IDERA PHARMACEUTICALS, INC.
Form 10-Q
November 05, 2009

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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 September 30, 2009,

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**	**02139**
(Address of principal executive offices)	*(zip code)*

(617) 679-5500

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes 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	**23,471,178**

Class	Outstanding as of October 30, 2009

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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)	September 30, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 42,660	$ 45,165
Short-term investments	1,202	10,441
Receivables	900	474
Prepaid expenses and other current assets	1,055	876
Total current assets	45,817	56,956
Property and equipment, net	1,417	1,824
Non-current portion of prepaid expenses	104	104
Long-term investments	2,209	
Restricted cash, net of current portion	414	516
Total assets	$ 49,961	$ 59,400
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,496	$ 1,345
Accrued expenses	2,035	1,199
Current portion of capital lease	18	18
Current portion of deferred revenue	16,661	22,295
Total current liabilities	20,210	24,857
Capital lease obligation, net of current portion	15	31
Deferred revenue, net of current portion	1,050	12,165
Other liabilities	232	180
Total liabilities	21,507	37,233
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.01 par value, Authorized 5,000 shares Series A convertible preferred stock, Designated 1,500 shares; Issued and outstanding 1 share at September 30, 2009 and December 31, 2008		
Common stock, $0.001 par value, Authorized 70,000 shares at September 30, 2009 and December 31, 2008; Issued and outstanding 23,467 and 23,413 shares at September 30, 2009 and December 31, 2008, respectively	23	23
Additional paid-in capital	366,038	363,405
Accumulated deficit	(337,610)	(341,225)
Accumulated other comprehensive income (loss)	3	(36)

Total stockholders equity	28,454	22,167
Total liabilities and stockholders equity	$ 49,961	$ 59,400

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 September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	**2009**	**2008**	**2009**	**2008**
Alliance revenue	$ 6,538	$ 7,517	$ 24,338	$ 20,196
Operating expenses:				
Research and development	4,288	3,580	14,177	11,866
General and administrative	2,210	2,323	6,492	8,013
Total operating expenses	6,498	5,903	20,669	19,879
Income from operations	40	1,614	3,669	317
Other income (expense):				
Investment income, net	20	369	122	1,185
Interest expense		(3)		(90)
Foreign currency exchange loss	(6)		(6)	(267)
Income before income taxes	54	1,980	3,785	1,145
Income tax provision	(30)		(170)	
Net income	$ 24	$ 1,980	$ 3,615	$ 1,145
Net income per share (Note 15):				
Basic	$	$ 0.09	$ 0.15	$ 0.05
Diluted	$	$ 0.08	$ 0.15	$ 0.04
Shares used in computing basic net income per common share	23,441	23,022	23,409	22,428
Shares used in computing diluted net income per common share	24,341	25,779	24,188	25,538

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)	Nine Months Ended September 30, 2009	2008
Cash Flows from Operating Activities:		
Net income	$ 3,615	$ 1,145
Adjustments to reconcile net income to net cash (used in) provided by operating activities		
Loss of disposal of property and equipment		2
Stock-based compensation	2,304	1,955
Non-employee stock options	108	712
Depreciation	420	391
Amortization of investment premiums	25	53
Issuance of common stock for services rendered	17	17
Changes in operating assets and liabilities		
Accounts receivable	(426)	(1,078)
Prepaid expenses and other current assets	(179)	(170)
Accounts payable and accrued expenses	1,039	421
Deferred revenue	(16,749)	24,111
Net cash (used in) provided by operating activities	(9,826)	27,559
Cash Flows from Investing Activities:		
Purchase of available-for-sale securities	(2,206)	(22,985)
Proceeds from maturity of available-for-sale securities	9,250	13,145
Decrease (increase) in restricted cash	102	(11)
Purchase of property and equipment	(13)	(355)
Net cash provided by (used in) investing activities	7,133	(10,206)
Cash Flow from Financing Activities:		
Proceeds from exercise of common stock options and warrants and employee stock purchases	245	9,831
Payments on note payable		(1,143)
Purchase of treasury stock	(41)	(95)
Payments on capital lease	(16)	(16)
Net cash provided by financing activities	188	8,577
Net (decrease) increase in cash and cash equivalents	(2,505)	25,930
Cash and cash equivalents, beginning of period	45,165	12,588
Cash and cash equivalents, end of period	$ 42,660	$ 38,518
Supplemental disclosure of cash flow information:		
Cash paid for interest	$	$ 90
Cash paid for income taxes	$ 195	$ 50

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

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IDERA PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
September 30, 2009
(UNAUDITED)

(1) (a) Organization

Idera Pharmaceuticals, Inc. (Idera or the Company) is a biotechnology company engaged in the discovery and development of DNA- and RNA-based drug candidates targeted to Toll-Like Receptors, or TLRs, to treat infectious diseases, autoimmune and inflammatory diseases, cancer, and asthma and allergies, and for use as vaccine adjuvants. Drug candidates are compounds that the Company is developing and that have not been approved for any commercial use. TLRs are specific receptors present in immune system cells. Certain TLRs recognize the DNA or RNA of pathogens such as 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, antagonists, and antisense 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. Compounds that we refer to as TLR antisense inhibit production of a specific TLR or of a protein involved in activating a TLR-mediated immune response by inhibiting the translation of the messenger RNA that encodes the target protein.

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 is seeking 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 Idera 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, and cancer. IMO-2125, a TLR9 agonist, is the Company s lead drug candidate for infectious diseases. The Company is conducting a Phase 1 clinical trial of IMO-2125 in patients with chronic hepatitis C virus, or HCV, infection who have not responded to current standard of care therapy. The trial is designed to assess the safety of IMO-2125. In addition, the trial is designed to evaluate the effects of IMO-2125 on HCV RNA levels and on parameters of immune system activation. The Company also is conducting a Phase 1 clinical trial of IMO-2125 to assess the safety of IMO-2125 in combination with ribavirin in treatment-naïve patients with chronic HCV infection. This clinical trial is also designed to evaluate the effects of IMO-2125 and ribavirin combination treatment on HCV RNA levels and on parameters of immune system activation.

As part of its infectious disease program, the Company is evaluating RNA-based compounds that act as agonists of TLR7 and/or TLR8. The Company refers to its TLR7 and TLR8 agonists as **s**tabilized **i**mmune **m**odulatory **RNA**, or SIMRA, compounds. It is evaluating the mechanism of action of its SIMRA compounds in preclinical studies in human cell-based assays and *in vivo* in non-human primates.

In the Company s autoimmune and inflammatory disease program, it has identified DNA-based compounds that act as antagonists of TLR7 and TLR9. Studies by independent researchers have suggested that immune complexes involved in certain autoimmune diseases trigger inflammatory immune responses mediated through TLR7 and TLR9. As a result, the Company believes that the use of a TLR antagonist to block responses to such immune complexes may provide a novel mechanism of action for potential treatment of autoimmune diseases. The Company has evaluated some of its TLR antagonist compounds in mouse models of lupus, rheumatoid arthritis, multiple sclerosis, psoriasis, colitis, and pulmonary inflammation. The Company has selected IMO-3100 as a lead TLR antagonist drug candidate, and anticipates submitting an Investigational New Drug, or IND, application to the United States Food and Drug Administration, or FDA, by the end of 2009. The Company has formed an Autoimmune

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Disease Scientific Advisory Board to assist it in developing the clinical development strategy for IMO-3100 and other antagonist candidates in autoimmune and inflammatory diseases. The Company also is studying the potential application of TLR antisense in autoimmune and inflammatory diseases.

The Company s cancer treatment research program is focused on potential applications of its TLR7 and/or TLR8 agonists. The Company is studying its TLR7 and TLR8 agonists in preclinical models of cancer and has observed antitumor activity as monotherapy and in combination with selected targeted agents.

Idera is also collaborating with three pharmaceutical companies to advance its TLR-targeted compounds in additional disease areas. The Company is collaborating with Merck KGaA for cancer treatment excluding cancer vaccines, with Merck & Co., Inc., or Merck & Co., for vaccine adjuvants, and with Novartis International Pharmaceutical, Ltd., or Novartis, for the treatment of asthma and allergies. Merck KGaA and Merck & Co. are not related.

The Company has incurred operating losses in all fiscal years except 2002 and 2008 and had an accumulated deficit of $337.6 million at September 30, 2009. The Company may incur substantial operating losses in future periods. The Company does not expect to generate significant funds internally until it successfully completes development and obtains marketing approval for its products, either alone or in collaborations with third parties, which the Company expects will take a number of years. In order to commercialize its therapeutic products, the Company needs to address a number of technological challenges and to comply with comprehensive regulatory requirements.

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

(b) Recently Adopted Accounting Pronouncements

On January 1, 2009, the Company adopted Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 808-10 (*Prior authoritative literature:* Emerging Issues Task Force (EITF) 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property)* on a retrospective basis for all collaborative arrangements existing as of January 1, 2009. ASC 808-10 defines collaborative arrangements and establishes reporting requirements for transactions between participants in collaborative arrangements and between participants in the arrangement and third parties. The adoption of ASC 808-10 did not have a material impact on the Company s financial statements.

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 is generally entitled to receive non-refundable license fees, milestone payments, reimbursements of internal and external research and development expenses and patent-related expenses and royalties on product sales. The Company classifies all of these cash in-flows as revenue in its statement of operations since it considers licensing intellectual property and providing research and development and patent-related services to be part of its central business operations. Revenue recognized under the Company s collaborative arrangements is as follows for the three and nine months ended September 30, 2009 and 2008:

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(in thousands)	Three Months Ended September 30, 2009	Three Months Ended September 30, 2008	Nine Months Ended September 30, 2009	Nine Months Ended September 30, 2008
Merck KGaA	$ 5,066	$ 4,587	$ 19,844	$ 12,235
Merck & Co.	1,437	1,639	4,381	5,915
Novartis	7	1,208	19	1,859
Total	$ 6,510	$ 7,434	$ 24,244	$ 20,009

During the three months ended September 30, 2009 and 2008, the Company incurred approximately $738,000 and $403,000, respectively, in third-party expenses in connection with its collaborative arrangements. During the nine months ended September 30, 2009 and 2008, the Company incurred approximately $2,891,000 and $1,351,000, respectively, in third-party expenses in connection with its collaborative arrangements. 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 the components of the arrangement represent separate units of accounting. The Company recognizes revenue from non-refundable upfront fees received under collaboration agreements, not specifically tied to a separate earnings process, ratably over the term of the contractual obligation or the estimated continuing involvement of the Company under the research arrangement. If the estimated period of continuing involvement is subsequently modified, the period over which the up-front fee is recognized is modified accordingly on a prospective basis.

The Company recognizes revenue from reimbursements received in connection with research and development collaboration agreements as related research and development costs are incurred, and contractual services are performed, provided collectability is reasonably assured. Amounts contractually owed under these research and development collaboration agreements, including any earned but unbilled receivables, are included in trade accounts receivable in the accompanying balance sheets. The Company s principal costs under these agreements are generally for the Company s 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.

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

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets. Amounts not expected to be recognized within the next twelve months are classified as long-term deferred revenue.

Although the Company follows detailed guidelines in measuring revenue, certain judgments affect the application of the Company s revenue policy. For example, in connection with its existing collaboration agreements, the Company has recorded on its balance sheet short-term and long-term deferred revenue based on its best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue in the next twelve months. Amounts that the Company does not expect to recognize prior to the next twelve months are classified as long-term deferred revenue. However, this estimate is based on the Company s collaboration agreements and its current operating plan and, if either should change in the future, the Company may recognize a

different amount of revenue over the next twelve-month period.

The estimate of deferred revenue also reflects management s estimate of the periods of its continuing 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 estimates may change in the future. Such changes to estimates would result in a change in revenue recognition

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amounts. If these estimates and judgments change over the course of these agreements, it may affect the timing and amount of revenue that the Company recognizes and records in future periods.

Additional information on the Company s collaborative arrangements is included in Notes (10), (11) and (12).

During the second quarter of 2009, the Company adopted ASC 825-10 *(Prior authoritative literature:* FASB Staff Position No. FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments).* ASC 825-10 requires disclosures about the fair value of financial instruments in interim as well as in annual financial statements. The adoption of ASC 825-10 did not have a significant impact on the Company s financial position or results of operations.

During the second quarter of 2009, the Company adopted ASC 820-10 (*Prior authoritative literature*: FASB Staff Position No. FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly).* ASC 820-10 provides additional guidelines for making fair value measurements, provides authoritative guidance in determining whether a market is active or inactive and whether a transaction is distressed. ASC 820-10 requires additional disclosures of the input and valuation techniques used to measure fair value and the defining of the major security types comprising debt and equity securities held based upon the nature and risk of the security. The adoption of ASC 820-10 did not impact the Company s financial position or results of operations.

During the second quarter of 2009, the Company adopted ASC 320-10 (*Prior authoritative literature*: FASB Staff Position No. FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments).* ASC 320-10 changes existing accounting requirements for other-than-temporary impairment of debt securities. The adoption of ASC 320-10 did not impact the Company s financial position or results of operations.

During the second quarter of 2009, the Company adopted ASC 855-10 (*Prior authoritative literature*: FASB Statement of Financial Accounting Standards No. 165, *Subsequent Events).* ASC 855-10 is similar to the subsequent events guidance in the current auditing literature except that it clarifies and discloses the period during which companies monitor subsequent events in order to determine what impact, if any, the subsequent events have on the information disclosed in the financial statements and footnotes. The adoption of ASC 855-10 did not impact the Company s financial position or results of operations.

(c) Subsequent Events

The Company evaluates subsequent events occurring between the most recent balance sheet date and the date that the financial statements are available to be issued in order to determine whether the subsequent events are to be disclosed in the Company s financial statements and footnotes. The financial statements are considered to be available to be issued at the time that they are filed with the Securities and Exchange Commission.

(2) Unaudited Interim Financial Statements

The accompanying unaudited financial statements included herein have been prepared by the Company in accordance with generally accepted accounting principles for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission. 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, considered necessary for a fair presentation of interim period results have been included. The Company believes that its disclosures are adequate to make the information presented not misleading. Interim results for the three- and nine-month periods ended September 30, 2009 are not necessarily indicative of results that may be expected for the year ended December 31, 2009. 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, 2008, which was filed with the Securities and Exchange Commission on March 11, 2009.

(3) Reclassifications

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Certain amounts in the prior year s financial statements have been reclassified to be consistent with the current year s presentation.

(4) Cash Equivalents and Investments

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be cash equivalents. Cash and cash equivalents at September 30, 2009 and December 31, 2008 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 (loss) on the accompanying balance sheets. The amortization of premiums and accretion of discounts, and any realized gains and losses and declines in value judged to be other-than-temporary, and interest and dividends for all available-for-sale securities are included in Investment income, net on the accompanying statements of operations. The Company had no held-to-maturity investments at either September 30, 2009 or December 31, 2008. The cost of securities sold is based on the specific identification method.

The Company had no realized gains or losses from available-for-sale securities in three or nine months ended September 30, 2009 and 2008. There were no losses or other-than-temporary declines in value included in Investment income, net for any securities for the three or nine months ended September 30, 2009 and 2008.

The Company s long-term investments as of September 30, 2009 consist of government bonds. The Company had no long-term investments as of December 31, 2008. The Company had no auction rate securities as of September 30, 2009 and December 31, 2008.

The Company s available-for-sale investments at market value consisted of the following at September 30, 2009 and December 31, 2008:

	September 30, 2009			
(in thousands)	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Estimated Fair Value
Corporate bonds due in one year or less	$ 1,202	$	$	$ 1,202
Government bonds due in more than one year	2,206		3	2,209
Total	$ 3,408	$	$ 3	$ 3,411

	December 31, 2008			
(in thousands)	Amortized Cost	Gross Unrealized Losses	Gross Unrealized Gains	Estimated Fair Value
Corporate bonds due in one year or less	$ 10,477	$ 44	$ 8	$ 10,441

(5) Fair Values of Assets and Liabilities

The Company measures fair value at the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Assumptions that market participants would use in pricing the asset or liability (the inputs) are prioritized into a three-tier fair value hierarchy. This fair value hierarchy gives the highest priority (Level 1) to quoted prices in active markets for identical assets or liabilities and the lowest priority (Level 3) to unobservable inputs in which little or no market data exists, requiring companies to develop their own assumptions. Observable inputs that do not meet the criteria of Level 1, and include quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets and liabilities in

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markets that are not active, are categorized as Level 2. Level 3 inputs are those that reflect the Company s estimates about the assumptions market participants would use in pricing the asset or liability, based on the best information available in the circumstances. Valuation techniques for assets and liabilities measured using Level 3 inputs may include unobservable inputs such as projections, estimates and management s interpretation of current market data. These unobservable Level 3 inputs are only utilized to the extent that observable inputs are not available or cost-effective to obtain.

The table below presents the assets and liabilities measured at fair value on a recurring basis at September 30, 2009 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	$ 42,614	$ 42,614	$	$
Investments	3,411		3,411	
Total	$ 46,025	$ 42,614	$ 3,411	$
Liabilities	$	$	$	$

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

The fair value of investments is generally determined from quoted market prices received from pricing services based upon quoted prices from active markets and/or other significant observable market transactions at fair value. Since these prices may not represent actual transactions of identical securities, they are classified as Level 2. Since all investments are classified as available-for-sale securities, any gains or losses are recorded in other comprehensive gains or losses in the equity section of the balance sheet.

There were no unrealized losses on investments at September 30, 2009. See Note (4).

(6) Property and Equipment

At September 30, 2009 and December 31, 2008, net property and equipment at cost consists of the following:

(in thousands)	September 30, 2009	December 31, 2008
Leasehold improvements	$ 514	$ 514
Laboratory equipment and other	2,707	2,694
Total property and equipment, at cost	3,221	3,208
Less: Accumulated depreciation and amortization	1,804	1,384
Property and equipment, net	$ 1,417	$ 1,824

As of September 30, 2009 and December 31, 2008, laboratory equipment and other includes approximately $79,000 of office equipment financed under a capital lease with accumulated depreciation of approximately $37,000 and $25,000, respectively. Total depreciation expense, which includes amortization of assets recorded under capital leases, was approximately $139,000 and $135,000 for the three months ended September 30, 2009 and 2008, respectively, and approximately $420,000 and $391,000 for the nine months ended September 30, 2009 and 2008, respectively.

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(7) Restricted Cash

As part of the operating lease entered into by the Company in October 2006, the Company was required to restrict $619,000 of cash for a security deposit. The restricted cash was reduced by approximately $102,000 in June 2009 upon the second anniversary of the lease commencement date. As a result, at September 30, 2009 restricted cash was $516,000, including $102,000 classified in other current assets. The restricted cash is held in certificates of deposit securing a line of credit for the lessor. The restricted cash is expected to be further reduced by approximately $102,000 upon each of the third and fourth anniversaries of the lease commencement date of June 2007, subject to certain conditions.

(8) Note Payable

In June 2007, the Company executed a promissory note in the aggregate principal amount of $1,278,000 (the Note) in favor of General Electric Capital Corporation (GE). The Note was fully secured by specific laboratory, manufacturing, office and computer equipment and was subject to the terms of a master security agreement dated April 23, 2007 by and between the Company and GE. The Note bore interest at a fixed rate of 11% per annum, and was payable in 48 consecutive monthly installments of principal and accrued interest, with the first installment having been paid out of the proceeds of the borrowing.

In March 2008, the Company paid approximately $1,189,000 to GE as payment in full of all obligations outstanding under the Note. The payment represented approximately $1,121,000 of principal plus accrued interest through the date of payment of approximately $12,000 and a prepayment premium of approximately $56,000. The Note has been cancelled.

(9) Comprehensive Income

The following table includes the components of comprehensive income for the three and nine months ended September 30, 2009 and 2008.

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	**2009**	**2008**	**2009**	**2008**
Net income	$ 24	$ 1,980	$ 3,615	$ 1,145
Other comprehensive (loss) income	(7)	(291)	39	(346)
Total comprehensive income	$ 17	$ 1,689	$ 3,654	$ 799

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

(10) 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, Idera granted Merck KGaA worldwide exclusive rights to its lead TLR9 agonists, IMO-2055 and IMO-2125, and to a specified number of novel, follow-on TLR9 agonists to be identified by Merck KGaA and the Company under a research collaboration, for use in the treatment, cure and/or delay of the onset or progression of cancer in humans. Under the terms of the agreement: Merck KGaA paid the Company in February 2008 a $40.0 million upfront license fee in Euros of which $39.7 million was received due to foreign currency exchange rates in effect at that time; Merck KGaA agreed to reimburse future development costs for certain of the Company s ongoing IMO-2055 clinical trials; 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 royalties on net sales of products containing the Company s TLR9 agonists that are marketed. In February 2009, the Company amended its license agreement with Merck KGaA so that Idera could initiate and conduct on behalf of Merck KGaA additional clinical trials of IMO-2055, until such time as Merck KGaA has filed an IND application for IMO-2055 with the FDA and assumes sponsorship of these trials. Under the amendment, Merck

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KGaA has agreed to reimburse the Company for costs associated with any additional trials that the Company initiated and conducted. In September 2009, Merck KGaA assumed sponsorship of the Company s ongoing Phase 1b clinical trials of IMO-2055 and responsibility for conducting all future clinical trials of IMO-2055 for the treatment of cancer excluding vaccines.

The Company is recognizing the $40.0 million upfront payment as revenue over the twenty-eight-month research term. The Company has estimated that this is its period of continuing involvement under the research arrangement. This estimated period was not impacted by the February 2009 amendment.

In February 2009, the Company achieved a milestone under its agreement with Merck KGaA upon the dosing of the first patient in a clinical trial of IMO-2055 in combination with Erbitux ® and Camptosar ® in patients with colorectal cancer. Under the terms of the agreement, the Company received a payment of $4.0 million from Merck KGaA in the second quarter of 2009 and recognized the revenue in the second quarter of 2009.

(11) License Agreement with Merck & Co., Inc.

In December 2006, the Company entered into an exclusive license and research collaboration agreement with Merck & Co. 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 & Co. worldwide exclusive rights to a number of the Company s TLR7, 8 and 9 agonists for use in combination with Merck & Co. s therapeutic and prophylactic vaccines under development in the fields of cancer, infectious diseases, and Alzheimer s disease. The Company also agreed with Merck & Co. to engage in a two-year research and development collaboration to generate novel agonists targeting TLR7 and TLR8 and incorporating both Merck & Co. and Idera chemistry for use in vaccines in the defined fields, with Merck & Co. having the right to extend the collaboration for two additional one-year periods. In November 2008, Merck & Co. extended this research collaboration for an additional one-year period to December 2009. Under the terms of the agreement: Merck & Co. paid the Company a $20.0 million upfront license fee; Merck & Co. purchased $10.0 million of the Company s common stock at $5.50 per share; and Merck & Co. agreed to fund the research and development collaboration. Merck & Co. 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 & Co. develops and commercializes additional vaccines using the Company s agonists, it would be entitled to receive additional milestone payments. In addition, Merck & Co. agreed to pay the Company royalties on net product sales of vaccines using the Company s TLR agonist technology that are developed and marketed.

The Company is recognizing the $20.0 million upfront payment as revenue over the two-year initial research term and the additional two-year-period over which the research term could be extended. The Company has estimated that this is its period of continuing involvement under the research arrangement.

In May 2008, under the Company s collaboration agreement with Merck & Co., a preclinical milestone was achieved with one of its novel TLR9 agonists being used as an adjuvant in cancer vaccines. As a result, the Company received a $1.0 million milestone payment from Merck & Co. in May 2008 and recognized the revenue in the second quarter of 2008.

(12) Collaboration and License Agreement with Novartis International Pharmaceutical, Ltd.

In May 2005, the Company entered into a research collaboration and option agreement and a separate license, development, and commercialization agreement with Novartis to discover, develop, and potentially commercialize TLR9 agonists that are identified as potential treatments for asthma and allergies. In addition, beginning on May 31, 2007, if specified conditions are satisfied, Novartis may expand the collaboration to include additional human disease areas, other than oncology and infectious diseases. Under the terms of the agreements, upon execution of the agreements, Novartis paid the Company a $4.0 million upfront license fee; Novartis agreed to fund substantially all research activities during the research collaboration phase; if Novartis elects to exercise its option to develop and

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commercialize licensed TLR9 agonists in the initial collaboration disease areas, Novartis is potentially obligated to pay the Company up to $132.0 million based on the achievement of clinical development, regulatory approval, and annual net sales milestones; Novartis is potentially obligated to pay the Company additional milestone payments if Novartis elects to expand the collaboration to include additional disease areas and then develops and commercializes licensed TLR9 agonists in the additional disease areas based on the achievement of clinical development and regulatory approval milestones; and Novartis is also obligated to pay the Company royalties on net sales of all products, if any, commercialized by Novartis, its affiliates and sublicensees. Novartis license rights under the agreements to products that it elects to develop and commercialize are worldwide, exclusive rights.

The Company and Novartis agreed that the term of the research and collaboration phase would be two years commencing in May 2005. The Company initially was recognizing the $4.0 million upfront payment as revenue over the two-year term of the research collaboration. In February 2007, the Company received notice that Novartis had elected to extend the research collaboration by an additional year until May 2008, and for such extension Novartis paid the Company an additional $1.0 million. In connection with this amendment, the Company extended the time period over which it was amortizing the upfront payment and the $1.0 million extension payment. In 2008, the research collaboration was extended until December 31, 2008. The Company amortized the upfront payment and the extension payment through the third quarter of 2008 by which time Novartis had initiated a Phase 1 clinical study of QAX935, a novel agonist of TLR9, and the Company s continuing obligations under the agreement were completed. As a result of the initiation of the Phase 1 clinical study of QAX935, the Company recognized milestone revenue in the third quarter of 2008 and received a $1.0 million milestone payment from Novartis in October 2008.

(13) Stock-Based Compensation

The Company recognizes all share-based payments to employees in the financial statements based on their fair values. The Company records compensation expense over an award s 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. The Company included charges of $797,000 and $653,000 in its statements of operations for the three months ended September 30, 2009 and 2008, respectively, and $2,304,000 and $1,955,000 in its statements of operations for the nine months ended September 30, 2009 and 2008, respectively, representing the stock compensation expense attributable to share-based payments made to employees and directors.

The Company s stock compensation plans include the 1995 Stock Option Plan, the 1995 Director Stock Option Plan, the 1995 Employee Stock Purchase Plan, the 1997 Stock Incentive Plan, the 2005 Stock Incentive Plan and the 2008 Stock Incentive Plan, all of which have been approved by the Company s stockholders. No additional options are being granted under the 1995 Stock Option Plan, the 1995 Director Stock Option Plan, the 1997 Stock Incentive Plan and the 2005 Stock Incentive Plan. In 2001, the Company also granted options to purchase shares of Common Stock pursuant to agreements that were not approved by stockholders.

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 130,800 and 658,500 options granted to employees and directors during the nine months ended September 30, 2009 and 2008, respectively:

	Nine Months Ended September 30,	
	2009	**2008**
Average risk free interest rate	2.7%	3.3%
Expected dividend yield		
Expected lives	5.0 years	4.9 years
Expected volatility	68.6%	65.4%
Weighted average grant date fair value of options granted during the period (per share)	$ 3.82	$ 7.62

The Company awarded stock options to non-employees to purchase 10,000 shares of common stock during the first nine months of 2009. These options had a Black-Scholes fair value of $58,000 at the time of grant based on a risk free interest rate of 3.7%, an expected life of 10 years, and an expected volatility of 88%. The Company

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awarded stock options to non-employees to purchase 87,250 shares of common stock during the first nine months of 2008. These options had a Black-Scholes fair value of $1,055,000 at the time of grant based on a risk free interest rate of 3.9%, an expected life of 10 years, and an expected volatility of 94%. The fair value of the nonvested portion of the non-employee options is remeasured each quarter. This remeasured fair value is partially expensed each quarter based upon the percentage of the nonvested portion of the option s vesting period that has elapsed to date less the amount expensed in prior periods. The resulting expense for non-employee options was $114,000 and $242,000 for the three months ended September 30, 2009 and 2008, respectively, and $108,000 and $712,000 for the nine months ended September 30, 2009 and 2008, respectively.

(14) Alternative Minimum Tax

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. In the three months ended March 31, 2008, the Company made an estimated quarterly tax payment of $50,000 since it believed that this payment generated income subject to the alternative minimum tax, or AMT. In the three months ended June 30, 2008, the Company reversed the $50,000 recorded as income tax expense as the Company no longer expected to have income subject to AMT. During the three and nine months ended September 30, 2009, the Company recognized $30,000 and $170,000 respectively, in AMT taxes.

(15) Net Income per Common Share

The following table sets forth the computation of basic and diluted income per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	**2009**	**2008**	**2009**	**2008**
Numerator for basic and dilutive net income per share:				
Net income	$ 24	$ 1,980	$ 3,615	$ 1,145
Denominator for basic income (loss) per share:				
Weighted average common shares outstanding	23,441	23,022	23,409	22,428
Effect of dilutive securities:				
Common stock options and warrants	900	2,757	779	3,110
Denominator for diluted net income (loss) per share	24,341	25,779	24,188	25,538
Basic net income per share	$	$ 0.09	$ 0.15	$ 0.05
Diluted net income per share	$	$ 0.08	$ 0.15	$ 0.04

For the three months ended September 30, 2009 and 2008, 1,818,919 and 20,426 shares, respectively, were not included in the computation of diluted net income per share as the effects of certain stock options are antidilutive. For the nine months ended September 30, 2009 and 2008, 1,902,202 and 739,863 shares, respectively, were not included in the computation of diluted net income per share as the effects of certain stock options are antidilutive. Net income applicable to common stockholders is the same as net income for all periods presented.

(16) Stockholders Equity

In January 2008, the Company sent notice to holders of the Company s warrants to purchase common stock that were issued in August 2004 with an expiration date of August 27, 2009 (the August 2004 Warrants) that under the terms of the warrant agreement, it intended to redeem on March 31, 2008 any August 2004 Warrants not exercised as of that date for a redemption price of $0.08 per share of common stock underlying the August 2004 Warrants. The

Company was entitled to exercise this redemption right because the closing price of the Company s common stock for twenty consecutive trading days ending December 20, 2007 was greater than $10.72 or 200% of the exercise price of the warrant. The August 2004 Warrants were exercisable by cash payment only and had an exercise price of $5.36 per share of common stock. Following such notice and through March 31, 2008, the Company received approximately $1,472,000 in proceeds from the exercise of August 2004 Warrants to purchase 274,650

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shares of common stock. As of March 31, 2008, all August 2004 Warrants had been exercised.

During the nine months ended September 30, 2009 and 2008, the Company issued 57,654 and 1,801,215 shares, respectively, of common stock in connection with warrant and stock option exercises and employee stock purchases resulting in total proceeds to the Company of $245,000 and $9,831,000, respectively.

(17) Related Party Transactions

During the nine months ended September 30, 2009 and 2008, the Company recorded expense of $8,000 and $91,000, respectively, for consulting services provided by Dr. Robert W. Karr, a director of the Company.

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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 asthma and allergies, and for use as vaccine adjuvants. Drug candidates are compounds that we are developing and have not been approved for any commercial use. TLRs are specific receptors present in immune system cells. Certain TLRs recognize the DNA or RNA of pathogens such as 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, antagonists and antisense 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. Compounds that we refer to as TLR antisense inhibit production of a specific TLR or of a protein involved in activating a TLR-mediated immune response by inhibiting the translation of the messenger RNA that encodes the target protein.

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 are seeking 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, and cancer. IMO-2125, a TLR9 agonist, is our lead drug candidate for infectious diseases. We are conducting a Phase 1 clinical trial of IMO-2125 in patients with chronic hepatitis C virus, or HCV, infection who have not responded to current standard of care therapy. We also are conducting a Phase 1 clinical trial of IMO-2125 in combination with ribavirin in treatment-naïve patients with chronic HCV infection. As part of our infectious disease program, we are also evaluating RNA-based compounds that act as agonists of TLR7 and/or TLR8. We refer to our TLR7 and TLR8 agonists as stabilized **i**mmune **m**odulatory **R**N**A**, or SIMRA, compounds. We are evaluating the mechanism of action of our TLR7 and TLR8 agonist compounds in preclinical studies in human cell-based assays and *in vivo* in non-human primates.

In our autoimmune and inflammatory disease program, we have identified DNA-based compounds that act as antagonists of TLR7 and TLR9. Studies by independent researchers have suggested that immune complexes involved in certain autoimmune diseases trigger inflammatory immune responses mediated through TLR7 and TLR9. As a result, we believe that the use of a TLR antagonist to block responses to such immune complexes may provide a novel mechanism of action for the treatment of autoimmune diseases. We have evaluated some of these compounds in mouse models of lupus, rheumatoid arthritis, multiple sclerosis, psoriasis, colitis, and pulmonary inflammation. We have selected IMO-3100 as a lead TLR antagonist drug candidate, and anticipate submitting an Investigational New Drug, or IND, application to the United States Food and Drug Administration, or FDA, by the end of 2009. We are also studying the potential application of TLR antisense in autoimmune and inflammatory diseases.

Our cancer treatment research program is focused on potential applications of our TLR7 and/or TLR8 agonists. We are studying our TLR7 and TLR8 agonists in preclinical models of cancer and have observed antitumor activity as monotherapy and in combination with selected targeted agents.

We are also collaborating with three pharmaceutical companies to advance our TLR-targeted compounds in additional disease areas. We are collaborating with Merck KGaA for cancer treatment excluding cancer vaccines, with Merck & Co., Inc., or Merck & Co., for vaccine adjuvants, and with Novartis International Pharmaceutical, Ltd., or Novartis, for treatment of asthma and allergies. Merck KGaA and Merck & Co. are not related.

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At September 30, 2009, we had an accumulated deficit of $337.6 million. We may incur substantial operating losses in future periods. We do not expect to generate significant funds until we successfully complete development and obtain marketing approval for products, either alone or in collaborations with third parties, which we expect will take a number of years. In order to commercialize our products, we need to address a number of technological challenges and to comply with comprehensive regulatory requirements. We expect that our research and development expenses in 2009 will be higher than our research and development expenses in 2008 as we expand our IMO-2125 development program, conduct IND-enabling preclinical evaluations of IMO-3100, accelerate our early-stage programs on TLR antagonists and on agonists of TLR7 and TLR8, and continue evaluation of TLR antisense.

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. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We regard an accounting estimate or assumption underlying our financial statements as a critical accounting estimate where (i) the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and (ii) the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are described in Note 2 of the Notes to Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2008. Not all of these significant accounting policies, however, fit the definition of critical accounting estimates. We believe that our accounting policies relating to revenue recognition and stock-based compensation, as described under the caption Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates in our Annual Report on Form 10-K for the year ended December 31, 2008, fit the definition of critical accounting estimates and judgments.

RESULTS OF OPERATIONS

Three and Nine Months Ended September 30, 2009 and 2008

Alliance Revenue

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

The following is a summary of our alliance revenues:

	Three Months Ended September 30, (in thousands)		Percentage Increase	Nine Months Ended September 30, (in thousands)		Percentage Increase
	2009	2008	(Decrease)	2009	2008	(Decrease)
License fees	$ 5,553	$ 5,805	(4%)	$ 16,658	$ 15,947	4%
Research and development	969	693	40%	3,626	2,188	66%
Milestones		1,000	(100%)	3,996	2,000	100%
Other	16	19	(16%)	58	61	(5%)
Total alliance revenue	$ 6,538	$ 7,517	(13%)	$ 24,338	$ 20,196	21%

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Total alliance revenues decreased by approximately $979,000, or 13%, for the three months ended September 30, 2009 compared to the same period in 2008 and increased by approximately $4,142,000, or 21%, for the nine months ended September 30, 2009 compared to the same period in 2008.

License fees primarily include license fee revenue recognized under our collaborations with Merck KGaA, Merck & Co., and Novartis. License fee revenue is comprised of a portion of upfront license fee payments and, if applicable, any research period extension payment we have received from collaborative alliances with which we are still involved. License fee revenue is recognized on a straight-line basis over the expected period of our continuing involvement in the collaborations. 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 and a $20,000,000 upfront payment from Merck & Co. in December 2006. We also received from Novartis a $4,000,000 upfront payment in July 2005 and an additional $1,000,000 payment, to extend the research portion of the agreement, in May 2007.

License fees decreased by $252,000 for the three months ended September 30, 2009 compared to the same period in 2008 primarily due to license fee revenue recognized under our May 2005 research collaboration with Novartis included in the three months ended September 30, 2008 but not the three months ended September 30, 2009 as we completed our research obligations under that collaboration in the third quarter of 2008. License fees increased by $711,000 for the nine months ended September 30, 2009 compared to the same period in 2008 primarily due to an additional $1,619,000 in license fee revenue we recognized in the nine months ended September 30, 2009 compared to the same period in 2008 under our collaboration with Merck KGaA, which became effective February 4, 2008. This increase in the nine months ended September 30, 2009 compared to the same period in 2008 was offset, in part, by a decrease in license fee revenue recognized under our May 2005 research collaboration with Novartis in the nine months ended September 30, 2009 as we completed our research obligations in the third quarter of 2008. We also recognized $1,250,000 in license fee revenue under our collaboration with Merck & Co. during both the three months ended September 30, 2009 and 2008 and $3,750,000 in license fee revenue under our collaboration with Merck & Co. during both the nine months ended September 30, 2009 and 2008.

Research and development revenue increased by $276,000 and $1,438,000 in the three and nine months ended September 30, 2009, respectively, due to reimbursable clinical trial costs associated with clinical trials we are conducting under our collaboration agreement with Merck KGaA. These increases were offset by a decrease in revenue from research reimbursements under our collaboration agreement with Merck & Co. We expect research and development revenue to be substantially lower in future periods because the sponsorship of the two on-going Phase 1b clinical trials of IMO-2055 was transferred to Merck KGaA in September 2009 and as a result we expect our reimbursable clinical trial costs to be substantially lower.

The decrease in milestone revenue in the three-month period is attributable to a $1,000,000 milestone earned in the 2008 period under our collaboration with Novartis relating to an initiation of a Phase 1 clinical trial by Novartis. The increase in milestone revenue in the nine-month period is attributable to a $3,996,000 milestone earned in the 2009 period under our collaboration with Merck KGaA as a result of the dosing in February 2009 of the first patient in the clinical trial of IMO-2055 in combination with Erbitux ® and Camptosar ® in patients with colorectal cancer. In the nine months ended September 30, 2008, our milestone revenue also included a $1,000,000 milestone earned under our collaboration with Merck & Co. relating to a preclinical milestone achieved with one of our novel TLR9 agonists used as an adjuvant in cancer vaccines.

Research and Development Expenses

Research and development expenses increased by $708,000, or 20%, from $3,580,000 for the three months ended September 30, 2008 to $4,288,000 for the three months ended September 30, 2009 and increased by $2,311,000 or 19%, from $11,866,000 for the nine months ended September 30, 2008 to $14,177,000 for the nine months ended September 30, 2009. The increase in research and development expenses in the three and nine months ended September 30, 2009 compared to the three and nine months ended September 30, 2008 was primarily due to increased clinical costs associated with IMO-2055, a portion of which are reimbursable under our agreement with

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Merck KGaA, increased clinical costs associated with IMO-2125 and increased non-clinical safety study costs associated with IMO-3100. These increases were offset, in part, by decreased manufacturing and non-clinical safety studies associated with IMO-2125.

	Three Months Ended September 30, (in thousands)		Percentage Increase	Nine Months Ended September 30, (in thousands)		Percentage Increase
	2009	2008	(Decrease)	2009	2008	(Decrease)
IMO-2055 External Development Expense	$ 732	$ 402	82%	$ 2,869	$ 1,513	90%
IMO-2125 External Development Expense	432	556	(22%)	1,507	2,348	(36%)
Other Drug Development Expense	1,260	964	31%	4,460	2,947	51%
Basic Discovery Expense	1,864	1,658	12%	5,341	5,058	6%
Total Research and Development Expense	$ 4,288	$ 3,580	20%	$ 14,177	$ 11,866	19%

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

IMO-2055 External Development Expenses. IMO-2055 is a lead compound being developed for oncology applications under our collaboration with Merck KGaA that we entered into in December 2007. External development expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-2055 clinical trials but exclude internal costs such as payroll and overhead expenses. Since 2003, when we commenced clinical development of IMO-2055 and through September 30, 2009, we have incurred approximately $17.3 million in external expenses in connection with IMO-2055.

Under our collaboration, Merck KGaA is responsible for all development of IMO-2055 for the treatment of cancer excluding vaccines. In February 2009, we amended our license agreement with Merck KGaA so that we could initiate and conduct on behalf of Merck KGaA additional clinical trials of IMO-2055, until such time as Merck KGaA filed an IND application for IMO-2055 with the FDA and assumed sponsorship of these trials. Merck KGaA agreed to reimburse us for costs associated with any trials that we initiated and conducted, including costs associated with the Phase 1b clinical trials of IMO-2055 in non-small cell lung cancer and in colorectal cancer and a Phase 1 clinical trial of IMO-2055 in healthy subjects that we incur after February 4, 2008, which is the date our agreement with Merck KGaA became effective. In September 2009, Merck KGaA assumed sponsorship of the Company s ongoing Phase 1b clinical trials of IMO-2055 and responsibility for conducting all future clinical trials of IMO-2055 for the treatment of cancer excluding vaccines. As a result, we expect expenses incurred by us for IMO-2055 development to be substantially lower in future periods.

External development expenses for IMO-2055 increased by $330,000, or 82%, from $402,000 for the three months ended September 30, 2008 to $732,000 for the three months ended September 30, 2009 and increased by $1,356,000, or 90%, from $1,513,000 for the nine months ended September 30, 2008 to $2,869,000 for the nine months ended September 30, 2009. The increases in the three- and nine-month periods were primarily attributable to increases in costs, which are reimbursable under our collaboration with Merck KGaA, associated with our Phase 1b clinical trials in non-small cell lung cancer patients, which we initiated in December 2007, and in colorectal cancer patients, for which we commenced dosing in February 2009, and costs associated with the Phase 1 clinical trial in healthy subjects that we initiated in April 2009. These increases were offset, in part, by a decrease in IMO-2055 expenses associated with our Phase 2 Stage A clinical trial in renal cell carcinoma patients which was completed in the second quarter of 2009.

In December 2007, we initiated a Phase 1b clinical trial of IMO-2055 in combination with Avastin® and Tarceva® in non-small cell lung cancer patients whose cancer had progressed during a prior course of standard therapy. This clinical trial was designed with a target enrollment of up to 40 patients. In September 2009, we reported preliminary data from the dose-escalation portion of the trial, in which IMO-2055 was administered at four escalating dose levels up to 0.48 mg/kg/week with fixed standard dose regimens of Avastin and Tarceva. IMO-2055 was well tolerated at all dose levels, and eight of the 16 patients enrolled in the dose-escalation portion of the trial remained on treatment for at least 18 weeks. Of the 13 patients evaluable for tumor response in the dose-escalation portion of the trial, three had a partial response and eight experienced stable disease. Based on the dose escalation portion, a dose level of IMO-2055 has been selected for expanded patient recruitment to evaluate further the safety and pharmacokinetics of the combination.

In February 2009, we began dosing the first patient in a Phase 1b clinical trial of IMO-2055 in combination with Erbitux and Camptosar in patients with colorectal cancer whose cancer had progressed during a prior course of standard therapy. Patients currently are being recruited for this clinical trial, which was designed with a target enrollment of up to 50 patients.

In April 2009, we initiated a Phase 1 clinical trial of IMO-2055 monotherapy in healthy subjects, and all scheduled patient visits were completed by June 2009. The objective of the Phase 1 healthy subjects trial was to characterize further the pharmacokinetic and pharmacodynamic profiles of IMO-2055 after single and multiple weekly subcutaneous and

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intravenous administrations.

We reported final data from a Phase 2 Stage A clinical trial of IMO-2055 monotherapy in renal cell carcinoma in September 2009. The study contained four arms, comprised of treatment-naïve and second-line patients randomly assigned to receive IMO-2055 subcutaneously at either 0.16 mg/kg/week or 0.64 mg/kg/week. The primary objective of tumor response based on Response Evaluation Criteria in Solid Tumors, or RECIST, was not achieved in the study. Based on the final data analysis, the median progression-free survival was 4.5 months and 1.9 months for the 0.16- and 0.64-mg/kg/week treatment-naïve patients, and 3.4 months and 4.3 months for the 0.16- and 0.64-mg/kg/week second-line patients, respectively. Median overall survival was 23.5 months over all arms, and 58% of patients had stable disease. Two patients had confirmed partial responses, and seven patients received weekly IMO-2055 treatment for at least one year. IMO-2055 treatment was generally well-tolerated with good dose intensity in all arms of the study.

Approximately $643,000 and $237,000 of expenses in the three months ended September 30, 2009 and 2008, respectively, and $2,710,000 and $601,000 of expenses in the nine months ended September 30, 2009 and 2008, respectively, related to the Phase 1b non-small cell lung cancer trial, the Phase 1b colorectal cancer trial, and the Phase 1 clinical trial in healthy subjects, all of which are being reimbursed by Merck KGaA.

IMO-2125 External Development Expenses. These expenses include external expenses that we have incurred in connection with IMO-2125, our lead compound initially being developed for chronic HCV infection. These external expenses reflect payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-2125 trials 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 $6.0 million in external development expenses through September 30, 2009, including costs associated with the initiation of our two on-going Phase 1 clinical trials and related nonclinical studies and manufacturing and related process development.

External development expenses for IMO-2125 decreased by $124,000, or 22%, from $556,000 in the three months ended September 30, 2008 to $432,000 in the three months ended September 30, 2009 and decreased by $841,000, or 36%, from $2,348,000 in the nine months ended September 30, 2008 to $1,507,000 in the nine months ended September 30, 2009. The decrease in IMO-2125 expenses in the three and nine months ending September 30, 2009 compared to the three and nine months ending September 30, 2008 was primarily attributable to lower manufacturing costs and lower nonclinical safety studies of IMO-2125. The decreases in the three- and nine-month periods were partially offset by expenses incurred in 2009 related to the initiation of our Phase 1 clinical trial in treatment naïve patients with chronic HCV infection. The decrease in the nine-month period was also offset by higher expenses in 2009 as compared to the same period in 2008 related to our ongoing Phase 1 clinical trial of IMO-2125 in patients with chronic HCV infection who have not responded to the current standard of care therapy.

In our Phase 1 study of IMO-2125 in patients with chronic HCV infection who have not responded to the current standard of care therapy, we are currently recruiting patients and plan to enroll approximately 40 patients in four cohorts at escalating IMO-2125 dose levels, with four weeks of treatment. Of the ten patients per cohort, eight will be randomized to receive IMO-2125 treatment and two will be randomized to receive placebo treatment. The trial is designed to assess the safety of IMO-2125 after subcutaneous administration at each dose level. In addition, the trial is designed to evaluate the effects of IMO-2125 on HCV RNA levels and on parameters of immune system activation. The trial is being conducted at six U.S. sites. In this trial, we are enrolling the first five patients per cohort sequentially and allowing each patient to complete at least two weekly injections prior to enrollment of the next patient. Following a safety review of these first five patients in each cohort, the remaining patients of the cohort are enrolled. Due to this enrollment procedure, completion of each cohort has taken longer than anticipated. Currently, we expect to complete enrollment in the fourth cohort of this trial by the end of 2009 and to announce interim results in the first quarter of 2010.

In October 2009, we initiated a Phase 1 clinical trial to assess the safety of IMO-2125 in

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combination with ribavirin in treatment-naïve patients with chronic HCV infection. We plan to enroll approximately 45 patients in three cohorts at escalating IMO-2125 dose levels, with four weeks of treatment. Of the 15 patients per cohort, 12 will be randomized to receive weekly IMO-2125 by subcutaneous administration and daily oral ribavirin, and three will be randomized to receive placebo and daily oral ribavirin. This clinical trial also is designed to evaluate the effects of IMO-2125 and ribavirin combination treatment on HCV RNA levels and on parameters of immune system activation. We currently are considering modifications to the trial design based on regulatory discussions. We intend to conduct the trial at five or more sites in France and Russia.

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, our Oncology Clinical Advisory Board, and our Autoimmune Disease Scientific Advisory Board.

Other drug development expenses increased by $296,000, or 31%, from $964,000 for the three months ended September 30, 2008 to $1,260,000 for the three months ended September 30, 2009 and increased by $1,513,000, or 51%, from $2,947,000 for the nine months ended September 30, 2008 to $4,460,000 for the nine months ended September 30, 2009. The increases in the three and nine months ended September 30, 2009 compared to the same periods in 2008 was primarily due to increased costs for nonclinical safety studies and manufacturing associated with IMO-3100 and other compounds. We selected IMO-3100 as a lead TLR antagonist drug candidate in August 2008 and anticipate submitting an IND application to FDA by the end of 2009. The increase in the nine-month period was offset, in part, by decreases in consulting and employee and employee-related expenses.

Basic Discovery Expenses. These expenses include our internal and external expenses relating to the discovery and development of our TLR-targeted programs, including agonists and antagonists of TLRs 7, 8 and 9 and TLR antisense. These expenses reflect payments for laboratory supplies, external research, and professional fees, as well as payroll and overhead expenses. Basic discovery expenses increased by $206,000, or 12%, from $1,658,000 for the three months ended September 30, 2008 to $1,864,000 for the three months ended September 30, 2009 and increased by $283,000, or 6%, from $5,058,000 for the nine months ended September 30, 2008 to $5,341,000 for the nine months ended September 30, 2009. The increases for the three and nine months ended September 30, 2009 compared to the same periods in 2008 were primarily attributable to higher employee expenses, relating to payroll and stock compensation, and use of research supplies.

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 $113,000, or 5%, from $2,323,000 in the three months ended September 30, 2008 to $2,210,000 in the three months ended September 30, 2009 and decreased by $1,521,000, or 19%, from $8,013,000 in the nine months ended September 30, 2008 to $6,492,000 in the nine months ended September 30, 2009. General and administrative expenses consisted primarily of salary expense, stock compensation expense, consulting fees and professional legal fees associated with our patent applications and maintenance, our corporate regulatory filing requirements, our corporate legal matters and our business development initiatives.

The decreases in general and administrative expenses in the three and nine months ended September 30, 2009 compared to the three and nine months ended September 30, 2008 were primarily due to lower consulting and other

professional fees, patent expenses and stock-based compensation expense for consultants in the 2009 periods. The

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decrease in the nine-month period was also attributable to lower corporate legal fees. These decreases were offset, in part, by higher employee expenses, primarily related to stock-based compensation.

Investment Income, net

Investment income, net decreased by approximately $349,000, or 95%, from $369,000 in the three months ended September 30, 2008 to $20,000 in the three months ended September 30, 2009 and decreased by approximately $1,063,000, or 90%, from $1,185,000 in the nine months ended September 30, 2008 to $122,000 in the nine months ended September 30, 2009. This decrease resulted from lower interest rates and lower average investment balances in the three and nine months ended September 30, 2009.

Interest Expense

We did not have interest expense in the three and nine months ended September 30, 2009. In the three and nine months ended September 30, 2008, interest expense was $3,000 and $90,000, respectively. The interest expense in the nine months ended September 30, 2008 was primarily related to interest and a prepayment premium associated with a note payable. We repaid the note payable in full in March 2008 and the note was cancelled.

Foreign Currency Exchange Loss

We have a clinical trial contract denominated in Euros and had a foreign currency exchange loss of $6,000 in the three and nine months ended September 30, 2009 as a result of the declining value of the U.S. dollar. We had no foreign currency exchange loss in the three months ended September 30, 2008. Foreign currency exchange loss was $267,000 in the nine months ended September 30, 2008. In February 2008, Merck KGaA paid us a $40,000,000 upfront license fee denominated in Euros. We received $39,733,000 U.S. dollars due to foreign currency exchange rates in effect at the time we received the payment, which resulted in the foreign currency exchange loss.

Income Tax Provision

For the three and nine months ended September 30, 2009, we recorded approximately $30,000 and $170,000, respectively, as income tax expense as a result of income subject to the alternative minimum tax, or AMT. We had no income subject to AMT during the three and nine months ended September 30, 2008.

Net Income

As a result of the factors discussed above, our net income was $24,000 for the three months ended September 30, 2009 compared to $1,980,000 for the three months ended September 30, 2008 and $3,615,000 for the nine months ended September 30, 2009 compared to $1,145,000 for the nine months ended September 30, 2008. We have incurred losses of $77.4 million since January 1, 2001. We also incurred net losses of $260.2 million prior to December 31, 2000 during which time we were primarily involved in the development of non-TLR targeted antisense technology. Since our inception, we had an accumulated deficit of $337.6 million through September 30, 2009. We may continue to incur substantial operating losses in the future.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

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

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

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In January 2008, we sent notice to holders of our warrants to purchase common stock that were issued in August 2004 with an expiration date of August 27, 2009, or the August 2004 Warrants, that under the terms of the warrant agreement, we intended to redeem on March 31, 2008 any August 2004 Warrants not exercised as of that date for a redemption price of $0.08 per share of common stock underlying the August 2004 Warrants. We were entitled to exercise this redemption right because the closing price of our common stock for twenty consecutive trading days ending December 20, 2007 was greater than $10.72 or 200% of the exercise price of the warrant. The August 2004 Warrants were exercisable by cash payment only and had an exercise price of $5.36 per share of common stock. Following the January 2008 notice of redemption and through March 31, 2008, we received approximately $1.5 million in proceeds from the exercise of August 2004 Warrants to purchase 274,650 shares of common stock. As of March 31, 2008, all August 2004 Warrants had been exercised.

During the nine months ended September 30, 2009 and 2008, we received total proceeds of $245,000 and $9,831,000, respectively, from purchases under our employee stock plan and warrant and stock option exercises.

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 the treatment of cancer, excluding cancer vaccines. Under the terms of the agreement, 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. In the second quarter of 2009, we received a milestone payment of $3,996,000 from Merck KGaA.

In June 2007, we executed a promissory note in the aggregate principal amount of $1,278,000 in favor of General Electric Capital Corporation, or GE. The promissory note was secured by specific laboratory, manufacturing, office and computer equipment and was subject to the terms of a master security agreement between us and GE. The promissory note bore interest at a fixed rate of 11% per annum, and was payable in 48 consecutive monthly installments of principal and accrued interest, with the first installment having been paid out of the proceeds of the borrowing. In March 2008, we paid approximately $1,189,000 to GE as payment in full of all obligations outstanding under our promissory note with GE. The payment represented approximately $1,121,000 of principal amount outstanding plus accrued interest through the date of payment of approximately $12,000 and a prepayment premium of approximately $56,000. The note has been cancelled.

Cash Flows

As of September 30, 2009, we had approximately $46,071,000 in cash and cash equivalents and investments, a net decrease of approximately $9,535,000 from December 31, 2008. Operating activities used $9,826,000 of cash during the nine months ended September 30, 2009, reflecting our $3,615,000 net income for the period, as adjusted for non-cash expenses, including depreciation, stock-based compensation, and changes in deferred revenue and our accounts receivable and payable and prepaid expenses and other current assets.

The net cash provided by investing activities during the nine months ended September 30, 2009 of $7,133,000 reflects the proceeds of approximately $9,250,000 from securities that matured in the three months ended September 30, 2009 and an increase in available cash of $102,000 as a result of a reduction to our restricted cash requirements for a security deposit under the terms of our facility operating lease offset, in part, by our purchase of $2,206,000 of available-for-sale securities and $13,000 of laboratory and computer equipment in the nine-month period.

The net cash provided by financing activities during the nine months ended September 30, 2009 of $188,000 reflects proceeds of $245,000 received from the exercise of stock options and employee stock purchases during the nine-month period offset by payments against our capital leases and the repurchase of 6,615 shares of our common stock.

Funding Requirements

We have incurred operating losses in all fiscal years except 2002 and 2008 and had an accumulated deficit of $337.6 million at September 30, 2009. We had cash, cash equivalents and available-for-sale investments of $46.1 million at September 30, 2009. We believe that based on our current operating plan our existing cash, cash equivalents and short-term investments will be sufficient to fund our operations at least through December 31, 2010.

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We may incur substantial operating losses in future periods. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, total assets and working capital.

We have received no revenues from the sale of drugs. To date, almost all of our revenues have been from collaboration and license agreements. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any drugs. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our products will become commercially available, or when we will become profitable, if at all.

We do not expect to generate significant additional funds internally until we successfully complete development and obtain marketing approval for products, either alone or in collaboration with third parties, which we expect will take a number of years. In addition, we have no committed external sources of funds. Should we be unable to raise sufficient funds in the future, we may be required to significantly curtail our operating plans and possibly relinquish rights to portions of our technology or products. In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require further cost reductions. No assurance can be given that we will be able to operate profitably on a consistent basis, or at all, in the future.

We believe that the key factors that will affect our internal and external sources of cash are:

the success of our clinical and preclinical development programs;

the success of our existing strategic collaborations with Merck KGaA, Merck & Co. and Novartis;

the cost, timing and outcome of regulatory reviews; and

our ability to enter into new 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 arrangements with collaborators 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.

Contractual Obligations

We have had no material changes to our contractual obligations.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of September 30, 2009, we have no significant foreign currency exposure, as compared to the U.S. dollar, 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, within this context, 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 do not own 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,

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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 September 30, 2009, 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 September 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information included or incorporated by reference in this quarterly report on Form 10-Q before purchasing our common stock. If any of the following risks actually occurs, our business, financial condition or results of operations would likely suffer, possibly materially. In that case, the trading price of our common stock could fall, and you may lose all or part of 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 and 2008 when our recognition of revenues under license and collaboration agreements resulted in our reporting net income for those years. As of September 30, 2009, we had an accumulated deficit of $337.6 million. We have incurred losses of $77.4 million since January 1, 2001. We also incurred losses of $260.2 million prior to December 31, 2000 during which time we were primarily involved in the development of 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 drugs. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our products will become commercially available, or when we will become profitable, if at all. We may incur substantial operating losses in

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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 believe that, based on our current operating plan, our existing cash, cash equivalents, and short-term investments will be sufficient to fund our operations at least through December 31, 2010.

We will need to raise additional funds to operate our business beyond such time, including completing any ongoing clinical trials involving IMO-2125 or other drug candidates we may develop. 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, Merck & Co., and Novartis;

the cost, timing and outcome of regulatory reviews;

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

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

If we cannot obtain adequate funds, we may 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, or curtail research and development programs for new drug candidates.

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 significantly curtail one or more of our discovery or development programs 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 our lead drug candidate for infectious diseases, IMO-2125, 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 candidate for infectious diseases, IMO-2125. We anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of IMO-2125 and other drug candidates, including drug candidates being developed by our collaborators. The commercial success of these drug candidates will depend on several factors, including the following:

acceptable safety profile during clinical trials;

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demonstration of statistically recognized efficacy in clinical trials;

ability to combine IMO-2125 safely and successfully with other antiviral agents;

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

establishment of commercial manufacturing arrangements with third-party manufacturers;

the successful commercial launch of the drug candidates, whether alone or in collaboration with other products;

acceptance of the products by the medical community and third-party payors;

competition from other companies and their therapies;

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

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

Our efforts to commercialize IMO-2125 are at an early stage, as we are currently conducting initial Phase 1 safety clinical trials of this drug candidate in defined populations of patients with chronic HCV infection. If we are not successful in commercializing this or our other drug candidates, or are significantly delayed in doing so, our business will be materially harmed.

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

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 and other regulatory authorities may not approve any of our potential products for any indication. We may not be able to obtain authority from the FDA or other equivalent foreign regulatory agencies 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. Moreover, companies developing drugs targeted to TLRs have experienced setbacks in clinical trials. For example in June 2007, Coley Pharmaceutical Group, which since has been acquired by Pfizer, Inc., discontinued four clinical trials in lung cancer for PF-3512676, its investigational TLR9 agonist compound, in combination with cytotoxic chemotherapy. In addition, in January 2007, Coley Pharmaceutical Group announced that it had 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 March 2008 that two investigational new drug applications for its investigational hepatitis B vaccine, HEPLISAV®, which includes a proprietary TLR9 agonist, had been placed on clinical hold by the FDA. Dynavax Technologies Corporation also announced in May 2008 discontinuation of the clinical development program for TOLAMBA®, which comprises a TLR9 agonist covalently attached to ragweed antigen.

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

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regulators or Institutional Review Boards 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;