

IDERA PHARMACEUTICALS, INC.

Form 424B4

November 15, 2013

[Table of Contents](#)

**Filed Pursuant to Rule 424(b)(4)**

**Registration File No. 333-187155**

**PROSPECTUS SUPPLEMENT NO. 3**

**To Prospectus dated May 1, 2013**

**Idera Pharmaceuticals, Inc.**

**17,500,000 Shares of Common Stock**

**Warrants to Purchase 49,132,654 Shares of Common Stock**

This prospectus supplement no. 3 supplements the prospectus dated May 1, 2013, relating to the offering of (i) the 17,500,000 shares of our common stock, and the warrants to purchase 49,132,654 shares of our common stock that we issued and sold on May 7, 2013 and (ii) the shares of common stock that are issuable from time to time upon exercise of the warrants.

This prospectus supplement incorporates into the prospectus the information contained in the following document filed by us with the Securities and Exchange Commission, or SEC, which is attached to this prospectus supplement:

our quarterly report on Form 10-Q, which was filed with the SEC on November 14, 2013.

You should read this prospectus supplement in conjunction with the prospectus, including any supplements and amendments thereto. This prospectus supplement is qualified by reference to the prospectus except to the extent that the information in this prospectus supplement supersedes the information contained in the prospectus.

This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the prospectus, including any supplements and amendments thereto.

**Investing in our common stock involves risks. Please read carefully the section entitled **Risk Factors** beginning on page 8 of the prospectus and in our Quarterly Report on Form 10-Q that was filed on November 14, 2013.**

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

The date of this prospectus supplement is November 15, 2013.

**Table of Contents**

**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 September 30, 2013**

**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**  
**(State or other jurisdiction of**  
**incorporation or organization)**

**04-3072298**  
**(I.R.S. Employer**  
**Identification No.)**

**167 Sidney Street**

**Cambridge, Massachusetts**  
**(Address of principal executive offices)**

**02139**  
**(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  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  No

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 424B4

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  (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

**Common Stock, par value \$.001 per share**  
**Class**

**63,690,084**  
**Outstanding as of October 31, 2013**

**Table of Contents**

**IDERA PHARMACEUTICALS, INC.**

**FORM 10-Q**

**INDEX**

	<b>Page</b>
<b>PART I FINANCIAL INFORMATION</b>	
<u>Item 1 Financial Statements Unaudited</u>	1
<u>Condensed Balance Sheets as of September 30, 2013 and December 31, 2012</u>	1
<u>Condensed Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2013 and 2012</u>	2
<u>Condensed Statements of Cash Flows for the Nine Months Ended September 30, 2013 and 2012</u>	3
<u>Notes to Condensed Financial Statements</u>	4
<u>Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 3 Quantitative and Qualitative Disclosures about Market Risk</u>	28
<u>Item 4 Controls and Procedures</u>	29
<b>PART II OTHER INFORMATION</b>	
<u>Item 1A Risk Factors</u>	30
<u>Item 6 Exhibits</u>	50
<u>Signatures</u>	51

IMO® and Idera® are our trademarks. All other trademarks and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

**Table of Contents**

**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.

**Table of Contents****PART I FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS.****IDERA PHARMACEUTICALS, INC.****CONDENSED BALANCE SHEETS****(UNAUDITED)**

<b>(In thousands, except per share amounts)</b>	<b>September 30, 2013</b>	<b>December 31, 2012</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 38,749	\$ 10,096
Restricted cash	311	
Prepaid expenses and other current assets	397	198
Total current assets	39,457	10,294
Property and equipment, net	116	218
Restricted cash		311
Total assets	\$ 39,573	\$ 10,823
<b>LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 254	\$ 1,129
Accrued expenses	2,204	3,002
Total current liabilities	2,458	4,131
Other liabilities	6	65
Total liabilities	2,464	4,196
Commitments and contingencies		
Series D Redeemable Convertible Preferred Stock, \$0.01 par value, Designated, issued and outstanding - 1,124 shares at December 31, 2012		5,921
Non-redeemable preferred stock, common stock, and other 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	3,701
Series D convertible preferred stock, Designated, issued and outstanding 1,124 shares at September 30, 2013	5,464	
Series A convertible preferred stock, Designated 1,500 shares, issued and outstanding 1 share		



Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 424B4

Common stock, \$0.001 par value, Authorized 280,000 and 140,000 shares at September 30, 2013 and December 31, 2012, respectively; Issued and outstanding 62,682 and 27,643 shares at September 30, 2013 and December 31, 2012, respectively	63	28
Additional paid-in capital	432,848	391,635
Accumulated deficit	(406,794)	(394,658)
<b>Total stockholders' equity</b>	<b>37,109</b>	<b>706</b>
Total liabilities, redeemable preferred stock and stockholders' equity	\$ 39,573	\$ 10,823

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

Table of Contents**IDERA PHARMACEUTICALS, INC.****CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS****(UNAUDITED)**

<b>(In thousands, except per share amounts)</b>	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30, 2013</b>	<b>2012</b>	<b>September 30, 2013</b>	<b>2012</b>
Alliance revenue	\$ 7	\$ 3	\$ 43	\$ 40
Operating expenses:				
Research and development	2,510	3,278	6,835	10,595
General and administrative	2,179	1,477	5,305	5,014
Total operating expenses	4,689	4,755	12,140	15,609
Loss from operations	(4,682)	(4,752)	(12,097)	(15,569)
Other income (expense):				
Decrease in fair value of warrant liability		109		106
Investment income, net	2	2	6	8
Foreign currency exchange (loss) gain	(58)	(28)	(45)	13
Net loss	(4,738)	(4,669)	(12,136)	(15,442)
Loss on extinguishment of convertible preferred stock and preferred stock dividends	278	160	2,587	480
Net loss applicable to common stockholders	\$ (5,016)	\$ (4,829)	\$ (14,723)	\$ (15,922)
Basic and diluted net loss per common share applicable to common stockholders (Note 11)	\$ (0.11)	\$ (0.17)	\$ (0.40)	\$ (0.58)
Shares used in computing basic and diluted net loss per common share applicable to common stockholders	45,720	27,640	37,203	27,639
Comprehensive loss	\$ (4,738)	\$ (4,669)	\$ (12,136)	\$ (15,442)

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

**Table of Contents**

**IDERA PHARMACEUTICALS, INC.**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
**(UNAUDITED)**

<b>(In thousands)</b>	<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (12,136)	\$ (15,442)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	994	1,628
Decrease in fair value of warrant liability		(106)
Non-employee stock option expense	41	2
Depreciation expense	106	201
Other	18	5
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(199)	111
Accounts payable, accrued expenses, and other liabilities	(1,499)	(2,194)
Net cash used in operating activities	(12,675)	(15,795)
<b>Cash Flows from Investing Activities:</b>		
Purchases of property and equipment	(4)	
Net cash used in investing activities	(4)	
<b>Cash Flows from Financing Activities:</b>		
Proceeds from equity financings	40,538	
Dividends paid	(1,067)	(423)
Proceeds from exercise of common stock options and warrants and employee stock purchases	1,864	3
Payments on capital lease	(3)	(4)
Net cash provided by (used in) financing activities	41,332	(424)
Net increase (decrease) in cash and cash equivalents	28,653	(16,219)
Cash and cash equivalents, beginning of period	10,096	24,571
Cash and cash equivalents, end of period	\$ 38,749	\$ 8,352

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



**Table of Contents**

**IDERA PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

**September 30, 2013**

**(UNAUDITED)**

**(1) Organization**

Idera Pharmaceuticals, Inc. ( Idera or the Company ) is a clinical stage biotechnology company using its proprietary technology to create novel nucleic acid therapeutics designed to inhibit over-activation of Toll-like Receptors, or TLRs. The Company plans to develop and commercialize these therapeutics for the treatment of genetically defined forms of B-cell lymphoma and for orphan autoimmune diseases with serious unmet medical needs. The Company believes that clinical proof of concept of its approach of targeting specific TLRs for the treatment of psoriasis and potentially other autoimmune and inflammatory diseases has been established in a Phase 2 trial of one of its drug candidates.

The Company's lead drug candidate is IMO-8400, an antagonist for TLR7, TLR8, and TLR9 that is designed to block over-activation of the targeted TLRs. In a completed Phase 1 clinical trial of IMO-8400 in 42 healthy subjects, IMO-8400 was well tolerated and showed inhibition of TLR7, TLR8, and TLR9. The Company is conducting a randomized, double-blinded, placebo-controlled Phase 2 clinical trial of IMO-8400 in patients with moderate to severe plaque psoriasis.

The Company has initiated plans for clinical development of IMO-8400 for the treatment of genetically defined forms of B-cell lymphoma. The Company has submitted an Investigational New Drug application, or IND, to the United States Food and Drug Administration, or FDA, to conduct a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia. The Company anticipates initiating this trial in the first quarter of 2014. The Company also plans to submit to the FDA in the first quarter of 2014 a protocol for a Phase 1/2 clinical trial of IMO-8400 in patients with diffuse large B-cell lymphoma, or DLBCL, that it expects to initiate in the first quarter of 2014.

The Company has also selected IMO-9200, 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 IND-enabling studies of IMO-9200 and expects to submit an IND for IMO-9200 in the third quarter of 2014.

The Company had cash and cash equivalents of approximately \$38,749,000 at September 30, 2013. The Company believes that its existing cash and cash equivalents will be sufficient to fund its operations at least through the second quarter of 2015.

At September 30, 2013, the Company had an accumulated deficit of \$406,794,000. The Company expects to incur substantial operating losses in future periods. The Company does not expect to generate product revenue or sales-based milestones or royalties until it successfully completes development and obtains marketing approval for drug candidates, either alone or in collaborations with third parties, which it expects will take a number of years. In order to commercialize its drug candidates, the Company needs to complete clinical development and to 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 nine months ended

---

**Table of Contents**

September 30, 2013 are not necessarily indicative of results that may be expected for the year ended December 31, 2013. 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, 2012, which was filed with the SEC on March 11, 2013.

**(3) April 2013 Pillar Agreements**

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

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

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

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

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

modify the Series D Certificate of Designations to provide, in the event of a sale of the Company, for the distribution of any assets that remain available for distribution to its stockholders, after payment to the holders of its Series A convertible preferred stock and any other class of its capital stock that ranks

senior to its Series D preferred stock, to the holders of our Series D preferred stock on a pro rata basis with the holders of its common stock, Series E preferred stock and such new series of non-voting preferred stock; and

amendments to the Certificate of Designations, Preferences and Rights of Series E Preferred Stock (the Series E Certificate of Designations ) to:

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

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

Under the second agreement with the Pillar Entities (the April 30, 2013 Pillar Agreement ), Pillar I irrevocably waived the right of the holders of the Series D preferred stock under Section 2.1 of the Series D Certificate of Designations to receive, in the event of a voluntary or involuntary liquidation, dissolution or winding up of the Company (a

Liquidation ), an amount per share of Series D preferred stock equal to the original issue price of such share of Series D preferred stock plus any dividends accrued or declared but unpaid thereon to the extent such amount is greater than the amount that would have been payable with respect to such share had all shares of Series D preferred stock been converted into shares of the Company's common stock immediately prior to such Liquidation, and that upon a Liquidation the holders of the Series D preferred stock will receive an amount per share of Series D preferred stock equal to the amount that would be payable with respect to such share had all shares of Series D preferred stock been converted into shares of common stock immediately prior to such Liquidation.



## Table of Contents

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

In accordance with the terms of the Pillar Agreements, the Company sought approval from its stockholders of amendments to the Series D Certificate of Designations and Series E Certificate of Designations to effect the changes described above to the dividend and liquidation provisions of the Company's Series D preferred stock and Series E preferred stock, the redemption rights of the holders of its Series D preferred stock and the rights of the holders of its Series D preferred stock to distributions in the event of a sale of the Company. These matters were approved at the Annual Meeting that took place on July 26, 2013. Additional information on the amendments to the Series D Certificate of Designations and Series E Certificate of Designations that were approved by the Company's stockholders at the Annual Meeting is included in Note 14.

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

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

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

In connection with the Pillar Agreements, the Company filed a registration statement that became effective on July 10, 2013, registering the resale of the shares of common stock issuable upon exercise of the Pillar Warrants.

The amendments to the Series D Certificate of Designations and Series E Certificate of Designations did not become effective until the amendments were approved by our stockholders at the Annual Meeting, which occurred during the Company's fiscal quarter that began on July 1, 2013.

Since Pillar I irrevocably waived and agreed to not exercise the Series D Redemption Rights, the Company reassessed its accounting in May 2013 for the Series D preferred stock, which had been classified as temporary equity in the Company's condensed balance sheet because the Series D Redemption Rights represented a contingent put feature that

was outside the Company's control. Since Pillar I irrevocably waived the Series D Redemption Rights, the contingent put feature ceased to exist at the time that Pillar I's waiver of the Series D Redemption Rights became effective. In addition, the Pillar Entities irrevocably waived the liquidation preferences of both the Series D preferred stock and the Series E preferred stock. The Company concluded that these irrevocable waivers of the Series D Redemption Rights and the Series D and Series E liquidation preferences, which became effective when the Company consummated a follow-on underwritten public offering of its common stock on May 7, 2013, represented changes to the fundamental terms of both the Series D preferred stock and the Series E preferred stock. As a result, the Company has accounted for these irrevocable waivers as an extinguishment of the Series D preferred stock and the Series E preferred stock and changed the classification of the Series D preferred stock from temporary equity to permanent equity. The Company compared (1) the sum of the fair values of the Series D preferred stock, the Series E preferred stock and the Pillar Warrants immediately after the effectiveness of

**Table of Contents**

the waivers to (2) the sum of the carrying values of the Series D preferred stock and Series E preferred stock immediately prior to the effectiveness of the waivers on May 7, 2013. The Company recorded the excess of the aggregate fair value of the preferred stock plus the Pillar Warrants immediately after the effectiveness of the waivers over the aggregate carrying value of the preferred stock immediately prior to May 7, 2013 as a loss on extinguishment and classified the fair values, immediately after the effectiveness of the waivers, of the Series D preferred stock, the Series E preferred stock and the Pillar Warrants within permanent equity on its condensed balance sheet.

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

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

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

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

The closing price of the Company's common stock is readily determinable since it is publicly traded. The warrant exercise prices and the warrant terms are readily determinable from the warrant agreements. The expected volatility is based on the actual stock-price volatility over a period equal to the greater of the term of the warrant or three years. The assumed risk-free interest rate is based on the U.S. Treasury security rate with a term equal to the term of the warrant. The assumed dividend yield of zero is based on the fact that the Company has never paid cash dividends to common stockholders and has no present intention to pay cash dividends to common stockholders. The Company assumed that future financings would dilute the warrant holder's ownership in the Company such that the 19.99%

ownership limitation would not prevent the warrant holder from exercising all of the warrants during the term of the warrants.

**(4) Financings**

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

On September 30, 2013, the Company closed a follow-on underwritten public offering, in which it sold 13,727,251 shares of common stock at \$1.55 per share and pre-funded warrants to purchase up to 4,175,975 shares of common stock at \$1.54 per share for aggregate gross proceeds of \$27.7 million. The pre-funded warrants have an exercise price of \$0.01 per share and will expire if not exercised by September 30, 2020. The 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 \$25.6 million.

**Table of Contents***May 7, 2013 Follow-on Underwritten Public Offering*

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

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

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 \$14.6 million.

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

The Company received approximately \$1,713,000 in proceeds from the exercise of warrants issued on May 7, 2013 to purchase 3,645,000 shares of common stock at an exercise price of \$0.47 per share during the three and nine months ended September 30, 2013.

**(5) 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 September 30, 2013 and December 31, 2012 consisted of cash and money market funds.

**(6) 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 No. 2011-04, Fair Value Measurement (Topic 820) (ASU No. 2011-04), which updated the previous fair value measurement guidance that had been included in the Accounting Standards Codification (ASC) to achieve common fair value measurement and disclosure requirements in U.S. GAAP and International Financial Reporting Standards.

**Table of Contents**

The table below presents the assets and liabilities measured and recorded in the financial statements at fair value on a recurring basis at September 30, 2013 and December 31, 2012 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)
<b>September 30, 2013</b>				
Assets				
Money market fund	\$ 38,720	\$ 38,720	\$	\$
Total assets	\$ 38,720	\$ 38,720	\$	\$
Total liabilities	\$	\$	\$	\$
<b>December 31, 2012</b>				
Assets				
Money market fund	\$ 9,990	\$ 9,990	\$	\$
Total assets	\$ 9,990	\$ 9,990	\$	\$
Total liabilities	\$	\$	\$	\$

The Level 1 assets consist of money market funds, which are actively traded daily. Although the Company did not have any Level 2 assets at September 30, 2013 or December 31, 2012, Level 2 assets typically consist of corporate bond investments whose fair value 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. Since these prices may not represent 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.

**(7) Property and Equipment**

At September 30, 2013 and December 31, 2012, net property and equipment at cost consisted of the following:

(In thousands)	September 30, 2013	December 31, 2012
Leasehold improvements	\$ 525	\$ 525

Laboratory equipment and other	2,850	2,856
Total property and equipment, at cost	3,375	3,381
Less: accumulated depreciation	3,259	3,163
Property and equipment, net	\$ 116	\$ 218

Depreciation expense was approximately \$31,000 and \$51,000 in the three months ended September 30, 2013 and 2012, respectively, and approximately \$106,000 and \$201,000 in the nine months ended September 30, 2013 and 2012, respectively.

#### **(8) Restricted Cash**

As part of the Company's lease arrangement for its office and laboratory facility, the Company is required to restrict \$311,000 of cash held in a certificate of deposit securing a line of credit for the lessor. During 2013, the \$311,000 was transferred from non-current assets to other current assets since the Company's lease term expires on May 31, 2014.

#### **(9) Collaboration and License Agreement**

In December 2006, the Company entered into an exclusive, worldwide license and research collaboration agreement with Merck & Co. to research, develop, and commercialize vaccine products containing the Company's TLR7, TLR8, and TLR9 agonists in the fields of cancer, infectious diseases, and Alzheimer's disease. Under the terms of the agreement, the Company granted Merck & Co. exclusive rights to a number of the Company's TLR7, TLR8, and TLR9 agonists for use in combination with Merck & Co.'s therapeutic and prophylactic vaccines under development in the fields of cancer, infectious diseases, and Alzheimer's disease. There is



**Table of Contents**

no limit under the agreement to the number of vaccines to which Merck & Co. can apply the Company's agonists within these fields. The Company also agreed with Merck & Co. to engage in a two-year research collaboration to generate novel agonists targeting TLR7 and TLR8 incorporating both Merck & Co. and the Company's chemistry for use in vaccines in the defined fields. Under the terms of the agreement, Merck & Co. extended the research collaboration for two additional years to December 2010. Under the terms of the agreement:

Merck & Co. paid the Company a \$20.0 million upfront license fee;

Merck & Co. purchased \$10.0 million of the Company's common stock at \$5.50 per share;

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

Merck & Co. agreed to pay the Company milestone payments as follows:

up to \$165.0 million if vaccines containing the Company's TLR9 agonist compounds are successfully developed and marketed in each of the oncology, infectious disease, and Alzheimer's disease fields;

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

if Merck & Co. develops and commercializes additional vaccines using the Company's agonists, the Company would be entitled to receive additional milestone payments; and

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

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

In December 2006, in connection with the execution of the license and collaboration agreement, the Company entered into a stock purchase agreement with Merck & Co. Pursuant to such stock purchase agreement, the Company issued and sold to Merck & Co. 1,818,182 shares of the Company's common stock for a price of \$5.50 per share resulting in aggregate gross proceeds of \$10.0 million.



**Table of Contents****(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. Prior to December 2011, the vesting of all of the Company's stock options was based on the passage of time and the employees' continued service. In December 2011 and January 2012, the Company granted performance-based stock options to purchase 697,500 shares of common stock to employees. As of the grant date of such options, options to purchase 174,375 shares were to vest immediately upon the achievement of various performance conditions and options to purchase 523,125 shares were to vest over a three year service period upon the achievement of the same performance conditions. During 2012, three of the specified performance conditions were achieved. As a result, options to purchase 80,213 shares vested immediately, and options to purchase 240,640 shares began vesting over a three-year period in accordance with the terms of the performance-based options. As of June 30, 2013, the remaining performance-based options were forfeited as the remaining performance conditions had not been met by their deadlines. The Company recognizes expense over the implicit and explicit service periods for awards with performance conditions when the Company determines the achievement of the performance conditions to be probable.

The Company recorded charges of \$476,000 and \$505,000 in its statements of operations and comprehensive loss for the three months ended September 30, 2013 and 2012, respectively, and \$994,000 and \$1,628,000 in its statements of operations and comprehensive loss for the nine months ended September 30, 2013 and 2012, 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 3,130,083 and 157,500 shares of common stock granted to employees and directors during the nine months ended September 30, 2013 and 2012, respectively:

	<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
Average risk free interest rate	1.3%	0.9%
Expected dividend yield		
Expected lives (years)	5.2	5.6
Expected volatility	62.0%	63.0%
Weighted average grant date fair value of options granted during the period (per share)	\$ 0.49	\$ 0.54
Weighted average exercise price of options granted during the period (per share)	\$ 0.92	\$ 0.97

**Table of Contents**

The expected lives and the expected volatility of the options are based on historical experience. All options granted during the nine months ended September 30, 2013 and 2012 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant.

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

For the three and nine months ended September 30, 2013 and 2012, 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 87,624,124 and 16,021,649 for the nine months ended September 30, 2013 and 2012, respectively, and consist of stock options, preferred stock and warrants.

For the three and nine months ended September 30, 2013, net loss per common share applicable to common stockholders reflects \$278,000 and \$837,000, respectively, in dividends accrued on shares of Series D preferred stock and Series E preferred stock. For the nine months ended September 30, 2013, net loss per common share applicable to common stockholders reflects \$1,750,000 related to the loss on extinguishment of the Series D preferred stock and the Series E preferred stock that the Company issued in November 2011 and November 2012, respectively, that has been charged to net loss applicable to common stockholders as a preferred stock dividend. For the three and nine months ended September 30, 2012, net loss per common share applicable to common stockholders reflects \$160,000 and \$480,000, respectively, in dividends accrued on shares of Series D preferred stock.

**(12) Stockholders' Equity**

During the nine months ended September 30, 2013, the Company issued 3,780,945 shares of common stock in connection with purchases under the Company's 1995 Employee Stock Purchase Plan (the "ESPP") and warrant and stock option exercises resulting in total proceeds to the Company of \$1,864,000.

During the nine months ended September 30, 2012, the Company issued 3,006 shares of common stock in connection with employee stock purchases under the ESPP, which resulted in total proceeds to the Company of \$3,000.

See Notes 3, 4 and 13 for more information on changes in stockholders' equity during the nine months ended September 30, 2013.

**Table of Contents**

**(13) Related Party Transactions**

In connection with the Company's follow-on underwritten public offering on May 7, 2013, the Company sold 5,000,000 shares of common stock and warrants to purchase 5,000,000 shares of common stock at \$0.47 per share for an aggregate purchase price of \$2,500,000 to Pillar Pharmaceuticals III, L.P. ( Pillar III ) and an entity affiliated with Pillar III (together with Pillar III, the Pillar III Entities ).

In connection with the Company's follow-on underwritten public offering on September 30, 2013, the Company sold 1,774,193 shares of common stock for an aggregate purchase price of \$2,750,000 to Pillar Pharmaceuticals IV, L.P. ( Pillar IV ) and an entity affiliated with Pillar IV (together with Pillar IV, the Pillar IV Entities ).

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

The Company issued 31,117 and 1,216 shares of common stock in lieu of director board and committee fees of approximately \$18,000 and \$1,000 pursuant to the Company's director compensation program during the nine months ended September 30, 2013 and 2012, respectively.

The Company paid a director consulting fees of approximately \$1,000 in the nine months ended September 30, 2012 for services performed in 2011. The Company did not pay consulting fees to directors during the three and nine months ended September 30, 2013 or the three months ended September 30, 2012.

See Note 3 for more information on related party transactions during the nine months ended September 30, 2013.

**(14) 2013 Annual Meeting of Stockholders**

At the Annual Meeting that took place on July 26, 2013, the Company's stockholders approved the following:

an amendment to the Company's restated certificate of incorporation to increase the number of authorized shares of common stock from 140,000,000 to 280,000,000;

a non-binding, advisory proposal on the compensation of the Company's named executive officers;

the Company's 2013 Stock Incentive Plan;

the ratification of the appointment of Ernst & Young LLP as the independent registered public accounting firm for the Company for the fiscal year ending December 31, 2013;

amendments (collectively the Series D Proposals ) to the Company s restated certificate of incorporation amending the Series D Certificate of Designations to:

provide that (a) the beneficial ownership limitation that prohibits the Company from paying a holder of the Company s Series D preferred stock dividends payable in shares of the Company s common stock to the extent the issuance of such shares would result in the holder of the Series D preferred stock and its affiliates beneficially owning more than 19.99% of the outstanding common stock (including shares of common stock issuable upon conversion of the Series D preferred stock) would be increased from 19.99% to 35% in the event that the Nasdaq Proposal (as defined below) was approved by the Company s stockholders and (b) the beneficial ownership limitation that prohibits a holder of Series D preferred stock from converting its shares to the extent such conversion would result in the holder and its affiliates beneficially owning more than 19.99% of the outstanding common stock (including shares of common stock issuable upon conversion of the Series D preferred stock) would be increased from 19.99% to 35% in the event that the Nasdaq Proposal was approved by the Company s stockholders;

eliminate the requirement that the Company pay corresponding dividends to the holders of Series D preferred stock upon payment of dividends to holders of the Company s Series E preferred stock;

change the date after which the Company may elect to pay dividends in shares of common stock from December 31, 2014 to October 1, 2013, and to allow for the payment of such dividends in shares of a to-be-created new series of

**Table of Contents**

non-voting preferred stock in the event that payment of such dividends may not be made in shares of common stock as a result of the application of the beneficial ownership limitation set forth in the Series D Certificate of Designations;

eliminate the right of holders of Series D preferred stock to receive, in the event of a liquidation, dissolution or winding up of the Company (a Liquidation ), an amount per share of Series D preferred stock equal to the original issue price of such share of Series D preferred stock plus any dividends accrued or declared but unpaid thereon to the extent such amount is greater than the amount that would have been payable with respect to such share had all shares of Series D preferred stock been converted into shares of common stock immediately prior to such Liquidation, such that upon a Liquidation the holders of Series D preferred stock will receive an amount per share of Series D preferred stock equal to the amount that would be payable with respect to such share had all shares of Series D preferred stock been converted into shares of common stock immediately prior to such Liquidation; and

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

amendments (collectively the Series E Proposals ) to the Company's restated certificate of incorporation amending the Series E Certificate of Designations to:

permit the Company to elect to pay dividends to the holders of Series E preferred stock in shares of common stock in lieu of cash beginning October 1, 2013, and to allow for the payment of such dividends in shares of a to-be-created new series of non-voting preferred stock in the event that payment of such dividends may not be made in shares of common stock as a result of the application of the beneficial ownership limitation set forth in the Series E Certificate of Designations; and

eliminate the right of the holders of Series E preferred stock to receive, in the event of a Liquidation, an amount per share of Series E preferred stock equal to the original issue price of such share of Series E preferred stock plus any dividends accrued or declared but unpaid thereon to the extent such amount is greater than the amount that would have been payable with respect to such share had all shares of Series E preferred stock been converted into shares of common stock immediately prior to such Liquidation, such that upon a Liquidation the holders of Series E preferred stock will receive an amount per share of Series E preferred stock equal to the amount that would be payable with respect to such share had all shares of Series E preferred stock been converted into shares of common stock immediately prior to such Liquidation.

The proposals submitted to the Company's stockholders at the Annual Meeting to (i) amend the Company's restated certificate of incorporation and bylaws to (a) declassify the Company's board of directors, (b) provide that the

Company's stockholders may remove directors with or without cause following declassification of the Company's board of directors and (c) eliminate the supermajority voting requirement for amending or repealing Article ELEVENTH of the Company's restated certificate of incorporation (collectively, the Declassification Proposal ) and (ii) approve the issuance and sale by the Company to certain affiliates of Pillar Invest Corporation (including prior issuances and sales of the Company's securities to such affiliates in November 2011 and November 2012) of a number of shares of the Company's common stock (including securities convertible into or exercisable for shares of the Company's common stock) that is greater than 19.99% of the total number of issued and outstanding shares of common stock and of the outstanding voting power of the Company's securities after such issuance and sale in accordance with Nasdaq Listing Rule 5635(b) (the Nasdaq Proposal ), were not approved by the Company's stockholders at the Annual Meeting.

As a result of the approval by the Company's stockholders of the Series D Proposals and Series E Proposals, certificates of amendment to the Series D Certificate of Designations and Series E Certificate of Designations were filed by the Company with the Delaware Secretary of State on July 26, 2013. Because the Nasdaq Proposal was not approved by the Company's stockholders, the beneficial ownership limitation applicable to the Series D preferred stock and Series E preferred stock set forth in the Series D Certificate of Designations and Series E Certificate of Designations, each as amended, will remain at 19.99% and the threshold above which the holders of the Series D preferred stock and Series E preferred stock must vote any shares held by them in the same manner and percentage as the holders of the Company's common stock vote on such matter, will remain at 19.99%.



**Table of Contents**

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

**GENERAL**

We are a clinical stage biotechnology company using our proprietary technology to create novel nucleic acid therapeutics designed to inhibit over-activation of Toll-like Receptors, or TLRs. We plan to develop and commercialize these therapeutics for the treatment of genetically defined forms of B-cell lymphoma and for orphan autoimmune diseases with serious unmet medical needs. We believe that clinical proof of concept of our approach of targeting specific TLRs for the treatment of psoriasis and potentially other autoimmune and inflammatory diseases has been established in a Phase 2 trial of one of our drug candidates.

Our lead drug candidate is IMO-8400, an antagonist for TLR7, TLR8, and TLR9 that is designed to block over-activation of the targeted TLRs. We have completed a Phase 1 clinical trial in 42 healthy subjects in which IMO-8400 was well tolerated and showed inhibition of TLRs 7, 8, and 9. Data from this trial was presented at the Federation of Clinical Immunology Societies meeting in June, 2013.

We are conducting a randomized, double-blinded, placebo-controlled Phase 2 clinical trial of IMO-8400 in patients with moderate to severe plaque psoriasis. The purpose of this study is to evaluate the clinical activity of IMO-8400 with a treatment period of up to 12 weeks. Under the protocol for this trial, 32 adult patients with moderate to severe plaque psoriasis, as indicated by a score of 12 or greater on the Psoriasis Area Severity Index, or PASI, were randomized 1:1:1:1 into one of four cohorts and assigned to receive placebo or weekly subcutaneous doses of IMO-8400 at a dose level of 0.075, 0.15, or 0.3 mg/kg/week for 12 weeks, with a six-week follow-up period. Safety and improvements in PASI score will be monitored throughout the trial. Patient enrollment in this clinical trial was initiated in the second quarter of 2013 and the last patient was enrolled in September 2013. While the dosing is ongoing and the data remain blinded, all treatments have been well tolerated to date. Based on the safety data to date, we have expanded the trial to include a higher dose cohort of 0.6 mg/kg or placebo with up to 12 patients. We plan to consider further dose escalation based on the safety and tolerability observed in the expansion cohort. We expect to have top-line data from this Phase 2 trial with respect to the first three dosing groups by the end of the first quarter of 2014 and data from the 0.6-mg/kg cohort by the end of the second quarter of 2014.

We have begun a strategic review of orphan autoimmune disease indications with unmet medical needs suited for TLR antagonist therapy, and expect to identify priority indications in early 2014.

We have also selected IMO-9200, 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 IND-enabling studies of IMO-9200, and we expect IMO-9200 would be available for clinical development in the second half of 2014.

We have initiated plans for clinical development of IMO-8400 for the treatment of genetically defined forms of B-cell lymphoma. We have submitted an Investigational New Drug application, or IND, to the United States Food and Drug Administration, or FDA, to conduct a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia. We anticipate initiating this trial in the first quarter of 2014. We also plan to submit in the first quarter of 2014 a protocol for a Phase 1/2 clinical trial of IMO-8400 in patients with diffuse large B-cell lymphoma, or DLBCL, that we expect to initiate in the first quarter of 2014.

We had cash and cash equivalents of approximately \$38,749,000 at September 30, 2013. We believe that our existing cash and cash equivalents will be sufficient to fund our operations at least through the second quarter of 2015. Specifically, we believe that our existing cash and cash equivalents will be sufficient to enable us to complete our

ongoing Phase 2 clinical trial of IMO-8400 in patients with psoriasis, our planned 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 our planned submission of an IND for IMO-9200. We will need to raise additional funds in order to conduct additional clinical development of IMO-8400, IMO-9200 or our other drug candidates or technologies.

***Program in Autoimmune and Inflammatory Disease.*** The Company has completed a randomized, double-blinded, placebo-controlled Phase 2 trial of IMO-3100, an antagonist of TLRs 7 and 9, in patients with plaque psoriasis. In this trial, patients were treated weekly for four weeks at two dose levels and placebo. Treatment with IMO-3100 was well tolerated and showed significant

---

**Table of Contents**

improvement in Psoriasis Area and Severity Index, or PASI, which correlated with down-regulation of the IL-17 pathway compared to placebo-treated patients. We believe that these results validate the clinical proof-of-concept of our therapeutic approach. In the second quarter of 2013, data from this study was presented at a scientific meeting. Based on our evaluation of the comparative profiles of IMO-3100 and IMO-8400, including the engagement of TLR8 by IMO-8400, we selected IMO-8400 for further clinical development.

We are conducting a randomized, double-blinded, placebo-controlled Phase 2 clinical trial of IMO-8400 in patients with moderate to severe plaque psoriasis. Enrollment in this study began in the second quarter of 2013 and the last patient was enrolled in September 2013. In this trial, patients are receiving treatment for 12 weeks. If successful, we believe that the results of this clinical trial will extend the clinical proof of concept established in our Phase 2 trial of IMO-3100 to a longer treatment duration. In this trial, we enrolled 32 patients who were randomized for treatment at three dose levels, 0.075 mg/kg, 0.15 mg/kg and 0.3 mg/kg, and in a placebo cohort. While the dosing is ongoing and the data remain blinded, all treatments have been well tolerated to date. Based on the safety data to date, we have expanded the trial to include a higher dose cohort of 0.6 mg/kg or placebo with up to 12 patients. We expect to have top-line data from this Phase 2 trial with respect to the first three dosing groups by the end of the first quarter of 2014 and data from the 0.6-mg/kg cohort by the end of the second quarter of 2014.

We have begun a strategic review of orphan autoimmune disease indications with unmet medical needs suited for TLR antagonist therapy, and expect to identify priority indications in early 2014 for which we may initiate clinical development of IMO-8400. We have selected IMO-9200, a novel antagonist of TLR7, TLR8, and TLR9, for development as a second drug candidate and may consider developing it with third parties for the treatment of autoimmune disease indications such as psoriasis, lupus and arthritis. In the fourth quarter of 2013, we initiated IND-enabling studies of IMO-9200 and, pending the results from these studies, anticipate that IMO-9200 would be available for clinical development in the second half of 2014.

***Program in Genetically Defined Forms of B-cell Lymphoma.*** We have initiated plans for clinical development of IMO-8400 for the treatment of genetically defined forms of B-cell lymphoma. This program is designed to leverage an emerging scientific understanding of the central role that TLR7 and TLR9 play in several forms of B-cell lymphoma with a specific mutation. Recent reports from independent investigators have provided evidence that in certain B-cell lymphomas the presence of a specific genetic mutation leads to over-activation of TLR7 and TLR9, and that blocking these TLRs leads to tumor cell death. This specific genetic mutation has been reported in several types of B-cell lymphomas, including Waldenström's macroglobulinemia and activated B-cell-like diffuse large B-cell lymphoma, or ABC-DLBCL. Waldenström's macroglobulinemia is a lymphoma that commonly involves the blood and bone marrow and may spread to almost any organ in the body, and approximately 90% of the patients are reported to have this specific genetic mutation. DLBCL is a fast-growing lymphoma that can arise in lymph nodes or outside of the lymphatic system, and approximately 30% of the patients with the ABC sub-type are reported to have the specific genetic mutation.

We have conducted preclinical studies in human lymphoma cells that have the specific genetic mutation. In these studies, we have observed that treatment with IMO-8400 led to cell death, decreased cytokine production, and decreased levels of cytokines and key components of signaling pathways. In addition, IMO-8400 monotherapy showed anti-tumor activity in a mouse model using human lymphoma cells that have the mutation. We believe that these observations provide the scientific rationale for clinical evaluation of IMO-8400 for the treatment of genetically defined forms of B-cell lymphoma.

We submitted an IND to the FDA in October 2013 to conduct a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia. The planned Phase 1/2 clinical trial is designed to evaluate safety and tolerability of IMO-8400 in dose-escalation cohorts and to evaluate the clinical activity in expansion cohorts at one or more dose

levels. We expect to initiate patient enrollment in this Phase 1/2 clinical trial in the first quarter of 2014.

We also plan to conduct a Phase 1/2 clinical trial of IMO-8400 in patients with diffuse large B-cell lymphoma, or DLBCL. We are designing the Phase 1/2 clinical trial to evaluate safety and tolerability of IMO-8400 in dose-escalation cohorts and to evaluate the clinical activity in expansion cohorts at one or more dose levels. We expect to enroll patients in the expansion cohorts based on the presence or absence of the specific genetic mutation. We anticipate submitting a protocol for this Phase 1/2 clinical trial and initiating enrollment in the first quarter of 2014.

Based on the Surveillance, Epidemiology, and End-Results, or SEER, Cancer Statistics Review, 1975-2001, from the National Cancer Institute's SEER database and published independent reports of the frequency of the specific genetic mutation among patients with B-cell lymphoma, and allowing for population growth, we estimate that there will be 1,200 patients with Waldenström's macroglobulinemia and 2,000 patients with ABC-DLBCL newly diagnosed in the United States per year. Based on this information, we also believe that at least 7,500 patients in the United States currently have B-cell lymphoma with the specific genetic mutation.

## **Table of Contents**

We believe Waldenström's macroglobulinemia and DLBCL are orphan indications with unmet medical need. There are currently no drugs specifically approved for the treatment of Waldenström's macroglobulinemia or DLBCL. Currently, patients with any form of non-Hodgkin lymphoma are most often treated with the monoclonal antibody rituximab and/or with one or more chemotherapeutic agents.

If we observe a therapeutic effect in either or both of these 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 they will receive regulatory approval or if we will be able to participate in FDA expedited review and approval programs, including breakthrough and fast track designation.

In July 2013, we entered into a materials cooperative research and development agreement, or M-CRADA, with the National Cancer Institute, or NCI, to evaluate our TLR antagonists as a potential approach for the treatment of certain genetically defined B-cell lymphomas. Work under this agreement is proceeding both at the NCI and within Idera.

***Gene Silencing Oligonucleotides.*** We have created gene silencing oligonucleotides, or GSOs, which are designed to inhibit the production of disease-associated proteins by targeting RNA, and have received US patent coverage for this technology. Preclinical proof of concept of our GSO technology has been established with multiple therapeutic targets. We believe our GSO technology provides us with a platform from which drug candidates for multiple disease indications can be developed. We are currently undertaking an analysis of priority indications and development strategies to determine next steps in development of this technology.

At September 30, 2013, we had an accumulated deficit of \$406,794,000. 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 to comply with comprehensive regulatory requirements.

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

This management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. 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, 2012. Not all of these significant policies, however, fit the definition of critical accounting policies and estimates. We believe that our accounting policies relating to revenue recognition, 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, 2012, fit the description of critical accounting estimates and judgments. There were no changes in these policies during the nine months ended September 30, 2013, except that irrevocable waivers by Pillar Pharmaceuticals I, L.P., or Pillar I, Pillar Pharmaceuticals II, L.P., or Pillar II, and an entity affiliated with Pillar I and Pillar II, together with Pillar I and Pillar II, the Pillar Entities, of the Series D preferred stock redemption rights and the Series D preferred stock and Series E preferred stock liquidation preferences, which became effective when we completed a qualified financing on May 7, 2013, required us to reassess our accounting in May 2013 for our Series D preferred stock and our Series E preferred stock.

**Table of Contents**

Since Pillar I irrevocably waived and agreed to not exercise the Series D Redemption Rights, we reassessed our accounting for the Series D preferred stock, which had been classified as temporary equity in our condensed balance sheet because the Series D Redemption Rights represented a contingent put feature that was outside our control. Since Pillar I irrevocably waived its Series D Redemption Rights, the contingent put feature ceased to exist at the time that Pillar I's waiver of the Series D Redemption Rights became effective. In addition, the Pillar Entities irrevocably waived the liquidation preferences of both the Series D preferred stock and the Series E preferred stock. We concluded that these irrevocable waivers of the Series D Redemption Rights and the Series D and Series E liquidation preferences, which became effective when we consummated a follow-on underwritten public offering of our common stock on May 7, 2013, represented changes to the fundamental terms of both the Series D preferred stock and the Series E preferred stock. As a result, we accounted for these irrevocable waivers as an extinguishment of the Series D preferred stock and the Series E preferred stock and changed the classification of the Series D preferred stock from temporary equity to permanent equity. We compared (1) the sum of the fair values of the Series D preferred stock, the Series E preferred stock and the Pillar Warrants immediately after the effectiveness of the waivers to (2) the sum of the carrying values of the Series D preferred stock and Series E preferred stock immediately prior to the effectiveness of the waivers on May 7, 2013. We recorded the excess of the aggregate fair value of the preferred stock plus the Pillar Warrants immediately after the effectiveness of the waivers over the aggregate carrying value of the preferred stock immediately prior to May 7, 2013 as a loss on extinguishment and classified the fair values, immediately after the effectiveness of the waivers, of the Series D preferred stock, the Series E preferred stock and the Pillar Warrants within permanent equity on our condensed balance sheet.

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

**RESULTS OF OPERATIONS*****Three and Nine Months Ended September 30, 2013******Alliance Revenue***

Alliance revenue consisted primarily of reimbursement by licensees of costs associated with patent maintenance, amounting to \$7,000 and \$3,000 in the three months ended September 30, 2013 and 2012, respectively, and \$43,000 and \$40,000 in the nine months ended September 30, 2013 and 2012, respectively.

***Research and Development Expenses***

Research and development expenses decreased by \$768,000, or 23%, from \$3,278,000 for the three months ended September 30, 2012, to \$2,510,000 for the three months ended September 30, 2013. Research and development expenses decreased by \$3,760,000 or 35% from \$10,595,000 for the nine months ended September 30, 2012 to \$6,835,000 for the nine months ended September 30, 2013. In the following table, research and development expense is set forth in the following four categories which are discussed beneath the table:

	Three Months Ended September 30, 2013			Three Months Ended September 30, 2012			Nine Months Ended September 30, 2013			Nine Months Ended September 30, 2012		
	(in thousands)		Percentage Increase (Decrease)	(in thousands)		Percentage Increase (Decrease)	(in thousands)		Percentage Increase (Decrease)	(in thousands)		Percentage Increase (Decrease)
	2013	2012		2013	2012		2013	2012		2013	2012	
IMO-8400 external development expense	\$ 922	\$	%	\$ 2,118	\$	%						
IMO-3100 external development expense	43	761	(94)%	334	1,809	(82)%						
Other drug development expense	673	1,328	(49)%	1,908	4,667	(59)%						
Basic discovery expense	872	1,189	(27)%	2,475	4,119	(40)%						
	\$ 2,510	\$ 3,278	(23)%	\$ 6,835	\$ 10,595	(35)%						



---

**Table of Contents**

*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 \$2,607,000 in external development expenses through September 30, 2013, 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, and additional nonclinical studies. We classified the IMO-8400 external development expenses incurred prior to October 2012 as Other Drug Development Expenses.

We expect our external development expenses to increase when we initiate separate Phase 1/2 clinical trials of IMO-8400 in patients with Waldenström's macroglobulinemia and in patients with diffuse large B-cell lymphoma under an IND that we submitted to the FDA in the fourth quarter of 2013.

*IMO-3100 External Development Expenses.* These expenses include external expenses that we have incurred in connection with IMO-3100 since November 2009, when we commenced clinical development of IMO-3100. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-3100 clinical development but exclude internal costs such as payroll and overhead expenses. We incurred approximately \$10,278,000 in external development expenses from November 2009 through September 30, 2013, including costs associated with our clinical trials, manufacturing and process development activities related to the production of IMO-3100, and additional nonclinical toxicology studies.

IMO-3100 expenses during both the three and nine months ended September 30, 2013 and the three and nine months ended September 30, 2012 related primarily to our Phase 2 clinical trial to evaluate IMO-3100 in patients with psoriasis over a four-week period. The costs related to our Phase 2 clinical trial were lower in the three and nine months ended September 30, 2013, as compared to the three and nine months ended September 30, 2012. In the three and nine months ended September 30, 2013, IMO-3100 expenses consisted of payments to the central laboratory for immunological analysis of RNA isolated from clinical samples, data analysis and trial close-out activities. In the three and nine months ended September 30, 2012, our costs were related to our preparation for and conduct of our Phase 2 clinical trial of IMO-3100 that we initiated in April 2012.

Based on our evaluation of the comparative profiles of IMO-3100 and IMO-8400, including the engagement of TLR8 by IMO-8400, we determined to focus our resources on the development of IMO-8400 and to conduct the 12-week clinical trial in patients with psoriasis with IMO-8400. As a result, we do not anticipate incurring material external development expenses with respect to IMO-3100 in future periods.

*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 associated with products in clinical development include costs associated with our Autoimmune Disease Scientific Advisory Board. These expenses also include external expenses associated with our selection of IMO-9200, a novel antagonist of TLR7, TLR8, and TLR9, for development as a drug candidate for additional autoimmune disease indications such as psoriasis, lupus and arthritis, for which we have initiated IND-enabling studies to support the submission of an IND in the third quarter of 2014.

The decreases in other drug development expenses in the three and nine months ended September 30, 2013, as compared to the three and nine months ended September 30, 2012, was primarily due to costs incurred during the three and nine months ended September 30, 2012 for nonclinical safety studies and manufacture of drug supply to support the IND for IMO-8400 that we submitted during the third quarter of 2012. Costs associated with the clinical development of IMO-8400 are included in IMO-8400 External Development Expenses in the three and nine months ended September 30, 2013.

*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 gene silencing oligonucleotides. These expenses reflect payments for laboratory supplies, external research, and professional fees, as well as payroll and overhead expenses. The decrease in basic discovery expenses in the three and nine months ended September 30, 2013, as compared to the three and nine months ended September 30, 2012, was primarily due to a decrease in the cost of employee compensation reflecting reduced activity and reduced headcount resulting from our September 2011 re-assessment and prioritization of our drug development programs. The decrease in basic discovery expenses in the nine months ended September 30, 2013, as compared to the nine months ended September 30, 2012, was also due to a decrease in the cost of laboratory supplies.

---

**Table of Contents**

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 outcome of our ongoing Phase 2 clinical trial of IMO-8400 in patients with moderate to severe plaque psoriasis, our planned 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 our IND-enabling studies 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 \$702,000, or 48%, from \$1,477,000 in the three months ended September 30, 2012, to \$2,179,000 in the three months ended September 30, 2013 and increased by \$291,000, or 6%, from \$5,014,000 in the nine months ended September 30, 2012 to \$5,305,000 in the nine months ended September 30, 2013. 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 September 30, 2013, as compared to the three months ended September 30, 2012, was primarily due to consulting fees associated with business and strategic initiatives during 2013. Stock compensation cost also increased during the three months ended September 30, 2013 due to stock options granted during the quarter.

The increase in general and administrative expenses during the nine months ended September 30, 2013, as compared to the nine months ended September 30, 2012, was primarily due to consulting fees associated with business and strategic initiatives during 2013. Corporate legal expenses associated with our corporate regulatory filing requirements also increased during the nine months ended September 30, 2013. The increase in general and administrative expenses was partially offset by lower legal costs associated with patent matters and lower stock compensation cost during the nine months ended September 30, 2013.

*Decrease (Increase) in Fair Value of Warrant Liability*

During November 2011 we recorded a warrant liability reflecting the fair value of the Series D warrants issued in our November 2011 Series D financing. We determined the Series D warrants to be a derivative instrument because they contained a specified anti-dilution provision that did not meet the indexed to the company's own stock exemption requirements in Accounting Standards Codification 815-40, Derivatives and Hedging Contracts in an Entity's own Stock, ASC 815-40. The Series D warrants were classified as a liability, recorded at fair value as of the transaction date and marked to fair value through earnings each quarter. The fair value of the warrants decreased from \$1,181,000 at June 30, 2012 to \$1,072,000 at September 30, 2012 primarily due to decreases in the market price of our common stock and the remaining term of the warrants resulting in the recognition of \$109,000 in non-operating income during the three months ended September 30, 2012. The fair value of the warrants decreased from \$1,178,000 at December 31, 2011 to \$1,072,000 at September 30, 2012 primarily due to decreases in the market price of our common stock and the remaining term of the warrants, which resulted in the recognition of \$106,000 of non-operating income during the nine months ended September 30, 2012.

The sale of shares of Series E preferred stock and Series E warrants in our November 2012 Series E financing triggered an anti-dilution adjustment under the terms of the Series D warrants, resulting in the exercise price of the

Series D warrants being reduced and fixed at the minimum \$1.46 per share and the Series D warrants no longer being subject to any anti-dilution adjustments. Once the exercise price of the Series D warrants became fixed, the Series D warrants then met the exception under ASC 815-40 as they were now indexed to the company's own stock and met certain criteria for equity classification, thus we marked the Series D warrants to fair value through earnings as of November 9, 2012, and we then reclassified the remaining \$503,000 Series D warrant liability to stockholders equity at that time. Consequently, we did not record any non-operating income or expense related to the Series D warrants during the three and nine months ended September 30, 2013.

*Investment Income, Net*

Investment income, net amounted to \$2,000 in each of the three months ended September 30, 2013 and 2012 and \$6,000 and \$8,000 in the nine months ended September 30, 2013 and 2012, respectively.

*Foreign Currency Exchange (Loss) Gain*

Our foreign currency exchange loss was \$58,000 and \$28,000 in the three months ended September 30, 2013 and 2012, respectively, and \$45,000 during the nine months ended September 30, 2013 primarily due to the impact that the decreasing value of the U.S. dollar had on our Euro-denominated accrued liabilities during these periods. Our foreign currency exchange gain was \$13,000 in the nine months ended September 30, 2012 primarily due to the impact that the increasing value of the U.S. dollar had on our Euro-denominated accrued liabilities during this period.

## **Table of Contents**

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

The \$278,000 in preferred stock dividends in the three months ended September 30, 2013 consists of \$174,000 in dividends accrued on shares of our Series D preferred stock and \$104,000 in dividends accrued on shares of our Series E preferred stock. The \$2,587,000 in preferred stock dividends in the nine months ended September 30, 2013 consists of \$1,750,000 related to the loss on extinguishment, of the Series D preferred stock that we issued in November 2011 and the Series E preferred stock that we issued in November 2012, that we have charged to net loss applicable to common stockholders as a preferred stock dividend, as described in Note 3 of the notes to our condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, \$596,000 in dividends accrued on shares of our Series D preferred stock and \$241,000 in dividends accrued on shares of our Series E preferred stock. The \$160,000 and \$480,000 in preferred stock dividends in the three and nine months ended September 30, 2012, respectively, consists of dividends accrued on shares of our Series D preferred stock. The dividends accrued on shares of Series D preferred stock increased in the three and nine months ended September 30, 2013, as compared to the three and nine months ended September 30, 2012, respectively, because the terms of the Series D preferred stock required that dividends that we accrued, up to July 26, 2013, on the Series E preferred stock also be accrued on the Series D preferred stock on an as-converted to common stock basis. As a result of the approval of amendments to the dividend provisions of the Series D Certificate of Designations at our 2013 annual meeting of stockholders, or the Annual Meeting, effective July 26, 2013, dividends accrued on the Series E preferred stock are no longer required to be accrued on the Series D preferred stock.

### *Net Loss Applicable to Common Stockholders*

As a result of the factors discussed above, our net loss applicable to common stockholders was \$5,016,000 for the three months ended September 30, 2013, compared to \$4,829,000 for the three months ended September 30, 2012 and \$14,723,000 for the nine months ended September 30, 2013 compared to \$15,922,000 for the nine months ended September 30, 2012. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through September 30, 2013, we incurred losses of \$146,601,000. 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 \$406,794,000 through September 30, 2013. 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:

equity and debt financing;

license fees, research funding and milestone payments under collaborative and license agreements;

interest income; and

lease financings.

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

On September 30, 2013, we closed a follow-on underwritten public offering, in which we sold 13,727,251 shares of common stock at \$1.55 per share and pre-funded warrants to purchase up to 4,175,975 shares of common stock at \$1.54 per share for aggregate gross proceeds of \$27.7 million. The pre-funded warrants have an exercise price of \$0.01 per share and will expire if not exercised by September 30, 2020. The 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 \$25.6 million.

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

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

**Table of Contents**

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

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 \$14.6 million.

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

We received approximately \$1,713,000 in proceeds from the exercise of May 7, 2013 warrants to purchase 3,645,000 shares of common stock during the three and nine months ended September 30, 2013.

*Series E Preferred Stock and Warrant Financing*

In November 2012, we entered into a Convertible Preferred Stock and Warrant Purchase Agreement, or Series E Purchase Agreement, for the issuance and sale of shares of Series E preferred stock and Series E warrants, with Pillar II and a second purchaser, or the Series E purchasers. Pillar II is an investment partnership managed by two of our directors and one of our significant stockholders. Under the Series E Purchase Agreement, we issued and sold to the Series E purchasers, for an aggregate purchase price of approximately \$7.0 million, 424,242 shares of Series E preferred stock and Series E warrants to purchase up to 8,484,840 shares of common stock. The shares of Series E preferred stock are convertible, subject to limitations, into an aggregate of 8,484,840 shares of common stock at a conversion price of \$0.70 per share. The initial exercise price of the Series E warrants is \$0.70 per share. The Series E warrants may not be exercised with respect to any portion of the Series E warrants, to the extent that such exercise would result in a Series E purchaser and its affiliates beneficially owning more than 19.99% of the number of shares of 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 the Series E warrants. Subject to the foregoing, the warrants to purchase common stock are exercisable immediately, and will expire if not exercised on or prior to November 9, 2017. We agreed to pay to the Series E preferred stockholders quarterly dividends payable in cash in arrears at the rate of 4.6% per annum with the first dividend payment being due on March 31, 2013. Under the terms of the Series D preferred stock, prior to the Annual Meeting, any dividends that we paid on the Series E preferred stock were also to be paid on the Series D preferred stock on an as-converted to common stock basis. As a result of the approval of amendments to the dividend provisions of the Series D Certificate of Designations at the Annual Meeting, effective July 26, 2013, the Series E preferred stockholders are entitled to receive dividends payable in cash quarterly in arrears at the rate of 8% per annum and dividends accrued on the Series E preferred stock are no longer required to be paid on the Series D preferred stock. The net proceeds to us from the Series E financing,

excluding the proceeds of any future exercise of the Series E warrants, were approximately \$5.9 million.

Under the terms of the Series E Purchase Agreement, we granted the Series E purchasers participation rights in future financings.

Also under the terms of the Series E Purchase Agreement, each Series E purchaser agreed:

for so long as the Series E purchaser and its affiliates beneficially own more than 19.99% or 25% (if, at the Annual Meeting, our stockholders had approved the proposal allowing us to issue and sell to Pillar II (together with all prior issuances and sales to Pillar I) a number of shares of common stock (including securities converted into or exercisable for common stock) that is greater than 19.99% of our outstanding common stock or the combined voting power of all of our securities then outstanding after such issuance and sale in accordance with Nasdaq Listing Rule 5635(b), or the Nasdaq Proposal) of our outstanding common stock, that the Series E purchaser and its affiliates will vote any shares held by



**Table of Contents**

them in excess of the number of shares equal to 19.99% or 25%, as applicable, of the outstanding common stock (including the shares of common stock issuable upon conversion or exercise of securities that are convertible into or exercisable for shares of common stock held by such Series E purchaser and its affiliates) with respect to any matter put to a vote of the holders of common stock in the same manner and percentage as the holders of the common stock (other than the Series E purchasers) vote on such matter;

to certain restrictions on the transfer of any securities issued to such Series E purchaser pursuant to the Series E Purchase Agreement, including to not sell or transfer any such securities in one or a series of transactions if such transfer would, in the aggregate, result in the transfer more than 5% of the then outstanding combined voting power of our outstanding securities (excluding from this restriction certain transfers to permitted transferees or in connection with an underwritten public offering by us that has been approved by the board of directors); and

to be subject to a standstill provision that continues for so long as such Series E purchaser and its affiliates beneficially own more than 15% of our outstanding common stock.

After the later of November 9, 2014 and the date that no shares of Series D preferred stock remain outstanding, we may redeem all or a portion of the Series E preferred stock for a cash payment equal to the \$14.00 original Series E preferred stock issue price per share plus any accrued or declared but unpaid dividends thereon following notice to the holders of the Series E preferred stock if the closing price of the Common Stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to \$2.80, which amount represents 400% of the Series E preferred stock conversion price. We may not redeem any shares of Series E preferred stock from a holder that cannot convert such shares of Series E preferred stock into common stock as a result of the beneficial ownership limitations described above. In such event, we may redeem such nonredeemable shares pursuant to alternative redemption provisions set forth in the Series E Certificate of Designations following notice to the holders of the nonredeemable shares, for a cash payment equal to the greater of the 20 consecutive trading day average closing price per share of the common stock ending on the trading day immediately prior to redemption date plus any dividends accrued or declared but unpaid thereon and the Series E conversion price plus any dividends accrued or declared but unpaid thereon. After November 9, 2014, we may redeem the Series E warrants for \$0.01 per share of common stock issuable on exercise of the Series E warrants following notice to the Series E purchasers if the closing price of the common stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to \$2.80, subject to adjustment.

In connection with the Series E Purchase Agreement, we filed a registration statement that became effective on January 17, 2013, registering the resale of the shares of common stock issuable upon conversion of the Series E preferred stock and the shares of common stock issuable upon exercise of the Series E warrants.

In April 2013, the Company entered into two agreements, which we refer to collectively as the Pillar Agreements, with the Pillar Entities. The agreements, including our obligations to issue the warrants under the Pillar Agreements, became effective upon the consummation of our follow-on underwritten public offering of our securities on May 7, 2013.

Under the first agreement, which we refer to as the April 22, 2013 Pillar Agreement, we agreed to seek and each of Pillar I and Pillar II agreed to vote in favor of, amendments to the Series E Certificate of Designations to:

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

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

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

## Table of Contents

In accordance with the terms of the Pillar Agreements, we sought approval from our stockholders of amendments to the Series E Certificate of Designations to effect the above described changes to the dividend and liquidation provisions of our Series E preferred stock. These amendments were approved at the Annual Meeting that took place on July 26, 2013. Additional information on the proposals that were approved by our stockholders at the Annual Meeting is included in Note 14 of the notes to our financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

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

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

In connection with the Pillar Agreements, we filed a registration statement that became effective on July 10, 2013, registering the resale of the shares of common stock issuable upon exercise of the Pillar warrants to purchase 2,000,000 shares of our common stock.

### *Series D Preferred Stock and Warrant Financing*

In November 2011, we entered into a Convertible Preferred Stock and Warrant Purchase Agreement, or Series D Purchase Agreement, with Pillar I. The Series D Purchase Agreement was amended in November 2012 in connection with the Series E financing. Under the Series D Purchase Agreement, we issued and sold to Pillar I, for an aggregate purchase price of \$9,500,000, 1,124,260 shares of our Series D preferred stock and Series D warrants to purchase up to 2,810,650 shares of our common stock. The shares of Series D preferred stock were initially convertible, subject to limitations, into 5,621,300 shares of our common stock at an initial conversion price of \$1.63. The initial exercise price of the warrants was \$1.63 per share.

The net proceeds to us from the offering, excluding the proceeds of any exercise of the Series D warrants, were approximately \$9,073,000. No holder of the Series D preferred stock may convert its shares to the extent such conversion would result in the holder and its affiliates beneficially owning more than 19.99% of the common stock outstanding. As a result of the dilutive effect of our November 2012 Series E financing, the 1,124,260 shares of our Series D preferred stock became convertible, subject to limitations, into 6,266,175 shares of our common stock and the exercise price of the Series D warrants became fixed at \$1.46 per share.

The Series D Purchase Agreement was amended in connection with the Series E financing to provide:

for so long as Pillar I and its affiliates beneficially own more than 19.99% or 25% (in the event that our stockholders had approved the Nasdaq Proposal at the Annual Meeting) of the outstanding common stock, that Pillar I and its affiliates will vote any shares held by them in excess of the number of shares equal to 19.99% or 25%, as applicable, of the outstanding common stock (including the shares of common stock issuable upon conversion of securities convertible into or exercisable for shares of common stock held by

Pillar I and its affiliates) with respect to any matter put to a vote of the holders of common stock in the same manner and percentage as the holders of the common stock (other than the Series E purchasers and their affiliates) vote on such matter; and

for certain restrictions on the transfer of any securities issued to Pillar I (including securities convertible into or exercisable for common stock) pursuant to the Series D Purchase Agreement, including to not sell or transfer any such securities in one or a series of transactions if such transfer would, in the aggregate, result in the transfer of more than 5% of the then outstanding combined voting power of the outstanding securities of the Company (excluding from this restriction certain transfers to permitted transferees or in connection with an underwritten public offering by the Company that has been approved by our board of directors).

The Series D preferred stockholders are entitled to receive dividends payable quarterly in arrears at the rate of 7% per annum. Such dividends shall be paid in cash through December 31, 2014 and thereafter in cash or with shares of common stock, as determined by us in our sole discretion, except that we may not pay any dividends to a holder of Series D preferred stock in shares of common stock to the extent the issuance of such shares would result in the holder of Series D preferred stock and its affiliates beneficially owning more than 19.99% of the common stock outstanding or the combined voting power of our securities outstanding immediately after giving effect to the issuance of such shares of common stock. Under the Series E Certificate of Designations we are required to pay to the Series E preferred stockholders quarterly dividends payable in cash in arrears at the rate of 8.0% per annum. Prior to the approval of amendments to the dividend provisions of the Series D Certificate of Designations at the Annual Meeting, any dividends that we paid to the Series E preferred stockholders were also required to be paid to the Series D preferred stockholders on an as-converted to common stock basis. As a result of the approval of amendments to the dividend provisions of the Series D Certificate of Designations at the Annual Meeting, effective July 26, 2013, the Series D preferred stockholders are no longer entitled to corresponding dividends.

## **Table of Contents**

After November 4, 2013 and following written notice by us, we may redeem, for a cash payment equal to the \$8.1375 original Series D preferred stock issue price per share plus any accrued or declared but unpaid dividends thereon, all or a portion of the Series D preferred stock if the closing price of our common stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to 200% of the Series D preferred stock conversion price. In addition, the holders of shares of Series D preferred stock then outstanding are entitled to require us to purchase the shares of Series D preferred stock at a price equal to the original Series D preferred stock purchase price per share plus all accrued or declared but unpaid dividends thereon upon the occurrence of specified fundamental changes such as mergers, consolidations, business combinations, stock purchases or similar transactions resulting in a person or group unaffiliated with any holder of Series D preferred stock owning 66.67% or more of the outstanding voting securities of the Company or successor entity.

Under the terms of the Series D Purchase Agreement, Pillar I agreed to be subject to a standstill provision that continues for so long as Pillar I and its affiliates beneficially own more than 15% of our outstanding common stock.

The sale of shares of Series E preferred stock and Series E warrants in our November 2012 Series E financing triggered an anti-dilution adjustment under the terms of the Series D warrants, resulting in the exercise price of the Series D warrants being reduced and fixed at the minimum \$1.46 per share and the Series D warrants no longer being subject to any anti-dilution adjustments. The Series D warrants may be exercised at Pillar I's option at any time on or before November 4, 2016. The Series D warrants, as amended in connection with the November 2012 Series E financing, provide that the Series D warrants may not be exercised with respect to any portion of the warrants, to the extent that such exercise would result in Pillar I and its affiliates beneficially owning more than 19.99% of the number of shares of 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 the Series D warrants. After November 4, 2013, we may redeem the Series D warrants for \$0.01 per share of common stock issuable on exercise of the Series D warrants following notice to Pillar I if the closing price of the common stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to \$6.51, subject to adjustment.

In connection with the Series D Purchase Agreement, we also filed a registration statement that became effective on December 21, 2011, registering the resale of the shares of common stock issuable upon conversion of the Series D preferred stock and the shares of common stock issuable upon exercise of the Series D warrants. In February 2013, we filed a registration statement that became effective on February 8, 2013 covering the resale of additional shares of common stock issuable upon conversion of the Series D preferred stock.

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

In addition, under the April 22, 2013 Pillar Agreement, we agreed to seek approval and each of Pillar I and Pillar II agreed to vote in favor, of amendments to the Series D Certificate of Designations to:

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

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

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

## **Table of Contents**

Series D preferred stock will receive an amount per share of Series D preferred stock equal to the amount that would be payable with respect to such share had all shares of Series D preferred stock been converted into shares of our common stock immediately prior to such Liquidation.

In accordance with the terms of the Pillar Agreements, we sought approval from our stockholders of amendments to the Series D Certificate of Designations to effect the above described changes to the dividend and liquidation provisions of our Series D preferred stock, the redemption rights of the holders of our Series D preferred stock and the rights of the holders of our Series D preferred stock to distributions in the event of a sale of our company. These amendments were approved at the Annual Meeting that took place on July 26, 2013. Additional information on the amendments to the Series D Certificate of Designations that were approved by our stockholders at the Annual Meeting is included in Note 14 of the notes to our financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

The Pillar Agreements, including our obligations to issue the Pillar Warrants under the Pillar Agreements, became effective upon the consummation of our follow-on underwritten public offering of our securities on May 7, 2013.

### *Cowen Sales Agreement*

In April 2012, we entered into a sales agreement with Cowen pursuant to which we may issue and sell shares of our common stock, having an aggregate offering price of up to \$10.0 million from time to time through Cowen as our sales agent. Cowen may sell our common stock by methods deemed to be an at-the-market offering, as defined under the Securities Act, including sales made directly on the Nasdaq Capital Market, on any other existing trading market for our common stock or to or through a market maker other than on an exchange. With our prior written approval, Cowen may also sell our common stock by any other method permitted by law, including in privately negotiated transactions.

Cowen has agreed to offer the common stock subject to the terms and conditions of the sales agreement on a daily basis or as otherwise agreed upon by us and Cowen. Under the arrangement, we will designate the maximum amount of our common stock to be sold through Cowen on a daily basis or otherwise determine such maximum amount together with Cowen. Subject to the terms and conditions of the sales agreement, Cowen has agreed to use its commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us. We may instruct Cowen not to sell common stock if the sales cannot be effected at or above the price designated by us in any such instruction. We or Cowen may suspend the offering of the common stock being made through Cowen under the sales agreement upon proper notice to the other party. We and Cowen each have the right, by giving written notice as specified in the sales agreement, to terminate the sales agreement in each party's sole discretion at any time.

The sales agreement provides that Cowen will be entitled to aggregate compensation for its services equal to 3.0% of the gross sales price per share of all shares sold through Cowen under the sales agreement. We have no obligation to sell any shares under the sales agreement. We have agreed in the sales agreement to provide indemnification and contribution to Cowen against certain liabilities, including liabilities under the Securities Act. In addition, we have agreed, under certain circumstances, to reimburse a portion of the expenses of Cowen in connection with the offering of common stock up to a maximum of \$50,000. The shares will be issued pursuant to our shelf registration statement on Form S-3 (File No. 333-169060).

We had not sold any shares under the sales agreement as of October 31, 2013.

### *Collaboration Agreements*

Under the terms of our collaboration with Merck KGaA for developing TLR9 agonists for the treatment of cancer, 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. 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 September 30, 2013 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 September 30, 2013, we have paid 1.0 million of the 1.8 million (\$1.3 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 September 30, 2013 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.



## **Table of Contents**

Under the terms of our collaboration with Merck & Co., Merck & Co. paid us a \$20.0 million license fee in December 2006 and purchased 1,818,182 shares of our common stock for a price of \$5.50 per share for an aggregate purchase price of \$10.0 million. In addition, we received \$1.0 million in milestone payments and \$3.4 million in research and development payments.

### *Cash Flows*

#### *Nine Months Ended September 30, 2013*

As of September 30, 2013, we had approximately \$38,749,000 in cash and cash equivalents, a net increase of approximately \$28,653,000 from December 31, 2012. Net cash used in operating activities totaled \$12,675,000 during the nine months ended September 30, 2013, reflecting our \$12,136,000 net loss, as adjusted for non-cash income and expenses, including stock-based compensation and depreciation. Net cash used in operating activities also reflects changes in our prepaid expenses and accounts payable, accrued expenses and other liabilities.

The \$41,332,000 net cash provided by financing activities during the nine months ended September 30, 2013 primarily reflects \$40,538,000 in net proceeds from our equity financings, including our follow-on underwritten public offerings of our securities in May and September, 2013, and \$1,864,000 in net proceeds from the exercise of common stock options and warrants and employee stock purchases under our employee stock purchase plan which were partially offset by \$111,000 in costs related to the 2012 Series E financing that were paid in 2013 and dividends paid on our Series D preferred stock and our Series E preferred stock.

#### *Nine Months Ended September 30, 2012*

As of September 30, 2012, we had approximately \$8,352,000 in cash and cash equivalents, a net decrease of approximately \$16,219,000 from December 31, 2011. Net cash used in operating activities totaled \$15,795,000 during the nine months ended September 30, 2012, reflecting our \$15,442,000 net loss for the nine months ended September 30, 2012, as adjusted for non-cash income and expenses, including stock-based compensation, depreciation and the decrease in the warrant liability. It also reflects changes in our prepaid expenses and accounts payable, accrued expenses and a liability associated with recording rent expense on a straight-line basis over the term of our facility lease. The net cash used in financing activities totaled \$424,000 during the nine months ended September 30, 2012 representing the dividends paid on our Series D preferred stock and payments on our capital lease less the proceeds received from employee stock purchases under our employee stock purchase plan.

### *Funding Requirements*

We have incurred operating losses in all fiscal years except 2002, 2008 and 2009, and we had an accumulated deficit of \$406,794,000 at September 30, 2013. 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 October 31, 2013, 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 and cash equivalents of approximately \$38,749,000 at September 30, 2013. We believe that our existing cash and cash equivalents will be sufficient to fund our operations at least through the second quarter of 2015. Specifically, we believe that our existing cash and cash equivalents will be sufficient to enable us to complete our ongoing Phase 2 clinical trial of IMO-8400 in patients with psoriasis, our planned 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 our planned submission of an IND for IMO-9200. We will need to raise additional funds in order to conduct additional clinical development of IMO-8400, IMO-9200 or our other drug candidates or technologies.

## Table of Contents

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

the results of our clinical and preclinical development programs, including the results of our ongoing Phase 2 clinical trial of IMO-8400 in patients with moderate to severe plaque psoriasis that we initiated in June 2013 and the results of our planned Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia and our planned Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL;

the cost, timing and outcome of regulatory reviews;

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

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

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

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

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

### *Contractual Obligations*

During the three months ended September 30, 2013, 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, 2012.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Foreign currency exchange gains and losses may result from amounts to be paid under our Merck KGaA collaboration and termination agreements and payments under our clinical trial agreements that are denominated in Euros. As of September 30, 2013, we had net accrued obligations of 0.8 million (\$1.1 million using a September 30, 2013 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 September 30, 2013, all of our invested funds were invested in a money market fund classified in cash and cash equivalents on the accompanying balance sheet.

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.

**Table of Contents**

**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 Exchange Act) as of September 30, 2013. In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our chief executive officer and chief financial officer concluded that as of September 30, 2013, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our chief executive officer and chief financial officer by others, particularly during the period in which this report was prepared, and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

(b) *Changes in Internal Controls.* No change in our internal control over financial reporting occurred during the fiscal quarter ended September 30, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

**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 described below, together with all of 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 and cash equivalents of approximately \$38.7 million at September 30, 2013. We believe that our existing cash and cash equivalents will be sufficient to fund our operations at least through the second quarter of 2015. Specifically, we believe that our existing cash and cash equivalents will be sufficient to enable us to complete our ongoing Phase 2 clinical trial of IMO-8400 in patients with psoriasis, our planned 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 our planned submission of an IND for IMO-9200. We will need to raise additional funds in order to conduct additional clinical development of IMO-8400, IMO-9200 or our other drug candidates or technologies.

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

the results of our clinical and preclinical development programs, including the results of our ongoing Phase 2 clinical trial of IMO-8400 in patients with moderate to severe plaque psoriasis that we initiated in June 2013 and the results of our planned Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia and our planned Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL;

the cost, timing, and outcome of regulatory reviews;

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

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

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

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

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

## **Table of Contents**

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 September 30, 2013, we had an accumulated deficit of \$406.8 million. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 to September 30, 2013, we incurred losses of \$146.6 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 September 30, 2013, almost all of our revenues have been from collaborative and license agreements. We have devoted substantially all of our efforts to research and development, including clinical trials, and have not completed development of any drug candidates. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our drug candidates will become commercially available, or when we will become profitable, if at all. We expect to incur substantial operating losses in future periods.

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

We have received a report dated March 11, 2013 from Ernst & Young LLP, our independent registered public accounting firm, regarding our financial statements as of December 31, 2012 and for the fiscal year then ended, which included an explanatory paragraph stating that the financial statements were prepared assuming we will continue as a going concern. The report also stated that our recurring losses and negative cash flows from operations will require us to raise additional capital or obtain alternative means of financial support, or both, prior to December 31, 2013 in order to continue to fund our operations and that these factors raised substantial doubt about our ability to continue as a going concern. The going concern explanatory paragraph included in our auditor's report on our financial statements could inhibit our ability to finance our operations. We raised an aggregate of \$44.2 million in gross proceeds from follow-on underwritten public offerings of our securities on May 7, 2013 and September 30, 2013, increasing our cash resources sufficiently to fund our operations at least through the second quarter of 2015. We will need to raise substantial additional funds in order to conduct research and development, including preclinical testing and clinical trials of our drug candidates, and to fund our operations beyond such time. If we are unable to obtain adequate funding on a timely basis or at all, we will be required to terminate, modify or delay preclinical or clinical trials of one or more of our drug candidates, significantly curtail or terminate discovery or development programs for new drug candidates or relinquish rights to portions of our technology, drug candidates and/or products.

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

***We are depending heavily on the development of TLR-targeted drug candidates for the treatment of autoimmune and inflammatory diseases and certain genetically defined B-cell lymphomas. If we terminate the development of any of our programs or any of our drug candidates in such programs, are unable to successfully develop and commercialize any of our drug candidates, or experience significant delays in doing so, our business may be***



*materially harmed.*

We have invested a significant portion of our time and financial resources in the development of clinical stage lead drug candidates as part of our autoimmune and inflammatory disease program. In June 2013, we initiated a Phase 2 clinical trial in patients with psoriasis to, among other things, evaluate the clinical activity of IMO-8400 with a treatment period of up to 12 weeks. We expect to have top-line data from this Phase 2 trial with respect to the first three dosing groups by the end of the first quarter of 2014 and data from the 0.6-mg/kg cohort by the end of the second quarter of 2014.

In the future, we also intend to invest a significant portion of our time and financial resources in the development of IMO-8400 for the treatment of certain genetically defined forms of B-cell lymphomas.

We are planning to initiate a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia and a Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL in the first quarter of 2014. We have initiated IND-enabling studies of IMO-9200 and expect to submit an IND for IMO-9200 in the third quarter of 2014. We will need to raise additional funds in order to conduct additional clinical development of IMO-8400, IMO-9200 or our other drug candidates or technologies. We expect to seek such additional funding through public or private equity offerings, debt financings, collaborations and licensing arrangements, and other sources.

## **Table of Contents**

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

Our ability to generate product revenues under our collaboration with Merck Sharp & Dohme Corp. (formerly Merck & Co., Inc.), or Merck & Co., and under any other collaboration that we enter into with respect to our autoimmune disease program, will depend on the development and commercialization of the drug candidates being developed. Our efforts, and the efforts of Merck & Co., to develop and commercialize these compounds are at an early stage and are subject to many challenges. We have experienced setbacks with respect to our programs for IMO-3100, IMO-2125, and IMO-2055, including:

During the fourth quarter of 2010, we commenced additional nonclinical studies of IMO-3100 in light of some reversible immune responses that were observed in the 13-week nonclinical toxicology studies and that were inconsistent with observations made in our other nonclinical studies of IMO-3100. In June 2011, we submitted a Phase 2 protocol to the United States Food and Drug Administration, or FDA, to conduct a 12-week clinical trial of IMO-3100 in patients with psoriasis. In July 2011, the FDA placed a clinical hold on the protocol that we had submitted. In October 2011, we submitted to FDA a new Phase 2 protocol to evaluate IMO-3100 in adult patients with moderate to severe plaque psoriasis, over a four-week treatment period. In December 2011, the FDA removed the clinical hold. We subsequently initiated in the second quarter of 2012 the four-week Phase 2 clinical trial that we completed in the fourth quarter of 2012. We cannot be certain that the FDA will allow us to conduct further clinical trials of IMO-3100 for treatment periods of more than four weeks or at all without additional clinical or preclinical data.

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

In July 2011, Merck KGaA, Darmstadt, Germany, or Merck KGaA, informed us that, based on increased incidence of neutropenia and electrolyte imbalances reported in its Phase 1 trial of IMO-2055 in combination with cisplatin/5-FU and cetuximab in patients with first-line squamous cell carcinoma of the head and neck, or SCCHN, and subsequent re-evaluation of its clinical development program, Merck KGaA had determined that it would not conduct further clinical development of IMO-2055. In November 2011, as part of an agreed-upon termination of our collaboration with Merck KGaA, we regained global rights to IMO-2055 and our other TLR9 agonists, including preclinical lead drug candidates selected for further evaluation under the collaboration, for the treatment of cancer. In May 2012, we announced that in the Phase 2 trial of IMO-2055 in combination with cetuximab in patients with second-line SCCHN, the combination of IMO-2055 and cetuximab did not meet the primary endpoint of the trial.

We intend to seek to enter into collaborations with pharmaceutical companies to advance the use of our TLR antagonist product candidates. Our setbacks with respect to our programs for IMO-3100, IMO-2125, and IMO-2055 could negatively impact our ability to license any of such compounds to a third party.

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

the drug candidates demonstrating activity in clinical trials;

the drug candidates demonstrating an acceptable safety profile in nonclinical toxicology studies and during clinical trials;

timely enrollment in clinical trials of IMO-8400 and other drug candidates, which may be slower than anticipated, potentially resulting in significant delays;

satisfying conditions imposed on us and/or our collaborators by the FDA or equivalent foreign regulatory authorities regarding the scope or design of clinical trials;

**Table of Contents**

the ability to demonstrate to the satisfaction of the FDA, or equivalent foreign regulatory authorities, the safety and efficacy of the drug candidates through current and future clinical trials;

timely receipt of necessary marketing approvals from the FDA and equivalent foreign regulatory authorities;

the ability to combine our drug candidates and the drug candidates being developed by Merck & Co. and any other collaborators safely and successfully with other therapeutic agents;

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

establishment of commercial manufacturing arrangements with third-party manufacturers;

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

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

competition from other companies and their therapies;

changes in treatment regimens;

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

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

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

We are in the early stages of developing our program in genetically defined B-cell lymphomas, an area in which we have little experience. In connection with this program, we are focusing our efforts on the research and development of TLR antagonist product candidates for use in the treatment of certain genetically defined B-cell lymphomas. The scientific evidence to support the feasibility of developing product candidates for this use is both preliminary and limited. We have conducted preclinical studies in human lymphoma cell lines that carry the specific genetic mutation and have also entered into a M-CRADA with NCI to evaluate our TLR antagonists as a potential approach to the treatment of certain genetically defined B-cell lymphomas. Although the preliminary results of our preclinical studies have been promising, it is unknown whether these results are indicative of results that may be obtained in our planned clinical trials. Therefore, we do not know if our approach of inhibiting TLRs to treat patients with genetically defined

B-cell lymphomas will be successful or if we will ever succeed in obtaining regulatory approval to market any product for this purpose. In addition, in the event that our development efforts for such a product candidate progress towards commercialization, we will need to develop companion diagnostics for such product candidate. We have no experience in developing companion diagnostics and will be dependent on the efforts of third party collaborators to successfully develop and commercialize these companion diagnostics on our behalf.

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

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

**Table of Contents**

Patient enrollment is affected by other factors including:

the severity of the disease under investigation;

the eligibility criteria for the study in question;

the perceived risks and benefits of the TLR antagonist product candidates under study;

the efforts to facilitate timely enrollment in clinical trials;

the patient referral practices of physicians;

the ability to monitor patients adequately during and after treatment; and

the proximity and availability of clinical trial sites for prospective patients.

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

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

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

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

The results from preclinical testing of a drug candidate that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of

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

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

**Table of Contents**

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

manufacturing sufficient quantities of drug candidate that satisfy the required quality standards for use in clinical trials;

demonstrating sufficient safety to obtain regulatory approval for conducting a clinical trial;

reaching an agreement with any collaborators on all aspects of the clinical trial;

**Table of Contents**

reaching agreement with contract research organizations, if any, and clinical trial sites on all aspects of the clinical trial;

resolving any objections from the FDA or any regulatory authority on an Investigational New Drug application, or IND, or proposed clinical trial design;

obtaining IRB approval for conducting a clinical trial at a prospective site; and

enrolling patients in order to commence the clinical trial.

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

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

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

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

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

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

We are developing our TLR-targeted drug candidates for use in the treatment of autoimmune and inflammatory diseases and genetically defined B-cell lymphomas and for use as vaccine adjuvants. We have one drug candidate, IMO-8400, in clinical development in our autoimmune and inflammatory disease program. With respect to our

genetically defined B-cell lymphoma program we have conducted preclinical studies on and entered into a M-CRADA with NCI to evaluate our TLR antagonists as a potential approach to the treatment of certain genetically defined B-cell lymphomas, and plan to initiate a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia and a Phase 1/2 clinical trial of IMO-8400 in patients with DLBCL during the first quarter of 2014. We are also collaborating with Merck & Co. for the use of agonists of TLR7, TLR8, and TLR9 as vaccine adjuvants for cancer, infectious diseases and Alzheimer's disease. Finally, we are seeking to enter into collaborative alliances with pharmaceutical companies to advance our TLR-targeted programs in broader autoimmune disease indications, such as psoriasis, lupus and arthritis, as well as applications of our GSO technology platform. For all of these disease areas, there are many other companies, public and private, that are actively engaged in discovery, development, and commercializing products and technologies that may compete with our drug candidates and programs, including TLR targeted compounds as well as non-TLR targeted therapies.

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

## **Table of Contents**

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

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

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

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

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

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

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

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

We are a party to an employment agreement with Dr. Agrawal that expires on October 19, 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.

## **Table of Contents**

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

### **Regulatory Risks**

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

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

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

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

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

the regulatory agency's delay in approving, or refusal to approve, an application for marketing of a product or a supplement to an approved application;

restrictions on our products or the marketing or manufacturing of our products;

withdrawal of our products from the market;

warning letters;

voluntary or mandatory product recalls;

finest;

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.

## **Table of Contents**

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

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

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

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

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

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

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

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

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



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

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

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

**Table of Contents**

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

We plan to develop companion diagnostics for our TLR antagonist product candidates in our genetically defined B-cell lymphoma programs. We expect that, at least in some cases, the FDA and similar regulatory authorities outside the United States may require the development and regulatory approval of a companion diagnostic as a condition to approving our TLR antagonist product candidates specifically for the treatment of patients with a genetically defined B-cell lymphoma. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely on third parties or collaborators to perform these functions. To date, we have not entered into any agreements for the development or commercialization of companion diagnostics for use with any of our product candidates. However, we expect to enter into such agreements in the future with respect to our TLR antagonist product candidates in our genetically defined B-cell lymphoma programs. Companion diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval prior to commercialization.

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

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

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

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

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

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

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

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

We intend to market our products, if approved, in markets outside the United States, which will require separate regulatory approvals and compliance with numerous and varying regulatory requirements. The approval procedures

vary among such markets and may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all.

### **Risks Relating to Collaborators**

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

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

## **Table of Contents**

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

We may have difficulty establishing additional collaborative alliances, particularly with respect to our TLR-targeted drug candidates and technology. Potential partners may note that our TLR collaborations with Novartis and with Merck KGaA have been terminated. Potential partners may also be reluctant to establish collaborations with respect to IMO-2125, IMO-3100, IMO-2055, and our other TLR-targeted drug candidates, given our recent setbacks with respect to these drug candidates. We also face, and expect to continue to face, significant competition in seeking appropriate collaborators.

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

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

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

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

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

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

our collaborators may control the public release of information regarding the developments, and we may not be able to make announcements or data presentations on a schedule favorable to us;

disputes may arise in the future with respect to the ownership of rights to technology developed with our collaborators;

disagreements with our collaborators could delay or terminate the research, development or commercialization of products, or result in litigation or arbitration;

we may have difficulty enforcing the contracts if any of our collaborators fail to perform;

our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect the perception of us in the business or financial communities;

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

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

## Table of Contents

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

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

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

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

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

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

### **Risks Relating to Intellectual Property**

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

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

obtain patents;

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

operate without infringing upon the proprietary rights of others;

prevent others from infringing on our proprietary rights; and

protect our trade secrets.

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

---

**Table of Contents**

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 October 31, 2013, we owned more than 45 U.S. patents and patent applications and more than 85 patents and patent applications throughout the rest of the world for our TLR-targeted immune modulation technologies. These patents and patent applications include novel chemical compositions of matter and methods of use of our IMO compounds, including IMO-3100, IMO-8400, IMO-9200, and IMO-2055. As of October 31, 2013, all of our intellectual property covering immune modulatory compositions and methods of their use is based on discoveries made solely by us. These patents expire at various dates ranging from 2017 to 2031. With respect to IMO-3100, we have issued U.S. patents that cover the chemical composition of matter of IMO-3100 and methods of its use that will expire at the earliest in 2026. With respect to IMO-8400, we have an issued U.S. patent that covers the chemical composition of matter of IMO-8400 and methods of its use that will expire at the earliest in 2031. With respect to IMO-9200, we have a provisional U.S. patent application that covers the chemical composition for IMO-9200 and methods of its use, which, if issued, would expire at the earliest in 2034. With respect to IMO-2055, we have issued U.S. patents that cover the chemical composition of matter of IMO-2055 and methods of its use, including in combination with marketed cancer products, with the earliest composition claims in the United States expiring in 2023.

As of October 31, 2013, 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 patents 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 October 31, 2013, our antisense patent portfolio included more than 60 U.S. patents, one U.S. patent application and more than 60 patents throughout the rest of the world. These antisense patents and patent applications include novel compositions of matter, the use of these compositions for various genes, sequences and therapeutic targets, and oral and other routes of administration. Some of the patents and patent applications in our antisense portfolio were in-licensed. These in-licensed patents expire at various dates ranging from 2013 to 2021.

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

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



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

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

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

## **Table of Contents**

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

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

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

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

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

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

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

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

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

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

reliance on the third party for regulatory compliance and quality assurance;

the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control;

the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us;

the potential that third-party manufacturers will develop know-how owned by such third party in connection with the production of our drug candidates that becomes necessary for the manufacture of our drug candidates; and

reliance upon third-party manufacturers to assist us in preventing inadvertent disclosure or theft of our proprietary knowledge.

---

**Table of Contents**

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 October 31, 2013, our third-party manufacturers have met our manufacturing requirements, but we cannot be assured that they will continue to do so. Furthermore, changes in the manufacturing process or procedure, including a change in the location where the drug substance or drug product is manufactured or a change of a third-party manufacturer, may require prior FDA review and approval in accordance with the FDA's cGMP and NDA/BLA regulations. Contract manufacturers may also be subject to comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a drug candidate. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. If we or our contract manufacturers are unable to comply, we or they may be subject to regulatory action, civil actions or penalties.

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

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

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

We do not have the ability to independently conduct the clinical trials required to obtain regulatory approval for our drug candidates. We depend on independent clinical investigators, contract research organizations, and other third-party service providers in the conduct of the clinical trials of our drug candidates and expect to continue to do so. We contracted with contract research organizations to manage our Phase 1 and Phase 2 clinical trials of IMO-3100, our Phase 1 clinical trial of IMO-8400 and our ongoing Phase 2 clinical trial of IMO-8400 in patients with psoriasis, and expect to contract with such organizations for future clinical trials. We rely heavily on these parties for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and foreign regulatory agencies require us to comply with certain standards, commonly referred to as good clinical practices, and applicable regulatory requirements, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and

confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or at all, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval, and commercialization of our drug candidates. If we seek to conduct any of these activities ourselves in the future, we will need to recruit appropriately trained personnel and add to our infrastructure.

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

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

may not perform their obligations as expected;

**Table of Contents**

may encounter production difficulties that could constrain the supply of the companion diagnostics;

may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community;

may not pursue commercialization of any TLR antagonist product candidates that achieve regulatory approval;

may elect not to continue or renew commercialization programs based on changes in the collaborators strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

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

may terminate their relationship with us.

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

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

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

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

the efficacy and potential advantages over alternative treatments;

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

relative convenience and ease of administration;

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

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

publicity concerning our products or competing products and treatments.

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

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

Most patients rely on Medicare, Medicaid, private health insurers, and other third-party payors to pay for their medical needs, including any drugs we may market. If third-party payors do not provide adequate coverage or reimbursement for any products that we may develop, our revenues and prospects for profitability will suffer. Congress enacted a limited prescription drug benefit for Medicare recipients in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. While the program established

## **Table of Contents**

by this statute may increase demand for our products if we were to participate in this program, our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than we might otherwise obtain. Non-Medicare third-party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries or may otherwise negotiate the price they are willing to pay.

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

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

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

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

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

decreased demand for our drug candidates and products;



damage to our reputation;

regulatory investigations that could require costly recalls or product modifications;

withdrawal of clinical trial participants;

costs to defend related litigation;

substantial monetary awards to clinical trial participants or patients, including awards that substantially exceed our product liability insurance, which we would then have to pay using other sources, if available, and would damage our ability to obtain liability insurance at reasonable costs, or at all, in the future;

loss of revenue;

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

the inability to commercialize any products that we may develop.

## **Table of Contents**

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

### **Risks Relating to Ownership of Our Common Stock**

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

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

a classified board of directors;

limitations on the removal of directors;

limitations on stockholder proposals at meetings of stockholders;

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

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

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

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

In connection with our November 2011 Series D redeemable convertible preferred stock financing, which we refer to as our November 2011 Series D financing, we issued to Pillar Pharmaceuticals I, L.P., or Pillar I, 1,124,260 shares of our Series D redeemable convertible preferred stock, or Series D preferred stock, which shares are convertible into 6,266,175 shares of our common stock, and warrants exercisable for up to 2,810,650 shares of our common stock. In connection with our November 2012 Series E convertible preferred stock financing, which we refer to as our

November 2012 Series E financing, we issued to Pillar Pharmaceuticals II, L.P., or Pillar II, and an affiliated second purchaser an aggregate of 424,242 shares of our Series E convertible preferred stock, or Series E preferred stock, which shares are convertible into 8,484,840 shares of our common stock, and warrants exercisable for up to 8,484,840 shares of our common stock. In connection with the Pillar Agreements, we issued to the Pillar Entities warrants exercisable for up to 2,000,000 shares of common stock. In connection with our follow-on underwritten public offering in May 2013, we issued to the Pillar Entities and Pillar Pharmaceuticals III, L.P., or Pillar III, 5,000,000 shares of our common stock and warrants exercisable for up to 5,000,000 shares of common stock. In connection with our follow-on underwritten public offering in September 2013, we issued to the Pillar Entities and Pillar Pharmaceuticals IV, L.P., or Pillar IV, and together with the Pillar Entities and Pillar III, the Pillar Investment Entities, 1,774,193 shares of our common stock. As a result, the Pillar Investment Entities are collectively our largest stockholder group. In addition, two members of our board of directors are affiliates of the Pillar Investment Entities. In connection with their ownership of shares of our Series D preferred stock and 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. As a result, the interests of the Pillar Investment Entities may differ from the interests of the holders of our common stock in material respects. Although there are contractual limitations on the beneficial ownership and voting rights of the Pillar Investment Entities, the Pillar Investment Entities may still be able to exert substantial influence over our business.

**Table of Contents**

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

The rights, preferences and privileges of the Series D preferred stock and Series E preferred stock that we issued and sold in our November 2011 Series D financing and November 2012 Series E financing, respectively, provide the holders of such securities with significant rights, including preferential rights with respect to dividends, which are not provided to the holders of our common stock. The dividend rights of the Series D preferred stock and Series E preferred stock may adversely affect our liquidity. For example, our obligation to pay quarterly cash dividends to the holders of our preferred stock during the nine month period ended September 30, 2013 reduced the funds that would otherwise have been available to us for working capital and other general corporate purposes. In addition, from and after October 1, 2013, we are entitled to pay dividends on our Series D preferred stock and Series E preferred stock in shares of capital stock. If we were to pay such dividends in shares of our capital stock, our existing stockholders will experience dilution.

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

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

Our stock price has been volatile. During the period from January 1, 2011 to October 31, 2013, the closing sales price of our common stock ranged from a high of \$3.25 per share to a low of \$0.46 per share. The stock market has also experienced periods of significant price and volume fluctuations and the market prices of biotechnology companies in particular have been highly volatile, often for reasons that have been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

our cash resources;

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

the regulatory status of our drug candidates;

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

the success of competitive products or technologies;

regulatory developments in the United States and foreign countries;

our success in entering into collaborative agreements;

developments or disputes concerning patents or other proprietary rights;

the departure of key personnel;

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

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

the terms of any financing consummated by us;

changes in the structure of healthcare payment systems;

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

general economic, industry, and market conditions.

**Table of Contents**

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

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

***We must continue to meet the Nasdaq Capital Market continued listing requirements or we risk delisting. If our common stock were to be delisted, our stock price may decline and it would likely make it more difficult for us to sell securities in a financing and for our stockholders to trade our stock.***

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

**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.

Table of Contents

**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: November 14, 2013

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

(Principal Executive Officer)

Date: November 14, 2013

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

**Table of Contents**

**Exhibit Index**

**Exhibit No.**

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



**Table of Contents**

EXHIBIT 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

I, Sudhir Agrawal, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 14, 2013

/s/ SUDHIR AGRAWAL  
Sudhir Agrawal  
Chief Executive Officer

**Table of Contents**

EXHIBIT 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

I, Louis J. Arcudi, III certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 14, 2013

/s/ LOUIS J. ARCUDI, III  
Louis J. Arcudi, III  
Chief Financial Officer

Table of Contents

EXHIBIT 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

In connection with the Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc. (the Company ) for the period ended September 30, 2013 as filed with the Securities and Exchange Commission on the date hereof (the Report ), the undersigned, Sudhir Agrawal, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Idera Pharmaceuticals, Inc. and will be retained by Idera Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: November 14, 2013

/s/ SUDHIR AGRAWAL  
Sudhir Agrawal  
Chief Executive Officer

Table of Contents

EXHIBIT 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

In connection with the Quarterly Report on Form 10-Q of Idera Pharmaceuticals, Inc. (the Company ) for the period ended September 30, 2013 as filed with the Securities and Exchange Commission on the date hereof (the Report ), the undersigned, Louis J. Arcudi, III, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Idera Pharmaceuticals, Inc. and will be retained by Idera Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: November 14, 2013

/s/ LOUIS J. ARCUDI, III  
Louis J. Arcudi, III  
Chief Financial Officer