

IDERA PHARMACEUTICALS, INC.

Form 10-Q

May 04, 2010

**Table of Contents**

**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, 2010,**

**or**

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

**For transition period from \_\_\_\_\_ to \_\_\_\_\_.**

**Commission File Number: 001-31918**

**IDERA PHARMACEUTICALS, INC.**

*(Exact name of registrant as specified in its charter)*

**Delaware**

**04-3072298**

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

*(I.R.S. Employer Identification No.)*

**167 Sidney Street**

**Cambridge, Massachusetts**

*(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  Smaller reporting company   
(Do not check if a smaller reporting company)

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

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

**23,488,925**  
Outstanding as of March 31, 2010



**IDERA PHARMACEUTICALS, INC.**  
**FORM 10-Q**  
**INDEX**

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<u>Item 1 Financial Statements</u>	4
<u>Unaudited Condensed Balance Sheets as of March 31, 2010 and December 31, 2009</u>	4
<u>Unaudited Condensed Statements of Operations for the Three Months ended March 31, 2010 and 2009</u>	5
<u>Unaudited Condensed Statements of Cash Flows for the Three Months ended March 31, 2010 and 2009</u>	6
<u>Notes to Condensed Financial Statements</u>	7
<u>Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
<u>Item 3 Quantitative and Qualitative Disclosures about Market Risk</u>	20
<u>Item 4 Controls and Procedures</u>	20
<b><u>PART II OTHER INFORMATION</u></b>	
<u>Item 1A. Risk Factors</u>	21
<u>Item 6 Exhibits</u>	34
<u>Signatures</u>	35
<u>EX-10.1</u>	
<u>EX-10.2</u>	
<u>EX-10.3</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	
<u>EX-32.2</u>	

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

**Table of Contents**

**FORWARD-LOOKING STATEMENTS**

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

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

<b>(in thousands, except per share amounts)</b>	<b>March 31, 2010</b>	<b>December 31, 2009</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 14,836	\$ 25,471
Short-term investments, available-for-sale	18,782	6,270
Receivables	42	4,497
Prepaid expenses	2,134	540
Other current assets	479	490
 Total current assets	 36,273	 37,268
Property and equipment, net	1,303	1,387
Non-current portion of prepaid expenses	104	104
Long-term investments, available-for-sale	4,028	8,466
Restricted cash, net of current portion	414	414
 Total assets	 \$ 42,122	 \$ 47,639
 <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 758	\$ 1,166
Accrued expenses	2,060	931
Current portion of capital lease	19	19
Current portion of deferred revenue	6,562	12,098
 Total current liabilities	 9,399	 14,214
Capital lease obligation, net of current portion	4	9
Deferred revenue, net of current portion	56	67
Other liabilities	255	244
 Total liabilities	 9,714	 14,534
 Commitments and contingencies		
Stockholders equity:		
Preferred stock, \$0.01 par value, Authorized 5,000 shares Series A convertible preferred stock, Designated 1,500 shares, Issued and outstanding 1 share at March 31, 2010 and December 31, 2009		
Common stock, \$0.001 par value, Authorized 70,000 shares Issued and outstanding 23,489 and 23,479 shares at March 31, 2010 and December 31, 2009, respectively	23	23
Additional paid-in capital	368,009	366,780

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

Accumulated deficit	(335,622)	(333,679)
Accumulated other comprehensive loss	(2)	(19)
Total stockholders' equity	32,408	33,105
Total liabilities and stockholders' equity	\$ 42,122	\$ 47,639

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

4

---

**Table of Contents**

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

<b>(in thousands, except per share amounts)</b>	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2010</b>	<b>2009</b>
Alliance revenue	\$ 5,577	\$ 6,303
Operating expenses:		
Research and development	4,586	4,478
General and administrative	2,732	2,148
Total operating expenses	7,318	6,626
Loss from operations	(1,741)	(323)
Other income (expense):		
Investment income, net	26	71
Foreign currency exchange loss	(228)	
Net loss	\$ (1,943)	\$ (252)
Basic and diluted net loss per share	\$ (0.08)	\$ (0.01)
Shares used in computing basic and diluted net loss per common share	23,462	23,379

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

**Table of Contents**

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

<b>(in thousands)</b>	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (1,943)	\$ (252)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	1,173	743
Non-employee stock options	14	(7)
Depreciation	144	140
Amortization of investment premiums	49	
Issuance of common stock for services rendered	1	
Changes in operating assets and liabilities		
Accounts receivable	4,455	(149)
Prepaid expenses and other current assets	(1,583)	(276)
Accounts payable and accrued expenses	734	110
Deferred revenue	(5,547)	(5,656)
Net cash used in operating activities	(2,503)	(5,347)
<b>Cash Flows from Investing Activities:</b>		
Purchase of available-for-sale securities	(8,106)	
Proceeds from maturity of available-for-sale securities		7,250
Purchase of property and equipment	(60)	(3)
Net cash (used in) provided by investing activities	(8,166)	7,247
<b>Cash Flow from Financing Activities:</b>		
Proceeds from exercise of common stock options and employee stock purchases	39	72
Payments on capital lease	(5)	(5)
Net cash provided by financing activities	34	67
Net (decrease) increase in cash and cash equivalents	(10,635)	1,967
Cash and cash equivalents, beginning of period	25,471	45,165
Cash and cash equivalents, end of period	\$ 14,836	\$ 47,132

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

**Table of Contents**

**IDERA PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**March 31, 2010**  
**(UNAUDITED)**

(1) (a) Organization

Idera Pharmaceuticals, Inc. ( Idera or the Company ) is a biotechnology company engaged in the discovery and development of DNA- and RNA-based drug candidates targeted to Toll-Like Receptors, or TLRs, to treat infectious diseases, autoimmune and inflammatory diseases, cancer, and asthma and allergies, and for use as vaccine adjuvants. Drug candidates are compounds that the Company is developing and that have not been approved for any commercial use. TLRs are specific receptors present in immune system cells that recognize the DNA or RNA of bacteria or viruses and initiate an immune response. Relying on its expertise in DNA and RNA chemistry, the Company has designed and created proprietary TLR agonists and antagonists to modulate immune responses. A TLR agonist is a compound that stimulates an immune response through the targeted TLR. A TLR antagonist is a compound that blocks activation of an immune response through the targeted TLR.

Idera's business strategy is to advance applications of its TLR-targeted drug candidates in multiple disease areas simultaneously. The Company is advancing some of these applications through internal programs, and it seeks to advance other applications through collaborative alliances with pharmaceutical companies. Collaborators provide the necessary resources and drug development experience to advance the Company's compounds in their programs. Upfront payments and milestone payments received from collaborations help to provide the Company with the financial resources for its internal research and development programs.

The Company's internal programs are focused on developing TLR-targeted drug candidates for the potential treatment of infectious diseases, autoimmune and inflammatory diseases, cancer, and asthma and allergies.

In addition to its internal programs, the Company is currently collaborating with two pharmaceutical companies to advance other applications of its TLR-targeted compounds. The Company is collaborating with Merck KGaA, Darmstadt, Germany, for cancer treatment, excluding cancer vaccines, and with Merck Sharp & Dohme Corp. (previously known as Merck & Co., Inc. and which is referred to herein as Merck) for vaccine adjuvants in the fields of cancer, infectious diseases, and Alzheimer's disease. Merck KGaA and Merck are not related.

At March 31, 2010, the Company had an accumulated deficit of \$335.6 million. The Company may incur substantial operating losses in future periods. The Company does not expect to generate significant funds or product revenue until it successfully completes development and obtains marketing approval for products, either alone or in collaborations with third parties, which it expects will take a number of years. In order to commercialize its products, the Company needs to address a number of technological challenges and to comply with comprehensive regulatory requirements. In 2010, the Company expects that its research and development expenses will be higher than its research and development expenses in 2009 as it expands its clinical trials and accelerates its early-stage programs of TLR antagonists and of agonists of TLR7 and TLR8.

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.

(b) New Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board issued new accounting requirements for accounting for revenue recognition under multiple-element arrangements, which will be effective for fiscal years beginning after June 15, 2010. The Company is currently evaluating the effect of these new requirements on its financial statements.

(2) Unaudited Interim Financial Statements

The accompanying unaudited financial statements included herein have been prepared by the Company in accordance with generally accepted accounting principles 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 United States generally accepted accounting principles 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-month period ended March 31, 2010 are not necessarily indicative of results that may be expected for the year ended December 31, 2010. 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, 2009, which was filed with the SEC on March 10, 2010.

**Table of Contents****(3) Cash Equivalents and Investments**

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, 2010 and December 31, 2009 consisted of cash and money market funds.

Management determines the appropriate classification of marketable securities at the time of purchase. Investments that the Company does not have the positive intent to hold to maturity are classified as available-for-sale and reported at fair market value. Unrealized gains and losses associated with available-for-sale investments are recorded in

Accumulated other comprehensive loss on the accompanying balance sheets. The amortization of premiums and accretion of discounts, and any realized gains and losses and declines in value judged to be other-than-temporary, and interest and dividends for all available-for-sale securities are included in Investment income, net on the accompanying statements of operations. The Company had no held-to-maturity investments at either March 31, 2010 or December 31, 2009. The cost of securities sold is based on the specific identification method.

The Company had no realized gains or losses from available-for-sale securities in three months ended March 31, 2010 and 2009. There were no losses or other-than-temporary declines in value included in Investment income, net for any securities for the three months ended March 31, 2010 and 2009.

The Company's investments as of March 31, 2010 and December 31, 2009 consist of government, agency and corporate bonds. The Company had no auction rate securities as of March 31, 2010 and December 31, 2009.

The Company's available-for-sale investments consisted of the following at March 31, 2010 and December 31, 2009:

(in thousands)	Cost	March 31, 2010		Estimated Fair Value
		Gross Unrealized (Losses)	Gross Unrealized Gains	
Corporate bonds due in one year or less	\$ 1,024	\$ (1)	\$	\$ 1,023
Agency bonds due in one year or less	7,553	(11)		7,542
U.S. government bonds due in one year or less	10,203		14	10,217
Total short-term investments	18,780	(12)	14	18,782
Corporate bonds due in one year or more	1,018	(3)		1,015
U.S. government bonds due in one year or more	3,014	(1)		3,013
Total long-term investments	4,032	(4)		4,028
Total investments	\$ 22,812	\$ (16)	\$ 14	\$ 22,810

(in thousands)	Cost	December 31, 2009		Estimated Fair Value
		Gross Unrealized (Losses)	Gross Unrealized Gains	
Agency bonds due in one year or less	\$ 4,283	\$ (6)	\$	\$ 4,277
U.S. government bonds due in one year or less	1,994	(1)		1,993
Total short-term investments	6,277	(7)		6,270
Agency bonds due in one year or more	1,256	(4)		1,252
U.S. government bonds due in one year or more	7,222	(8)		7,214

Total long-term investments	8,478	(12)		8,466
Total investments	\$ 14,755	\$ (19)	\$	\$ 14,736

(4) Fair Values 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. Assumptions that market participants would use in pricing the asset or liability (the inputs) are prioritized 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 table below presents the assets and liabilities measured at fair value on a recurring basis at March 31, 2010 categorized by the level of inputs used in the valuation of each asset and liability.

**Table of Contents**

<b>(in thousands)</b>	<b>Total</b>	<b>Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Assets				
Money market fund	\$ 14,819	\$ 14,819	\$	\$
Short-term investments	18,782	10,217	8,565	
Long-term investments	4,028	3,013	1,015	
Total	\$ 37,629	\$ 28,049	\$ 9,580	\$
Liabilities	\$	\$	\$	\$

Level 1 investments include money market funds and U.S. Government bond investments. The money market fund primarily consists of investments in certificates of deposit, commercial paper, time deposits, U.S. Government agency securities, corporate bonds and repurchase agreements and is classified as Level 1 since it is actively traded daily at \$1.00 net asset value per share. U.S. Government bond investments are actively traded daily.

Level 2 investments consist of federal agency and 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 all investments are classified as available-for-sale securities, any gains or losses are recorded in other comprehensive gains or losses in stockholders equity.

There were no significant unrealized losses on investments at March 31, 2010. See Note (3).

**(5) Property and Equipment**

At March 31, 2010 and December 31, 2009, net property and equipment at cost consists of the following:

<b>(in thousands)</b>	<b>March 31, 2010</b>	<b>December 31, 2009</b>
Leasehold improvements	\$ 514	\$ 514
Laboratory equipment and other	2,865	2,811
Total property and equipment, at cost	3,379	3,325
Less: Accumulated depreciation and amortization	2,076	1,938
Property and equipment, net	\$ 1,303	\$ 1,387

As of March 31, 2010 and December 31, 2009, laboratory equipment and other included approximately \$79,000 of office equipment financed under capital leases with accumulated depreciation of approximately \$45,000 and \$41,000, respectively.

Depreciation expense, which includes amortization of assets recorded under capital leases, was approximately \$144,000 and \$140,000 in the three months ended March 31, 2010 and 2009, respectively.

**(6) Restricted Cash**

As part of the lease arrangement entered into by the Company in October 2006 to lease its office and laboratory facility commencing in June 2007, the Company was required to restrict \$619,000 of cash for a security deposit. The restricted cash was reduced by approximately \$102,000 in June 2009 upon the second anniversary of the lease commencement date. As a result, at March 31, 2010 restricted cash was \$516,000, including \$102,000 classified in other current assets. The restricted cash is held in certificates of deposit securing a line of credit for the lessor. The restricted cash is expected to be further reduced by approximately \$102,000 upon each of the third and fourth anniversaries of the lease commencement date, subject to certain conditions.

(7) Comprehensive Income (Loss)

The following table includes the components of comprehensive income (loss) for the three months ended March 31, 2010 and 2009.

<b>(in thousands)</b>	<b>Three months ended March</b>	
	<b>2010</b>	<b>2009</b>
Net loss	\$ (1,943)	\$ (252)
Other comprehensive income	17	3
Total comprehensive loss	\$ (1,926)	\$ (249)

**Table of Contents**

Other comprehensive income (loss) represents the net unrealized gains and losses on available-for-sale investments.

**(8) License Agreement with Merck KGaA**

In December 2007, the Company entered into an exclusive, worldwide license agreement with Merck KGaA to research, develop and commercialize products containing its TLR9 agonists for the treatment of cancer, excluding cancer vaccines, which became effective February 4, 2008. Under the terms of the agreement, Idera granted Merck KGaA worldwide exclusive rights to its lead TLR9 agonists, IMO-2055 and IMO-2125, and to a specified number of novel, follow-on TLR9 agonists to be identified by Merck KGaA and the Company under a research collaboration, for use in the treatment, cure and/or delay of the onset or progression of cancer in humans. 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; Merck KGaA agreed to reimburse future development costs for certain of the Company's IMO-2055 clinical trials for the period in which Idera continued to conduct the trials on behalf of Merck KGaA; Merck KGaA agreed to pay up to EUR 264 million in development, regulatory approval, and commercial success milestone payments if products containing the Company's TLR9 agonist compounds are successfully developed and marketed for treatment, cure and/or delay of the onset or progression of cancer in humans; and Merck KGaA agreed to pay mid single-digit to low double digit royalties on net sales of products containing our TLR9 agonists that are marketed. 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 until such time as Merck KGaA had filed an Investigational New Drug ( IND ) application with the U.S. Food and Drug Administration ( FDA ) and assumed sponsorship of these trials. Under the amendment, Merck KGaA agreed to reimburse the Company for costs associated with any additional trials that the Company initiated and conducted. Merck KGaA has now filed an IND and, as of March 2010, Merck KGaA is the sponsor of all ongoing clinical trials of IMO-2055, which Merck KGaA refers to as EMD1201081, for the treatment of cancer, and has assumed responsibility for all further clinical development of IMO-2055 in the treatment of cancer, excluding vaccines.

The Company is recognizing the \$40.0 million upfront payment as revenue over the twenty-eight month research term ending June 2010. The Company has estimated that this is its period of continuing involvement under the research arrangement. In 2009, the Company recognized milestone revenue of \$4.0 million under its collaboration with Merck KGaA relating to the dosing in January 2009 of the first patient in a Phase 1b clinical trial of IMO-2055 in patients with colorectal cancer and \$4.3 million related to Merck KGaA's initiation in December 2009 of a Phase 2 clinical trial of IMO-2055 in patients with recurrent or metastatic squamous cell carcinoma of the head and neck.

**(9) License Agreement with Merck Sharp & Dohme Corp.**

In December 2006, the Company entered into an exclusive, worldwide license and research collaboration agreement with Merck to research, develop, and commercialize vaccine products containing the Company's TLR7, 8 and 9 agonists in the fields of cancer, infectious diseases, and Alzheimer's disease. Under the terms of the agreement, the Company granted Merck exclusive rights to a number of the Company's TLR7, 8 and 9 agonists for use in combination with Merck's therapeutic and prophylactic vaccines under development in the fields of cancer, infectious diseases, and Alzheimer's disease. The Company also agreed with Merck to engage in a two-year research collaboration to generate novel agonists targeting TLR7 and TLR8 incorporating both Merck and Idera chemistry for use in vaccines in the defined fields, which could be extended by Merck for two additional one-year periods. Under the terms of the agreement: Merck paid the Company a \$20.0 million upfront license fee; Merck purchased \$10.0 million of the Company's common stock at \$5.50 per share; and Merck agreed to fund the research and development collaboration. Merck also 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 develops and commercializes additional vaccines using the Company's agonists, it would be entitled to receive additional milestone payments. In addition, Merck 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.

In November 2008, Merck extended the research collaboration for an additional one-year period to December 2009. In November 2009, Merck extended the research collaboration for the fourth and final year to December 2010. The Company has estimated that this is its period of continuing involvement under the research arrangement. Accordingly, the Company is recognizing the \$20.0 million upfront payment as revenue over the two-year initial research term and the additional two-year-period over which the research term has been extended.

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

**Table of Contents**

\$10.0 million. Merck agreed, subject to certain exceptions, that prior to December 8, 2007, it would not sell any of the shares of the Company's common stock acquired by it and that, for the duration of the research and collaboration term, its ability to sell such shares will be subject to specified volume limitations.

In May 2008, under the Company's collaboration with Merck, a preclinical milestone was achieved with one of its novel TLR9 agonists used as an adjuvant in cancer vaccines. As a result, the Company received a \$1.0 million milestone payment from Merck, which it recognized as revenue in 2008.

(10) License Agreement with Novartis International Pharmaceutical, Ltd.

In May 2005, the Company entered into a research collaboration and option agreement and a separate license, development, and commercialization agreement with Novartis to discover, develop, and potentially commercialize TLR9 agonists that are identified as potential treatments for asthma and allergies. Under the terms of the agreements, upon execution of the agreements, Novartis paid the Company a \$4.0 million upfront license fee and Novartis agreed to fund substantially all research activities during the research collaboration phase. In 2007, Novartis extended the research collaboration by an additional year until May 2008. In connection with this extension, Novartis paid the Company an additional license fee of \$1.0 million.

In November 2009, Novartis notified the Company that it was terminating the research collaboration and option agreement, effective as of February 2010. This termination canceled Novartis' option to implement the license, development, and commercialization agreement. Upon the termination, the Company regained the rights to QAX935, a novel agonist of TLR9 which the Company refers to as IMO-2134, without any financial obligations to Novartis and will no longer be subjected to restrictions under the collaboration on its right to develop TLR-targeted compounds, including TLR antagonist and TLR antisense compounds, as potential treatments for human allergy and respiratory diseases. Sponsorship of the Phase 1 clinical trial of QAX935 that Novartis initiated has not been transferred to Idera.

(11) Revenue Recognition under Collaborative Arrangements

An important part of the Company's business strategy is to enter into research and development collaborations with biotechnology and pharmaceutical corporations that bring expertise and resources to the potential research and development and commercialization of drugs based on the Company's technology. Under the Company's existing collaborative arrangements, the Company is generally entitled to receive non-refundable license fees, milestone payments, reimbursements of certain internal and external research and development expenses and patent-related expenses and royalties on product sales. The Company classifies all of these amounts as revenue in its statement of operations since it considers licensing intellectual property and providing research and development and patent-related services to be part of its central business operations. Revenue recognized under the Company's collaborative arrangements with Merck KGaA and Merck and its collaboration with Novartis International Pharmaceutical Ltd., which was terminated in February 2010, is as follows for the three months ended March 31, 2010 and 2009:

<b>(in thousands)</b>	<b>Three Months Ended March</b>	
	<b>31,</b>	
	<b>2010</b>	<b>2009</b>
Merck KGaA	\$ 4,303	\$ 4,792
Merck	1,250	1,479
Novartis	1	5
Total collaboration revenue	5,554	6,276
Other revenue	23	27
Total alliance revenue	\$ 5,577	\$ 6,303

During the three months ended March 31, 2010 and 2009, the Company incurred approximately \$15,000 and \$479,000, respectively, in third-party expenses in connection with its collaborative arrangements. These third party expenses are classified as either research and development or general and administrative expenses in the Company's statement of operations.

When evaluating multiple element arrangements, the Company considers whether the components of the arrangement represent separate units of accounting. The Company recognizes revenue from non-refundable upfront fees received under collaboration agreements, not specifically tied to a separate earnings process, ratably over the term of the contractual obligation or the Company's estimated continuing involvement under the research arrangement. If the estimated period of continuing involvement is subsequently modified, the period over which the upfront fee is recognized is modified accordingly on a prospective basis.

The Company recognizes revenue from reimbursements earned in connection with research and development collaboration agreements as related research and development costs are incurred, and contractual services are performed, provided collectability is reasonably assured. The Company includes amounts contractually owed to it under these research and development collaboration agreements, including any earned but unbilled receivables, in receivables in its balance sheets. The Company's principal costs under these agreements are generally for its personnel and related expenses of conducting research and development, as well as for research

**Table of Contents**

and development performed by outside contractors or consultants or related research and development materials provided by third parties or for clinical trials it conducts on behalf of a collaborator.

For payments that are specifically associated with a separate earnings process, the Company recognizes revenue when the specific performance obligation is completed. Performance obligations typically consist of significant milestones in the development life cycle of the related technology, such as initiating clinical trials, filing for approval with regulatory agencies and obtaining approvals from regulatory agencies. The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, it has no further performance obligations relating to the event and collectability is reasonably assured. In the event that the agreement provides for payment to be made subsequent to the Company's standard payment terms, the Company recognizes revenue when payment becomes due.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the Company's balance sheets. The Company classifies amounts that it expects to recognize in the next twelve months as short-term deferred revenue. The Company classifies amounts that it does not expect to recognize within the next twelve months as long-term deferred revenue.

Although the Company follows detailed guidelines in measuring revenue, certain judgments affect the application of its revenue policy. For example, in connection with its existing collaboration agreements, the Company has recorded on its balance sheet short-term and long-term deferred revenue based on its best estimate of when such revenue will be recognized. However, this estimate is based on the Company's collaboration agreements and its current operating plan and, if either should change, the Company may recognize a different amount of deferred revenue over the next twelve-month period.

The Company's estimate of deferred revenue also reflects management's estimate of the periods of its involvement in its collaborations and the estimated periods over which its performance obligations will be completed. In some instances, the timing of satisfying these obligations can be difficult to estimate. Accordingly, the Company's estimates may change in the future. Such changes to estimates would result in a change in revenue recognition amounts. If these estimates and judgments change over the course of these agreements, it may affect the timing and amount of revenue that the Company recognizes and records in future periods.

**(12) Stock-Based Compensation**

The Company recognizes all share-based payments to employees in the financial statements based on their fair values. The Company records stock-based 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 record the fair value of stock options as an expense on a straight-line basis over the vesting period which is generally four years. The Company included charges of \$1,173,000 and \$743,000 in its statements of operations for the three months ended March 31, 2010 and 2009, respectively, representing the stock-based compensation expense attributable to share-based payments made to employees and directors. The \$1,173,000 charge for the three months ended March 31, 2010 includes \$290,000 attributable to a modification of non-employee director stock options.

The Company's shareholder-approved stock compensation plans include the current 2008 Stock Incentive Plan, the earlier plans, under which options are no longer being granted, and the 1995 Employee Stock Purchase Plan. In 2001, the Company also granted options to purchase shares of common stock pursuant to agreements that were not approved by shareholders.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model and expensed over the requisite service period on a straight-line basis. The following assumptions apply to the options to purchase 39,500 shares of common stock that were granted to employees and directors during the three months ended March 31, 2010:

**Three Months  
Ended  
March 31,  
2010**

Average risk free interest rate	2.7%
Expected dividend yield	
Expected lives	5.3 years
Expected volatility	67.0%

Weighted average grant date fair value of options granted during the period (per share) \$ 3.08

The Company did not grant any stock options during the three months ended March 31, 2009.

In connection with the adoption of a director retirement policy during the first quarter of 2010, the stock options held by non-employee members of the Company's board of directors were modified. The effect of the modification was to provide that upon the director's retirement from the board of directors, as defined in such policy, the vesting of all unvested options would be accelerated in full and the period during which options may be exercised after a director's qualifying retirement would be extended to one year, subject to the requirement that all options be cancelled if not exercised within ten years of the date granted. The modification of the

**Table of Contents**

non-employee director stock options increased the fair value of those options by \$85,000, of which \$58,000 was expensed during the three months ended March 31, 2010. As a result of the modification of non-employee director stock options, the Company recognized additional stock-based compensation expense for such options during the three months ended March 31, 2010 of \$290,000, including the \$58,000 attributable to the increase in fair value and \$232,000 which resulted from the accelerated recognition of the original fair value of options held by three of the Company's directors who satisfy the policy for retirement prior to the normal vesting period, which would otherwise have been expensed over the vesting period on a straight line basis.

During prior periods, the Company awarded stock options to non-employees to purchase shares of common stock. The Black-Scholes fair value of the nonvested portion of the non-employee options is remeasured each quarter. This remeasured fair value is partially expensed each quarter based upon the percentage of the nonvested portion of the option's vesting period that has elapsed to date less the amount expensed in prior periods. The resulting expense for non-employee options was \$14,000 for the three months ended March 31, 2010. During the three months ended March 31, 2009, there was a \$7,000 credit to operations for non-employee options.

(13) Net Loss per Common Share

Basic and diluted net loss per common share is computed using the weighted average number of shares of common stock outstanding during the period. For the three months ended March 31, 2010 and 2009, diluted net loss per share is the same as basic net loss per common share as the effects of the Company's potential common stock equivalents are antidilutive. Total antidilutive securities were 7,000,394 and 6,189,932 for the three months ended March 31, 2010 and 2009, respectively, and consist of stock options, warrants and convertible preferred stock. Net loss applicable to common stockholders is the same as net loss for the three months ended March 31, 2010 and 2009.

(14) Stockholders' Equity

During the three months ended March 31, 2010 and 2009, the Company issued 9,724 and 16,580 shares, respectively, of common stock in connection with stock option exercises and employee stock purchases resulting in total proceeds to the Company of \$39,000 and \$72,000, respectively.

(15) Related Party Transactions

The Company paid a director consulting fees of approximately \$8,000 and \$1,000 in the three months ended March 31, 2010 and 2009, respectively.

(16) Subsequent Events

The Company evaluates subsequent events occurring between the most recent balance sheet date and the date that the financial statements are issued in order to determine whether the subsequent events are to be disclosed in the Company's financial statements and footnotes.

**Table of Contents**

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

**GENERAL**

We are engaged in the discovery and development of DNA- and RNA-based drug candidates targeted to Toll-Like Receptors, or TLRs, to treat infectious diseases, autoimmune and inflammatory diseases, cancer, and asthma and allergies, and for use as vaccine adjuvants. Drug candidates are compounds that we are developing and that have not been approved for any commercial use. TLRs are specific receptors present in immune system cells that recognize the DNA or RNA of bacteria or viruses and initiate an immune response. Relying on our expertise in DNA and RNA chemistry, we have designed and created proprietary TLR agonists and antagonists to modulate immune responses. A TLR agonist is a compound that stimulates an immune response through the targeted TLR. A TLR antagonist is a compound that blocks activation of an immune response through the targeted TLR.

Our business strategy is to advance applications of our TLR-targeted drug candidates in multiple disease areas simultaneously. We are advancing some of these applications through internal programs, and we seek to advance other applications through collaborative alliances with pharmaceutical companies. Collaborators provide the necessary resources and drug development experience to advance our compounds in their programs. 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 infectious diseases, autoimmune and inflammatory diseases, cancer, and asthma and allergies. We are conducting two Phase 1 clinical trials of IMO-2125, our lead TLR9 agonist drug candidate, in patients with chronic hepatitis C virus, or HCV, infection. We are conducting a Phase 1 clinical trial of IMO-3100, our lead TLR7 and TLR9 antagonist drug candidate, in healthy subjects. We are evaluating the next steps in the development of IMO-2134, our lead TLR9 agonist drug candidate for respiratory diseases, for which Novartis initiated a Phase 1 clinical trial under our prior collaborative agreement.

In addition to our internal programs, we currently are collaborating with two pharmaceutical companies to advance other applications of our TLR-targeted compounds. We are collaborating with Merck KGaA, Darmstadt, Germany, for cancer treatment, excluding cancer vaccines. We also are collaborating with Merck Sharp & Dohme Corp. (previously known as Merck & Co., Inc. and which we refer to herein as Merck) for vaccine adjuvants in the fields of cancer, infectious diseases, and Alzheimer's disease. Merck KGaA and Merck are not related.

In December 2007, we initiated a Phase 1b clinical trial of IMO-2055, a TLR9 agonist, in combination with Avastin<sup>®</sup> and Tarceva<sup>®</sup>, agents approved for the treatment of specific cancers, in non-small cell lung cancer patients whose cancer had progressed during a prior course of standard therapy. In January 2009, we initiated a Phase 1b clinical trial of IMO-2055 in combination with Erbitux<sup>®</sup>, a biological agent approved for the treatment of certain cancers, and chemotherapy in patients with colorectal cancer whose cancer had progressed during a prior course of standard therapy. In accordance with our agreement, Merck KGaA has assumed sponsorship of these two Phase 1b clinical trials. Merck KGaA refers to IMO-2055 as EMD 1201081. In December 2009, Merck KGaA initiated a Phase 2 clinical trial of EMD 1201081 in patients with recurrent or metastatic squamous cell carcinoma of the head and neck. The study is designed to enroll 104 adult patients who have had disease progression on a first-line cytotoxic chemotherapy regimen. Enrolled patients will be randomized to receive Erbitux alone or Erbitux combined with EMD 1201081. The primary endpoint of the trial is progression-free survival time of patients treated with EMD 1201081 plus Erbitux compared to Erbitux alone.

At March 31, 2010, we had an accumulated deficit of \$335.6 million. We may incur substantial operating losses in future periods. We do not expect to generate significant funds or product revenue until we successfully complete development and obtain marketing approval for products, either alone or in collaborations with third parties, which we expect will take a number of years. In order to commercialize our products, we need to address a number of technological challenges and to comply with comprehensive regulatory requirements. In 2010, we expect that our research and development expenses will be higher than our research and development expenses in 2009 as we expand our clinical trials of IMO-2125 and IMO-3100 and accelerate our preclinical studies of TLR antagonists and of agonists of TLR7 and TLR8.

**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

**Table of Contents**

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 and stock-based compensation. 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 (i) 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 (ii) 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 Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2009. Not all of these significant accounting policies, however, fit the definition of critical accounting estimates. We believe that our accounting policies relating to revenue recognition and stock-based compensation, 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, 2009, fit the definition of critical accounting estimates and judgments.

**RESULTS OF OPERATIONS****Three Months Ended March 31, 2010 and 2009***Alliance Revenue*

Our alliance revenues were comprised primarily of revenue earned under various collaboration and licensing agreements including license fees, research and development revenues including reimbursement of internal and third-party expenses, milestones and patent-related reimbursements.

The following table is a summary of our alliance revenue earned under our collaboration and licensing agreements:

	<b>Three Months Ended March</b>		<b>Percentage Increase/ (Decrease)</b>
	<b>31, (in thousands)</b>		
	<b>2010</b>	<b>2009</b>	
License fees	\$ 5,553	\$ 5,553	
Research and development	18	735	(98%)
Other	6	15	(60%)
Total alliance revenue	\$ 5,577	\$ 6,303	(12%)

*License Fees.* License fees primarily include license fee revenue recognized under our collaborations with Merck KGaA and Merck License fee revenue during the three months ended March 31, 2010 and 2009 was comprised of amortization of the upfront license fee payments under these collaborations. We recognize license fee revenue ratably over the expected period of our continuing involvement in the collaborations, which generally represents the estimated research period of the agreement.

We received a \$40,000,000 upfront payment from Merck KGaA in Euros in February 2008 of which we received \$39,733,000 due to foreign currency exchange rates in effect at the time. We are recognizing the \$40,000,000 upfront payment as revenue over the twenty-eight month research term, which will continue until June 2010. We received a \$20,000,000 upfront payment from Merck in December 2006. We are recognizing the \$20,000,000 upfront payment as revenue over the two-year initial research term, which commenced in December 2006, and the additional two-year-period until December 2010 over which the research term has been extended. As of March 31, 2010, we have \$3,048,000 of deferred revenue under our Merck KGaA collaboration and \$3,472,000 of deferred revenue under

our Merck collaboration. We expect to recognize these deferred revenue balances as license fee revenue in 2010.

*Research and Development.* Research and development revenue decreased by \$717,000 in the three months ended March 31, 2010 due to decreased reimbursements of clinical trial costs associated with the two Phase 1b clinical trials of IMO-2055 and the Phase 1 clinical trial of IMO-2055 in healthy subjects that we were conducting in 2009 under our collaboration agreement with Merck KGaA. As of March 2010, Merck KGaA has assumed sponsorship of all clinical trials of IMO-2055 for the treatment of cancer, excluding vaccines, and responsibility for all further clinical development of IMO-2055 in the treatment of cancer, excluding vaccines. We have no further responsibility for conducting clinical trials on behalf of Merck KGaA. The decrease was also attributable to a decrease in revenue from research reimbursements under our collaboration with Merck as we no longer had employee expenses that were reimbursed under our collaboration with Merck in the three months ended March 31, 2010. We do not expect to have significant research and development revenue in future periods under our agreements with Merck KGaA and Merck.

**Table of Contents***Research and Development Expenses*

Research and development expenses increased by \$108,000, or 2%, from \$4,478,000 for the three months ended March 31, 2009 to \$4,586,000 for the three months ended March 31, 2010. The increase in research and development expenses in the three months ended March 31, 2010 compared to the three months ended March 31, 2009 was primarily due to increased clinical activities associated with IMO-2125 and IMO-3100. These increases were offset, in part, by decreased clinical activities associated with IMO-2055 and decreased non-clinical safety study activities associated with IMO-3100.

	<b>Three Months Ended March 31, (in thousands)</b>		<b>Percentage Increase (Decrease)</b>
	<b>2010</b>	<b>2009</b>	
IMO-2055 external development expense	\$ 14	\$ 473	(97%)
IMO-2125 external development expense	881	500	76%
IMO-3100 external development expenses	891		
Other drug development expense	967	1,780	(46%)
Basic discovery expense	1,833	1,725	6%
Total research and development expense	\$ 4,586	\$ 4,478	2%

In the preceding table, research and development expense is set forth in the following five categories:

*IMO-2055 External Development Expenses.* IMO-2055 is being developed for cancer, excluding vaccines, under our collaboration with Merck KGaA. External development expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-2055 clinical development but exclude internal costs such as payroll and overhead expenses. Since 2003, when we commenced clinical development of IMO-2055 and through March 31, 2010, we have incurred approximately \$17.4 million in external expenses in connection with IMO-2055.

Under our collaboration, Merck KGaA is responsible for development of IMO-2055 for the treatment of cancer excluding vaccines. Under the agreement, Merck KGaA agreed to reimburse us for costs associated with any trials that we initiated and conducted, including costs associated with the Phase 1b clinical trials of IMO-2055 in patients with non-small cell lung cancer and in patients with colorectal cancer and a Phase 1 clinical trial of IMO-2055 in healthy subjects, and that were incurred after February 4, 2008, which is the date our agreement with Merck KGaA became effective. As of March 2010, Merck KGaA has 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. As a result, we do not expect to incur significant expenses for IMO-2055 development in future periods.

IMO-2055 external development expenses decreased by \$459,000, or 97%, from \$473,000 in the three months ended March 31, 2009 to \$14,000 in the three months ended March 31, 2010, as a result of Merck KGaA assuming sponsorship of the ongoing Phase 1b clinical trials of IMO-2055 in September 2009 and the Phase 1 clinical trial of IMO-2055 in healthy subjects that we were conducting in 2009 and that Merck assumed sponsorship of in March 2010.

Approximately \$12,000 and \$442,000 of expenses in the three months ended March 31, 2010 and 2009, respectively, were reimbursed by Merck KGaA.

*IMO-2125 External Development Expenses.* These expenses include external expenses that we have incurred in connection with IMO-2125. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-2125 clinical development but exclude internal costs such as payroll and overhead expenses. We commenced clinical development of IMO-2125 in May 2007 and since then we have incurred approximately \$7.6 million in external development expenses through March 31, 2010, including costs associated with our Phase 1 clinical trials and related nonclinical studies and manufacturing and

related process development.

External development expenses for IMO-2125 increased by \$381,000, or 76%, from \$500,000 in the three months ended March 31, 2009 to \$881,000 in the three months ended March 31, 2010. The increase in IMO-2125 expenses in the three month period ending March 31, 2010 compared to the same period in 2009 was attributable to increased manufacturing activities related to IMO-2125 in 2010, additional nonclinical safety studies of IMO-2125 and increased expenses resulting from the initiation of our second Phase 1 clinical trial and the progression of our ongoing Phase 1 trial.

In May 2007, we submitted an Investigational New Drug, or IND, application for IMO-2125 to the U.S. Food and Drug Administration, or FDA. In September 2007, we initiated a Phase 1 clinical trial of IMO-2125 in patients with chronic HCV infection who had no response

**Table of Contents**

to a prior regimen of the current standard of care therapy. We refer to these patients as null responder HCV patients, specified by the protocol as patients who failed to achieve a 2 log<sub>10</sub> reduction in HCV viral load after at least 12 weeks of treatment with the current standard of care therapy. HCV viral load refers to the concentration of virus in the blood. A log<sub>10</sub> reduction means a decrease in virus concentration to 10% of the original concentration. A 2 log<sub>10</sub> reduction means a decrease to 1% of the original concentration. The clinical trial is currently being conducted at six sites in the United States. In the trial, we are enrolling cohorts of ten patients at escalating IMO-2125 dose levels. Of the ten patients in a cohort, eight are randomized to receive IMO-2125 treatment and two are randomized to receive placebo treatment. Patients receive a single dose of IMO-2125 or placebo once per week by subcutaneous injection for four weeks. The primary objective of the trial is to assess the safety of IMO-2125 at each dose level. We are also evaluating the effects of IMO-2125 on HCV viral load and on immune system activation in this trial. We have enrolled patients in four cohorts, evaluating IMO-2125 at 0.04 mg/kg/week, 0.08 mg/kg/week, 0.16 mg/kg/week and 0.32 mg/kg/week for four weeks of treatment. Based on interim results from these cohorts through December 2009, we extended the trial to a fifth dose level. At present, recruitment is continuing at the IMO-2125 dosage of 0.48 mg/kg/week. We expect to complete enrollment at the 0.48-mg/kg/week dose level within the second quarter of 2010. We also intend to evaluate twice-weekly administration of IMO-2125 in null responder HCV patients during 2010.

In April 2010, we announced interim results at the 45<sup>th</sup> Annual Meeting of the European Association for the Study of the Liver from a Phase 1 clinical trial of IMO-2125 in null responder HCV patients treated through the originally planned four cohorts of this trial. IMO-2125 was well tolerated by all patients in the four cohorts, with no discontinuations due to drug-related adverse events. All adverse events were of short duration, mild to moderate grade, and consistent with the intended mechanism of action for IMO-2125, being related to either injection site reactions or flu-like symptoms. IMO-2125-treated patients showed dose-dependent increases in natural interferon-alpha and other antiviral proteins, consistent with the intended mechanism of action. The induction by IMO-2125 of natural interferon-alpha was stronger after the fourth dose compared to after the first dose. In addition, an increasing percentage of patients, ranging from 40% at the 0.08 mg/kg/week dose level to 75% at the 0.32 mg/kg/week dose level, achieved a maximum reduction in HCV viral load of 1 log<sub>10</sub> or more at least once during the four-week treatment period. The mean maximum viral load reduction during the four-week treatment period in the eight null responder HCV patients who received IMO-2125 at 0.32 mg/kg/week was -1.7 log<sub>10</sub>. Six of the eight null responder HCV patients who received IMO-2125 at 0.32 mg/kg/week showed maximum viral load reductions ranging from 1.0 to 3.5 log<sub>10</sub> at least once during the treatment period. In comparison, none of the patients who received placebo treatment or IMO-2125 at the 0.04-mg/kg/week dose level achieved a maximum reduction in viral load of 1 log<sub>10</sub> or greater at any time during the four-week treatment period. Therefore, levels of interferon-alpha induced by IMO-2125 treatment correlated with reductions in viral load.

In addition to the on-going Phase 1 clinical trial of IMO-2125 in null responder HCV patients, we are conducting a Phase 1 clinical trial of IMO-2125 in combination with ribavirin, an antiviral medication approved for use in combination with interferon-alpha in the treatment of HCV infection, in treatment-naïve patients with chronic HCV infection. We initiated the trial in October 2009. In this clinical trial, patients receive IMO-2125 by subcutaneous injection once per week for four weeks at escalating dose levels in combination with daily oral administration of standard doses of ribavirin. A total of 15 patients are planned for the first cohort, with 12 randomized to receive IMO-2125 and ribavirin and three randomized to receive placebo and ribavirin. Starting with the second cohort, 12 patients will be randomized to receive IMO-2125 and ribavirin and six patients will be randomized to receive pegylated recombinant alfa-2a interferon and ribavirin. The primary objective of the trial is to assess the safety and tolerability of IMO-2125 in combination with ribavirin. In addition, we plan to monitor the effect of treatment on HCV viral load. The clinical trial is currently being conducted at sites in France and Russia.

During the second half of 2010, we plan to initiate a Phase 2 clinical trial with IMO-2125 administered in combination with ribavirin for 12 weeks. As a result, we expect IMO-2125 external development expenses to increase in 2010.

*IMO-3100 External Development Expenses.* These expenses include external expenses that we have incurred in connection with 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 commenced clinical development of IMO-3100 in November 2009 and since then we have incurred approximately \$1.5 million in external development expenses through March 31, 2010, including costs associated with the start-up of our Phase 1 clinical trial of IMO-3100 in healthy subjects and manufacturing and related process development.

In November 2009, we submitted to the FDA an IND application for the clinical evaluation of IMO-3100 in autoimmune diseases. In January 2010, we initiated a Phase 1 clinical trial of IMO-3100 in healthy subjects. In this rising single-dose Phase 1 trial, IMO-3100 is being administered by subcutaneous injection. The primary objective is to evaluate safety and tolerability of IMO-3100. Secondary objectives are to characterize the blood levels of IMO-3100 and to assess the pharmacodynamic mechanism of action, which is how IMO-3100 affects the immune system in the intended manner, through measurement of the response of peripheral blood mononuclear cells, or PBMCs, to TLR7 and TLR9 agonists. The trial is being conducted at a single U.S. site.

We plan to use the results from this rising single-dose clinical trial to select dosages for an anticipated follow-up trial in healthy subjects. The purpose of the second Phase 1 trial would be to evaluate the safety, blood levels of IMO-3100, and pharmacodynamic mechanism of action of IMO-3100 with repeat-dose subcutaneous administration over four weeks. We intend to identify an initial autoimmune disease indication for further clinical development of IMO-3100 by the end of 2010.

*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,

**Table of Contents**

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. Expenses associated with products in clinical development include costs associated with our Hepatitis C Clinical Advisory Board, our Oncology Clinical Advisory Board, and our Autoimmune Disease Scientific Advisory Board.

Other drug development expenses decreased by \$813,000, or 46%, from \$1,780,000 for the three months ended March 31, 2009 to \$967,000 for the three months ended March 31, 2010. The decrease in the three months ended March 31, 2010 compared to the same periods in 2009 was primarily due to a decrease in IMO-3100 expenses due to attribution in the 2010 period of IMO-3100 expenses incurred after commencement of clinical development to a specific IMO-3100 External Development Expense category shown separately above. In 2009, non-clinical safety study expenses related to IMO-3100 were included in this category.

*Basic Discovery Expenses.* These expenses include our internal and external expenses relating to the discovery and development of our TLR-targeted programs, including agonists and antagonists of TLRs 7, 8 and 9 and TLR antisense. These expenses reflect payments for laboratory supplies, external research, and professional fees, as well as payroll and overhead expenses. Basic discovery expenses increased by \$108,000, or 6%, from \$1,725,000 for the three months ended March 31, 2009 to \$1,833,000 for the three months ended March 31, 2010. The increase for the three months ended March 31, 2010 compared to the same period in 2009 was primarily attributable to higher employee expenses, relating to payroll and stock compensation, and higher allocated costs. These increases were offset by a decrease in research supplies related to decreased research conducted under our collaboration agreements.

We do not know if we will be successful in developing any drug candidate from our research and development programs. At this time, without knowing the results of our ongoing clinical trials 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 increased by \$584,000, or 27%, from \$2,148,000 in the three months ended March 31, 2009 to \$2,732,000 in the three months ended March 31, 2010. General and administrative expenses consisted primarily of salary expense, stock compensation expense, consulting fees and professional legal fees associated with our patent applications and maintenance, our corporate regulatory filing requirements, our corporate legal matters and our business development initiatives.

The increase in general and administrative expenses in the three months ended March 31, 2010 compared to the three months ended March 31, 2009 was primarily due to higher stock compensation expense as a result of a modification to the non-employee Board of Director stock options, higher employee expenses as we recruited a Vice President of Corporate Development to our general and administrative staff, and higher legal fees related to corporate matters and patent maintenance. These increases were offset by lower consulting fees associated with business and strategic initiatives.

*Investment Income, net*

Investment income, net decreased by approximately \$45,000, or 63%, from \$71,000 in the three months ended March 31, 2009 to \$26,000 in the three months ended March 31, 2010. This decrease resulted from lower average cash and investment balances in the three months ended March 31, 2010.

*Foreign Currency Exchange Loss*

We have a clinical trial contract denominated in Euros and the milestone earned under our Merck KGaA collaboration was paid in Euros. In 2009, we earned a milestone under our Merck KGaA collaboration, for which we had a \$4,300,000 receivable at December 31, 2009. Merck KGaA paid us for this milestone in February 2010, and we received \$4,074,000 based on foreign exchange rates in effect at the time of payment as a result of the strengthening

value of the U.S. dollar. Consequently, we had a foreign currency exchange loss of \$228,000 in the three months ended March 31, 2010. We had no foreign currency exchange loss in the three months ended March 31, 2009.

*Net Loss*

As a result of the factors discussed above, our net loss was \$1,943,000 for the three months ended March 31, 2010 compared to \$252,000 for the three months ended March 31, 2009. We have incurred losses of \$75.4 million since January 1, 2001. We also incurred net 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. Since our inception, we had an accumulated deficit of \$335.6 million through March 31, 2010. We may continue to incur substantial operating losses in the future.

**Table of Contents**

**LIQUIDITY AND CAPITAL RESOURCES**

*Sources of Liquidity*

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

equity and debt financing;

license fees and research funding under collaborative and license agreements;

interest income; and

lease financings.

As of March 31, 2010, warrants to purchase 1,704,545 shares of our common stock at an exercise price of \$5.20 and warrants to purchase 761,718 shares of our common stock at an exercise price of \$5.92 per share were outstanding. These warrants were issued in March 2006 and expire on September 24, 2011.

Under the terms of our collaboration agreement with Merck KGaA, we have earned \$8,313,000 in milestone payments for which we received \$8,070,000 due to foreign currency exchange rates in effect at the time of payment. We received \$4,074,000 of these milestone payments from Merck KGaA during the three months ended March 31, 2010, for which we had a receivable at December 31, 2009. Merck KGaA has also reimbursed us for \$4,517,000 for expenses related to the development of IMO-2055.

*Cash Flows*

As of March 31, 2010, we had approximately \$37,646,000 in cash and cash equivalents and investments, a net decrease of approximately \$2,561,000 from December 31, 2009. Operating activities used \$2,503,000 of cash during the three months ended March 31, 2010, reflecting our \$1,943,000 net loss for the period, as adjusted for non-cash expenses, including depreciation, stock-based compensation, and changes in deferred revenue and our accounts receivable and payable and prepaid expenses and other current assets.

The net cash used in investing activities during the three months ended March 31, 2010 of \$8,166,000 reflects our purchase of \$8,106,000 in available-for-sale securities in the three months ended March 31, 2010 and our purchase of \$60,000 of laboratory and computer equipment in the three-month period.

The net cash provided by financing activities during the three months ended March 31, 2010 of \$34,000 reflects proceeds of \$39,000 received from the exercise of stock options and employee stock purchases during the three-month period offset by payments against our capital leases.

*Funding Requirements*

We have incurred operating losses in all fiscal years except 2002, 2008 and 2009, and we had an accumulated deficit of \$335,622,000 at March 31, 2010. We may incur substantial operating losses in future periods. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital.

We have received no revenues from the sale of drugs. To date, 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 believe that our existing cash, cash equivalents, and investments will be sufficient to fund our operations at least through December 31, 2011 based on our current operating plan, which assumes that we will continue to conduct our three ongoing clinical trials and that we will conduct the 12-week Phase 2 clinical trial of IMO-2125 in HCV patients and the 4-week Phase 1 clinical trial of IMO-3100 in healthy subjects that we plan to initiate in 2010 but does not assume that we will conduct any other clinical trials. We will need to raise additional funds to operate our business

beyond December 31, 2011. However, if we elect to conduct additional clinical trials beyond our ongoing clinical trials and the planned IMO-2125 and IMO-3100 trials, we will likely need to raise additional funds to operate our business earlier than December 31, 2011. We may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

## **Table of Contents**

We may seek additional funding through collaborations, the sale or license of assets or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain additional funding are:

the success of our clinical and preclinical development programs;

the success of our existing strategic collaborations with Merck KGaA and Merck;

the cost, timing and outcome of regulatory reviews;

the receptivity of the capital markets to financings by biotechnology companies; 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. Additional financing may not be available to us when we need it or may not be available to us on favorable 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. 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 may be required to significantly curtail one or more of our discovery or development programs and possibly relinquish rights to portions of our technology or products.

### *Contractual Obligations*

We have had no material changes to our contractual obligations since December 31, 2009.

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

As of March 31, 2010, we had an accrued expense relating to contract research organization services for our Phase 1 clinical trial of IMO-2125 currently being conducted at sites in France and Russia of EUR 55,000, or \$74,000. 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.

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 Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the period covered by this report. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the

Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2010, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

**Table of Contents**

(b) *Changes in Internal Controls.* No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act) occurred during the fiscal quarter ended March 31, 2010 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**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information included or incorporated by reference in this Quarterly Report on Form 10-Q before purchasing our common stock. If any of the following risks actually occurs, our business, financial condition or results of operations would likely suffer, possibly materially. In that case, the trading price of our common stock could fall, and you may lose all or part of your investment in our common stock.*

**Risks Relating to Our Financial Results and Need for Financing**

***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, 2010, we had an accumulated deficit of \$335.6 million. We have incurred losses of \$75.4 million since January 1, 2001. We also incurred losses of \$260.2 million prior to December 31, 2000 during which time we were primarily involved in the development of 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. To date, almost all of our revenues have been from collaborative and license agreements. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any 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 may incur substantial operating losses in future periods.

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

We will require substantial funds to conduct research and development, including preclinical testing and clinical trials of our drug candidates. We will also require substantial funds to conduct regulatory activities and to establish commercial manufacturing, marketing, and sales capabilities. We had cash, cash equivalents, and investments of \$37.6 million at March 31, 2010. We believe that our existing cash, cash equivalents, and investments will be sufficient to fund our operations at least through December 31, 2011 based on our current operating plan, which assumes that we will continue to conduct our three ongoing clinical trials and that we will conduct the 12-week Phase 2 clinical trial of IMO-2125 in HCV patients and the 4-week Phase 1 clinical trial of IMO-3100 in healthy subjects that we plan to initiate in 2010 but does not assume that we will conduct any other clinical trials. We will need to raise additional funds to operate our business beyond December 31, 2011. However, if we elect to conduct additional clinical trials beyond our ongoing clinical trials and the planned IMO-2125 and IMO-3100 trials, we will likely need to raise additional funds to operate our business earlier than December 31, 2011.

We may seek additional funding through collaborations, the sale or license of assets, or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain additional funding are:

the success of our clinical and preclinical development programs;

the success of our existing strategic collaborations with Merck KGaA and Merck;

the cost, timing, and outcome of regulatory reviews;

the receptivity of the capital markets to financings by biotechnology companies; and

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

Additional financing may not be available to us when we need it or may not be available to us on favorable terms. We could be required to seek funds through collaborative alliances or through other means that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing

**Table of Contents**

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. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and are likely to include rights that are senior to the holders of our common stock. Any additional debt financing or equity that we raise may contain terms, such as liquidation and other preferences, or liens or other restrictions on our assets, which are not favorable to us or our stockholders. If we are unable to obtain adequate funding on a timely basis or at all, we may be required to terminate, modify or delay preclinical or clinical trials of one or more of our drug candidates, fail to establish or delay the establishment of manufacturing, sale or marketing capabilities, curtail research and development programs for new drug candidates and/or possibly relinquish rights to portions of our technology, drug candidates and/or products. For example, we significantly curtailed expenditures on our research and development programs during 1999 and 2000 because we did not have sufficient funds available to advance these programs at planned levels.

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

***We are depending heavily on the success of IMO-2125, IMO-3100, and our collaborative alliances. If we or our collaborators are unable to successfully develop and commercialize our drug candidates, or experience significant delays in doing so, our business will be materially harmed.***

We are investing a significant portion of our time and financial resources in the development of our clinical stage lead drug candidates for infectious diseases, IMO-2125, and for autoimmune and inflammatory diseases, IMO-3100. We anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of IMO-2125, IMO-3100, and other drug candidates, including drug candidates being developed by our collaborators. The commercial success of these drug candidates will depend on several factors, including the following:

acceptable safety profile during clinical trials;

timely enrollment in our Phase 1 clinical trials of IMO-2125 and IMO-3100 and our other on-going or planned clinical trials, which may be slower than we anticipate, potentially resulting in significant delays;

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

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

our ability to combine our drug candidates and drug candidates being developed by our collaborators safely and successfully with other therapeutic agents;

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

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;

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 our drug candidates following approval.

Our efforts to commercialize IMO-2125 and IMO-3100 are at early stages, as we are currently conducting Phase 1 safety clinical trials of these drug candidates. If we are not successful in commercializing these or our other drug candidates, or are significantly delayed in doing so, our business will be materially harmed.

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

## **Table of Contents**

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.

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.

For example, in April 2010 we announced interim results from a Phase 1 clinical trial of IMO-2125 in patients with chronic HCV infection who had no response to the current standard of care therapy. However, while these results were positive, these interim results may not be predictive of the final results of this trial, the Phase 1 clinical trial of IMO-2125 in combination with ribavirin in treatment-naïve patients with chronic HCV infection, or other planned clinical trials of IMO-2125 as a monotherapy or in combination with other treatments.

Moreover, companies developing drugs targeted to TLRs have experienced setbacks in clinical trials. For example in 2007, Coley Pharmaceutical Group, which since has been acquired by Pfizer, Inc., discontinued four clinical trials for PF-3512676, its investigational TLR9 agonist compound, in combination with cytotoxic chemotherapy in cancer, and suspended its development of a TLR9 agonist, Actilon<sup>®</sup>, for HCV infection. In July 2007, Anadys Pharmaceuticals, Inc. and its partner Novartis announced that they had decided to discontinue the development of ANA975, the investigational TLR7 agonist compound for HCV infection. Dynavax Technologies Corporation announced in May 2008 discontinuation of the clinical development program for TOLAMBA<sup>®</sup>, which comprises a TLR9 agonist covalently attached to a ragweed antigen.

There are few data on the long-term clinical safety of our lead compounds under conditions of prolonged use in humans, or on any long-term consequences subsequent to human use. Effects seen in preclinical studies, even if not observed in clinical trials, may result in limitations or restrictions on our clinical trials. We may experience numerous unforeseen events during, or as a result of, preclinical testing, nonclinical testing or the clinical trial process that could delay or inhibit our ability to receive regulatory approval or to commercialize our products, including:

- 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

**Table of Contents**

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 Stage A of our Phase 2 clinical trial of IMO-2055 in renal cell cancer, enrollment was slower than projected due to the then-recent approval of two new therapies, Sutent<sup>®</sup> and Nexavar<sup>®</sup>, developed by other companies for treatment of the same patient populations. In addition, in our on-going Phase 1 clinical trial of IMO-2125 in patients with chronic HCV infection who have not responded to the current standard of care therapy, completion of each cohort has taken longer than anticipated due to enrollment procedures. Patient accrual is a function of many factors, including:

the size of the patient population;

the proximity of patients to clinical sites;

the eligibility criteria for the study;

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

the existence of competitive clinical trials; and

the availability of alternative treatments.

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

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

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

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

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

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

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

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

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

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

enrolling patients in order to commence the clinical trial.

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

Our technologies or therapeutic approaches are relatively new and unproven. We have focused our efforts on the research and development of RNA- and DNA-based compounds targeted to TLRs. Neither we nor any other company

have obtained regulatory approval to market such compounds as therapeutic drugs, and no such products currently are being marketed. It is unknown whether the results of preclinical studies with TLR-targeted compounds will be indicative of results that may be obtained in clinical trials, and results we have obtained in the initial small-scale clinical trials we have conducted to date may not be predictive of results in subsequent large-scale clinical trials. Further, the chemical and pharmacological properties of RNA- and DNA-based compounds targeted to TLRs 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

## **Table of Contents**

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 based upon TLR technology being developed by our competitors have negative clinical trial results or otherwise are viewed negatively, the perception of our TLR technology and market acceptance of our products could be impacted negatively.

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 infectious diseases, autoimmune and inflammatory diseases, asthma and allergies, and cancer, and as vaccine adjuvants. For all of the disease areas in which we are developing potential therapies, there are many other companies, public and private, that are actively engaged in discovering, developing, and commercializing products and technologies that may compete with our technologies and drug candidates and technology, including TLR targeted compounds as well as non-TLR targeted therapies.

There are a number of companies developing TLR compounds for chronic HCV infection, including Dynavax Technologies Corporation and Anadys Pharmaceuticals, Inc. Our principal competitors developing TLR-targeted compounds for our autoimmune and inflammatory diseases program include Pfizer, Inc. and Dynavax Technologies Corporation, with its collaborator, GlaxoSmithKline plc and for our respiratory disease program include Dynavax Technologies Corporation in collaboration with AstraZeneca Pharmaceuticals plc, Pfizer, Inc., in collaboration with Sanofi-Aventis Groupe, Cytos Biotechnology AG and VentiRx Pharmaceuticals. For our partnered programs, our principal competitors developing TLR-targeted compounds for cancer treatment include Pfizer, Inc., Anadys Pharmaceuticals, Inc. and VentiRx Pharmaceuticals. Merck's vaccines using our TLR7, 8 or 9 agonists as adjuvants may compete with vaccines being developed or marketed by GlaxoSmithKline plc, Novartis, Dynavax Technologies Corporation, VaxInnate, Inc., Intercell AG, Cytos Biotechnology AG and Celldex Therapeutics, Inc.

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

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

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

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

Our success is highly dependent on the retention of principal members of our technical and management staff, including Dr. Sudhir Agrawal. Dr. Agrawal serves as our President, Chief Executive Officer, and Chief Scientific 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 worldwide. 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.

## **Table of Contents**

We are a party to an employment agreement with Dr. Agrawal that expires on October 19, 2012, but automatically extends annually for an additional year. This agreement may be terminated by us or Dr. Agrawal for any reason or no reason at any time upon notice to the other party. We do not carry key man life insurance for Dr. Agrawal.

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

### **Regulatory Risks**

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

All of the drug candidates that we are developing, or may develop in the future, will require additional research and development, extensive preclinical studies, non-clinical testing, clinical trials, and regulatory approval prior to any commercial sales. This process is lengthy, often taking a number of years, is uncertain, and is expensive. Since our inception, we have conducted clinical trials of a number of compounds. Currently, we are conducting clinical trials of IMO-2125 and IMO-3100. 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 violations of regulatory requirements, or discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, may result in:

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

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

withdrawal of our products from the market;

warning letters;

voluntary or mandatory product recalls;

finest;

suspension or withdrawal of regulatory approvals;

product seizure or detention;

**Table of Contents**

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**

***We need to establish additional collaborative alliances in order to succeed.***

We seek to advance our products through collaborative alliances with pharmaceutical companies. Collaborators provide the necessary resources and drug development experience to advance our compounds in their programs. 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 infectious diseases, autoimmune and inflammatory diseases, cancer, and asthma and allergies. 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, our ability to advance our compounds will be jeopardized and we may fail to meet our business objectives. If we cannot enter into additional collaboration agreements, we may not be able to obtain the expertise and resources necessary to achieve our business objectives. We face, and will continue to face, significant competition in seeking appropriate collaborators. 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 or other alternative arrangements. The terms of any collaborations or other arrangements that we establish, if any, may not be favorable to us.

***Our existing collaborations 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 to research, develop, and commercialize vaccine products containing our TLR7, 8, and 9 agonists in the fields of cancer, infectious diseases, and Alzheimer's disease.

Any collaboration that we enter into may not be successful. The success of our collaborative alliances, if any, will depend heavily on the efforts and activities of our collaborators. Our existing collaborations 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;

**Table of Contents**

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, which recently merged with Schering-Plough, which has been involved with certain TLR-targeted research and development programs. Although we have no indication that the merger will affect our partnership with Merck, 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 underfund or not commit sufficient resources to the testing, marketing, distribution or development of our products; and

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

Given these risks, it is possible that any collaborative alliance into which we enter may not be successful. Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. For example, effective as of February 2010, Novartis International Pharmaceutical, Ltd. terminated the research collaboration and option agreement that we entered into with them in May 2005. Merck may terminate its license and research collaboration agreement with us at any time in its sole discretion (a) during the research collaboration period, by giving us 180 days advance notice or (b) after the conclusion of the research collaboration period, by giving us 90 days advance notice. Merck KGaA may terminate its license agreement with us at its convenience by giving us 90 days advance notice. The termination or expiration of either of these agreements 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.

**Table of Contents**

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, 2010, we owned 67 U.S. patents and U.S. patent applications and 235 corresponding worldwide patents and patent applications 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-2055, IMO-2125 and IMO-3100. With respect to IMO-2055, we have issued 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 expiring in 2023. With respect to IMO-2125, we have issued patents that cover the chemical composition of matter of IMO-2125 and methods of its use, with the earliest composition claims expiring in 2026. With respect to IMO-3100, we have patent applications that cover the chemical composition of matter of IMO-3100 and methods of its use that, if issued, would expire at the earliest in 2026.

In addition to our TLR-targeted patent portfolio, we are the owner or hold licenses of patents and patent applications related to antisense technology. As of April 15, 2010, our antisense patent portfolio included 103 U.S. patents and patent applications and 126 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 patents expire at various dates ranging from 2014 to 2022.

***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 United States 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 patents 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 United States 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. However, we are party to seven 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 2014 to 2022. 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.***

## **Table of Contents**

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

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

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

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

*Because we have limited manufacturing experience, and no manufacturing facilities or infrastructure, we are dependent on third-party manufacturers to manufacture products 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 products, 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, preclinical, 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 and rely on only one contract manufacturer from whom we purchase material on a purchase order basis. If this contract manufacturer ceases to manufacture active material for us, our business will be negatively impacted.

There are a limited number of manufacturers that operate under the FDA's cGMP regulations capable of manufacturing our products. 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 products on a timely basis, or to do so on commercially reasonable terms, we may not be able to complete development of our products or market them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products 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 products that is necessary for the manufacture of our products; 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. Any failure by our third-party manufacturers to comply with such requirements, regulations or standards could lead to a delay in, or failure to obtain, regulatory approval of any of our product 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.

**Table of Contents**

Additionally, contract manufacturers may not be able to manufacture our TLR-targeted drug candidates at a cost or in quantities necessary to make them commercially viable. To date, 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 is manufactured or a change of a third-party manufacturer, may require prior FDA review and approval in accordance with the FDA's cGMP 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 product. 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 products, 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 products 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 products. We depend on independent clinical investigators, contract research organizations and other third-party service providers in the conduct of the clinical trials of our products and expect to continue to do so. We have contracted with contract research organizations to manage our current Phase 1 clinical trials of IMO-2125 in patients with chronic HCV infection and our Phase 1 clinical trial of IMO-3100 in healthy subjects. 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 products. 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

**Table of Contents**

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 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.

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 U.S. Congress passed and President Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act. 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 beginning in 2011 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 decrease 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

**Table of Contents**

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 an Investment in Our Common Stock**

***Our corporate governance structure, including provisions in our certificate of incorporation and by-laws, our stockholder rights plan 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, by-laws, and stockholder rights plan contain provisions that might enable our management to resist a takeover of our company or discourage a third party from attempting to take over our company. These provisions include:

a classified board of directors;

limitations on the removal of directors;

limitations on stockholder proposals at meetings of stockholders;

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

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

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

***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, 2009 to May 1, 2010, the closing sales price of our common stock ranged from a high of \$9.06 per share to a low of \$4.60 per share. The stock market has also experienced significant price and volume fluctuations, particularly within the past two years, 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:

results of 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;

33

---

**Table of Contents**

developments or disputes concerning patents or other proprietary rights;

the departure of key personnel;

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

our cash resources;

the terms of any financing conducted 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.

**Table of Contents**

**SIGNATURES**

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

**IDERA PHARMACEUTICALS, INC.**

Date: May 4, 2010

/s/ Sudhir Agrawal

Sudhir Agrawal  
President, Chief Executive Officer, and  
Chief Scientific Officer  
(Principal Executive Officer)

Date: May 4, 2010

/s/ Louis J. Arcudi, III

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

35

---

**Table of Contents**

**Exhibit Index**

**Exhibit No.**

- 10.1 Consulting Agreement dated as of April 1, 2010 between Idera Pharmaceuticals, Inc. and Malcolm MacCoss, Ph.D.
- 10.2 Amendment No. 2 dated December 15, 2009 amending Consulting Agreement dated as of January 1, 2008 between Idera Pharmaceuticals, Inc. and Karr Pharma Consulting, LLC.
- 10.3 Stock Purchase Agreement dated as of December 8, 2006 by and among Idera Pharmaceuticals, Inc. and Merck & Co., Inc.
- 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.