IDERA PHARMACEUTICALS, INC.
Form 10-Q
May 05, 2011

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

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

For the quarterly period ended March 31, 2011,

or

o **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 þ No o

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 o No o

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 o	Accelerated filer þ	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

Common Stock, par value $.001 per share	27,615,933
Class	Outstanding as of April 30, 2011

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

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this report regarding our strategy, future operations, collaborations, intellectual property, 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.

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PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

IDERA PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS
(UNAUDITED)

(In thousands, except per share amounts)	March 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,109	$ 17,008
Short-term investments	7,237	17,635
Receivables	9	2
Prepaid expenses and other current assets	1,167	995
Total current assets	29,522	35,640
Property and equipment, net	820	930
Restricted cash, net of current portion	311	311
Total assets	$ 30,653	$ 36,881
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 968	$ 1,757
Accrued expenses	2,501	1,775
Current portion of capital lease	4	8
Total current liabilities	3,473	3,540
Other liabilities	231	240
Total liabilities	3,704	3,780
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		
Common stock, $0.001 par value, Authorized 70,000 shares Issued and outstanding 27,611 and 27,596 shares at March 31, 2011 and December 31, 2010, respectively	28	28
Additional paid-in capital	385,404	384,702
Accumulated deficit	(358,487)	(351,642)
Accumulated other comprehensive income	4	13
Total stockholders equity	26,949	33,101
Total liabilities and stockholders equity	$ 30,653	$ 36,881

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

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

	Three Months Ended March 31,	
(In thousands, except per share amounts)	**2011**	**2010**
Alliance revenue	$ 8	$ 5,577
Operating expenses:		
Research and development	4,553	4,586
General and administrative	2,286	2,732
Total operating expenses	6,839	7,318
Loss from operations	(6,831)	(1,741)
Other income (expense):		
Investment income, net	21	26
Foreign currency exchange loss	(35)	(228)
Net loss	$ (6,845)	$ (1,943)
Basic and diluted net loss per share (Note 12):	$ (0.25)	$ (0.08)
Shares used in computing basic and diluted net loss per common share	27,604	23,462

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

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

(In thousands)	**Three Months Ended March 31, 2011**	**2010**
Cash Flows from Operating Activities:		
Net loss	$ (6,845)	$ (1,943)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	660	1,173
Non-employee stock option expense	6	14
Depreciation expense	128	144
Amortization of investment premiums	29	49
Issuance of common stock for services rendered	13	1
Changes in operating assets and liabilities:		
Accounts receivable	(7)	4,455
Prepaid expenses and other current assets	(172)	(1,583)
Accounts payable, accrued expenses and other liabilities	(72)	734
Deferred revenue		(5,547)
Net cash used in operating activities	(6,260)	(2,503)
Cash Flows from Investing Activities:		
Purchases of available-for-sale securities	(1,025)	(8,106)
Proceeds from maturity of available-for-sale securities	11,385	
Purchases of property and equipment	(18)	(60)
Net cash provided by (used in) investing activities	10,342	(8,166)
Cash Flows from Financing Activities:		
Proceeds from exercise of common stock options and employee stock purchases	23	39
Payments on capital lease	(4)	(5)
Net cash provided by financing activities	19	34
Net increase (decrease) in cash and cash equivalents	4,101	(10,635)
Cash and cash equivalents, beginning of period	17,008	25,471
Cash and cash equivalents, end of period	$ 21,109	$ 14,836

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

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IDERA PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
March 31, 2011
(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 respiratory diseases, 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 respiratory diseases, and for use as vaccine adjuvants. The Company also is advancing its gene silencing oligonucleotide, or GSO, technology for potential application as research reagents and as therapeutic agents.

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 for the use of TLR9 agonists in cancer treatment, excluding cancer vaccines. Merck KGaA is conducting clinical trials of IMO-2055, which Merck KGaA refers to as EMD 1201081, in combination with other cancer therapy agents in cancer indications including a Phase 2 clinical trial in squamous cell carcinoma of the head and neck. The Company also is collaborating with Merck Sharp & Dohme Corp. formerly Merck & Co., Inc. which is referred to herein as Merck, for the use of TLR7, TLR8, and TLR9 agonists as vaccine adjuvants in the fields of cancer, infectious diseases, and Alzheimer s disease. Merck KGaA and Merck are not related.

At March 31, 2011, the Company had an accumulated deficit of $358.5 million. The Company expects to incur substantial operating losses in future periods. The Company does not expect to generate significant product revenue or royalties until it successfully completes development and obtains marketing approval for drug candidates, either alone or in collaborations with third parties, which it expects will take a number of years. In order to commercialize its drug candidates, the Company needs to complete clinical development and to comply with comprehensive regulatory requirements. In 2011, the Company expects that its research and development expenses will be lower than its research and development expenses in 2010 reflecting the completion of multiple Phase 1 clinical trials in 2010 and the Company s clinical development plans for 2011.

The Company had cash, cash equivalents, and investments of $28.3 million at March 31, 2011. The Company believes that its existing cash, cash equivalents, and investments will be sufficient to fund its operations at least through March 31, 2012 based on its current operating plan. The Company expects to need to raise additional funds in order to operate its business beyond March 31, 2012. Additional financing may not be available to the Company when it needs it or may not be available on favorable terms.

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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 success and timeliness of development, including clinical trial outcomes, uncertainty of funding, and history of operating losses.

(b) New Accounting Pronouncements

The Company adopted Financial Accounting Standards Board, or FASB, Accounting Standard Update No. 2009-13, Multiple-Element Revenue Arrangements (ASU No. 2009-13) on January 1, 2011. ASU No. 2009-13 updates the existing multiple-element revenue arrangements guidance currently included in Accounting Standards Codification No. 605-25 in two ways. The first change relates to the determination of when the individual deliverables included in multiple-element arrangements may be treated as separate units of accounting. This is significant since it may result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. The Company is applying ASU No. 2009-13 prospectively to arrangements entered into or materially modified after the adoption date. Since the Company s period of continuing involvement in the research portions of all of its current collaboration agreements was completed during 2010 and since all of the up-front payments received under these collaborations were fully amortized as of December 31, 2010, the adoption of ASU No. 2009-13 had no effect on the Company s financial position and results of operations through March 31, 2011. The effect that ASU No. 2009-13 may have on the Company s policy for recognizing revenue under any future collaboration agreements will depend upon the terms of those future collaboration agreements, if any.

The Company adopted FASB Accounting Standard Update No. 2010-17, Milestone Method of Revenue Recognition (ASU No. 2010-17) on January 1, 2011. ASU No. 2010-17 provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. The Company is applying ASU No. 2010-17 prospectively to arrangements entered into or materially modified after the adoption date. Since the Company did not earn any milestones during the first quarter of 2011, the adoption of ASU No. 2010-17 has had no effect on the Company s financial position and results of operations through March 31, 2011. Since the Company used a similar method of recognizing milestone revenue prior to adopting ASU No. 2010-17, the Company does not expect that the adoption of ASU No. 2010-17 will have a significant effect on its policy for recognizing revenue on any milestones that it receives in future periods.

(2) Unaudited Interim Financial Statements

The accompanying unaudited financial statements included herein have been prepared by the Company in accordance with United States generally accepted accounting principles 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, 2011 are not necessarily indicative of results that may be expected for the year ended December 31, 2011. 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, 2010, which was filed with the SEC on March 10, 2011.

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(3) Cash, Cash Equivalents and Short-Term 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, 2011 and December 31, 2010 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 income 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. Investments that the Company intends to hold to maturity are classified as held-to-maturity investments. The Company had no held-to-maturity investments at either March 31, 2011 or December 31, 2010. 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 the three months ended March 31, 2011 and 2010. 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, 2011 and 2010. The Company had no auction rate securities as of March 31, 2011 and December 31, 2010.

The Company s available-for-sale short-term investments consisted of the following at March 31, 2011 and December 31, 2010:

	March 31, 2011			
(In thousands)	**Cost**	**Gross Unrealized (Losses)**	**Gross Unrealized Gains**	**Estimated Fair Value**
Corporate bonds due in one year or less	$ 4,232	$	$ 3	$ 4,235
U.S. government bonds dues in one year or less	3,001		1	3,002
Total	$ 7,233	$	$ 4	$ 7,237

	December 31, 2010			
(In thousands)	**Cost**	**Gross Unrealized (Losses)**	**Gross Unrealized Gains**	**Estimated Fair Value**
Agency bonds due in one year or less	$ 3,201	$	$	$ 3,201
Corporate bonds due in one year or less	3,214		4	3,218
U.S. government bonds dues in one year or less	11,207		9	11,216
Total	$ 17,622	$	$ 13	$ 17,635

(4) Fair Value of Assets and Liabilities

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

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The table below presents the assets and liabilities measured at fair value on a recurring basis at March 31, 2011 categorized by the level of inputs used in the valuation of each asset and liability.

(In thousands)	Total	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market fund	$ 19,911	$ 19,911	$	$
Other cash equivalents	1,000		1,000	
Short-term investments	7,237	3,002	4,235	
Total	$ 28,148	$ 22,913	$ 5,235	$
Liabilities	$	$	$	$

The Level 1 assets consist of money market funds and U.S. Government bond investments, both of which are actively traded daily. The Level 2 assets consist of corporate bond investments whose fair value is generally determined from quoted market prices received from pricing services based upon quoted prices from active markets and/or other significant observable market transactions at fair value. Since these prices may not represent actual transactions of identical securities, they are classified as Level 2. Since all investments are classified as available-for-sale securities, any unrealized gains or losses are recorded in accumulated other comprehensive income or loss within stockholders equity on the balance sheet. The Company did not elect to measure any other financial assets or liabilities at fair value. See Note (3).

(5) Property and Equipment

At March 31, 2011 and December 31, 2010, net property and equipment at cost consisted of the following:

(In thousands)	March 31, 2011	December 31, 2010
Leasehold improvements	$ 525	$ 515
Laboratory equipment and other	2,897	2,889
Total property and equipment, at cost	3,422	3,404
Less: accumulated depreciation	(2,602)	(2,474)
Property and equipment, net	$ 820	$ 930

As of March 31, 2011 and December 31, 2010, laboratory equipment and other included approximately $79,000 of office equipment financed under capital leases with accumulated depreciation of approximately $60,000 and $56,000, respectively.

Depreciation expense, which includes amortization of assets recorded under capital leases, was approximately $128,000 and $144,000 in the three months ended March 31, 2011 and 2010, respectively.

(6) Restricted Cash

As part of the Company s lease arrangement for its office and laboratory facility, the Company was required to restrict $619,000 of cash for a security deposit. The restricted cash was reduced by a total of approximately $206,000 upon the second and third anniversaries of the June 2007 lease commencement date. As a result, at March 31, 2011, restricted cash was $413,000. 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 the fourth anniversary of the lease commencement date, subject to certain conditions. As a result, $102,000 of the $413,000 has been classified in Prepaid expenses and other current assets.

(7) Comprehensive Loss

The following table includes the components of comprehensive loss for the three months ended March 31, 2011 and 2010.

	Three months ended March 31,	
(In thousands)	**2011**	**2010**
Net loss	$ (6,845)	$ (1,943)
Other comprehensive (loss) income	(9)	17
Total comprehensive loss	$ (6,854)	$ (1,926)

Other comprehensive (loss) income represents the change in the net unrealized gains (losses) on available-for-sale investments during the period.

(8) Revenue Recognition

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 research and development collaborations, the Company has generally licensed specified portions of its intellectual property and provided research and development services to the collaborator during the period of continued involvement in the early portion of the collaborations. The collaborators have generally been responsible for drug development activities initiated after the collaboration is effective. The collaborators are also generally responsible for any commercialization activities that may be initiated if any of the drug candidates receive marketing approval from the appropriate regulatory authority.

Under the Company s existing collaborative arrangements, the Company has received non-refundable license fees, milestone payments, reimbursements of certain internal and external research and development expenses and patent-related expenses. The Company is also entitled to receive 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. In the three months ended March 31, 2010, alliance revenue consisted primarily of revenue recognized under the Merck KGaA and Merck collaborations. Since the Company completed the research portions of these collaborations during 2010, all of the upfront license fee payments were fully amortized and recognized by December 2010. Consequently, the Company did not recognize any revenue under the Merck KGaA and Merck collaborations during the three months ended March 31, 2011. Alliance revenue for the three months ended March 31, 2011 and 2010, including revenue recognized under the Company s collaborative arrangements with Merck KGaA and Merck during the 2010 period, was as follows:

	Three Months Ended March 31,	
(In thousands)	**2011**	**2010**
Collaboration revenue		
Merck KGaA	$	$ 4,303
Merck		1,250
		5,553
Other revenue	8	24
Total alliance revenue	$ 8	$ 5,577

During the three months ended March 31, 2010, the Company incurred approximately $15,000 in third-party expenses in connection with its collaborative arrangements. The Company did not incur any such expenses in the corresponding 2011 period. These third party expenses are classified as research and development and general and administrative expenses in the Company s statement of operations.

When evaluating multiple element arrangements, the Company considers whether each deliverable of the arrangement represents a separate unit of accounting based on specified criteria such as whether the deliverable has standalone value to the collaborator. Any fixed or determinable payments that the Company expects to receive under the arrangement are allocated among the separate units of accounting and the appropriate revenue recognition criteria are applied to each of these separate units. Any item that does not qualify as a separate unit of accounting is combined with other appropriate items and the combined deliverable is treated as a separate unit of accounting.

The allocation of fixed or determinable payments to the separate units of accounting is based on the relative-selling-price method which is based on the following hierarchy used in determining the selling price for each unit of accounting: (1) Vendor specific objective evidence, or VSOE , - the price at which the item is regularly sold by the vendor on a standalone basis, is the preferred method. (2) Third-party evidence, or TPE , of vendors selling similar goods to similarly situated customers on a standalone basis if VSOE of selling price of a product or service is not available. (3) Best estimate of selling price, or BESP , if neither VSOE nor TPE of selling price of a product or service is available.

The timing of revenue recognition from upfront license fees received under collaboration agreements depends upon the terms of the agreement.

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. 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 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 contingent upon milestone events or achieving a specific result from the research and development efforts the Company recognizes these milestone payments as revenue in their entirety upon achieving the related milestone provided the milestone meets the criteria specified below. Milestones typically consist of significant events 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 in their entirety upon achieving the related milestone, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the amount attributed to the milestone is reasonable in relation to the Company s performance and to the amounts attributed to the other deliverables in the arrangement and the Company has no further performance obligations relating to the milestone event. 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, any deferred revenue the Company has recorded on its balance sheet is classified as short-term or long-term deferred revenue based on its best estimate of when such amounts will be recognized. However, these estimates are based on the Company s collaboration agreements and its then current operating plan and, if either should change, the Company may recognize a different amount of deferred revenue over the subsequent 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 subsequent periods. 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 subsequent periods.

Additional information on the Company s collaborative arrangements is included in Notes (9) and (10).

(9) Collaboration and 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 agreement became effective February 4, 2008. Under the terms of the agreement, the Company 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 the Company continued to conduct the trials on behalf of Merck KGaA; Merck KGaA agreed to pay up to 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 the Company s TLR9 agonists that are marketed. Merck KGaA refers to IMO-2055 as EMD 1201081. In February 2009, the agreement was amended so that the Company could initiate and conduct on behalf of Merck KGaA additional clinical trials of EMD 1201081 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 filed an IND and, as of March 2010, Merck KGaA assumed sponsorship of all ongoing clinical trials of EMD 1201081, for the treatment of cancer, and has assumed responsibility for all further clinical development of EMD 1201081 in the treatment of cancer, excluding vaccines.

The Company recognized the $40.0 million upfront payment as revenue over the twenty-eight month term that ended in June 2010, which was the Company s period of continuing involvement under the research collaboration. The Company has recognized a total of $12.1 million of milestone revenue related to the initiation of clinical trials of EMD 1201081.

(10) Collaboration and 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 collaboration was 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, the Company 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.

The Company recognized the $20.0 million upfront payment as revenue over four years, including the initial two-year research term and the additional two-year research term that ended in December 2010, which was the Company s period of continuing involvement under the research collaboration.

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 such stock 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 aggregate gross proceeds of $10.0 million.

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 recognized $1.0 million of milestone revenue in 2008.

(11) Stock-Based Compensation

The Company recognizes all share-based payments to employees and directors in the financial statements based on their fair values. The Company records compensation expense over an award s requisite service period, or vesting period, based on the award s fair value at the date of grant. The Company s policy is to charge the fair value of stock options as an expense on a straight-line basis over the vesting period, which is generally four years for employees and three years for directors. The Company included charges of $660,000 and $1,173,000 in its statements of operations for the three months ended March 31, 2011 and 2010, respectively, representing the stock-based compensation expense attributable to share-based payments made to employees and directors.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model 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 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 (years)	5.3
Expected volatility	67.0%
Weighted average grant date fair value of options granted during the period (per share)	$3.08
Weighted average exercise price of options granted during the period (per share)	$5.23

The Company did not grant any stock options during the three months ended March 31, 2011.

During the first quarter of 2010, the Company adopted a policy with respect to the treatment of stock options in the event of a non-employee director retirement which resulted in the modification of stock options by accelerating the vesting of nonvested stock options held by, and by extending the post-retirement period during which stock options may be exercised by, those directors whose retirement would qualify under the terms of the policy. The stock option modifications increased the fair value of those options by $85,000 when modified, of which $2,000 and $58,000 was expensed during the three months ended March 31, 2011 and 2010, respectively.

As a result of the stock option modifications, the Company recognized $290,000 more of stock-based compensation expense during the three months ended March 31, 2010 than it would have recognized if the stock options had not been modified. Of that amount, $58,000 was attributable to the increase in fair value of the modified options and $232,000 was attributable to the accelerated recognition of the original fair value of options held by

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directors who were or would become eligible for retirement prior to the completion of the option vesting period, which amounts would otherwise have been expensed over the vesting period on a straight line basis. As a result of the stock option modifications, the Company did not recognize $28,000 of stock-based compensation expense during the three months ended March 31, 2011 that it otherwise would have recognized if the stock options had not been modified, which amount consisted of $30,000 that resulted from the accelerated recognition of the original fair value of options held by directors who were or will become eligible for retirement prior to the completion of the option vesting period, offset by a $2,000 increase in expense attributable to the increase in fair value.

During prior periods, the Company awarded stock options to purchase shares of common stock to persons who were neither employees nor directors. The fair value of the nonvested portion of the non-employee, non-director 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 Company recorded approximately $6,000 and $14,000 as an expense for non-employee, non-director options in the three months ended March 31, 2011 and 2010, respectively.

(12) 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, 2011 and 2010, 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 9,153,788 and 7,000,394 for the three months ended March 31, 2011 and 2010, respectively, and consist of stock options and warrants. Net loss applicable to common stockholders is the same as net loss for the three months ended March 31, 2011 and 2010.

(13) Stockholders Equity

During the three months ended March 31, 2011 and 2010, the Company issued 10,788 and 9,724 shares, respectively, of common stock in connection with stock option exercises and employee stock purchases resulting in total proceeds to the Company of $23,000 and $39,000, respectively. During the three months ended March 31, 2011, pursuant to its director compensation program, the Company issued 4,404 shares of common stock to a director in lieu of cash fees of approximately $13,000.

(14) Related Party Transactions

The Company paid certain directors consulting fees of approximately $10,000 and $8,000 in the three months ended March 31, 2011 and 2010, respectively.

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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 respiratory diseases, 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 respiratory diseases, and for use as vaccine adjuvants. We have completed two Phase 1 clinical trials of IMO-2125, a TLR9 agonist, in patients with chronic hepatitis C virus, or HCV, infection. We have chosen to delay initiation of our planned 12-week Phase 2 randomized clinical trial of IMO-2125 plus ribavirin in treatment-naïve HCV patients based on preliminary observations from a 26-week chronic nonclinical toxicology study of IMO-2125 in rodents. We plan to determine our path forward after full evaluation of the data from the chronic nonclinical toxicology study of IMO-2125 in rodents, as well as from a chronic nonclinical toxicology study of IMO-2125 in nonhuman primates. We expect these data to be available in the second half of 2011. We have completed two Phase 1 clinical trials of IMO-3100, an antagonist of TLR7 and TLR9, in healthy subjects. We expect to complete ongoing nonclinical studies of IMO-3100 during the second quarter of 2011 and to submit to the FDA a protocol for a Phase 2 clinical trial of IMO-3100 in a selected autoimmune disease indication during the third quarter of 2011, which trial we expect to initiate by the end of 2011.

We are also advancing our gene silencing oligonucleotide, or GSO, technology for potential application as research reagents and as therapeutic agents.

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 for the use of TLR9 agonists in cancer treatment, excluding cancer vaccines. Merck KGaA is conducting clinical trials of IMO-2055, which Merck KGaA refers to as EMD 1201081, in combination with other cancer therapy agents in cancer indications including a Phase 2 clinical trial in squamous cell carcinoma of the head and neck. We also are collaborating with Merck Sharpe & Dohme Corp., or Merck, for the use of TLR7, TLR8, and TLR9 agonists as vaccine adjuvants in the fields of cancer, infectious diseases, and Alzheimer s disease. Merck KGaA and Merck are not related.

At March 31, 2011, we had an accumulated deficit of $358,487,000. We expect to incur substantial operating losses in future periods. We do not expect to generate significant product revenue or royalties until we successfully complete development and obtain marketing approval for drug candidates, either alone or in collaborations with third parties, which we expect will take a number of years. In order to commercialize our drug candidates, we need to complete clinical trials and to comply with comprehensive regulatory requirements. In 2011, we expect that our research and development expenses will be lower than our research and development expenses in 2010 reflecting the completion of multiple Phase 1 clinical trials in 2010 and our clinical development plan for 2011.

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CRITICAL ACCOUNTING POLICIES AND ESTIMATES

This management s discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgments, including those related to revenue recognition 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:

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

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

Our significant accounting policies are described in Note 2 of the notes to our financial statements in our Annual Report on Form 10-K for the year ended December 31, 2010. Not all of these significant policies, however, fit the definition of critical accounting policies and estimates. We believe that our accounting policies relating to revenue recognition 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, 2010, fit the description of critical accounting estimates and judgments.

RESULTS OF OPERATIONS

Three Months Ended March 31, 2011 and 2010

Alliance Revenue

Our alliance revenues are comprised primarily of revenue earned under various collaboration and licensing agreements which include 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:

	Three Months Ended March 31, (in thousands) 2011	2010	Percentage Increase (Decrease)
License fees	$	$ 5,553	(100)%
Research and development		18	(100)%
Other	8	6	33%
Total alliance revenue	$ 8	$ 5,577	(100)%

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 was comprised of amortization of the upfront license fee payments under these collaborations. We recognized license fee revenue ratably over the expected period of our continuing involvement in the collaborations, which has generally represented 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 recognized the $40,000,000 upfront payment as revenue over the twenty eight-month research term that ended in June 2010. We received a $20,000,000 upfront payment from Merck in December 2006. We recognized the $20,000,000 upfront payment as revenue over the two-year initial research term and the two-year extension period that ended in December 2010. Since we completed the research portions of these collaborations during 2010, all of the upfront license fee payments were fully amortized by December 2010. Consequently, we did not recognize any license fee revenue under the Merck KGaA and Merck collaborations during the three months ended March 31, 2011.

Research and Development Revenue. Research and development revenue was $18,000 in the three months ended March 31, 2010 and consisted of reimbursement by Merck KGaA of costs associated with clinical trials of IMO-2055. Merck KGaA assumed sponsorship of these trials by March 2010, and consequently we did not recognize any research and development revenue in the three months ended March 31, 2011. We do not expect to have research and development revenue in future periods under our agreements with Merck KGaA and Merck.

Other Revenue. Other revenue consisted of reimbursement by licensees of costs associated with patent maintenance.

Research and Development Expenses

Research and development expenses decreased by $33,000, or 1%, from $4,586,000 for the three months ended March 31, 2010, to $4,553,000 for the three months ended March 31, 2011. In the following table, research and development expense is set forth in the following four categories which are discussed beneath the table:

	Three Months Ended March 31, (in thousands)		Percentage Increase (Decrease)
	2011	2010	
IMO-2125 External Development Expense	$ 1,231	$ 881	40%
IMO-3100 External Development Expense	254	891	(71)%
Other Drug Development Expense	1,024	981	4%
Basic Discovery Expense	2,044	1,833	12%
Total Research and Development Expense	$ 4,553	$ 4,586	(1)%

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 $15,464,000 in external development expenses through March 31, 2011, including costs associated with our clinical trials, manufacturing and process development activities related to the production of IMO-2125, and additional nonclinical toxicology studies.

The increase in IMO-2125 expenses in the three months ended March 31, 2011 as compared to the corresponding 2010 period was attributable to costs associated with preparation for the Phase 2 clinical trial of IMO-2125 we planned to initiate in the second quarter of 2011 and conduct of additional nonclinical toxicology studies of IMO-2125. These increases were partially offset by decreases in costs associated with the two Phase 1 clinical trials for which we completed all patient activities prior to the end of 2010 and manufacturing costs incurred during the first quarter of 2010 but not in the corresponding 2011 period.

In May 2007, we submitted an Investigational New Drug, or IND, application for IMO-2125 to the United States Food and Drug Administration, or FDA. In September 2007, we initiated a Phase 1 clinical trial of IMO-2125 in patients with genotype 1 chronic HCV infection who had no response to a prior regimen of the current standard of care therapy specified by the protocol as patients who failed to achieve a 2 $\log_{10}$ 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 $\log_{10}$ reduction means a decrease in virus concentration to 10% of the original concentration. A 2 $\log_{10}$ reduction means a decrease to 1% of the original concentration. We refer to these patients as null-responder HCV patients. The clinical trial was conducted at a total of eleven sites in the United States with a total of 58 patients. In the trial, we enrolled cohorts of ten patients at escalating IMO-2125 dose levels of 0.04 mg/kg/week, 0.08 mg/kg/week, 0.16 mg/kg/week, 0.32 mg/kg/week, and 0.48 mg/kg/week. Of the ten patients in a cohort, eight were randomized to receive IMO-2125 treatment and two were randomized to receive placebo treatment. Patients received a single dose of IMO-2125 or placebo once per week by subcutaneous injection for four weeks. Based on interim results from these cohorts, we enrolled seven additional patients who received 0.16 mg/kg of IMO-2125 twice weekly for four weeks. The primary objective of the trial was to assess the safety of IMO-2125 at each dose level. We also evaluated the effects of IMO-2125 on HCV RNA levels and on immune system activation in this trial. We presented results from the Phase 1 clinical trial of IMO-2125 in null-responder HCV patients at scientific meetings in April 2010 and in October 2010.

We also conducted 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 genotype 1 chronic HCV infection. We initiated the trial in October 2009. In this clinical trial, a total of 63 patients received IMO-2125 or a control article by subcutaneous injection once per week for four weeks at escalating dose levels in combination with daily oral administration of standard doses of ribavirin. Fifteen patients were enrolled in the first cohort, with 12 randomized to receive IMO-2125 at 0.08 mg/kg/week and ribavirin and three randomized to receive placebo and ribavirin as the control. Eighteen patients were enrolled in the second cohort, with 12 randomized to receive IMO-2125 at 0.16 mg/kg/week and ribavirin and six randomized to receive pegylated recombinant alfa-2a interferon and ribavirin as the control. The third cohort enrolled 30 patients randomized 12:12:6 to receive IMO-2125 at 0.32 mg/kg/week, IMO-2125 at 0.16 mg/kg twice per week, or pegylated recombinant alfa-2a interferon, respectively, all with ribavirin. The primary objective of the trial was to assess the safety and tolerability of IMO-2125 in combination with ribavirin. In addition, we monitored the effect of treatment on HCV RNA levels. The clinical trial was conducted at sites in France, Russia, and Hungary. In December 2010, we announced preliminary data from the Phase 1 clinical trial of IMO-2125 in treatment-naïve HCV patients, and in April 2011 we presented results at the 46th Annual Meeting of the European Association of the Study of the Liver.

In April 2011, we chose to delay initiation of our planned 12-week Phase 2 randomized clinical trial of IMO-2125 plus ribavirin in treatment-naïve, genotype 1 HCV patients based on preliminary observations in a 26-week chronic nonclinical toxicology study of IMO-2125 in rodents. We are completing a 26-week chronic nonclinical toxicology study of IMO-2125 in rodents and a 39-week chronic nonclinical toxicology study of IMO-2125 in non-human primates. Preliminary histology analysis from the rodent study showed instances of atypical lymphocytic proliferation. We expect data from the non-human primate study and additional histology data from the rodent study during the second half of 2011. We plan to determine our path forward after we have fully evaluated the data from our chronic nonclinical toxicology studies of IMO-2125.

IMO-3100 External Development Expenses. These expenses include external expenses that we have incurred in connection with IMO-3100 since November 2009, when we commenced clinical development of IMO-3100. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-3100 clinical development but exclude internal costs such as payroll and overhead expenses. Since November 2009, we have incurred approximately $6,036,000 in external development expenses through March 31, 2011, including costs associated with our clinical trials, manufacturing and process development activities related to the production of IMO-3100, and additional nonclinical toxicology studies.

The decrease in IMO-3100 expenses in the three months ended March 31, 2011 as compared to the corresponding 2010 period was primarily attributable to completion of all patient activities of the two Phase 1 clinical trials during 2010 and lower costs associated with nonclinical toxicology studies conducted during the three months ended March 31, 2011.

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 single-dose, dose escalation Phase 1 trial, IMO-3100 was administered by subcutaneous injection at dose levels of 0.04, 0.08, 0.16, 0.32, and 0.64 mg/kg to a total of 36 subjects. At each dose level, six subjects received IMO-3100. An additional six subjects received placebo treatment. The primary objective of the trial was to evaluate the safety and tolerability of IMO-3100. Secondary objectives were to characterize the pharmacokinetic profile of IMO-3100 and to assess the pharmacodynamic mechanism of action of IMO-3100. The pharmacodynamic mechanism of action is how IMO-3100 engages the immune system in the targeted manner, which we assessed through measurement of the inhibition of TLR7 and TLR9-mediated cytokine induction in peripheral blood mononuculear cells, or PBMCs. The trial was conducted at a single U.S. site. In October 2010 we announced results from the single-dose Phase 1 clinical trial of IMO-3100. IMO-3100 was well tolerated at all dose levels in the trial.

We have also conducted a four-week multiple-dose Phase 1 clinical trial of IMO-3100 in healthy subjects that we initiated in July 2010 and completed in the third quarter of 2010. We presented results of the multi-dose Phase 1 clinical trial at a scientific meeting in April 2011.

We intend for the next step in the clinical development of IMO-3100 to be a Phase 2 clinical trial in a selected autoimmune disease indication, which we expect to initiate by the end of 2011. We are currently conducting nonclinical studies of IMO-3100, in light of some reversible immune responses that were observed in the 13-week nonclinical toxicology studies we had conducted to support the initiation of Phase 2 clinical trials and that were inconsistent with observations in our other nonclinical studies of IMO-3100. We expect to complete these nonclinical studies during the second quarter of 2011 and submit to the FDA the results of these nonclinical studies and a protocol for the Phase 2 clinical trial of IMO-3100 in the selected autoimmune disease indication during the third quarter of 2011.

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

Other drug development expenses increased by $43,000, or 4%, in the three months ended March 31, 2011, as compared to the corresponding 2010 period. The increase in the three months ended March 31, 2011 compared to the corresponding 2010 period was primarily due to higher consulting costs partially offset by lower employee expenses in the 2011 period.

Basic Discovery Expenses. These expenses include our internal and external expenses relating to the discovery of our TLR-targeted programs, including agonists and antagonists of TLRs 3, 7, 8 and 9, and TLR antisense, and GSOs. These expenses reflect payments for laboratory supplies, external research, and professional fees, as well as payroll and overhead expenses. Basic discovery expenses increased by $211,000, or 12%, in the three months ended March 31, 2011, as compared to the corresponding 2010 period. The increase in basic discovery expenses in the three months ended March 31, 2011, as compared to the corresponding 2010 period was mainly due to increases in the cost of laboratory supplies, employee expenses and external nonclinical research costs.

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 decreased by $446,000 from $2,732,000 in the three months ended March 31, 2010, to $2,286,000 in the three months ended March 31, 2011. General and administrative expenses consist primarily of salary expense, stock compensation expense, consulting fees and professional legal fees associated with our patent applications and maintenance, our corporate regulatory filing requirements, our corporate legal matters, and our business development initiatives.

The decrease in general and administrative expenses in the three months ended March 31, 2011, compared to the three months ended March 31, 2010 was primarily due to a decrease in stock based compensation, mainly due to costs associated with the modification of non-employee director stock options in the three months ended March 31, 2010, and lower employee cash compensation expenses in the corresponding 2011 period. The decrease in general and administrative expenses was partially offset by an increase in legal costs associated with patent matters in the 2011 period.

Investment Income, net

Investment income, net was approximately the same in the three months ended March 31, 2011 as it was in the corresponding 2010 period.

Foreign Currency Exchange Loss

Foreign currency exchange loss was $35,000 in the three months ended March 31, 2011 compared to $228,000 in the corresponding 2010 period. Foreign currency exchange gains and losses result from amounts received under our Merck KGaA collaboration agreement and payments under our clinical trial agreements that are denominated 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

Net Loss

As a result of the factors discussed above, our net loss was $6,845,000 for the three months ended March 31, 2011, compared to $1,943,000 for the three months ended March 31, 2010. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through March 31, 2011, we incurred losses of $98,294,000. We also incurred net losses of $260,193,000 prior to December 31, 2000 during which time we were primarily involved in the development of non-TLR targeted antisense technology. Since our inception, we had an accumulated deficit of $358,487,000 through March 31, 2011. We expect to continue to incur substantial operating losses in the future.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

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

- equity and debt financing;
- license fees, research funding and milestone payments under collaborative and license agreements;
- interest income; and
- lease financings.

In August 2010, we raised $15,103,000 in gross proceeds from a registered direct offering of our common stock to institutional investors. In the offering, we sold 4,071,005 shares of common stock and warrants to purchase 1,628,402 shares of common stock. The common stock and the warrants were sold in units at a price of $3.71 per unit, with each unit consisting of one share of common stock and warrants to purchase 0.40 shares of common stock. The warrants to purchase common stock have an exercise price of $3.71 per share, are exercisable immediately, and will expire if not exercised on or prior to August 5, 2015. The net proceeds to us from the offering, excluding the proceeds of any future exercise of the warrants, were approximately $14,089,000.

In addition to the warrants mentioned above, as of March 31, 2011, warrants to purchase 1,704,545 shares of our common stock at an exercise price of $5.20 per share 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 with Merck KGaA, in February 2008 Merck KGaA paid us a $40,000,000 upfront license fee in Euros of which we received $39,733,000 due to foreign currency exchange rates. Since entering this agreement, we have received approximately $12,110,000 in milestone payments and have been reimbursed $4,542,000 for expenses related to the development of EMD 1201081.

In December 2006, we entered into an exclusive license and research collaboration agreement 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. Under the terms of the agreement, Merck paid us a $20,000,000 license fee in December 2006. In addition, in connection with the execution of the license and collaboration agreement, we issued and sold to Merck 1,818,182 shares of our common stock for a price of $5.50 per share resulting in an aggregate purchase price of $10,000,000. Since entering this agreement, we have received $1.0 million in milestone payments and $3.4 million in research and development payments.

Cash Flows

As of March 31, 2011, we had approximately $28,346,000 in cash and cash equivalents and investments, a net decrease of approximately $6,297,000 from December 31, 2010. Net cash used in operating activities totaled $6,260,000 during the three months ended March 31, 2011. The $6,260,000 reflects our $6,845,000 net loss for the period, as adjusted for non-cash expenses, including stock-based compensation, depreciation and amortization. It also reflects changes in our accounts receivable, prepaid expenses and accounts payable, accrued expenses and other liabilities.

The net cash provided by investing activities during the three months ended March 31, 2011 of $10,342,000 reflects the maturity of $11,385,000 in available-for-sale securities offset by the purchase of approximately $1,025,000 of securities and $18,000 of laboratory equipment and leasehold improvements during the period.

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The $19,000 net cash provided by financing activities during the three months ended March 31, 2011 reflects the proceeds of $23,000 received from employee stock purchases, offset, in part, by payments on our capital leases.

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. Net cash used in operating activities totaled $2,503,000 during the three months ended March 31, 2010, reflecting our $1,943,000 net loss for the period, as adjusted for non-cash revenue and expenses, including the reduction in deferred revenue associated with the recognition of deferred revenue under our collaboration agreements, stock-based compensation, depreciation and amortization. It also reflects changes in our accounts receivable, prepaid expenses and accounts payable, accrued expenses and other liabilities.

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 common stock options and employee stock purchases during the three-month period offset, in part, by payments on 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 $358,487,000 at March 31, 2011. We expect to incur substantial operating losses in future periods. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, total assets and working capital.

We have received no revenues from the sale of drugs. 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 had cash, cash equivalents, and investments of $28,346,000 at March 31, 2011. We believe that our existing cash, cash equivalents, and investments will be sufficient to fund our operations at least through March 31, 2012 based on our current operating plan. We expect to need to raise additional funds to operate our business beyond March 31, 2012. 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.

We expect to seek additional funding through collaborations, the sale or license of assets or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain 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;
- competitive and potentially competitive products and technologies and investors receptivity to our drug candidates and the technology underlying them in light of competitive products and technologies;

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

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

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

During the three months ended March 31, 2011, there were no material changes outside the ordinary course of our business to our contractual obligations as disclosed in our Annual Report of Form 10-K for the year ended December 31, 2010.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Foreign currency exchange gains and losses may result from amounts received under our Merck KGaA collaboration agreement and payments under our clinical trial agreements that are denominated in Euros. As of March 31, 2011, we had net accrued obligations of 0.5 million, or $0.7 million. 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, 2011, 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.

(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, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1A. *Risk Factors.*

RISK FACTORS

Investing in our 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 the money you paid to buy 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, 2011, we had an accumulated deficit of $358.5 million. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through March 31, 2011, we incurred losses of $98.3 million. We incurred losses of $260.2 million prior to December 31, 2000 during which time we were primarily involved in the development of non-TLR targeted antisense technology. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, total assets, and working capital.

We have never had any products of our own available for commercial sale and have received no revenues from the sale of drugs. 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 drug candidates. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our drug candidates will become commercially available, or when we will become profitable, if at all. We expect to incur substantial operating losses in future periods.

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 $28.3 million at March 31, 2011. We believe that our existing cash, cash equivalents, and investments will be sufficient to fund our operations at least through March 31, 2012 based on our current operating plan. We expect to need to raise additional funds to operate our business beyond March 31, 2012.

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

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

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

our ability to enter into additional 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 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 being developed by our collaborators, including IMO-2055. Our efforts, and the efforts of our collaborators, to develop and commercialize these compounds are at an early stage and are subject to many challenges. The ability to successfully develop and commercialize these drug candidates will depend on several factors, including the following:

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

timely enrollment in clinical trials of IMO-2125, IMO-3100 and other drug candidates, which may be slower than anticipated, potentially resulting in significant delays;

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

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

the ability to combine our drug candidates and the 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;

changes in treatment regimes;

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

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

In April 2011, we chose to delay initiation of our planned 12-week Phase 2 randomized clinical trial of IMO-2125 plus ribavirin in treatment-naïve, genotype 1 HCV patients based on preliminary observations in a 26-week chronic nonclinical toxicology study of IMO-2125 in rodents. We are completing a chronic nonclinical toxicology study of IMO-2125 in rodents and a chronic nonclinical toxicology study of IMO-2125 in non-human primates. Preliminary histology analysis from the rodent study showed instances of atypical lymphocytic proliferation. We expect data from the non-human primate study and additional histology data from the rodent study during the second half of 2011. We plan to determine our path forward after we have fully evaluated the data from our chronic nonclinical toxicology studies of IMO-2125. However, such data could negatively impact our ability or plans to proceed with the development and commercialization of IMO-2125.

If we or our collaborators are not successful in developing and commercializing IMO-2055, IMO-2125, IMO-3100 or 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.

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.

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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®, 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®, 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 nonclinical 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. For example, we are conducting additional nonclinical studies of IMO-3100 before we initiate a Phase 2 clinical trial, in light of some reversible immune responses that were observed in our 13-week nonclinical toxicology studies and that were inconsistent with our other nonclinical studies of IMO-3100. We chose to delay initiation of our planned Phase 2 clinical trial of IMO-2125 based on preliminary observations from a 26-week chronic nonclinical toxicology study of IMO-2125 in rodents. We plan to determine our path forward after full evaluation of the data from chronic nonclinical toxicology studies, which we expect to be available in the second half of 2011.

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

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

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

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

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

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

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

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

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

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

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

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

- the size of the patient population;
- the proximity of patients to clinical sites;
- the eligibility criteria for the 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.

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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 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, respiratory diseases, and cancer, and as vaccine adjuvants. We are also advancing our gene silencing oligonucleotide, or GSO, technology for potential application as research reagents and as therapeutic agents. 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.

We are developing IMO-2125 for use as an alternative to recombinant interferon in the treatment of HCV. The current standard of care in the treatment of HCV consists of a single recombinant interferon-alpha protein plus ribavarin. If we are able to commercialize IMO-2125 for chronic HCV infection, we will face competition from the interferons currently marketed today and advanced forms of recombinant interferons being developed, including those being developed by Bristol-Myers Squibb Company and Biolex Therapeutics, Inc. In addition, to the extent that a therapy is developed as an alternative to the current standard of care that does not include recombinant interferon or any alternative to recombinant interferon, we may face competition from those therapies as well, such as protease and polymerase inhibitors being developed by Merck, Vertex Pharmaceuticals, Inc. and Pharmasset, Inc. We are also aware of numerous other compounds in clinical trials that target chronic HCV infection through a number of different mechanisms of action, and we believe that there are many additional potential HCV treatments in research or early development. There are also a number of companies developing TLR-targeted compounds for chronic HCV infection, including Dynavax Technologies Corporation, Anadys Pharmaceuticals, Inc., and Gilead Sciences, Inc.

Our principal competitors developing TLR-targeted compounds for autoimmune and inflammatory diseases include Dynavax Technologies Corporation, with its collaborator, GlaxoSmithKline plc and for respiratory diseases include AstraZeneca Pharmaceuticals plc, Pfizer, Inc., in collaboration with Sanofi-Aventis Groupe, Cytos Biotechnology AG, Dynavax Technologies Corporation in collaboration with AstraZeneca Pharmaceuticals plc, 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 Chairman of the Board of Directors, President and Chief Executive Officer. Dr. Agrawal has made significant contributions to the field of oligonucleotide-based drug candidates, and has led the discovery and development of our compounds targeted to TLRs. He is named as an inventor on over 400 patents and patent applications 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.

We are a party to an employment agreement with Dr. Agrawal that expires on October 19, 2013, 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.

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Regulatory Risks

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

All of the drug candidates that we are developing, or may develop in the future, will require additional research and development, extensive preclinical studies, nonclinical testing, clinical trials, and regulatory approval prior to any commercial sales. This process is lengthy, often taking a number of years, is uncertain, and is expensive. Since our inception, we have conducted clinical trials of a number of compounds. Currently, we have two candidates, IMO-2125 and IMO-3100, in clinical development. The FDA and other regulatory authorities may not approve any of our potential products for any indication.

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

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

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

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

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

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

- the regulatory agency s delay in approving, or refusal to approve, an application for marketing of a product or a supplement to an approved application;
- restrictions on our products or the marketing or manufacturing of our products;
- withdrawal of our products from the market;
- warning letters;
- voluntary or mandatory product recalls;

fines;

suspension or withdrawal of regulatory approvals;

product seizure or detention;

refusal to permit the import or export of our products;

injunctions or the imposition of civil penalties; and

criminal penalties.

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

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

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

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

Risks Relating to Collaborators

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

We seek to advance some of 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 respiratory diseases. We are also advancing our GSO technology for potential application as research reagents and as therapeutic agents. 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.

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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;
- 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;