidilutive securities were 80,345,651 and 33,037,104 for the three months ended March 31, 2014 and 2013, respectively, and consist of stock options, preferred stock and warrants.

For the three months ended March 31, 2014 and 2013, net loss per common share applicable to common stockholders reflects $185,000 and $279,000, respectively, in dividends accrued on shares of our Series D convertible preferred stock (Series D preferred stock) and our Series E convertible preferred stock (Series E preferred stock).

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(12) Common Stock Warrant and Option Exercises and Employee Stock Purchases

During the three months ended March 31, 2014, the Company issued 2,050,578 shares of common stock in connection with warrant and stock option exercises and purchases under the Company s 1995 Employee Stock Purchase Plan (the ESPP) resulting in total proceeds to the Company of $5,768,000.

During the three months ended March 31, 2013, the Company issued 1,744 shares of common stock in connection with employee stock purchases under the ESPP, which resulted in total proceeds to the Company of $1,000. During this period, there were no warrant or option exercises.

(13) Related Party Transactions

February 6, 2014 Conversion of Series D Preferred Stock

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

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

Director Stock Purchases

The Company issued 2,855 shares of common stock in lieu of director board and committee fees of approximately $14,000 pursuant to the Company s director compensation program during the three months ended March 31, 2014.

(14) Financing

February 10, 2014 Follow-on Underwritten Public Offering

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

(15) Subsequent Events

In May 2014, the Company entered into a collaboration with Abbott Molecular, Inc. (Abbott Molecular) for the development of a companion diagnostic that can be used to identify patients with the MYD88 L265P oncogenic mutation in future clinical trials of IMO-8400. Under the agreement, Abbott Molecular has agreed to develop the companion diagnostic to comply with the requirements of the FDA Center for Devices and Radiological Health. The Company expects to pay approximately $6,700,000 in external development expenses to develop an assay as the prototype of the companion diagnostic, to validate the prototype during a Phase 2 clinical trial of IMO-8400, and to complete FDA and launch activities of the resultant final version of the companion diagnostic over five years under the agreement, subject to increase if Abbott Molecular incurs additional expenses in order to meet unexpected material requirements or obligations not included in the agreement or if the Company is required to conduct additional or different clinical trials which result in Abbott Molecular incurring additional costs. The Company will not receive any revenues from future sales, if any, of the companion diagnostic.

On April 29, 2014, the Company entered into an amendment to its exclusive license and research collaboration agreement with Merck Sharp & Dohme Corp. (formerly Merck & Co., Inc.). Under the license and research collaboration agreement, which the Company entered into with Merck Sharp & Dohme Corp. in December 2006, the Company had granted Merck Sharp & Dohme Corp. worldwide exclusive rights to its TLR7, TLR8, and TLR9 agonists for use in combination with Merck Sharp & Dohme Corp. s therapeutic and prophylactic vaccines under development in the fields of cancer, infectious diseases, and Alzheimer s disease. As a result of this amendment, Merck Sharp & Dohme Corp. s rights under the exclusive license and collaboration agreement have been limited to specified TLR7, TLR8, and TLR9 agonists that Merck Sharp & Dohme Corp. selected in January 2012, and the Company regained the rights to pursue its other independently discovered TLR7, TLR8, and TLR9 agonists for use as vaccine adjuvants in the fields of cancer, infectious diseases and Alzheimer s disease so that it now has the right to pursue its TLR7, TLR8, and TLR9 agonists for use as vaccine adjuvants in all fields. Merck Sharp & Dohme Corp. s obligations under the agreement to pay the Company milestone payments and royalties continue in effect with respect to the specified TLR7, TLR8, and TLR9 agonists. However, in connection with this amendment, the Company agreed that, to the extent that the Company licenses to third parties any TLR7, TLR8, and TLR9 agonists for use as vaccine adjuvants in the fields of cancer, infectious diseases and Alzheimer s disease and receives income under such licenses, Merck Sharp & Dohme Corp. may credit against any milestone payments and royalties it owes to the Company an amount equal to 15% of the license income received by the Company under the third party licenses, up to a maximum of $60.0 million in credits.

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ITEM 2. ***MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.***

GENERAL

We are a clinical stage biotechnology company advancing drug candidates for the treatment of certain genetically defined forms of B-cell lymphoma and for the treatment of autoimmune diseases. These drug candidates are designed to inhibit over-activation of specific Toll-like receptors, or TLRs. In addition to our TLR program, we have initiated a research program employing our gene silencing oligonucleotides, or GSOs, to inhibit the production of disease-associated proteins by targeting RNA.

Programs for Toll-like Receptor Antagonists

Our lead drug candidate in our TLR program is IMO-8400, an antagonist of TLR7, TLR8, and TLR9. A TLR antagonist is a compound that blocks activation of an immune response through the targeted TLR. IMO-8400 is in development for the treatment of certain genetically defined forms of B-cell lymphoma and for the treatment of selected orphan autoimmune diseases. To date, we have evaluated IMO-8400 in two clinical trials. IMO-8400 has been well tolerated at subcutaneous dosages up to 0.6 mg/kg/week for up to 12 weeks of treatment and has shown clinical activity in an autoimmune disease.

Our business strategy is to develop IMO-8400 and other TLR antagonist candidates for the treatment of certain genetically defined forms of B-cell lymphoma and for the treatment of orphan autoimmune diseases with unmet medical needs. In addition, we may seek to enter into collaborative alliances with pharmaceutical companies to advance our TLR antagonist candidates in broader autoimmune disease indications, such as psoriasis, lupus, and arthritis.

Program in Genetically Defined Forms of B-cell Lymphoma. Independent research has suggested that the inhibition of specific TLRs may be a useful approach to the treatment of certain B-cell lymphoma characterized by the presence of the oncogenic mutation referred to scientifically as MYD88 L265P. Oncogenic mutations are changes in the DNA of tumor cells that promote the survival and proliferation of the tumor cells. The MYD88 L265P oncogenic mutation has been reported in patients with Waldenström s macroglobulinemia, diffuse large B-cell lymphoma, or DLBCL, and other forms of B-cell malignancies, including Burkitt s lymphoma, cutaneous diffuse large B-cell lymphoma (leg type), chronic lymphocytic leukemia, gastric mucosa-associated lymphoid tissue lymphoma, marginal zone lymphoma, and splenic marginal zone lymphoma. In this research, the inhibition of TLR7 and TLR9 suppressed MYD88 L265P induced signaling and promoted tumor cell death.

We presented results from our preclinical studies of IMO-8400 in April 2014 at the annual meeting of the American Association for Cancer Research. In these studies, IMO-8400 induced cell death in human Waldenström s macroglobulinemia and DLBCL tumor cells harboring the MYD88 L265P oncogenic mutation. Consistent with its proposed mechanism of action, IMO-8400 treatment inhibited cell signaling pathways that promote tumor cell survival and proliferation including those referred to scientifically as IRAK1/4, NF-kB, STAT3 p38, and BTK. Further, in these studies, IMO-8400 treatment suppressed tumor cell production of cytokines such as interleukin-10, or IL-10, that create a favorable microenvironment for tumor cell survival and proliferation. In addition to inducing tumor cell death *in vitro*, IMO-8400 treatment of mice in xenograft models decreased tumor burden, even in studies where treatment was initiated after tumors had become well established. Tumor cells that did not harbor the MYD88 L265P mutation were not affected by IMO-8400 treatment, demonstrating the specificity of the treatment effect.

The preclinical observations reported by independent researchers and the data generated by us with IMO-8400 support our plans for the clinical development of IMO-8400 in B-cell lymphomas harboring the MYD88 L265P oncogenic mutation. It has been reported that approximately 90% of patients with Waldenström s macroglobulinemia have the MYD88 L265P oncogenic mutation. We have initiated patient treatment in an open-label, dose-escalation Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia who have relapsed or were refractory to prior therapy. Objectives of the trial include evaluation of safety and tolerability and assessment of the clinical activity of escalating IMO-8400 dose levels using disease-specific international guidelines for classifying clinical response. The initial dose level is 0.6 mg/kg once per week, administered by subcutaneous injection. We expect to enroll up to approximately 30 patients in this trial.

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We are also planning to conduct an open-label, dose-escalation Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL who have relapsed or were refractory to prior therapy. With the concurrence of the U.S. Food and Drug Administration, or FDA, Center for Devices and Radiological Health, or CDRH, we are planning to enroll in this trial only patients who are positive for the presence of the MYD88 L265P oncogenic mutation. Objectives of the trial include evaluation of safety and tolerability and assessment of the clinical activity of escalating IMO-8400 dose levels using disease-specific international guidelines for classifying clinical response. We expect to enroll up to approximately 30 patients in this trial, and expect to initiate patient treatment in the second half of 2014.

We believe that Waldenström s macroglobulinemia and DLBCL in patients with the MYD88 L265P mutation are each orphan indications with unmet medical need, based on prevalence of the indications. If we observe a therapeutic effect in either or both of our Phase 1/2 clinical trials, we plan to meet with regulatory authorities to discuss the possibility of an accelerated clinical development and regulatory path for the applicable program. We cannot predict whether or when any of our product candidates will prove effective or safe in humans, if we will be able to participate in FDA expedited review and approval programs, including breakthrough and fast track designation, or if they will receive regulatory approval.

In May 2014, we entered into a collaboration with Abbott Molecular, Inc., or Abbott Molecular, for the development of a companion diagnostic that can be used to identify patients with the MYD88 L265P oncogenic mutation in future clinical trials of IMO-8400. Under the agreement, Abbott Molecular has agreed to develop the companion diagnostic to comply with the requirements of the FDA CDRH. We expect to pay approximately $6,700,000 in external development expenses to develop an assay as the prototype of the companion diagnostic, to validate the prototype during a Phase 2 clinical trial of IMO-8400, and to complete FDA and launch activities of the resultant final version of the companion diagnostic over five years under the agreement, subject to increase if Abbott Molecular incurs additional expenses in order to meet unexpected material requirements or obligations not included in the agreement or if we are required to conduct additional or different clinical trials which result in Abbott Molecular incurring additional costs. We will not receive any revenues from future sales, if any, of the companion diagnostic.

Program in Autoimmune Diseases with Orphan Designation. We are planning to initiate clinical development of IMO-8400 for the treatment of autoimmune diseases which have been designated as orphan indications. We have evaluated autoimmune diseases with orphan indications for which we may develop our TLR antagonist candidates using selection criteria that include: the reported involvement of altered TLR expression; cytokine profile indicative of key TLR-mediated pathways; auto-antibody profile indicative of self-derived nucleic acids that can induce TLR-mediated immune responses; the identification of prospective clinical biomarkers for evaluation in early clinical trials; high unmet medical need; and established clinical diagnosis.

Based on these selection criteria, we have prioritized polymyositis, dermatomyositis, and graft-versus-host disease, or GvHD, as the initial orphan autoimmune disease indications for clinical evaluation. We anticipate initiating patient treatment in a clinical trial in patients with polymyositis or dermatomyositis and in a clinical trial in patients with GvHD in the second half of 2014. If we observe a therapeutic effect in one or more of these indications, we plan to meet with regulatory authorities to discuss the possibility of an accelerated clinical development and regulatory path for the applicable program. We cannot predict whether or when any of our product candidates will prove effective or safe in humans, if we will be able to participate in FDA expedited review and approval programs, including breakthrough and fast track designation, or if they will receive regulatory approval. We are continuing to use the above criteria to prioritize additional autoimmune diseases with orphan indications for which we may develop our TLR antagonist candidates.

Clinical Proof-of-Concept for TLR Antagonism. We believe that clinical proof-of-concept for TLR antagonists as a potential therapeutic approach for autoimmune diseases has been demonstrated by the results of randomized,

double-blinded Phase 2 clinical trials we have conducted in patients with moderate to severe psoriasis, including the top-line results from our Phase 2 clinical trial of IMO-8400 that we announced in the first quarter of 2014. We expanded the Phase 2 clinical trial of IMO-8400 in patients with psoriasis to include a higher dose cohort of 0.6 mg/kg or placebo with up to 12 patients. Dosing has been completed in all patients in the expansion cohort, and blinded data indicate all treatments were well tolerated. We intend to submit data from the Phase 2 clinical trial of IMO-8400 in patients with psoriasis for presentation at a medical meeting within 2014.

Expanding the Pipeline of TLR Antagonist Drug Candidates. We also have selected IMO-9200 as a second novel antagonist of TLR7, TLR8, and TLR9 for development as a drug candidate for potential use in selected autoimmune disease indications. We have initiated preclinical studies of IMO-9200 to support submission of an Investigational New Drug application, or IND, to the FDA. Pending the results of these studies, we expect to submit an IND for IMO-9200 and to initiate a Phase 1 clinical trial in the second half of 2014.

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Gene Silencing Oligonucleotide Technology to Target RNA

We have created our GSOs to inhibit the expression of disease-associated proteins by targeting RNA. Based on evaluations of GSOs targeted to disease-associated RNA in preclinical models, we believe our GSO technology has the potential to overcome several of the hurdles of antisense and RNA interference, or RNAi, technologies. We are currently undertaking an analysis of priority disease indications for development of drug candidates from our GSO technology. Our key considerations in identifying disease indications in our GSO program are: strong evidence that the disease is caused by a specific protein; clear criteria to identify a target patient population; biomarkers for early assessment of clinical proof-of-concept; a targeted therapeutic mechanism for action; and unmet medical need to allow for a rapid development path to approval. We expect to identify the first two disease indications to be targeted in our GSO program in the second half of 2014, with the goal of initiating disease model studies and an IND-enabling development program in the first half of 2015. Based on this timeline, we could initiate proof-of-concept clinical trials for the first two disease indications as early as the second half of 2015.

Our business strategy for our GSO program is focused on the further development of our GSO technology. We may seek to enter into collaborative alliances with pharmaceutical companies with respect to applications of our GSO technology program.

At March 31, 2014, we had an accumulated deficit of $421,845,000. We expect to incur substantial operating losses in future periods. We do not expect to generate product revenue, sales-based milestones or royalties until we successfully complete development and obtain marketing approval for drug candidates, either alone or in collaborations with third parties, which we expect will take a number of years. In order to commercialize our drug candidates, we need to complete clinical development and comply with comprehensive regulatory requirements.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

This management s discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgments, including those related to revenue recognition, stock-based compensation and our convertible preferred stock and related common stock warrants. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We regard an accounting estimate or assumption underlying our financial statements as a critical accounting estimate where:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are described in Note 2 of the notes to our financial statements in our Annual Report on Form 10-K for the year ended December 31, 2013. Not all of these significant policies, however, fit the definition of critical accounting policies and estimates. We believe that our accounting policies relating to stock-based compensation and convertible preferred stock and related common stock warrants, as described under the caption Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates in our Annual Report on Form 10-K for the year ended December 31, 2013, fit the description of critical accounting estimates and judgments. There were no changes in these policies during the three months ended March 31, 2014.

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RESULTS OF OPERATIONS

Three Months Ended March 31, 2014

Alliance Revenue

Alliance revenue consisted of reimbursement by licensees of costs associated with patent maintenance, amounting to $3,000 and $7,000 in the three months ended March 31, 2014 and 2013, respectively.

Research and Development Expenses

Research and development expenses increased by $4,605,000, or 198%, from $2,328,000 for the three months ended March 31, 2013, to $6,933,000 for the three months ended March 31, 2014. In the following table, research and development expenses are set forth in the following four categories which are discussed beneath the table:

	Three Months Ended March 31, (in thousands)		Percentage Increase (Decrease)
	2014	2013	
IMO-8400 external development expense	$ 2,433	$ 600	306 %
Companion diagnostic external development expense	800		
Other drug development expense	2,524	909	178%
Basic discovery expense	1,176	819	44%
	$ 6,933	$ 2,328	198%

IMO-8400 External Development Expenses. These expenses include external expenses that we have incurred in connection with IMO-8400 since October 2012, when we commenced clinical development of IMO-8400. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-8400 clinical development but exclude internal costs such as payroll and overhead expenses. Since October 2012, we have incurred approximately $6,396,000 in external development expenses through March 31, 2014, including costs associated with our Phase 1 clinical trial in healthy subjects, preparation for and conduct of our ongoing Phase 2 clinical trial in patients with psoriasis, preparation for and conduct of our ongoing Phase 1/2 clinical trial in patients with Waldenström s macroglobulinemia and our planned Phase 1/2 clinical trial in patients with DLBCL, and additional nonclinical studies.

The increase in our IMO-8400 external development expenses in the three months ended March 31, 2014, as compared to the three months ended March 31, 2013, was primarily attributable to costs incurred in 2014 in connection with preparation for our Phase 1/2 clinical trials in patients with genetically defined forms of B-cell lymphoma, manufacture of additional drug substance for use in our ongoing and planned clinical trials, and conduct of long-term nonclinical safety studies. These increases were partially offset by 2013 costs associated with our Phase 1 clinical trial in healthy subjects that was ongoing during the three months ended March 31, 2013.

We expect our IMO-8400 external development expenses to increase in 2014 due to patient enrollment as we conduct our ongoing and planned Phase 1/2 clinical trials of IMO-8400 in patients with genetically defined forms of B-cell

lymphoma, our planned Phase 1/2 clinical trial of IMO-8400 in patients with polymyositis or dermatomyositis, and our planned Phase 1/2 clinical trial of IMO-8400 in patients with GvHD, manufacturing costs for additional drug supplies of IMO-8400 for use in our ongoing and planned clinical trials and the conduct of ongoing long-term nonclinical safety studies of IMO-8400.

Companion Diagnostic External Development Expenses. These expenses include external expenses associated with our collaboration with Abbott Molecular for the development of a companion diagnostic for identification of patients with B-cell lymphomas harboring the MYD88 L265P oncogenic mutation since January 2014, when development of the companion diagnostic commenced. During the three months ended March 31, 2014, we incurred $800,000 in companion diagnostic external development expenses, reflecting costs associated with start-up activities and the initiation of development of an assay as the prototype of the companion diagnostic. We will not receive any revenues from future sales of the companion diagnostic, if any.

Other Drug Development Expenses. These expenses include external expenses associated with preclinical development of identified compounds in anticipation of advancing these compounds into clinical development. In addition, these expenses include internal costs, such as payroll and overhead expenses, associated with preclinical development and products in clinical development. The external expenses associated with preclinical compounds include payments to contract vendors for manufacturing and the related stability studies, preclinical studies, including animal toxicology and pharmacology studies, and professional fees. Internal expenses

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associated with products in clinical development include costs associated with our Autoimmune Disease Scientific Advisory Board. Other drug development expenses also include costs associated with compounds that were previously being developed but are not currently being developed.

The increase in other drug development expenses in the three months ended March 31, 2014, as compared to the three months ended March 31, 2013, was primarily due to costs of preclinical studies and manufacturing activities to support the planned IND submission for IMO-9200 in the second half of 2014. Increasing payroll costs, including the addition of a Chief Medical Officer in January 2014 and higher stock based compensation costs attributable to options granted after March 31, 2013, also contributed to the increase in other drug development expenses during the three months ended March 31, 2014. The increase in other drug development expenses in the three months ended March 31, 2014 was partially offset by a decrease in IMO-3100 development expenses, reflecting our decision in the second quarter of 2013 to focus our resources on the development of IMO-8400. We expect other drug development expenses to increase in 2014 due to costs associated with the planned IMO-9200 IND submission and increased headcount to support our drug development programs.

Basic Discovery Expenses. These expenses include our internal and external expenses relating to our discovery efforts with respect to our TLR-targeted programs, including agonists and antagonists of TLR3, TLR7, TLR8 and TLR9, TLR antisense, and our GSO program. These expenses reflect payments for laboratory supplies, external research, and professional fees, as well as payroll and overhead expenses. The increase in basic discovery expenses in the three months ended March 31, 2014, as compared to the three months ended March 31, 2013, was primarily due to increases in the cost of employee compensation and laboratory supplies reflecting increased activity and headcount associated with our GSO program. We anticipate an increase in basic discovery expenses in 2014 as we increase headcount and laboratory supply expenses consistent with our strategic plans to identify lead drug candidates for the first two disease indications to be targeted in our GSO program.

We do not know if we will be successful in developing any drug candidate from our research and development programs. At this time, and without knowing the full data set for our ongoing Phase 2 clinical trial of IMO-8400 in patients with moderate to severe plaque psoriasis, our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia, our planned Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL and the MYD88 L265P oncogenic mutation, our planned Phase 1/2 clinical trial of IMO-8400 in patients with polymyositis or dermatomyositis, our planned Phase 1/2 clinical trial of IMO-8400 in patients with GvHD, our IND-enabling development program and our planned Phase 1 proof-of-concept clinical trials in each of the first two disease indications selected for further development in our GSO program and our IND-enabling studies and planned Phase 1 clinical trial of IMO-9200, we cannot reasonably estimate or know the nature, timing, and costs of the efforts that will be necessary to complete the remainder of the development of, or the period, if any, in which material net cash inflows may commence from, any drug candidate from our research and development programs. Moreover, the clinical development of any drug candidate from our research and development programs is subject to numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of unanticipated events arising during clinical development.

General and Administrative Expenses

General and administrative expenses increased by $516,000, or 34%, from $1,527,000 in the three months ended March 31, 2013, to $2,043,000 in the three months ended March 31, 2014. General and administrative expenses consist primarily of salary expense, stock compensation expense, consulting fees and professional legal fees associated with our patent applications and maintenance, our corporate regulatory filing requirements, our corporate legal matters, and our business development initiatives. The increase in general and administrative expenses during the three months ended March 31, 2014, as compared to the three months ended March 31, 2013, was primarily due to

increases in corporate communications, investor relations and recruiting expenses and higher stock based compensation costs primarily attributable to options granted after March 31, 2013.

Investment Income, Net

Investment income, net increased by $13,000, from $2,000 in the three months ended March 31, 2013 to $15,000 in the three months ended March 31, 2014, primarily due to an increase in investment balances, including corporate debt securities, in the three months ended March 31, 2014 resulting from our follow-on underwritten public offerings in September 2013 and February 2014.

Foreign Currency Exchange (Loss) Gain

Our foreign currency exchange loss was $3,000 in the three months ended March 31, 2014 primarily due to the impact that the decreasing value of the U.S. dollar had on our Euro-denominated accrued liabilities during this period. Our foreign currency exchange gain was $39,000 in the three months ended March 31, 2013 primarily due to the impact that the increasing value of the U.S. dollar had on our Euro-denominated accrued liabilities during this period.

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Preferred Stock Dividends

The $185,000 and $279,000 in preferred stock dividends in the three months ended March 31, 2014 and 2013, respectively, reflects dividends accrued on shares of our Series D convertible preferred stock, or Series D preferred stock, and our Series E convertible preferred stock, or Series E preferred stock, during the respective periods. The decrease in preferred stock dividends during the three months ended March 31, 2014 is mainly attributable to the conversion of our Series D preferred stock into common stock on February 6, 2014 at which time dividends on our Series D preferred stock ceased to accrue. Dividends on our Series E preferred stock are expected to amount to approximately $119,000 per quarter during such time that the Series E preferred stock remains outstanding.

Net Loss Applicable to Common Stockholders

As a result of the factors discussed above, our net loss applicable to common stockholders was $9,146,000 for the three months ended March 31, 2014, compared to $4,086,000 for the three months ended March 31, 2013. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through March 31, 2014, we incurred losses of $161,652,000. We also incurred net losses of $260,193,000 prior to December 31, 2000 during which time we were primarily involved in the development of non-TLR targeted antisense technology. Since our inception, we had an accumulated deficit of $421,845,000 through March 31, 2014. We expect to continue to incur substantial operating losses in the future.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

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

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

February 10, 2014 Follow-on Underwritten Public Offering

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

Collaboration Agreement

Under the terms of our collaboration with Merck KGaA, which was terminated in November 2011, we received in February 2008 a $40.0 million upfront license fee in Euros of which we received $39.7 million due to foreign currency exchange rates and approximately $12.1 million in milestone payments. In addition, Merck KGaA reimbursed us $4.5 million for expenses related to the development of IMO-2055, a TLR9 agonist. In connection with the termination of the collaboration, we regained all rights for developing TLR9 agonists for the treatment of cancer and agreed to reimburse Merck KGaA for up to 1.8 million ($2.5 million using a March 31, 2014 exchange rate) of Merck KGaA s costs for the third-party contract research organization that was coordinating Merck KGaA s Phase 2 trial of IMO-2055 in combination with cetuximab, payable in eleven installments commencing on March 1, 2012 including a final payment payable upon Merck KGaA s completion of certain specified activities. As of March 31, 2014, we have paid 1.2 million of the 1.8 million ($1.6 million (using exchange rates in effect at the time that the payments were made) of the $2.5 million). We also agreed to pay to Merck KGaA one-time 1.0 million ($1.4 million using a March 31, 2014 exchange rate) milestone payments upon the occurrence of each of the following milestones: partnering of IMO-2055 with any third party, initiation of any Phase 2 or Phase 3 clinical trial for IMO-2055 and regulatory submission of IMO-2055 in any country.

Cash Flows

Three Months Ended March 31, 2014

As of March 31, 2014, we had approximately $70,644,000 in cash, cash equivalents and investments, a net increase of approximately $35,052,000 from December 31, 2013. Net cash used in operating activities totaled $7,602,000 during the three months ended March 31, 2014, reflecting our $8,961,000 net loss, as adjusted for non-cash income and expenses, including stock-based compensation, depreciation and amortization. Net cash used in operating activities also reflects changes in our prepaid expenses and accounts payable, accrued expenses and other liabilities.

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The net cash used in investing activities during the three months ended March 31, 2014 reflects the purchase of $616,000 of available-for-sale securities, which are investments that we do not have the positive intent to hold to maturity at the time of purchase, and payments for the purchase of $12,000 in property and equipment.

The $42,700,000 net cash provided by financing activities during the three months ended March 31, 2014 primarily reflects $37,378,000 in net proceeds from our follow-on underwritten public offering of our securities in February 2014, and $5,768,000 in net proceeds from the exercise of common stock options and warrants and employee stock purchases under our 1995 Employee Stock Purchase Plan, or ESPP, which were partially offset by dividends paid on our Series D preferred stock and our Series E preferred stock.

Three Months Ended March 31, 2013

As of March 31, 2013, we had approximately $6,149,000 in cash and cash equivalents, a net decrease of approximately $3,947,000 from December 31, 2012. Net cash used in operating activities totaled $3,699,000 during the three months ended March 31, 2013, reflecting our $3,807,000 net loss, as adjusted for non-cash income and expenses, including stock-based compensation and depreciation. It also reflects changes in our prepaid expenses and accounts payable, accrued expenses and other liabilities.

The $247,000 net cash used in financing activities during the three months ended March 31, 2013 primarily reflects dividends paid on our Series D preferred stock and payments on our capital lease offset, in part, by the proceeds received from employee stock purchases under the ESPP.

Funding Requirements

We have incurred operating losses in all fiscal years except 2002, 2008 and 2009, and we had an accumulated deficit of $421,845,000 at March 31, 2014. We expect to incur substantial operating losses in future periods. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, total assets and working capital. We have received no revenues from the sale of drugs. As of April 15, 2014, almost all of our revenues have been from collaboration and license agreements. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any drugs. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our products will become commercially available or when we will become profitable, if at all.

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

We had cash, cash equivalents and investments of approximately $70,644,000 at March 31, 2014. We believe that our existing cash, cash equivalents and investments will be sufficient to fund our operations into the second half of 2016. Specifically, we believe that our existing cash, cash equivalents and investments will be sufficient to enable us to:

- complete our ongoing Phase 2 clinical trial of IMO-8400 in patients with psoriasis, our ongoing Phase 1/2 clinical trial in patients with Waldenström s macroglobulinemia and our planned Phase 1/2 clinical trial in patients with DLBCL and the MYD88 L265P oncogenic mutation;

submit an IND to the FDA for IMO-9200 and conduct a Phase 1 clinical trial of IMO-9200;

conduct a Phase 1/2 clinical trial of IMO-8400 in patients with polymyositis or dermatomyositis and a Phase 1/2 clinical trial of IMO-8400 in patients with GvHD as the initial orphan indications that we have selected for further development in our autoimmune disease program;

conduct disease model studies and an IND-enabling development program in our GSO program; and

conduct a Phase 1 proof-of-concept clinical trial in each of the first two disease indications selected for further development in our GSO program.

We will need additional funds in order to conduct further clinical development of IMO-8400 or IMO-9200, or to conduct any further development of our GSO technology and our other drug candidates or technologies.

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We may 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 in our autoimmune disease and genetically defined forms of B-cell lymphoma programs and our GSO program and our ability to advance our product candidates and GSO technology on the timelines anticipated;
- the cost, timing and outcome of regulatory reviews;
- competitive and potentially competitive products and technologies and investors receptivity to our drug candidates and the technology underlying them in light of competitive products and technologies;
- the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies such as ours specifically; and
- our ability to enter into additional collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require additional funds or further cost reductions. Financing may not be available to us when we need it or may not be available to us on favorable or acceptable terms or at all. We could be required to seek funds through collaborative alliances or through other means that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing equity securities, our then existing stockholders will experience dilution. 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. The terms of any financing may adversely affect the holdings or the rights of existing stockholders.

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

Contractual Obligations

During the three months ended March 31, 2014, there were no material changes outside the ordinary course of our business to our contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Foreign currency exchange gains and losses may result from amounts to be paid under our terminated Merck KGaA collaboration and termination agreements and payments under our clinical trial agreements that are denominated in Euros. As of March 31, 2014, we had net accrued obligations of 831,000 ($1,143,000 using a March 31, 2014 exchange rate). All other assets and liabilities are in U.S. dollars, which is our functional currency.

We maintain investments in accordance with our investment policy. The primary objectives of our investment activities are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. We regularly review our investment holdings in light of the then current economic environment. We do not own auction rate securities or derivative financial investment instruments in our investment portfolio. At March 31, 2014, all of our invested funds were invested in a money market fund, classified in cash and cash equivalents on the accompanying balance sheet, corporate bonds and commercial paper classified in short-term investments.

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

ITEM 4. CONTROLS AND PROCEDURES.

(a) *Evaluation of Disclosure Controls and Procedures.* Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of March 31, 2014. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well

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designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of March 31, 2014, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others, particularly during the period in which this report was prepared, and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms.

(b) *Changes in Internal Controls*. No change in our internal control over financial reporting occurred during the fiscal quarter ended March 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1A. RISK FACTORS.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information included or incorporated by reference in this Quarterly Report on Form 10-Q before purchasing our common stock. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks or uncertainties. In that case, the market price of our common stock could decline, and you may lose all or part of your investment in our securities.

Risks Relating to Our Financial Results and Need for Financing

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

We had cash, cash equivalents and investments of approximately $70.6 million at March 31, 2014. We believe that our existing cash, cash equivalents and investments will be sufficient to fund our operations into the second half of 2016. Specifically, we believe that our existing cash, cash equivalents and investments will be sufficient to enable us to:

- complete our ongoing Phase 2 clinical trial of IMO-8400 in patients with psoriasis, our ongoing Phase 1/2 clinical trial in patients with Waldenström s macroglobulinemia and our planned Phase 1/2 clinical trial in patients with DLBCL and the MYD88 L265P oncogenic mutation;
- submit an IND to the FDA for IMO-9200 and conduct a Phase 1 clinical trial of IMO-9200;
- conduct a Phase 1/2 clinical trial of IMO-8400 in patients with polymyositis or dermatomyositis and a Phase 1/2 clinical trial of IMO-8400 in patients with GvHD as the initial orphan indications that we have selected for further development in our autoimmune disease program;
- conduct disease model studies and an IND-enabling development program in our GSO program; and
- conduct a Phase 1 proof-of-concept clinical trial in each of the first two disease indications selected for further development in our GSO program.

We will need additional funds in order to conduct further clinical development of IMO-8400 or IMO-9200, or to conduct any further development of our GSO technology and our other drug candidates or technologies.

We expect that we will require substantial additional funds to conduct additional research and development, including preclinical testing and clinical trials of our drug candidates, and to fund our operations. We may 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 in our genetically defined forms of B-cell lymphoma and autoimmune disease programs and our GSO program and our ability to advance our product candidates and GSO technology on the timelines anticipated;

- the cost, timing, and outcome of regulatory reviews;

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

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

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

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

Additional financing may not be available to us when we need it or may not be available to us on favorable or acceptable terms or at all. We could be required to seek funds through collaborative alliances or through other means that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing equity securities, our then existing stockholders will experience dilution. The terms of any financing may adversely affect the holdings or the rights of existing stockholders. An equity financing that involves existing stockholders may cause a concentration of ownership. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and are likely to include rights that are senior to the holders of our common stock. Any additional debt financing or equity that we raise may contain terms, such as liquidation and other preferences, or liens or other restrictions on our assets, which are not favorable to us or our stockholders.

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

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

We have incurred losses in every year since our inception, except for 2002, 2008, and 2009 when our recognition of revenues under license and collaboration agreements resulted in our reporting net income for those years. As of March 31, 2014, we had an accumulated deficit of $421.8 million. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 to March 31, 2014, we incurred losses of $161.6 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 March 31, 2014, 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 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 certain genetically defined forms of B-cell lymphoma and autoimmune diseases and on the development of our GSO technology. If we terminate the development of any of our programs or any of our drug candidates in such programs, are unable to successfully develop and commercialize any of our drug candidates, or experience significant delays in doing so, our business may be materially harmed.

We have invested a significant portion of our time and financial resources in the development of TLR-targeted clinical stage lead drug candidates as part of our autoimmune disease program. In the future, we intend to invest a significant portion of our time and financial resources in the development of our TLR- targeted candidates, including IMO-8400 and IMO-9200 for the treatment of certain genetically defined forms of B-cell lymphoma and for orphan autoimmune diseases. We also plan to invest substantial time and resources to further advance the development of our GSOs under our GSO program. For instance:

- we initiated patient treatment in a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia in the first half of 2014 and are planning to initiate patient treatment in a Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL and the MYD88 L265P oncogenic mutation in the second half of 2014;

- we initiated IND-enabling studies of IMO-9200 and, pending the results from these studies, expect to submit an IND for IMO-9200 and initiate a Phase 1 clinical trial of IMO-9200 in the second half of 2014;

- we are planning to initiate patient treatment in a Phase 1/2 clinical trial of IMO-8400 in patients with polymyositis or dermatomyositis and in a Phase 1/2 clinical trial of IMO-8400 in patients with GvHD in the second half of 2014; and

- we are planning to initiate a Phase 1 proof-of-concept clinical trial in each of the first two disease indications selected for further development in our GSO program in the second half of 2015.

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

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

Our efforts, and the efforts of Merck & Co., to develop and commercialize these compounds are at an early stage and are subject to many challenges. We have experienced setbacks with respect to our programs for IMO-3100, 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 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 in patients with psoriasis 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 may seek to enter into collaborative alliances with pharmaceutical companies to advance our TLR antagonist candidates in broader autoimmune disease indications, such as psoriasis, lupus and arthritis. We may seek to enter into collaborative alliances with pharmaceutical companies with respect to applications of our GSO technology program. Our setbacks with respect to our programs for IMO-3100, IMO-2125, and IMO-2055 could negatively impact our ability to license any of such compounds to a third party.

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

- the drug candidates demonstrating activity in clinical trials;
- the drug candidates demonstrating an acceptable safety profile in nonclinical toxicology studies and during clinical trials;
- timely enrollment in clinical trials of IMO-8400 and other drug candidates, which may be slower than anticipated, potentially resulting in significant delays;
- satisfying conditions imposed on us and/or our collaborators by the FDA or equivalent foreign regulatory authorities regarding the scope or design of clinical trials;
- the ability to demonstrate to the satisfaction of the FDA, or equivalent foreign regulatory authorities, the safety and efficacy of the drug candidates through current and future clinical trials;
- timely receipt of necessary marketing approvals from the FDA and equivalent foreign regulatory authorities;
- the ability to combine our drug candidates and the drug candidates being developed by Merck & Co. and any other collaborators safely and successfully with other therapeutic agents;

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achieving and maintaining compliance with all regulatory requirements applicable to the products;

establishment of commercial manufacturing arrangements with third-party manufacturers;

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

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

competition from other companies and their therapies;

changes in treatment regimens;

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

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

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

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

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

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

The future success of our GSO technology program depends on our success in identifying and developing marketable products based on such technology. Although the results of our preclinical studies to date have been supportive of the viability of this technology, it is unknown whether these results are indicative of results that may be obtained in any future clinical trials that we may conduct. We are currently undertaking an analysis of priority disease indications and development strategies to determine next steps in developing our GSO technology. However, we do not expect to identify the first two disease indications in our GSO program until the second half of 2014 at the earliest and, if and when a disease indication is identified, do not anticipate initiating our Phase 1 proof-of-concept clinical trials prior to the second half of 2015. Many steps must be successfully achieved prior to any initiation of clinical development with respect to a GSO-based product candidate. Given the level of uncertainty of our ability to successfully achieve these many steps and the uncertainty of the clinical development process in general, there can be no assurance that we will succeed in developing any marketable product as a result of our efforts with respect to our GSO technology program.

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In particular, because there are a limited number of patients with Waldenström s macroglobulinemia or DLBCL and the MYD88 L265P oncogenic mutation, and a limited number of patients with polymyositis, dermatomyositis, or GvHD, other autoimmune diseases having orphan indications for which we may determine to develop our TLR antagonists, our ability to enroll eligible patients in any clinical trials for these indications may be limited or may result in slower enrollment than we anticipate. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors product candidates.

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Patient enrollment is affected by other factors including:

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

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

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

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

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

the ability to receive regulatory approval or to commercialize drug products.

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

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;

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

the rate of enrollment or retention of patients in our clinical trials may be lower than we expect;

we might have to suspend or terminate our clinical trials if the participating subjects experience serious adverse events or undesirable side effects or are exposed to unacceptable health risks;

regulators or IRBs may hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements, issues identified through inspections of manufacturing or clinical trial operations or clinical trial sites, or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;

regulators may hold or suspend our clinical trials while collecting supplemental information on, or clarification of, our clinical trials or other clinical trials, including trials conducted in other countries or trials conducted by other companies;

we, along with our collaborators and subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA s Application Integrity Policy, or similar policy under foreign regulatory authorities. Employment of such debarred persons, even if inadvertent, may result in delays in the FDA s or foreign equivalent s review or approval of our products, or the rejection of data developed with the involvement of such person(s);

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

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

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

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

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

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

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

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

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

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As a result of these factors, we may never succeed in obtaining regulatory approval to market any product. Furthermore, the commercial success of any of our 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 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 certain genetically defined B-cell lymphoma and autoimmune diseases and for use as vaccine adjuvants. We have one drug candidate, IMO-8400, in clinical development for the treatment of certain genetically defined B-cell lymphomas, including Waldenström s macroglobulinemia and DLBCL with the MYD88 L265P oncogenic mutation, and our autoimmune 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 may seek to enter into collaborative alliances with pharmaceutical companies to advance our TLR antagonist candidates in broader autoimmune disease indications, such as psoriasis, lupus and arthritis. For all of these disease areas, there are many other companies, public and private, that are actively engaged in discovery, development, and commercializing products and technologies that may compete with our drug candidates and programs, including TLR-targeted compounds as well as non-TLR-targeted therapeutics.

Our principal competitor developing TLR-targeted compounds for autoimmune diseases is Dynavax, with its collaborator, 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, Pfizer, and Takeda Pharmaceutical Company Limited, Remicade, which is marketed by Janssen Biotech, Merck & Co., and Mitsubishi Tanabe Pharma, Humira, which is marketed by Abbott Laboratories, and Stelara, which is marketed by Janssen Biotech. In addition to existing treatments, we are also aware of additional compounds for the treatment of moderate to severe plaque psoriasis that are currently in late stage development, including apremilast, which is being developed by Celgene Corporation, tofacitinib, which is being developed by Pfizer, secukinumab, which is being developed by Novartis, ixekizumab, which is being developed by Eli Lilly and Company, and brodalumab, which is being developed by Amgen, AstraZeneca PLC, and Kyowa Hakko Kirin Co., Ltd.

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

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

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

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

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

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

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

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, 2016, but automatically extends annually for additional one-year periods. This agreement may be terminated by us or Dr. Agrawal for any reason or no reason at any time upon notice to the other party. We do not carry key man life insurance for Dr. Agrawal.

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

Regulatory Risks

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

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

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

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

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

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

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

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

- conducting a Phase 2 clinical trial of IMO-8400 in patients with moderate to severe plaque psoriasis;

- conducting a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia and planning to initiate patient treatment in a Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL and the MYD88 L265P oncogenic mutation in the second half of 2014;

- planning to submit an IND to the FDA for IMO-9200 and to initiate a Phase 1 clinical trial of IMO-9200 in the second half of 2014;

- planning to initiate patient treatment in a Phase 1/2 clinical trial of IMO-8400 in patients with polymyositis or dermatomyositis and in a Phase 1/2 clinical trial of IMO-8400 in patients with GvHD in the second half of 2014; and

- planning to initiate a Phase 1 proof-of-concept clinical trial in each of the first two disease indications selected for further development in our GSO program in the second half of 2015.

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

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

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

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

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

We intend to seek fast track designation for some applications of our product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

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

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

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

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

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

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mutation in our genetically defined forms of B-cell lymphoma program with our TLR antagonist product candidate IMO-8400. We may enter into similar agreements for our other product candidates and possible expansion indications for IMO-8400. Companion diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval prior to commercialization.

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

- the development of our TLR antagonist product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials;
- our TLR antagonist product candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and
- we may not realize the full commercial potential of any TLR antagonist product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients with the specific oncogenic mutation targeted by our TLR antagonist product candidates.

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

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

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

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

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

Risks Relating to Collaborators

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

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

Upfront payments and milestone payments received from collaborations help to provide us with the financial resources for our internal research and development programs. Our internal programs are focused on developing TLR-targeted drug candidates for the potential treatment of certain genetically defined forms of B-cell lymphoma and autoimmune diseases and on GSOs. We believe that additional resources will be required to advance compounds in all of these areas. If we do not reach agreements with additional collaborators in the future, we may not be able to obtain the expertise and resources necessary to achieve our business objectives, our ability to advance our compounds will be jeopardized and we may fail to meet our business objectives.

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

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

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

An important element of our business strategy includes entering into collaborative alliances with corporate collaborators, primarily large pharmaceutical companies, for the development, commercialization, marketing, and distribution of some of our drug candidates. In December 2006, we entered into an exclusive license and research collaboration with Merck & Co. to research, develop, and commercialize vaccine products containing our TLR7, TLR8 and TLR9 agonists in the fields of cancer, infectious diseases, and Alzheimer s disease. In December 2007, we entered into an exclusive, worldwide license agreement with Merck KGaA to research, develop, and commercialize products containing our TLR9 agonists for treatment of cancer, excluding cancer vaccines.

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

- our collaborators may control the development of the drug candidates being developed with our technologies and compounds including the timing of development;
- our collaborators may control the development of the companion diagnostic to be developed for use in conjunction with our drug candidates including the timing of development;
- our collaborators may control the public release of information regarding the developments, and we may not be able to make announcements or data presentations on a schedule favorable to us;
- disputes may arise in the future with respect to the ownership of rights to technology developed with our collaborators;
- disagreements with our collaborators could delay or terminate the research, development or commercialization of products, or result in litigation or arbitration;
- we may have difficulty enforcing the contracts if any of our collaborators fail to perform;
- our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect the perception of us in the business or financial

communities;

our collaboration agreements are likely to be for fixed terms and subject to termination by our collaborators in the event of a material breach or lack of scientific progress by us;

our collaborators may have the first right to maintain or defend our intellectual property rights and, although we would likely have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not, our ability to do so may be compromised by our collaborators acts or omissions;

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

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

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

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

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

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

Risks Relating to Intellectual Property

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

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

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

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

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

As of April 15, 2014, we owned more than 45 U.S. patents and patent applications and more than 80 patents and patent applications throughout the rest of the world for our TLR-targeted immune modulation technologies. These patents and patent applications include novel chemical compositions of matter and methods of use of our IMO compounds, including IMO-3100, IMO-8400, IMO-9200, and IMO-2055. As of April 15, 2014, all of our intellectual property covering immune modulatory compositions and methods of their use is based on discoveries made solely by us. These patents expire at various dates ranging from 2017 to 2031. With respect to IMO-3100, we have issued U.S. patents that cover the chemical composition of matter of IMO-3100 and methods of its use that will expire at the earliest in 2026. With respect to IMO-8400, we have an issued U.S. patent that covers the chemical composition of matter of IMO-8400 and methods of its use that will expire at the earliest in 2031. With respect to IMO-9200, we have a U.S. patent application that covers the chemical composition for IMO-9200 and methods of its use, which, if issued, would expire at the earliest in 2034.

As of April 15, 2014, we owned one issued U.S. patent, two U.S. patent applications and six foreign patent applications for our GSO compounds and methods of their use. The issued patent covering our GSO technologies would expire at the earliest in 2030.

In addition to our TLR-targeted and GSO patent portfolios, we are the owner or hold licenses of patents and patent applications related to antisense technology. As of April 15, 2014, our antisense patent portfolio included more than 55 U.S. patents, one U.S. patent application and more than 60 patents throughout the rest of the world. These antisense patents and patent applications include novel compositions of matter, the use of these compositions for various genes, sequences and therapeutic targets, and oral and other routes of administration. Some of the patents and patent applications in our antisense portfolio were in-licensed. These in-licensed patents expire at various dates ranging from 2014 to 2021.

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

Although we have many issued patents and pending patent applications in the United States and other countries, we may not have rights under certain third-party patents or patent applications related to our products. Third parties may own or control these patents and patent applications in the United States and abroad. In particular, we are aware of third-party U.S. patents that contain broad claims related to the use of certain oligonucleotides for stimulating an immune response, although we do not believe that these claims are valid. In addition, there may be other patents and patent applications related to our products of which we are not aware. Therefore, in some cases, in order to develop, manufacture, sell or import some of our products, we or our collaborators may choose to seek, or be required to seek, licenses under third-party patents issued in the United States and abroad or under third-party patents that might issue from U.S. and foreign patent applications. In such an event, we would be required to pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, we or our collaborators may not be able to develop, manufacture, sell or import these products.

We may lose our rights to patents, patent applications or technologies of third parties if our licenses from these third parties are terminated. In such an event, we might not be able to develop or commercialize products covered by the licenses.

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

Our failure to comply with these requirements could result in termination of the licenses. These licenses generally will otherwise remain in effect until the expiration of all valid claims of the patents covered by such licenses or upon earlier termination by the parties. The issued patents covered by these licenses expire at various dates ranging from 2014 to 2021. If one or more of these licenses is terminated, we may be delayed in our efforts, or be unable, to develop and market the products that are covered by the applicable license or licenses.

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

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

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we can because

of their substantially greater financial resources. If any patent litigation or other proceeding is resolved against us, we or our collaborators may be enjoined from developing, manufacturing, selling or importing our drugs without a license from the other party and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms or at all.

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

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

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

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

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

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

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

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

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

Additionally, contract manufacturers may not be able to manufacture our drug candidates at a cost or in quantities necessary to make them commercially viable. As of March 31, 2014, our third-party manufacturers have met our manufacturing requirements, but we cannot be assured that they will continue to do so. Furthermore, changes in the manufacturing process or procedure, including a change in the location where the drug substance or drug product is manufactured or a change of a third-party manufacturer, may require prior FDA review and approval in accordance with the FDA s cGMP and NDA/biologics license application regulations. Contract manufacturers may also be subject to comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a drug candidate. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. If we or our contract manufacturers are unable to comply, we or they may be subject to regulatory action, civil actions or penalties.

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

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

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

We do not have the ability to independently conduct the clinical trials required to obtain regulatory approval for our drug candidates. We depend on independent clinical investigators, contract research organizations, and other third-party service providers in the conduct of the clinical trials of our drug candidates and expect to continue to do so. We contracted with contract research organizations to manage our Phase 1 and Phase 2 clinical trials of IMO-3100, our Phase 1 clinical trial of IMO-8400, our ongoing

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Phase 2 clinical trial of IMO-8400 in patients with psoriasis, our ongoing Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström s macroglobulinemia, and our planned Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL and the MYD88 L265P oncogenic mutation, and expect to contract with such organizations for future clinical trials. We rely heavily on these parties for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and foreign regulatory agencies require us to comply with certain standards, commonly referred to as good clinical practices, and applicable regulatory requirements, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or at all, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval, and commercialization of our drug candidates. If we seek to conduct any of these activities ourselves in the future, we will need to recruit appropriately trained personnel and add to our infrastructure.

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

Some of the TLR antagonist product candidates that we develop with respect to our genetically defined forms of B-cell lymphoma program will necessitate the use of companion diagnostics. We do not plan to develop companion diagnostics internally and, as a result, we will be dependent on the efforts of our third-party collaborators to successfully commercialize these companion diagnostics. Our collaborators:

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

may not commit sufficient resources to the marketing and distribution of such product or products; and

may terminate their relationship with us.

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

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

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

the prevalence and severity of any side effects, including any limitations or warnings contained in the product s approved labeling;

the efficacy and potential advantages over alternative treatments;

the ability to offer our drug candidates for sale at competitive prices;

relative convenience and ease of administration;

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

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

publicity concerning our products or competing products and treatments.

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

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

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

A primary trend in the United States healthcare industry is toward cost containment. In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our drug candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization of our products. These further clinical trials would require additional time, resources, and expenses. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our prospects for generating revenue, if any, could be adversely affected and our business may suffer.

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

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

price we might establish for products that we or our current or future collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

We face a risk of product liability claims and may not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that is inherent in the manufacturing, testing, and marketing of human therapeutic drugs. We face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials and will face an even greater risk if we commercially sell any products. Regardless of merit or eventual outcome, liability claims and product recalls may result in:

- decreased demand for our drug candidates and products;
- damage to our reputation;
- regulatory investigations that could require costly recalls or product modifications;
- withdrawal of clinical trial participants;
- costs to defend related litigation;
- substantial monetary awards to clinical trial participants or patients, including awards that substantially exceed our product liability insurance, which we would then have to pay using other sources, if available, and would damage our ability to obtain liability insurance at reasonable costs, or at all, in the future;

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loss of revenue;

the diversion of management s attention away from managing our business; and

the inability to commercialize any products that we may develop.

Although we have product liability and clinical trial liability insurance that we believe is adequate, this insurance is subject to deductibles and coverage limitations. We may not be able to obtain or maintain adequate protection against potential liabilities. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our commercialization efforts.

Risks Relating to an Investment in Our Common Stock

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

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

a classified board of directors;

limitations on the removal of directors;

limitations on stockholder proposals at meetings of stockholders;

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

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

In addition, Section 203 of the Delaware General Corporation Law imposes restrictions on our ability to engage in business combinations and other specified transactions with significant stockholders. These provisions could have the effect of delaying, deferring or preventing a change in control of us or a change in our management that stockholders may consider favorable or beneficial. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock.

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

common stock.

As of March 14, 2014, Baker Bros. Advisors LLC, and certain of its affiliated funds, which we refer to collectively as Baker Brothers, held 1,613,076 shares of our common stock, warrants to purchase up to 20,316,327 shares of our common stock at an exercise price of $0.47 per share and pre-funded warrants to purchase up to 22,151,052 shares of our common stock at an exercise price of $0.01 per share. In addition, two members of our board of directors are affiliates of Baker Brothers. Under the terms of the warrants and pre-funded warrants issued to Baker Brothers, Baker Brothers is not permitted to exercise such warrants to the extent that such exercise would result in Baker Brothers (and its affiliates) beneficially owning more than 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such warrants. Baker Brothers has the right to increase this beneficial ownership limitation in its discretion on 61 days prior written notice to us, provided that in no event is Baker Brothers permitted to exercise such warrants to the extent that such exercise would result in Baker Brothers (and its affiliates) beneficially owning more than 19.99% of the number of shares of our common stock outstanding or the combined voting power of our securities outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such warrants. As of March 14, 2014, and after giving effect to the 4.99% beneficial ownership limitation currently in effect with respect to the warrants and pre-funded warrants held by Baker Brothers, Baker Brothers beneficially owns 4.99% of our outstanding common stock. If the warrants and pre-funded warrants held by Baker Brothers could be exercised without this limitation, as of March 14, 2014, Baker Brothers would have beneficially owned 35.3% of our common stock.

As of March 14, 2014, entities affiliated with Pillar Invest Corporation, which we refer to collectively as the Pillar Investment Entities, held 13,626,469 shares of our common stock, 424,242 shares of our Series E preferred stock, which are currently convertible into 8,484,840 shares of our common stock, and warrants to purchase up to 18,295,490 shares of our common stock at exercise prices ranging from $0.47 per share to $1.46 per share. In connection with their ownership of shares of our Series E preferred stock, the Pillar Investment Entities obtained various rights, preferences and privileges that are not held by the holders of our common stock and that in certain instances are preferential to the rights of the holders of our common stock. In addition, two members of our board of directors are affiliates of the Pillar Investment Entities. The Pillar Investment Entities are subject to contractual limitations that limit

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their ability to convert or exercise any securities held by them that are convertible or exercisable into shares of our common stock to the extent that such conversion or exercise would result in the Pillar Investment Entities (and their affiliates) beneficially owning more than 19.99% of the number of shares of our common stock outstanding or the combined voting power of our securities outstanding immediately after giving effect to the issuance of shares of common stock issuable upon conversion or exercise of such securities. As of March 14, 2014, and after giving effect to the 19.99% beneficial ownership limitation currently in effect with respect to the securities held by the Pillar Investment Entities, the Pillar Investment Entities beneficially own 19.99% of our outstanding common stock. If the Series E preferred stock and warrants held by the Pillar Investment Entities could be converted and exercised without these limitations, as of March 14, 2014, the Pillar Investment Entities would have beneficially owned 35.0% of our common stock.

Although there are contractual limitations on the beneficial ownership of Baker Brothers and the Pillar Investment Entities, which we refer to collectively as our significant securityholders, and on the voting rights of the Pillar Investment Entities, if our significant securityholders were to convert or exercise their preferred stock and warrants into common stock and were to choose to act together, they could be able to exert substantial influence over our business. This concentration of voting power could delay, defer or prevent a change of control, entrench our management and the board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire. In addition, in the event of a sale of our company, whether by merger, sale of all or substantially all of our assets or otherwise, our significant securityholders would be entitled to receive, with respect to each share of common stock issuable upon conversion or exercise of the preferred stock and warrants then held by them and without regard to the beneficial ownership limitations imposed on the conversion or exercise of such securities, the same amount and kind of securities, cash or property as they would have been entitled to receive if such securities had been converted into or exercised for shares of our common stock immediately prior to such sale of our company. Because the significant securityholders would receive this sale consideration with respect to preferred stock and warrants not included in their reported beneficial ownership of our common stock, in the event of a sale of our company, they would be entitled to receive a significantly larger portion of the total proceeds distributable to the holders of our securities than is represented by their reported beneficial ownership of our common stock.

Our stock price has been and may in the future be extremely volatile. In addition, because our common stock has historically been traded at low volume levels, our investors ability to trade our common stock may be limited. As a result, investors may lose all or a significant portion of their investment.

Our stock price has been volatile. During the period from January 1, 2013 to April 15, 2014, the closing sales price of our common stock ranged from a high of $6.59 per share to a low of $0.46 per share. The stock market has also experienced periods of significant price and volume fluctuations and the market prices of biotechnology companies in particular have been highly volatile, often for reasons that have been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

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

the regulatory status of our drug candidates;

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

the success of competitive products or technologies;

regulatory developments in the United States and foreign countries;

our success in entering into collaborative agreements;

developments or disputes concerning patents or other proprietary rights;

the departure of key personnel;

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

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

the terms of any financing consummated by us;

changes in the structure of healthcare payment systems;

market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts reports or recommendations; and

general economic, industry, and market conditions.

In addition, our common stock has historically been traded at low volume levels and may continue to trade at low volume levels. As a result, any large purchase or sale of our common stock could have a significant impact on the price of our common stock and it may be difficult for investors to sell our common stock in the market without depressing the market price for the common stock or at all.

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As a result of the foregoing, investors may not be able to resell their shares at or above the price they paid for such shares. Investors in our common stock must be willing to bear the risk of fluctuations in the price of our common stock and the risk that the value of their investment in our stock could decline.

ITEM 6. EXHIBITS.

The list of Exhibits filed as part of this Quarterly Report on Form 10-Q is set forth on the Exhibit Index immediately preceding such Exhibits and is incorporated herein by this reference.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

IDERA PHARMACEUTICALS, INC.

Date: May 12, 2014

/s/ Sudhir Agrawal
Sudhir Agrawal
President and Chief Executive Officer

(Principal Executive Officer)

Date: May 12, 2014

/s/ Louis J. Arcudi, III
Louis J. Arcudi, III
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit Index

Exhibit No.	
3.1	Certificate of Elimination of Number of Shares of Preferred Stock Designated as Series D Convertible Preferred Stock.
10.1	First Amendment dated February 21, 2014 to Lease Agreement dated October 31, 2006 between Idera Pharmaceuticals, Inc. and ARE-MA-Region No. 23, LLC.
10.2	Employment Letter Agreement by and between Idera Pharmaceuticals, Inc. and Louis Brenner, dated January 3, 2014.
10.3	Form of Pre-Funded Warrant issued to purchasers in Idera Pharmaceuticals, Inc. s registered public offering on Idera Pharmaceuticals, Inc. s registration statement on Form S-3 (File No. 333-191073).
10.4	Director Compensation Program.
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

Incorporated by reference to Exhibit 10.54 to the Company s Annual Report on Form 10-K filed on March 13, 2014 (SEC File No. 001-31918).
Incorporated by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K filed on February 5, 2014 (SEC File No. 001-31918).