

IDERA PHARMACEUTICALS, INC.  
Form 10-Q  
May 15, 2013

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended March 31, 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)

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-Q

**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

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

<b>Common Stock, par value \$.001 per share</b>	45,163,330
Class	Outstanding as of May 10, 2013

---

**IDERA PHARMACEUTICALS, INC.**

**FORM 10-Q**

**INDEX**

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<u>Item 1 Financial Statements Unaudited</u>	1
<u>Condensed Balance Sheets as of March 31, 2013 and December 31, 2012</u>	1
<u>Condensed Statements of Operations and Comprehensive Loss for the Three Months Ended March 31, 2013 and 2012</u>	2
<u>Condensed Statements of Cash Flows for the Three Months Ended March 31, 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>	13
<u>Item 3 Quantitative and Qualitative Disclosures about Market Risk</u>	30
<u>Item 4 Controls and Procedures</u>	30
<b><u>PART II OTHER INFORMATION</u></b>	
<u>Item 1A Risk Factors</u>	31
<u>Item 6 Exhibits</u>	51
<u>Signatures</u>	52

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.

**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, continue, will, and wo 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.

## PART I FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS.

## IDERA PHARMACEUTICALS, INC.

## CONDENSED BALANCE SHEETS

(UNAUDITED)

(In thousands, except per share amounts)	March 31, 2013	December 31, 2012
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 6,149	\$ 10,096
Prepaid expenses and other current assets	176	198
Total current assets	6,325	10,294
Property and equipment, net	178	218
Restricted cash	311	311
Total assets	\$ 6,814	\$ 10,823
<b>LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS (DEFICIT) EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 977	\$ 1,129
Accrued expenses	3,097	3,002
Total current liabilities	4,074	4,131
Other liabilities	30	65
Total liabilities	4,104	4,196
Commitments and contingencies		
Series D Redeemable Convertible Preferred Stock, \$0.01 par value, Designated, issued and outstanding - 1,124 shares; Redemption amount \$9,149; Liquidation preference \$9,389	5,921	5,921
Non-redeemable preferred stock, common stock, and other stockholders (deficit) equity:		
Preferred stock, \$0.01 par value, Authorized 5,000 shares		
Series E convertible preferred stock, Designated, issued and outstanding 424 shares; Liquidation preference \$6,048	3,701	3,701
Series A convertible preferred stock, Designated 1,500 shares, issued and outstanding 1 share		
Common stock, \$0.001 par value, Authorized 140,000 shares, issued and outstanding 27,645 and 27,643 shares at March 31, 2013 and December 31, 2012, respectively	28	28
Additional paid-in capital	391,525	391,635
Accumulated deficit	(398,465)	(394,658)
Total stockholders (deficit) equity	(3,211)	706
Total liabilities, redeemable preferred stock and stockholders (deficit) equity	\$ 6,814	\$ 10,823

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



## IDERA PHARMACEUTICALS, INC.

## CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

(In thousands, except per share amounts)	Three Months Ended March 31	
	2013	2012
Alliance revenue	\$ 7	\$ 9
Operating expenses:		
Research and development	2,328	3,813
General and administrative	1,527	1,689
Total operating expenses	3,855	5,502
Loss from operations	(3,848)	(5,493)
Other income (expense):		
Increase in fair value of warrant liability		(1,321)
Investment income, net	2	4
Foreign currency exchange gain (loss)	39	(76)
Net loss	(3,807)	(6,886)
Preferred stock dividends	279	160
Net loss applicable to common stockholders	\$ (4,086)	\$ (7,046)
Net loss per common share applicable to common stockholders (Note 10):		
Basic	\$ (0.15)	\$ (0.25)
Diluted	\$ (0.15)	\$ (0.25)
Shares used in computing net loss per common share applicable to common stockholders:		
Basic	27,644	27,637
Diluted	27,644	27,637
Net loss	\$ (3,807)	\$ (6,886)
Other comprehensive income		
Comprehensive loss	\$ (3,807)	\$ (6,886)

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

## IDERA PHARMACEUTICALS, INC.

## CONDENSED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(In thousands)	Three Months Ended March 31,	
	2013	2012
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (3,807)	\$ (6,886)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss from disposition of assets		1
Non-employee stock option expense	2	4
Stock-based compensation	253	588
Increase in fair value of warrant liability		1,321
Depreciation expense	42	83
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	22	(2)
Accounts payable, accrued expenses, and other liabilities	(211)	(889)
Net cash used in operating activities	(3,699)	(5,780)
<b>Cash Flows from Investing Activities:</b>		
Purchases of property and equipment	(1)	
Net cash used in investing activities	(1)	
<b>Cash Flows from Financing Activities:</b>		
Dividends paid	(160)	(103)
2012 financing transaction costs paid in 2013	(87)	
Proceeds from employee stock purchases	1	1
Payments on capital lease	(1)	
Net cash used in financing activities	(247)	(102)
Net (decrease) in cash and cash equivalents	(3,947)	(5,882)
Cash and cash equivalents, beginning of period	10,096	24,571
Cash and cash equivalents, end of period	\$ 6,149	\$ 18,689

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



---

**IDERA PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

**March 31, 2013**

**(UNAUDITED)**

(1) Organization

Idera Pharmaceuticals, Inc. ( Idera or the Company ) is a clinical stage biotechnology company engaged in the discovery and development of novel synthetic DNA- and RNA-based drug candidates that are designed to modulate immune responses mediated through Toll-like Receptors, or TLRs. The Company is focusing its development efforts on the treatment of autoimmune and inflammatory diseases. The Company has two drug candidates, IMO-3100, a TLR7 and TLR9 antagonist, and IMO-8400, a TLR7, TLR8, and TLR9 antagonist, in clinical development for the treatment of autoimmune and inflammatory diseases. The Company has presented data from a Phase 2 clinical trial of IMO-3100 in patients with moderate to severe plaque psoriasis. The Company believes that the results of this trial provide clinical proof of concept for its approach of targeting specific TLRs for the treatment of psoriasis and potentially other autoimmune and inflammatory diseases.

TLRs are specific receptors present in immune system cells. Using a chemistry-based approach, the Company has created synthetic DNA- and RNA-based compounds that are targeted to TLR3, TLR7, TLR8, and TLR9. A TLR antagonist is a compound that blocks activation of an immune response through the targeted TLR. A TLR agonist is a compound that stimulates an immune response through the targeted TLR.

The Company believes that the modulation of immune responses through TLRs provides a rationale for the development of drug candidates to treat a broad range of diseases, including autoimmune and inflammatory diseases, cancer, respiratory diseases, and for use as vaccine adjuvants. The Company is a party to a collaboration alliance with Merck Sharp & Dohme Corp. (formerly Merck & Co., Inc.) ( Merck & Co. ), for the use of agonists of TLR7, TLR8, and TLR9 as adjuvants in the development of vaccines for cancer, infectious diseases, and Alzheimer's disease. The Company is seeking to enter into additional collaborative alliances with third parties with respect to its TLR-targeted programs in oncology, hematological malignancies, respiratory diseases, and the use of TLR3 agonists as vaccine adjuvants.

The Company had cash and cash equivalents of approximately \$6,149,000 at March 31, 2013. The Company believes that the net proceeds of the follow-on public offering of its securities in May 2013, together with its existing cash and cash equivalents, will enable the Company to fund its operations at least through the fourth quarter of 2014. The Company believes that its available funds following the May 2013 offering will be sufficient to enable the Company to conduct its planned Phase 2 clinical trial of IMO-8400 in patients with psoriasis and to plan for further clinical development of IMO-8400. The Company will need to raise additional funds in order to conduct any other clinical development of IMO-3100 or IMO-8400 or to conduct any other development of its other product candidates or technologies. It is also possible that the Company will not achieve the progress that it expects with respect to IMO-8400 because the actual costs and timing of clinical development activities are difficult to predict and are subject to substantial risks and delays.

At March 31, 2013, the Company had an accumulated deficit of \$398,465,000. The Company expects to incur substantial operating losses in future periods. The Company does not expect to generate significant 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 three months ended March 31, 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) Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be cash equivalents. Cash and cash equivalents at March 31, 2013 and December 31, 2012 consisted of cash and money market funds.

(4) 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.

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-Q

The table below presents the assets and liabilities measured and recorded in the financial statements at fair value on a recurring basis at March 31, 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>March 31, 2013</b>				
Assets				
Money market fund	\$ 6,102	\$ 6,102	\$	\$
Total assets	\$ 6,102	\$ 6,102	\$	\$
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 March 31, 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' (deficit) equity on the balance sheet. The Company did not elect to measure any other financial assets or liabilities at fair value.

In connection with the sale of its Series D redeemable convertible preferred stock (Series D preferred stock) in November 2011, the Company issued warrants which contained provisions for anti-dilution protection in the event that the Company issued other equity securities at a price below \$1.46 per common share. Because of the potential adjustment to the warrant exercise price that could result from this anti-dilution protection, the warrants did not meet the criteria set forth in ASC 815-40, Derivatives and Hedging - Contracts in Entity's own Stock to be considered indexed to the Company's own stock. Accordingly, the Company recorded the fair value of these warrants as a liability. The Company estimated the fair value of these warrants at the issuance date using the Black-Scholes Model as the result was not significantly different than the use of a lattice or binomial model because the price protection provision was subject to a floor of \$1.46 per share and the initial exercise price was \$1.63. The Company characterized this warrant liability as a Level 3 liability because its fair value measurement was based, in part, on significant inputs not observed in the market and represented the Company's assumptions as to the expected warrant exercise price, the expected volatility of the Company's common stock, the expected dividend yield, the expected term of the warrant instrument and the expected percentage of warrants to be exercised.

The Company revalued the warrants at the end of each quarter using the Black-Scholes Model and recognized the change in the fair value of the warrants in the statements of operations and comprehensive loss as other income (expense). The following assumptions and other inputs were used to compute the fair value of the warrant liability as of March 31, 2012 and December 31, 2011:

	March 31 2012	December 31, 2011
Common stock price	\$ 1.73	\$ 1.05
Expected warrant exercise price	\$ 1.63	\$ 1.46
Remaining term of warrant (years)	4.6	4.8
Expected volatility	61%	58%
Average risk free interest rate	0.9%	0.8%
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 exercise price of the warrant was initially set at \$1.63 and was subject to adjustment to a price to as low as the \$1.46 minimum exercise price per share for diluting effects such as if in specified circumstances the Company sells its common stock at a price below \$1.46 per share. The Company used the \$1.46 minimum exercise price as an assumption in computing the fair value of the warrant at December 31, 2011 because the Company's common stock was trading below \$1.46. The Company used the \$1.63 maximum exercise price as an assumption in computing the fair value of the warrant at March 31, 2012 because the Company's common stock was trading above \$1.63 on March 31, 2012. The estimated remaining term of the warrant is readily determinable from the warrant agreement as it is the remaining contractual term. The expected volatility is based on the actual stock-price volatility over a period equal to the greater of the remaining 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 remaining 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.

The fair value of the warrant liability increased from \$1,178,000 at December 31, 2011 to \$2,499,000 at March 31, 2012 primarily due to an increase in the price of the Company's common stock. The increase in the fair value of the warrant liability resulted in the recognition of a \$1,321,000 expense in other income (expense) for the three months ended March 31, 2012.

The sale of shares of Series E convertible preferred stock (Series E preferred stock) and related warrants to purchase shares of our common stock (Series E warrants) in our November 2012 Series E financing triggered an anti-dilution adjustment, 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. Since 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 the Series D warrants were marked to fair value through earnings as of November 9, 2012 and then reclassified to stockholders equity at that time. Consequently, the Company did not record any non-operating income or expense related to the Series D warrants during the three months ended March 31, 2013.

##### (5) Property and Equipment

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

(In thousands)	March 31, 2013	December 31, 2012
Leasehold improvements	\$ 525	\$ 525
Laboratory equipment and other	2,858	2,856
<b>Total property and equipment, at cost</b>	<b>3,383</b>	<b>3,381</b>
Less: accumulated depreciation	3,205	3,163
<b>Property and equipment, net</b>	<b>\$ 178</b>	<b>\$ 218</b>

Depreciation expense was approximately \$42,000 and \$83,000 in the three months ended March 31, 2013 and 2012, respectively.

(6) Restricted Cash

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

(7) Collaboration and License Agreements

*(a) Collaboration and License Agreement with Merck & Co.*

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 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

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-Q

Company's common stock for a price of \$5.50 per share resulting in aggregate gross proceeds of \$10.0 million.

*(b) Collaboration and License Agreement with Merck KGaA*

In December 2007, the Company entered into an exclusive, worldwide license agreement with Merck KGaA, Darmstadt, Germany (Merck KGaA) to research, develop and commercialize products containing its TLR9 agonists, including IMO-2055, for the treatment of cancer, excluding cancer vaccines. Under the terms of the agreement: Merck KGaA paid the Company in February 2008 a \$40.0 million upfront license fee in Euros of which \$39.7 million was received due to foreign currency exchange rates in effect at that time, and Merck KGaA agreed to reimburse costs for the Company's IMO-2055 clinical trials for the period in which the Company continued to conduct the trials on behalf of Merck KGaA. In February 2009, the agreement was amended so that the Company could initiate and conduct on behalf of Merck KGaA additional clinical trials of IMO-2055, and Merck KGaA agreed to reimburse the Company for costs associated with any additional trials that the Company initiated and conducted. As of March 2010, Merck KGaA assumed sponsorship of all ongoing clinical trials of IMO-2055 for the treatment of cancer, and responsibility for all further clinical development of IMO-2055 in the treatment of cancer, excluding vaccines.

The Company recognized the \$40.0 million upfront payment as revenue over the twenty-eight month term that ended in June 2010, which was the Company's period of continuing involvement under the research collaboration. The Company has recognized a total of \$12.1 million of milestone revenue related to the initiation of clinical trials of IMO-2055.

In November 2011, the Company and Merck KGaA entered into a termination agreement terminating the license agreement. Under the termination agreement:

the license agreement was terminated and the Company regained all rights for developing TLR9 agonists for the treatment of cancer, including all rights to IMO-2055 and any follow-on TLR9 agonists;

Merck KGaA agreed to continue to conduct the Phase 2 trial of IMO-2055 in combination with cetuximab that was then ongoing and other specified related activities;

Merck KGaA agreed to complete and analyze all clinical trials that Merck KGaA had initiated or for which Merck KGaA had assumed sponsorship and to finalize clinical study reports;

the Company gained rights to the data from the Phase 2 trial of IMO-2055 in combination with cetuximab, as well as to the data from the Phase 1 trials conducted in other cancer indications;

the Company agreed to reimburse Merck KGaA a maximum of 1.8 million (\$2.3 million using a March 31, 2013 exchange rate) of Merck KGaA's costs for the third-party contract research organization that is coordinating the Phase 2 trial of IMO-2055 in combination with cetuximab, payable in eleven installments comprised of ten monthly installments to be invoiced by Merck KGaA to the Company commencing on March 1, 2012 and a final payment payable by the Company to Merck KGaA upon Merck KGaA's completion of certain specified activities. As of March 31, 2013, the Company has paid 0.8 of the 1.8 million (\$1.1 million (using exchange rates in effect at the time that the payments were made) of the \$2.3 million);

the Company agreed to pay to Merck KGaA one-time 1.0 million (\$1.3 million using a March 31, 2013 exchange rate) milestone payments upon occurrence of each of the following milestones: (i) partnering of IMO-2055 between the Company and any third party, (ii) initiation of any Phase 2 or Phase 3 clinical trial for IMO-2055 and (iii) regulatory submission of IMO-2055 in any country; and

Merck KGaA granted the Company an option to obtain a license to certain manufacturing and formulation know-how owned or developed by Merck KGaA under the License Agreement and to Merck KGaA's IMOXine trademark. The Company's option to license the IMOXine trademark has expired. If the Company elects to exercise its option with respect to the manufacturing and formulation know-how, the Company has agreed to pay a low single digit royalty on net sales of IMO-2055, with respect to such license.

## Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-Q

The Company recorded the 1.8 million (\$2.4 million using a November 30, 2011 exchange rate) that it has agreed to reimburse Merck KGaA in installment payments as research and development expense for the fourth quarter of 2011 as such amount represented the cost of regaining the Company's rights to IMO-2055 and follow-on compounds for use in the treatment of cancer, excluding cancer vaccines. As of March 31, 2013, 1.0 million (\$1.3 million using a March 31, 2013 exchange rate) of these installments remained payable under the termination agreement and is recorded under accrued expenses in the condensed balance sheet.



## (8) 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. In addition, as of March 31, 2013, five of the specified performance conditions were not met by their deadlines resulting in the cancellation of 265,597 performance-based options. 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 \$253,000 and \$588,000 for the three months ended March 31, 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 37,500 shares of common stock granted during the three months ended March 31, 2012:

	<b>Three Months Ended March 31, 2012</b>
Average risk free interest rate	1.1%
Expected dividend yield	
Expected lives (years)	5.8
Expected volatility	67.0%
Weighted average grant date fair value of options granted during the period (per share)	\$ 0.69
Weighted average exercise price of options granted during the period (per share)	\$ 1.15

The Company did not grant any stock options during the three months ended March 31, 2013. The expected lives and the expected volatility of the options are based on historical experience. All options granted during the three months ended March 31, 2012 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant.

## (9) Net Loss per Common Share Applicable to Common Stockholders

For the three months ended March 31, 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 33,037,104 and 16,018,566 for the three months ended March 31, 2013 and 2012, respectively, and consist of stock options, preferred stock and warrants.

For the three months ended March 31, 2013, net loss per common share applicable to common stockholders reflects \$279,000 in dividends payable on shares of our Series D preferred stock that were issued in November 2011 and our Series E preferred stock that were issued in November 2012. For the three months ended March 31, 2012, net loss per common share applicable to common stockholders reflects \$160,000 in dividends payable on shares of our Series D preferred stock that were issued in November 2011.

(10) Employee Stock Purchases

During the three months ended March 31, 2013 and 2012, the Company issued 1,744 shares and 721 shares, respectively, of common stock in connection with employee stock purchases under the Company's 1995 Employee Stock Purchase Plan, which resulted in total proceeds to the Company of approximately \$1,000 in each quarter.

(11) Related Party Transactions

The Company paid a director consulting fees of approximately \$1,000 in the three months ended March 31, 2012 for services performed in 2011. The Company did not pay consulting fees to directors during the three months ended March 31, 2013.

(12) Subsequent Events

*Follow-on Public Offering*

On May 7, 2013, the Company closed a follow-on 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, at a combined price to the public of \$0.50 per share and related warrant, 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, at a combined price to the public of \$0.49 per pre-funded warrant share and related warrant, for aggregate gross proceeds of \$16.5 million. 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 future exercise of the warrants, if any, were approximately \$14.7 million.

The warrants have an exercise price of \$0.47 per share of common stock and are exercisable for a period of five years from May 7, 2013 and the pre-funded warrants have an exercise price of \$0.01 per share of common stock and are exercisable for a period of seven years from May 7, 2013. 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.

*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 underwritten public offering 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.

Under the April 22, 2013 Pillar Agreement, the Company and each of Pillar I and Pillar II agreed, among other things:

to an amendment to the Series D Certificate of Designations for the Series D preferred stock to:

- n 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
- n in connection with the waiver of the right to require the Company to purchase the Series D preferred stock upon the occurrence of specified fundamental changes, to 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

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

- n 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
- n 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.

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.

Under the Pillar Agreements, the Company has agreed to seek approval from its stockholders at its 2013 annual meeting of stockholders of amendments to the Series D Certificate of Designations and Series E Certificate of Designations to effect these changes 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. Each applicable Pillar Entity has agreed:

to vote, and to cause its affiliates to vote, all shares of the Company's voting stock held by such Pillar Entity or its affiliates, and over which such Pillar Entity or its affiliates has the power to vote, in favor of such amendments; and

not to, and to cause its affiliates not to, sell or transfer any shares of common stock, Series D preferred stock or Series E preferred stock held by such Pillar Entity or its affiliates to any person, entity or group unless such proposed transferee agrees in a written instrument executed by such transferee, the applicable Pillar Entity and us to take and hold such securities subject to, among other things, the Pillar Agreements and to be bound by the terms of such Pillar Agreements, including the waiver of rights, voting agreements and restrictions on transfer set forth therein.

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 addition, the Company agreed to file a registration statement to register the resale of the shares of common stock issuable upon exercise of the Pillar Warrants.

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

### **GENERAL**

We are a clinical stage biotechnology company engaged in the discovery and development of novel synthetic DNA- and RNA-based drug candidates that are designed to modulate immune responses mediated through Toll-like Receptors, or TLRs. We are focusing our development efforts on the treatment of autoimmune and inflammatory diseases. We have two drug candidates, IMO-3100, a TLR7 and TLR9 antagonist, and IMO-8400, a TLR7, TLR8, and TLR9 antagonist, in clinical

development for the treatment of autoimmune and inflammatory diseases. We have presented data from a Phase 2 clinical trial of IMO-3100 in patients with moderate to severe plaque psoriasis. We believe that the results of this trial provide clinical proof of concept for our approach of targeting specific TLRs for the treatment of psoriasis and potentially other autoimmune and inflammatory diseases.

TLRs are specific receptors present in immune system cells. Using a chemistry-based approach, we have created synthetic DNA- and RNA-based compounds that are targeted to TLR3, TLR7, TLR8, and TLR9. A TLR antagonist is a compound that blocks activation of an immune response through the targeted TLR. A TLR agonist is a compound that stimulates an immune response through the targeted TLR.

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

We had cash and cash equivalents of approximately \$6,149,000 at March 31, 2013. We believe that the net proceeds of our follow-on public offering of our securities in May 2013, together with our existing cash and cash equivalents, will enable us to fund our operations at least through the fourth quarter of 2014. We believe that our available funds following the May 2013 offering will be sufficient to enable us to conduct our planned Phase 2 clinical trial of IMO-8400 in patients with psoriasis and to plan for further clinical development of IMO-8400. We will need to raise additional funds in order to conduct any other clinical development of IMO-3100 or IMO-8400 or to conduct any other development of our other product candidates or technologies. It is also possible that we will not achieve the progress that we expect with respect to IMO-8400 because the actual costs and timing of clinical development activities are difficult to predict and are subject to substantial risks and delays.

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

We are conducting a Phase 1 clinical trial to evaluate the safety and pharmacodynamics of IMO-8400 in healthy subjects. This trial is being conducted at a single U.S. site. The first portion of the trial involved escalating single doses of IMO-8400 and the second portion of the trial involved four weekly doses of IMO-8400. During the first quarter of 2013, we completed the escalating single-dose portion of this trial. In this portion of the trial, IMO-8400 was well-tolerated and showed target engagement of TLR7, TLR8, and TLR9 in subjects treated with IMO-8400 compared to placebo. During the second quarter of 2013, we completed dosing in the multiple-dose portion of the trial. We plan to present data from this trial at a scientific conference in June 2013.

Based on the clinical activity of IMO-3100 observed in our four-week Phase 2 clinical trial of IMO-3100 in patients with psoriasis, we have determined that the next step in our development program is to conduct a Phase 2 clinical trial in patients with psoriasis with a treatment period of up to 12 weeks. Based on our evaluation of the comparative profiles of IMO-3100 and IMO-8400, including the engagement of TLR8 by IMO-8400, we have determined to focus our resources on the development of IMO-8400 and to conduct this trial in patients with psoriasis with IMO-8400. We expect to initiate this trial during the second quarter of 2013 and to have top-line data by the end of 2013.

We are also planning to initiate a signal-seeking Phase 2 clinical trial of IMO-8400 in patients with lupus, and are considering conducting a proof-of-concept study of IMO-8400 in an orphan autoimmune disease indication. We expect to select the orphan autoimmune disease indication for further exploration in the second half of 2013. However, our plans to conduct the Phase 2 clinical trial of IMO-8400 in patients with lupus and the proof-of-concept study are subject to our ability to raise additional funding to fund the conduct of this trial and proof-of-concept study. We expect to seek such additional funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources.

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

**Additional Programs.** In addition to our TLR program in autoimmune and inflammatory diseases, and our collaboration with Merck & Co. for the use of TLR7, TLR8, and TLR9 agonists as vaccine adjuvants, we have identified TLR drug candidates for applications in the treatment of cancer, hematological malignancies and respiratory diseases, and created TLR3 agonists for use as vaccine adjuvants. We have also created gene silencing oligonucleotides, or GSOs, which are designed to inhibit the production of disease-associated proteins by targeting RNA. We believe our GSO technology provides us with a platform from which drug candidates for multiple disease indications can be developed. We are seeking to enter into collaborations with third parties to advance these drug candidates and technology platform. Except in connection with collaborations, we do not plan to expend any additional resources on these programs.

At March 31, 2013, we had an accumulated deficit of \$398.5 million. We expect to incur substantial operating losses in future periods. We do not expect to generate significant 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 three months ended March 31, 2013.

**RESULTS OF OPERATIONS***Three Months Ended March 31, 2013**Alliance Revenue*

Alliance revenue consisted of reimbursement by licensees of costs associated with patent maintenance, amounting to \$7,000 and \$9,000 in the three months ended March 31, 2013 and 2012, respectively.

*Research and Development Expenses*

Research and development expenses decreased by \$1,485,000, or 39%, from \$3,813,000 for the three months ended March 31, 2012, to \$2,328,000 for the three months ended March 31, 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 March 31, (in thousands)		Percentage Increase (Decrease) %
	2013	2012	
IMO-8400 external development expense	\$ 600	\$	
IMO-3100 external development expense	274	239	15%
Other drug development expense	635	2,024	(69)%
Basic discovery expense	819	1,550	(47)%
	\$ 2,328	\$ 3,813	(39)%

*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 \$1,088,000 in external development expenses through March 31, 2013, including costs associated with our Phase 1 clinical trial in healthy subjects that we initiated in 2012, preparation for a 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.

In the fourth quarter of 2012, we initiated a Phase 1 clinical trial of IMO-8400 in healthy subjects. The primary objectives of this Phase 1 clinical trial are to evaluate the safety and pharmacodynamics of IMO-8400. This trial is being conducted at a single U.S. site. The first portion of the trial involved escalating single doses of IMO-8400 administered by subcutaneous injection and the second portion of the trial involved IMO-8400 administered once per week for four weeks. During the first quarter of 2013, we completed the escalating single-dose portion of this trial. In this portion of the trial, IMO-8400 was well-tolerated and showed target engagement of TLR7, TLR8, and TLR9 in subjects treated with IMO-8400 compared to placebo. During the second quarter of 2013, we completed dosing in the multiple-dose portion of the trial. We plan to present data from this trial at a scientific conference in June 2013.

Based on the clinical activity of IMO-3100 observed in our four-week Phase 2 clinical trial of IMO-3100 in patients with psoriasis, we have determined that the next step in our development program is to conduct 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. Based on our evaluation of the comparative profiles of IMO-3100 and IMO-8400, including the engagement of TLR8 by IMO-8400, we have determined to focus our resources on the development of IMO-8400 and to conduct this trial in patients with psoriasis with IMO-8400. In March 2013, we submitted the proposed protocol for this trial to the regulatory authorities in the Netherlands for review and we received a no objection clearance from the Centrale Commissie Mensgebonden Onderzoek. Under the protocol, 32 adult patients with moderate to severe plaque psoriasis, as indicated by a score of 12.5 or greater on the Psoriasis Area Severity Index, or PASI, would be randomized into one of four cohorts and receive placebo or 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. We expect to initiate this trial in the second quarter of 2013 and to have top-line data by the end of the 2013.

We are also planning to initiate a signal-seeking Phase 2 clinical trial of IMO-8400 in patients with lupus, and are considering conducting a proof-of-concept study of IMO-8400 in an orphan autoimmune disease indication. We expect to select the orphan autoimmune disease indication for further exploration in the second half of 2013. However, our plans to conduct the Phase 2 clinical trial of IMO-8400 in patients with lupus and the proof-of-concept study are subject to our ability to raise additional funding to fund the conduct of this Phase 2 trial and proof-of-concept study. We expect to seek such additional funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources.

*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 \$10,218,000 in external development expenses from November 2009 through March 31, 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 months ended March 31, 2013 and the three months ended March 31, 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 higher in the three months ended March 31, 2013, as compared to the three months ended March 31, 2012. In the three months ended March 31, 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 months ended March 31, 2012, our costs were related to our preparation for the initiation of our Phase 2 clinical trial.

In the second quarter of 2012, we initiated a randomized, double-blind, placebo-controlled Phase 2 clinical trial of IMO-3100 in adult patients with moderate-to-severe plaque psoriasis. In the trial, 44 patients at 11 centers in the United States were randomized on a 1:1:1 basis to receive IMO-3100 monotherapy at a dose level of either 0.16 or 0.32 mg/kg or placebo by subcutaneous injection once weekly for four weeks with a four-week follow-up period. Patients were treated on Days 1, 8, 15, and 22, and were monitored during the treatment period and the follow-up period through approximately Day 57. Assessments of safety were performed throughout the trial. Multiple parameters were monitored to assess the clinical activity of IMO-3100, including PASI scores. In addition to the clinical assessments, biopsies were evaluated for treatment-related changes in epidermal thickness and immune cell infiltrates. PASI scores were monitored during the treatment period on Days 1, 15, and 29, and during the follow-up period on Days 36 and 57. Skin biopsies were collected prior to treatment on Day 1 and on Day 29.

The objectives of the Phase 2 trial of IMO-3100 were to evaluate the safety and tolerability and to evaluate the clinical activity of TLR antagonism in patients with psoriasis after four weeks of treatment. Top-line data from this trial were announced in December 2012. Full data from this trial were presented at the International Investigative Dermatology meeting in Edinburgh, Scotland in May 2013:

Safety:

Treatment with IMO-3100 was well tolerated at both dose levels studied

There were no treatment-related discontinuations or changes in laboratory parameters



Clinical Activity:

On day 57, 48% of patients treated with either dose of IMO-3100 (12 of 25) demonstrated statistically significant improvements of 35% to 90% from baseline PASI scores compared with 0 of 12 in the placebo cohort ( $p < 0.005$ )

Rapid improvement in PASI scores was observed as early as Day 15 in IMO-3100 treated patients compared to placebo-treated patients; improvement in PASI was sustained through five weeks after the last dose

The pre-specified clinical endpoint of reduction in PASI score at day 29 was achieved with statistical significance in the 0.16 mg/kg cohort ( $p < 0.02$  compared to placebo) but not in the 0.32 mg/kg cohort

PASI 50 was achieved in 7 of 25 patients treated with IMO-3100 (3 of 12 at 0.16 mg/kg and 4 of 13 at 0.32 mg/kg), compared to 0 of 12 placebo treated patients ( $p < 0.05$ ); PASI 75 was achieved in 1 patient in each IMO-3100 cohort during the trial period

The pre-specified clinical endpoint of improvement in induration, a measure of plaque thickness, at day 29, was achieved with statistical significance in the 0.16 mg/kg cohort ( $p < 0.02$ ) compared to placebo-treated patients

Mechanism of Action Based on Analysis of Skin Biopsies:

Median change in epidermal thickness (the histologically defined primary endpoint of the trial) was -6.4% in IMO-3100 treated patients compared to +7.7% in placebo treated patients, representing a favorable, but not statistically significant, trend. Because the histology endpoint was not statistically significant, the primary endpoint of this trial was not achieved. A known limitation of skin biopsies after four weeks of treatment is that psoriatic plaques do not resolve in a uniform fashion, and therefore, biopsies may not provide a representative sampling of lesions.

Representative patients treated with IMO-3100 showed K16 staining (marker of keratinocyte proliferation) reverting toward normal and decreasing infiltrates of CD3+ lymphocytes and CD11c+ cells.

DNA microarray analysis of biopsies from the IMO-3100 treated patients compared to placebo treated patients ( $n=6$  each) showed significant improvement ( $p < 10^{-6}$ ) in psoriasis disease-associated genes and of genes unique to the IL-17 pathway, which is central to the pathogenesis of psoriasis.

We believe that the results of this trial provide clinical proof of concept of our approach of targeting specific TLRs for the treatment of psoriasis and potentially other autoimmune and inflammatory diseases.

*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.

The decrease in other drug development expenses in the three months ended March 31, 2013, as compared to the three months ended March 31, 2012, was primarily due to costs incurred during the three months ended March 31, 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 months ended March 31, 2013.

## Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-Q

*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

months ended March 31, 2013, as compared to the three months ended March 31, 2012, was primarily due to decreases in the cost of laboratory supplies and employee compensation reflecting reduced activity and reduced headcount resulting from our September 2011 re-assessment and prioritization of our drug development programs.

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 1 clinical trial of IMO-8400, and without an established plan for future clinical tests of drug candidates, 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 decreased by \$162,000, or 10%, from \$1,689,000 in the three months ended March 31, 2012, to \$1,527,000 in the three months ended March 31, 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 decrease in general and administration expenses during the three months ended March 31, 2013, as compared to the three months ended March 31, 2012, was primarily due to lower legal costs associated with patent matters and lower employee compensation due to a decrease in stock based compensation during the three months ended March 31, 2013. These decreases were partially offset by higher corporate legal expenses associated with our corporate regulatory filing requirements.

#### *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 Series D warrants increased from \$1,178,000 at December 31, 2011 to \$2,499,000 at March 31, 2012 primarily due to an increase in the market price of our common stock. The increase in the fair value of the warrant liability resulted in the recognition of a \$1,321,000 non-operating expense in the three months ended March 31, 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 months ended March 31, 2013.

#### *Investment Income, Net*

Investment income was a negligible amount in the three months ended March 31, 2013 and 2012 because most of our invested funds have been deposited in a money market fund which pays minimal interest.

*Foreign Currency Exchange Gain (Loss)*

Our \$39,000 foreign currency exchange gain during the three months ended March 31, 2013 was primarily due to the impact that the increasing value of the U.S. dollar had on our Euro-denominated accrued liabilities. Our foreign currency exchange loss amounted to \$76,000 in the three months ended March 31, 2012 primarily due to the impact that the decreasing value of the U.S. dollar had on our Euro-denominated accrued liabilities.

*Preferred Stock Dividends*

The \$279,000 in preferred stock dividends in the three months ended March 31, 2013 consists of \$211,000 in dividends payable on shares of our Series D preferred stock that we issued in November 2011 and \$68,000 in dividends payable on shares of our Series E preferred stock that we issued in November 2012. The \$160,000 in preferred stock dividends in the three months ended March 31, 2012 consists of dividends payable on shares of our Series D preferred stock. The dividends payable to the Series D stockholders increased in the three months ended March 31, 2013, as compared to the three months ended March 31, 2012, because the terms of the Series D preferred stock require that dividends that we pay to the Series E preferred stockholders also be paid to the Series D preferred stockholders on an as-converted to common stock basis.

*Net Loss Applicable to Common Stockholders*

As a result of the factors discussed above, our net loss applicable to common stockholders was \$4,086,000 for the three months ended March 31, 2013, compared to \$7,046,000 for the three months ended March 31, 2012. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through March 31, 2013, we incurred losses of \$138,272,000. 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 \$398,465,000 through March 31, 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.

*Follow-on Public Offering*

On May 7, 2013, we closed a follow-on 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 our common stock, at a combined price to the public of \$0.50 per share and related warrant, 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, at a combined price to the public of \$0.49 per pre-funded warrant share and related warrant, for aggregate gross proceeds of \$16.5 million.

The warrants have an exercise price of \$0.47 per share of common stock and are exercisable for a period of five years from May 7, 2013 and the pre-funded warrants have an exercise price of \$0.01 per share of common stock and are exercisable for a period of seven years from May 7, 2013. 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.

The 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 future exercise of the warrants, if any, were approximately \$14.7 million.

#### *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 Pharmaceuticals II L.P., or Pillar II, and a second purchaser, which we refer to as 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 \$7,000,000, 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 warrants is \$0.70 per share. The warrants to purchase common stock are exercisable immediately, and will expire if not exercised on or prior to November 9, 2017. We have 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, any dividends that we pay to the Series E preferred stockholders will also be paid to the Series D preferred stockholders on an as-converted to common stock basis. We have agreed that, at our 2013 annual meeting of stockholders, we will propose an amendment to the Certificate of Designations, Preferences and Rights of Series D preferred stock, or the Series D Certificate of Designations, which is described below, to, among other things, modify the terms of the Series D preferred stock that currently require payment of dividends to Series D preferred stockholders upon payment of dividends to Series E stockholders. If such amendment is approved by our stockholders, the Series E preferred stockholders would become entitled to receive dividends payable in cash quarterly in arrears at the rate of 8% per annum and the Series D preferred stockholders would cease to be entitled to corresponding dividends. If such amendment is submitted to our stockholders and it is not approved, the holders of the Series E preferred stock will no longer be entitled to receive dividends. 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. In addition, we agreed to use our best efforts to file a preliminary proxy statement for our next annual meeting of stockholders that will, among other things, seek approval from our stockholders of the following matters:

the issuance and sale by us to the Series E purchasers (together with all prior issuances and sales to Pillar Pharmaceuticals I, L.P., or Pillar I, an investment partnership managed by one of our directors and significant stockholders) of a number of shares of common stock (including securities convertible into or exercisable for common stock) that is greater than 19.99% of our outstanding common stock or our outstanding voting power after such issuance and sale in accordance with Nasdaq Listing Rule 5635(b), or the Nasdaq Proposal;

an amendment to our restated certificate of incorporation and bylaws, as necessary, to eliminate the classification of our board of directors; and

an amendment to the Series D Certificate of Designations for our Series D preferred stock, which is held by Pillar I, to modify the dividend provisions of the Series D Certificate of Designations so that dividends on the Series E preferred stock are not required to be paid to the holders of Series D preferred stock and to conform the beneficial ownership limitations applicable to the conversion of the Series D preferred stock to the beneficial ownership limitations applicable to the conversion of the Series E preferred stock.

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% (prior to the date our stockholders approve the Nasdaq Proposal) or 25% (effective upon the date that our stockholders approve the Nasdaq Proposal) of our outstanding common stock, that the Series E purchaser 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 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 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 Certificate of Designations, Preferences and Rights of Series E Preferred Stock, or 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 D 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 Pillar I, Pillar II and an entity affiliated with Pillar I and Pillar II, together the Pillar Entities. The agreements, including our obligations to issue the warrants under the Pillar Agreements, became effective upon the consummation of our underwritten public offering on May 7, 2013.

Under the first agreement, which we refer to as the April 22, 2013 Pillar Agreement, we and each of Pillar I and Pillar II agreed, among other things, 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.

Under the Pillar Agreements, we agreed to seek approval from our stockholders at our 2013 annual meeting of stockholders of amendments to the Series E Certificate of Designations to effect these changes to the dividend and liquidation provisions of our Series E preferred stock, and Pillar II and its affiliated entity agreed:

to vote, and to cause its affiliates to vote, all shares of our voting stock held by Pillar II or its affiliates, and over which Pillar II or its affiliates has the power to vote, in favor of such amendments; and

not to, and to cause its affiliates not to, sell or transfer any shares of our common stock or Series E preferred stock held by Pillar II or its affiliates to any person, entity or group unless such proposed transferee agrees in a written instrument executed by such transferee, Pillar II and us to take and hold such securities subject to, among other things, the Pillar Agreements and to be bound by the terms of the Pillar Agreements, including the waiver of rights, voting agreements and restrictions on transfer set forth therein.

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.

#### *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 April 15, 2013.

#### *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 future 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% (prior to the date the stockholders of the Company approve the Nasdaq Proposal) or 25% (effective upon the date that the stockholders of the Company approve the Nasdaq Proposal) 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% (prior to the date the stockholders of the Company approve the Nasdaq Proposal) or 35% (effective upon the date that the stockholders of the Company approve the Nasdaq Proposal) 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. We have 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, any dividends that we pay to the Series E preferred stockholders will also be paid to the Series D preferred stockholders on an as-converted to common stock basis. We have agreed that, at our 2013 annual meeting of stockholders, we will propose an amendment to the Series D Certificate of Designations to, among other things, modify the terms of the Series D preferred stock that currently require payment of dividends to Series D preferred stockholders upon payment of dividends to Series E stockholders. If such amendment is approved by our stockholders, the Series E preferred stockholders would become entitled to receive dividends payable in cash quarterly in arrears at the rate of 8% per annum and the Series D preferred stockholders would cease to be entitled to corresponding dividends. If such amendment is submitted to our stockholders and it is not approved, the holders of the Series E preferred stock will no longer be entitled to receive dividends.

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, unless our stockholders approve the Nasdaq Proposal, in which case, the 19.99% limitation will be increased, with respect to Pillar I, to 35%. 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 and each of Pillar I and Pillar II agreed, among other things, 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

in connection with the waiver of the right to require us to purchase the Series D preferred stock upon the occurrence of specified fundamental changes, to 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 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 addition, under the Pillar Agreements, we agreed to seek approval from our stockholders at our 2013 annual meeting of stockholders of amendments to the Series D Certificate of Designations to effect these 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, and Pillar I has agreed:

to vote, and to cause its affiliates to vote, all shares of our voting stock held by Pillar I or its affiliates, and over which Pillar I or its affiliates has the power to vote, in favor of such amendments; and

not to, and to cause its affiliates not to, sell or transfer any shares of our common stock or Series D preferred stock held by Pillar I or its affiliates to any person, entity or group unless such proposed transferee agrees in a written instrument executed by such transferee, Pillar I and us to take and hold such securities subject to, among other things, the Pillar Agreements and to be bound by the terms of the Pillar Agreements, including the waivers of rights, voting agreements and restrictions on transfer set forth therein.

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

#### *Collaboration Agreements*

Under the terms of our collaboration with Merck KGaA, which was terminated in November 2011, we received in February 2008 a \$40.0 million upfront license fee in Euros of which we received \$39.7 million due to foreign currency exchange rates and approximately \$12.1 million in milestone payments. In addition, Merck KGaA reimbursed us \$4.5 million for expenses related to the development of IMO-2055. In connection with the termination of the collaboration, we agreed to reimburse Merck KGaA for up to 1.8 million (\$2.3 million using a March 31, 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 March 31, 2013, we have paid 0.8 of the 1.8 million (\$1.1 million (using exchange rates in effect at the time that the payments were made) of the \$2.3 million). We also agreed to pay to Merck KGaA one-time 1.0 million (\$1.3 million using a March 31, 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.

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. Since entering this agreement, we have also received \$1.0 million in milestone payments and \$3.4 million in research and development payments.

#### *Cash Flows*

##### *Three Months Ended March 31, 2013*

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

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

##### *Three Months Ended March 31, 2012*

Net cash used in operating activities totaled \$5,883,000 during the three months ended March 31, 2012, reflecting our \$6,886,000 net loss for the three months ended March, 31, 2012, as adjusted for non-cash expenses, including the increase in the warrant liability, stock-based compensation, depreciation expense and amortization. It also reflects changes in our prepaid expenses and accounts payable, accrued expenses and other liabilities.

The net cash provided by financing activities totaled \$1,000 during the three months ended March 31, 2012 representing the proceeds received from employee stock purchases under our employee stock purchase plan. We had no cash provided by investing activities during the three months ended March 31, 2012.

#### *Funding Requirements*

We have incurred operating losses in all fiscal years except 2002, 2008 and 2009, and we had an accumulated deficit of \$398,465,000 at March 31, 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' (deficit) equity, total assets and working capital.

We have received no revenues from the sale of drugs. As of April 15, 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 \$6,149,000 at March 31, 2013. We believe that the net proceeds of our follow-on public offering of our securities in May 2013, together with our existing cash and cash equivalents, will enable us to fund our operations at least through the fourth quarter of 2014. We believe that our available funds following the May 2013 offering will be sufficient to enable us to conduct our planned Phase 2 clinical trial of IMO-8400 in patients with psoriasis and to plan for further clinical development of IMO-8400. We will need to raise additional funds in order to conduct any other clinical development of IMO-3100 or IMO-8400 or to conduct any other development of our other product candidates or technologies. It is also possible that we will not achieve the progress that we expect with respect to IMO-8400 because the actual costs and timing of clinical development activities are difficult to predict and are subject to substantial risks and delays.

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

the results of our clinical and preclinical development programs, including the results of the ongoing Phase 1 clinical trial of IMO-8400 and the results of the planned Phase 2 clinical trial of IMO-8400 in patients with moderate to severe plaque psoriasis;

developments relating to our existing strategic collaboration with Merck & Co.;

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

the cost, timing and outcome of regulatory reviews;

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

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

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

In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require additional funds or further cost reductions. Financing may not be available to us when we need it or may not be available to us on favorable or acceptable terms. We could be required to seek funds through collaborative alliances or others 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. 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. An equity financing that involves existing stockholders may cause a concentration of ownership. The terms of any financing may adversely affect the holdings or the rights of existing stockholders. If we are unable to obtain adequate funding on a timely basis or at all, we will be required to terminate, modify or delay preclinical or clinical trials of one or more of our drug candidates, significantly curtail or terminate discovery or development programs for new drug candidates or relinquish rights to portions of our technology, drug candidates and/or products.



### *Nasdaq Listing*

Our common stock began trading on the Nasdaq Capital Market on February 7, 2013. In order to continue the listing of our common stock on the Nasdaq Capital Market, we are required to meet the continued listing requirements of the Nasdaq Capital Market. If we do not meet these continued listing requirements, our common stock will be delisted.

On November 26, 2012, we received a letter from the Listing Qualifications Staff of the Nasdaq Stock Market indicating that, based on the closing bid price of our common stock for the 30 consecutive business days prior to November 26, 2012, we no longer satisfied the requirement that our common stock maintain a minimum bid price of \$1.00 per share as required by Nasdaq Listing Rule 5450(a)(1). Nasdaq stated in its letter that in accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days, or until May 28, 2013, to regain compliance with the minimum bid price requirement. The Nasdaq letter stated that if, at any time before May 28, 2013, the closing bid price of our common stock is at or above \$1.00 per share for a minimum of 10 consecutive business days, we will be deemed to have regained compliance with the minimum bid price requirement and the matter will be closed. If we do not regain compliance with the minimum bid price requirement by May 28, 2013, Nasdaq will provide us with a written notification that our common stock is subject to delisting. We may be eligible to receive an additional 180-day grace period (for a total of 360 days from November 26, 2012) to regain compliance with the minimum bid price requirement provided that we satisfy the continued listing standard for market value of publicly held shares and all other applicable initial listing standards for the Nasdaq Capital Market, other than the minimum bid price requirement, as of May 28, 2013.

Prior to February 7, 2013, our common stock was traded on the Nasdaq Global Market where we were required to meet specified financial requirements, including requirements that we maintain a minimum stockholders' equity of \$10.0 million or a minimum market value of listed securities of \$50.0 million. On June 7, 2012, we received a notification letter from the Nasdaq Listing Qualifications staff of the Nasdaq Stock Market advising us that we were not in compliance with these requirements. Nasdaq also stated in its letter that, in accordance with Nasdaq Listing Rule 5810(c)(3)(C), we had been provided a compliance period of 180 calendar days, or until December 4, 2012, to regain compliance with these requirements. Because we were not able to regain compliance with these requirements by such date, we requested a hearing before the Nasdaq Listing Qualifications Hearings Panel, or the Panel, at which we requested continued listing pending our return to compliance. Our hearing request stayed the suspension of trading and delisting of our common stock pending the conclusion of the hearing process. On February 5, 2013, the Panel granted our request to transfer the listing of our common stock from the Nasdaq Global Market to the Nasdaq Capital Market and to continue the listing of our common stock on the Nasdaq Capital Market, provided that we satisfied the \$2.5 million stockholders' equity requirement on or before March 31, 2013, and otherwise met the continued listing requirements of the Nasdaq Capital Market. On March 5, 2013, the Panel extended this date to May 22, 2013 and indicated that by such date, in addition to satisfying the \$2.5 million stockholders' equity requirement for continued listing on that market and otherwise meeting the continued listing requirements of the Nasdaq Capital Market, we were also required to provide the Panel with additional information regarding our projected burn-rate and stockholders' equity through May 31, 2014. On May 8, 2013, we received formal notice from the Nasdaq Stock Market LLC that we had evidenced compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5450(b)(2) as required by the Panel and that the matter had been closed.

### *Contractual Obligations*

During the three months ended March 31, 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 March 31, 2013, we had net accrued obligations of 1.0 million (\$1.3 million using a March 31, 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 March 31, 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.

**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 March 31, 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 March 31, 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 March 31, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



---

**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 \$6,149,000 at March 31, 2013. We believe that the net proceeds of our follow-on public offering of our securities in May 2013, together with our existing cash and cash equivalents, will enable us to fund our operations at least through the fourth quarter of 2014. We believe that our available funds following the May 2013 offering will be sufficient to enable us to conduct our planned Phase 2 clinical trial of IMO-8400 in patients with psoriasis and to plan for further clinical development of IMO-8400. We will need to raise additional funds in order to conduct any other clinical development of IMO-3100 or IMO-8400 or to conduct any other development of our other product candidates or technologies. It is also possible that we will not achieve the progress that we expect with respect to IMO-8400 because the actual costs and timing of clinical development activities are difficult to predict and are subject to substantial risks and delays.

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

the results of our clinical and preclinical development programs, including the results of the ongoing Phase 1 clinical trial of IMO-8400 and the results of the planned Phase 2 clinical trial of IMO-8400 in patients with moderate to severe plaque psoriasis;

developments related to our existing collaboration with Merck & Co.;

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

the cost, timing, and outcome of regulatory reviews;

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

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

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



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

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

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

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

We have received a report from Ernst & Young LLP, our independent registered public accounting firm, regarding our financial statements as of December 31, 2012 and for the fiscal year then ended, which included an explanatory paragraph stating that the financial statements were prepared assuming we will continue as a going concern. The report also stated that our recurring losses and negative cash flows from operations will require us to raise additional capital or obtain alternative means of financial support, or both, prior to December 31, 2013 in order to continue to fund our operations. These factors raise substantial doubt about our ability to continue as a going concern. As we only have cash resources to fund our operations into the third quarter of 2013, 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. The going concern explanatory paragraph included in our auditor's report on our financial statements could inhibit our ability to finance our operations. If we are unable to obtain adequate funding on a timely basis or at all, we will be required to terminate, modify or delay preclinical or clinical trials of one or more of our drug candidates, significantly curtail or terminate discovery or development programs for new drug candidates or relinquish rights to portions of our technology, drug candidates and/or products.

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

Our common stock began trading on the Nasdaq Capital Market on February 7, 2013. In order to continue the listing of our common stock on the Nasdaq Capital Market, we are required to meet the continued listing requirements of the Nasdaq Capital Market. If we do not meet these continued listing requirements, our common stock will be delisted.

On November 26, 2012, we received a letter from the Listing Qualifications Staff of the Nasdaq Stock Market indicating that, based on the closing bid price of our common stock for the 30 consecutive business days prior to November 26, 2012, we no longer satisfied the requirement that our common stock maintain a minimum bid price of \$1.00 per share as required by Nasdaq Listing Rule 5450(a)(1). Nasdaq stated in its letter that in accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days, or until May 28, 2013, to regain compliance with the minimum bid price requirement. The Nasdaq letter stated that if, at any time before May 28, 2013, the closing bid price of our common stock is at or above \$1.00 per share for a minimum of 10 consecutive business days, we will be deemed to have regained compliance with the minimum bid price requirement and the matter will be closed. If we do not regain compliance with the minimum bid price requirement by May 28, 2013, Nasdaq will provide us with a written notification that our common stock is subject to delisting. We may be eligible to receive an additional 180-day grace period (for a total of 360 days from November 26,

2012) to regain compliance with the minimum bid price requirement provided that we satisfy the continued listing standard for market value of publicly held shares and all other applicable initial listing standards for the Nasdaq Capital Market, other than the minimum bid price requirement, as of May 28, 2013.

Prior to February 7, 2013, our common stock was traded on the Nasdaq Global Market where we were required to meet specified financial requirements, including requirements that we maintain a minimum stockholders' equity of \$10.0 million or a minimum market value of listed securities of \$50.0 million. On June 7, 2012, we received a notification letter from the Nasdaq Listing Qualifications staff of the Nasdaq Stock Market advising us that we were not in compliance with these requirements. Nasdaq also stated in its letter that, in accordance with Nasdaq Listing Rule 5810(c)(3)(C), we had been provided a compliance period of 180 calendar days, or until December 4, 2012, to regain compliance with these requirements. Because we were not able to regain compliance with these requirements by such date, we requested a hearing before the Nasdaq Listing Qualifications Hearings Panel, or the Panel, at which we requested continued listing pending our return to compliance. Our hearing request stayed the suspension of trading and delisting of our common stock pending the conclusion of the hearing process. On February 5, 2013, the Panel granted our request to transfer the listing of our common stock from the Nasdaq Global Market to the Nasdaq Capital Market and to continue the listing of our common stock on the Nasdaq Capital Market, provided that we satisfied the \$2.5 million stockholders' equity requirement on or before March 31, 2013, and otherwise met the continued listing requirements of the Nasdaq Capital Market. On March 5, 2013, the Panel extended this date to May 22, 2013 and indicated that by such date, in addition to satisfying the \$2.5 million stockholders' equity requirement for continued listing on that market and otherwise meeting the continued listing requirements of the Nasdaq Capital Market, we were also required to provide the Panel with additional information regarding our projected burn-rate and stockholders' equity through May 31, 2014. On May 8, 2013, we received formal notice from the Nasdaq Stock Market LLC that we had evidenced compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5450(b)(2) as required by the Panel and that the matter had been closed.

If our common stock were to be delisted from the Nasdaq Capital Market, it may be eligible to trade on the Over-The-Counter Bulletin Board, which may be a less liquid market, or on the pink sheets. In such case, our stockholders' ability to trade, or obtain quotations of the market value of, shares of our common stock would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our securities. There can be no assurance that our common stock, if in the future it were to be delisted from the Nasdaq Capital Market, would be listed on a national securities exchange, a national quotation service, the Over-The-Counter Bulletin Board or the pink sheets. Delisting from the Nasdaq Capital Market, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, adversely affect the market liquidity of our common stock, reduce security analysts' coverage of us and diminish investor, supplier and employee confidence.

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

We have incurred losses in every year since our inception, except for 2002, 2008, and 2009 when our recognition of revenues under license and collaboration agreements resulted in our reporting net income for those years. As of March 31, 2013, we had an accumulated deficit of \$398.5 million. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 to March 31, 2013, we incurred losses of \$138.3 million. We incurred losses of \$260.2 million prior to December 31, 2000 during which time we were primarily involved in the development of non-TLR targeted antisense technology. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets, and working capital.

We have never had any products of our own available for commercial sale and have received no revenues from the sale of drugs. As of April 15, 2013, almost all of our revenues have been from collaborative and license agreements. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any drug candidates. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our drug candidates will become commercially available, or when we will become profitable, if at all. We expect to incur substantial operating losses in future periods.

---

## Risks Relating to Our Business, Strategy and Industry

*We are depending heavily on the development of TLR-targeted drug candidates for the treatment of autoimmune and inflammatory diseases. If we terminate the development of the program or any of our drug candidates in the program, are unable to successfully develop and commercialize any of our drug candidates, or experience significant delays in doing so, our business may be materially harmed.*

We have invested a significant portion of our time and financial resources in the development of our clinical stage lead drug candidates, IMO-3100 and IMO-8400, as part of our autoimmune and inflammatory disease program. Based on the clinical activity of IMO-3100 observed in our four-week Phase 2 clinical trial of IMO-3100 in patients with psoriasis, we have determined that the next step in our development program is to conduct 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. Based on our evaluation of the comparative profiles of IMO-3100 and IMO-8400, including the engagement of TLR8 by IMO-8400, we have determined to focus our resources on the development of IMO-8400 and to conduct this trial in patients with psoriasis with IMO-8400. We expect to initiate this trial in the second quarter of 2013 and to have top-line data by the end of 2013.

We are also planning to initiate a signal-seeking Phase 2 clinical trial of IMO-8400 in patients with lupus, and are considering conducting a proof-of-concept study of IMO-8400 in an orphan autoimmune disease indication. We expect to select the orphan autoimmune disease indication for further exploration in the second half of 2013. However, our plans to conduct the Phase 2 clinical trial of IMO-8400 in patients with lupus and the proof-of-concept study are subject to our ability to raise additional funding to fund the conduct of this Phase 2 trial and proof-of-concept study. We expect to seek such additional funding through public or private equity offerings, debt financings, collaborations and licensing arrangements and other sources.

As such, we anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of our drug candidates in our autoimmune and inflammatory disease program. Our ability to generate product revenues will also depend on the development and commercialization of the drug candidates being developed under our collaboration with Merck & Co. Our efforts, and the efforts of Merck & Co., to develop and commercialize these compounds are at an early stage and are subject to many challenges. We have experienced setbacks with respect to our programs for IMO-3100, IMO-2125, and IMO-2055, including:

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

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

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

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

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

the drug candidates demonstrating activity in clinical trials;

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

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

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

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

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

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

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

establishment of commercial manufacturing arrangements with third-party manufacturers;

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

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

competition from other companies and their therapies;

changes in treatment regimes;

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

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

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

In order to obtain regulatory approvals for the commercial sale of our products, we are required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of our drug candidates. Clinical trials are lengthy, complex, and expensive processes with uncertain results. We may not be able to complete any clinical trial of a potential product within any specified time period. Moreover, clinical trials may not show our potential products to be both safe and

efficacious. The FDA or other equivalent foreign regulatory agencies may not allow us to complete these trials or commence and complete any other clinical trials. For example, in July 2011, the FDA placed a clinical hold on a protocol we had submitted for a proposed Phase 2 clinical trial of IMO-3100 in patients with psoriasis.

The results from preclinical testing of a drug candidate that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger scale, advanced stage clinical trials. Furthermore, interim results of a clinical trial do not necessarily predict final results, and failure of any of our clinical trials can occur at any stage of testing. Companies in the biotechnology and pharmaceutical industries, including companies with greater experience in preclinical testing and clinical trials than we have, have suffered significant setbacks 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.

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

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

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

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

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

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

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

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



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

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

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

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

the size of the patient population;

the proximity of patients to clinical sites;

the eligibility criteria for the trial;

the nature of the trial, including the pattern of patient enrollment;

the existence of competitive clinical trials; and

the availability of alternative treatments.

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

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

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

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

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

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

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

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

## Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-Q

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 for use as vaccine adjuvants. We have two drug candidates in clinical development in our autoimmune and inflammatory disease program. We are also collaborating with Merck & Co. for the use of agonists of TLR7, TLR8, and TLR9 as vaccine adjuvants for cancer, infectious diseases and Alzheimer's disease. Finally, we are seeking to enter into collaborative alliances with pharmaceutical companies to advance our TLR-targeted programs in oncology and respiratory diseases, and for the use of TLR3 agonists as vaccine adjuvants, as well as applications of our GSO technology platform. For all of these disease areas, there are many other companies, public and private, that are actively engaged in discovery, development, and commercializing products and technologies that may compete with our drug candidates and programs, including TLR targeted compounds as well as non-TLR targeted therapies.

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

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

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

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

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

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

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

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

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

## **Regulatory Risks**

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

All of the drug candidates that we are developing, or may develop in the future, will require additional research and development, extensive preclinical studies, nonclinical testing, clinical trials, and regulatory approval prior to any commercial sales. This process is lengthy, often taking a number of years, is uncertain, and is expensive. Since our inception, we have conducted clinical trials of a number of compounds. Currently two of our compounds, IMO-3100 and IMO-8400, are in clinical development. The FDA and other regulatory authorities may not approve any of our potential products for any indication.

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

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

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

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

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

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

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

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

withdrawal of our products from the market;

warning letters;

voluntary or mandatory product recalls;

fines;

suspension or withdrawal of regulatory approvals;

product seizure or detention;

refusal to permit the import or export of our products;

injunctions or the imposition of civil penalties; and

criminal penalties.

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

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

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

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

### **Risks Relating to Collaborators**

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

Collaborators provide the necessary resources and drug development experience to advance our compounds in their programs. We are seeking to enter into collaborative alliances with pharmaceutical companies to advance our TLR-targeted programs in oncology, infectious diseases, respiratory diseases, and the use of TLR3 agonists as vaccine adjuvants, as well as applications of our GSO technology platform.

Upfront payments and milestone payments received from collaborations help to provide us with the financial resources for our internal research and development programs. Our internal programs are focused on developing TLR-targeted drug candidates for the potential treatment of autoimmune and inflammatory diseases. We 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 public release of information regarding the developments, and we may not be able to make announcements or data presentations on a schedule favorable to us;

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

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

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

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

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

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

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

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

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

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

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

## Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-Q

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

---

**Risks Relating to Intellectual Property**

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

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

obtain patents;

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

operate without infringing upon the proprietary rights of others;

prevent others from infringing on our proprietary rights; and

protect our trade secrets.

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

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

As of April 15, 2013, we owned more than 50 U.S. patents and patent applications and more than 100 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 and IMO-2055. As of April 15, 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 U.S. patent applications that cover 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-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 April 15, 2013, we owned four U.S. patent applications and six worldwide patent applications for our GSO compounds and methods of their use. Patents issuing from these patent applications, if any, would expire at the earliest in 2030.

In addition to our TLR-targeted and GSO patent portfolios, we are the owner or hold licenses of patents and patent applications related to antisense technology. As of April 15, 2013, our antisense patent portfolio included more than 75 U.S. patents and patent applications and more than 75 patents and patent applications 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 antisense. Under these licenses we are obligated to pay royalties on net sales by us of products or processes covered by a valid claim of a patent or patent application licensed to us. We also are required in some cases to pay a specified percentage of any sublicense income that we may receive. These licenses impose various commercialization, sublicensing, insurance, and other obligations on us.

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

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

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

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

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

---

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

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

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

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

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

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

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

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

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

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

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

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

Additionally, contract manufacturers may not be able to manufacture our drug candidates at a cost or in quantities necessary to make them commercially viable. As of January 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 ongoing Phase 1 clinical trial of IMO-8400 and our planned 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.

***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. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

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

the efficacy and potential advantages over alternative treatments;

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

relative convenience and ease of administration;

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



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

publicity concerning our products or competing products and treatments.

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

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

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

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

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

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

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

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

decreased demand for our drug candidates and products;

damage to our reputation;

regulatory investigations that could require costly recalls or product modifications;

withdrawal of clinical trial participants;

costs to defend related litigation;

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

loss of revenue;

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

the inability to commercialize any products that we may develop.

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

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

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

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

a classified board of directors;

limitations on the removal of directors;

limitations on stockholder proposals at meetings of stockholders;

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

the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval. As part of the financing we consummated in November 2012, we agreed that we would seek stockholder approval of an amendment to the Company's certificate of incorporation and bylaws to eliminate the classified board of directors.

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

---

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

In connection with our Series D redeemable convertible preferred stock 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 2,810,650 shares of our common stock. In connection with our Series E convertible preferred stock 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 8,484,840 shares of our common stock. We refer to Pillar I, Pillar II and the affiliated second purchaser collectively as the Pillar Affiliates. As a result, the Pillar Affiliates are collectively our largest stockholder group. In addition, two members of our board of directors are affiliates of the Pillar Affiliates. In connection with their ownership of these securities, the Pillar Affiliates 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 Affiliates 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 Affiliates, the Pillar Affiliates may still be able to exert substantial influence over our business.

***The securities issued in our Series D and Series E financings have certain rights, preferences and privileges 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, liquidation and, upon certain transactions, redemption, which are not provided to the holders of our common stock. The dividend rights of the Series D preferred stock and Series E preferred stock may adversely affect our liquidity. For example, our obligation to pay quarterly cash dividends to the holders of our preferred stock has reduced and will continue to reduce the funds that would otherwise be available to us for working capital and other general corporate purposes. In addition, under certain circumstances, we are entitled to pay dividends on our Series D preferred stock in shares of common stock. If we were to pay such dividends in common stock, our existing stockholders will experience dilution. In the event of a liquidation, dissolution or winding up of our company, the holders of our Series D preferred stock and Series E preferred stock will be entitled to receive an aggregate of up to approximately \$15.4 million before any cash distribution may be made or any other assets may be distributed to the holders of our common stock. Further, pursuant to the redemption rights of the Series D preferred stock, upon the occurrence of specified fundamental changes such as mergers, consolidations, business combinations, stock purchases or similar transactions (and in lieu of any liquidation preference the Series D preferred stock may otherwise be entitled to), the holders of shares of our Series D preferred stock may require that we redeem the Series D preferred stock held by them at a cash price equal to the original Series D preferred stock purchase price (approximately \$9.1 million in the aggregate) plus all accrued or declared but unpaid dividends thereon.

On April 22, 2013, we entered into an agreement with Pillar I and Pillar II, which we refer to as the April 22, 2013 Pillar Agreement. Under the April 22, 2013 Pillar Agreement, Pillar I, as the sole holder of our Series D preferred stock, irrevocably waived and agreed to not exercise the redemption rights of the holders of our Series D preferred stock. In addition, we and each of Pillar I and Pillar II agreed 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;

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

the dividend provisions of the Series D Certificate of Designations and Series E Certificate of Designations 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 Series E Certificate of Designations, respectively.

In addition, on April 30, 2013, we entered into a second agreement with Pillar I, Pillar II and an entity affiliated with Pillar I and Pillar II, which we refer to collectively as the Pillar Entities. We refer to this agreement as the April 30, 2013 Pillar Agreement, and this agreement and the April 22, 2013 Pillar Agreement as the Pillar Agreements. Under the April 30, 2013 Pillar Agreement, each of the Pillar Entities irrevocably waived the approximate \$15.4 million liquidation preference described above in the event of a liquidation, dissolution or winding up of our company.

We agreed to seek approval from our stockholders at our 2013 annual meeting of stockholders of amendments to the Series D Certificate of Designations and Series E Certificate of Designations to effect these changes to the dividend and liquidation provisions of our Series D preferred stock and Series E 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, and the Pillar Entities agreed to vote in favor of these amendments.

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

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 April 15, 2013, the closing sales price of our common stock ranged from a high of \$3.25 per share to a low of \$0.46 per share. The stock market has also experienced periods of significant price and volume fluctuations and the market prices of biotechnology companies in particular have been highly volatile, often for reasons that have been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

our cash resources;

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

the regulatory status of our drug candidates;

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

the success of competitive products or technologies;

regulatory developments in the United States and foreign countries;

our success in entering into collaborative agreements;

developments or disputes concerning patents or other proprietary rights;

the departure of key personnel;

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

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

the terms of any financing consummated by us;

changes in the structure of healthcare payment systems;

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

general economic, industry, and market conditions.

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

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

**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.



**SIGNATURES**

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

**IDERA PHARMACEUTICALS, INC.**

Date: May 15, 2013

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

(Principal Executive Officer)

Date: May 15, 2013

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

**Exhibit Index**

**Exhibit No.**

- |          |  |
|----------|--|
| 10.1     | Agreement, dated April 22, 2013, among the Company, Pillar Pharmaceuticals I, L.P. and Pillar Pharmaceuticals II, L.P. (incorporated by reference to the exhibits to the Company's Current Report on Form 8-K filed April 23, 2013).   |
| 10.2     | Agreement, dated April 30, 2013, among the Company, Pillar Pharmaceuticals I, L.P., Pillar Pharmaceuticals II, L.P. and Participations Besancon (incorporated by reference to exhibits to the Company's Registration Statement on Form S-1, file number 333-187155, filed on May 1, 2013). |
| 10.3     | Form of Warrant issued to purchasers in the Company's registered public offering on the Company's registration statement on Form S-1 (File No. 333-187155)   |
| 10.4     | Form of Warrant issued to entities affiliated with Pillar Invest Corporation in the Company's registered public offering on the Company's registration statement on Form S-1 (File No. 333-187155)   |
| 10.5     | Form of Pre-Funded Warrant issued to purchasers in the Company's registered public offering on the Company's registration statement on Form S-1 (File No. 333-187155)  |
| 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   |

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-Q

\* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.