

IDERA PHARMACEUTICALS, INC.

Form 10-Q

November 05, 2009

**Table of Contents**

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

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

**For the quarterly period ended September 30, 2009,**

**or**

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

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

**Commission File Number: 001-31918  
IDERA PHARMACEUTICALS, INC.**

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

**Delaware**

**04-3072298**

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

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

**167 Sidney Street  
Cambridge, Massachusetts**

*(Address of principal executive offices)*

**02139**

*(zip code)*

**(617) 679-5500**

*(Registrant's telephone number, including area code)*

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

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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

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

**23,471,178**



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

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<u>Item 1 Financial Statements</u>	3
<u>Unaudited Condensed Balance Sheets as of September 30, 2009 and December 31, 2008</u>	3
<u>Unaudited Condensed Statements of Operations for the Three and Nine Months ended September 30, 2009 and 2008</u>	4
<u>Unaudited Condensed Statements of Cash Flows for the Nine Months ended September 30, 2009 and 2008</u>	5
<u>Notes to Condensed Financial Statements</u>	6
<u>Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
<u>Item 3 Quantitative and Qualitative Disclosures about Market Risk</u>	25
<u>Item 4 Controls and Procedures</u>	26
<b><u>PART II OTHER INFORMATION</u></b>	
<u>Item 1A. Risk Factors</u>	26
<u>Item 6 Exhibits</u>	40
<u>Signatures</u>	41
<u>EX-10.1 Offer letter, dated November 27, 2006, as amended</u>	
<u>EX-31.1 Section 302 Certification of CEO</u>	
<u>EX-31.2 Section 302 Certification of CFO</u>	
<u>EX-32.1 Section 906 Certification of CEO</u>	
<u>EX-32.2 Section 906 Certification of CFO</u>	

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.

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

<b>(in thousands, except per share amounts)</b>	<b>September 30, 2009</b>	<b>December 31, 2008</b>
<b>ASSETS</b>		
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
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
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.**

3

---

**Table of Contents**

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

<b>(in thousands, except per share amounts)</b>	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
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.**

**Table of Contents**

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

<b>(in thousands)</b>	<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>
<b>Cash Flows from Operating Activities:</b>		
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
<b>Cash Flows from Investing Activities:</b>		
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)
<b>Cash Flow from Financing Activities:</b>		
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
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$	\$ 90
Cash paid for income taxes	\$ 195	\$ 50



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

5

---

**Table of Contents**

**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 stabilized immune modulatory 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

**Table of Contents**

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:

**Table of Contents**

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	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

**Table of Contents**

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

**Table of Contents**

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:

	<b>September 30, 2009</b>			
	<b>Amortized</b>	<b>Gross</b>	<b>Gross</b>	<b>Estimated</b>
		<b>Unrealized</b>	<b>Unrealized</b>	
<b>(in thousands)</b>	<b>Cost</b>	<b>Losses</b>	<b>Gains</b>	<b>Value</b>
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
<b>Total</b>	<b>\$ 3,408</b>	<b>\$</b>	<b>\$ 3</b>	<b>\$ 3,411</b>

	<b>December 31, 2008</b>			
	<b>Amortized</b>	<b>Gross</b>	<b>Gross</b>	<b>Estimated</b>
		<b>Unrealized</b>	<b>Unrealized</b>	
<b>(in thousands)</b>	<b>Cost</b>	<b>Losses</b>	<b>Gains</b>	<b>Value</b>
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





**Table of Contents**

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.

<b>(in thousands)</b>	<b>Total</b>	<b>Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Assets				
Money market fund	\$ 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:

<b>(in thousands)</b>	<b>September 30, 2009</b>	<b>December 31, 2008</b>
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.

**Table of Contents****(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.

<b>(in thousands)</b>	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
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



**Table of Contents**

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<sup>®</sup> and Camptosar<sup>®</sup> 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



**Table of Contents**

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:

	<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>
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



**Table of Contents**

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:

<b>(in thousands, except per share amounts)</b>	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
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	\$ 0.00	\$ 0.09	\$ 0.15	\$ 0.05
Diluted net income per share	\$ 0.00	\$ 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

**Table of Contents**

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.

**Table of Contents**

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

**GENERAL**

We are engaged in the discovery and development of DNA- and RNA-based drug candidates targeted to Toll-Like Receptors, or TLRs, to treat infectious diseases, autoimmune and inflammatory diseases, cancer, and asthma and allergies, and for use as vaccine adjuvants. Drug candidates are compounds that we are developing and 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 immune modulatory RNA, 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.

**Table of Contents**

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		Percentage Increase (Decrease)	Nine Months Ended		Percentage Increase (Decrease)
	September 30, (in thousands) 2009	September 30, (in thousands) 2008		September 30, (in thousands) 2009	September 30, (in thousands) 2008	
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%



**Table of Contents**

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<sup>®</sup> and Camptosar<sup>®</sup> 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

**Table of Contents**

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			Nine Months Ended		
	September 30, (in thousands)		Percentage Increase (Decrease)	September 30, (in thousands)		Percentage Increase (Decrease)
	2009	2008		2009	2008	
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

**Table of Contents**

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

**Table of Contents**

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

**Table of Contents**

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.

**Table of Contents**

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.

## **Table of Contents**

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,

**Table of Contents**

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



## **Table of Contents**

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;



**Table of Contents**

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<sup>®</sup>, for HCV infection. In July 2007, Anadys Pharmaceuticals, Inc. and its partner Novartis announced that they had decided to discontinue the development of ANA975, the investigational TLR7 agonist compound for HCV infection. Dynavax Technologies Corporation announced in March 2008 that two investigational new drug applications for its investigational hepatitis B vaccine, HEPLISAV<sup>®</sup>, 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<sup>®</sup>, 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:

**Table of Contents**

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;

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

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

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

regulators or Institutional Review Boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements and any issues identified through inspections of manufacturing or clinical trial operations or clinical trial sites;

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

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

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

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

As an example, in 1997, after reviewing the results from the clinical trial of GEM91, a first generation antisense compound and our lead drug candidate at the time, we determined not to continue the development of GEM91 and suspended clinical trials of this drug candidate.

The rate of completion of clinical trials is dependent in part upon the rate of enrollment of patients. For example, in Stage A of our Phase 2 clinical trial of IMO-2055 in renal cell cancer, enrollment was slower than projected due to the then-recent approval of two new therapies, Sutent<sup>®</sup> and Nexavar<sup>®</sup>, developed by other companies for treatment of the same patient populations. In addition, in our 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, completion of each cohort has taken longer than anticipated due to the enrollment procedure. Patient accrual is a function of many factors, including:

the size of the patient population;

the proximity of patients to clinical sites;

the eligibility criteria for the study;

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

the existence of competitive clinical trials; and

the availability of alternative treatments.

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

**Table of Contents**

before we do and impair our ability to commercialize our products.

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

Our drug candidates and our collaborators' drug candidates will require preclinical and other nonclinical testing and extensive clinical trials prior to submission of any regulatory application for commercial sales. In 2007, we commenced a Phase 1b clinical trial of IMO-2055 in oncology, and we commenced a Phase 1 clinical trial of IMO-2125 for chronic HCV infection. In 2008, our collaborator Novartis commenced a Phase 1 clinical trial of QAX935, a novel agonist of TLR9, and in 2009 we commenced a Phase 1 clinical trial and a Phase 1b clinical trial of IMO-2055 under our collaboration with Merck KGaA, and a second Phase 1 clinical trial of IMO-2125 for chronic HCV infection. In conducting clinical trials, we cannot be certain that any planned clinical trial will begin on time, if at all. Delays in commencing clinical trials of potential products could increase our product development costs, delay any potential revenues and reduce the probability that a potential product will receive regulatory approval.

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

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

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

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

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

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

obtaining Institutional Review Board approval for conducting a clinical trial at a prospective site; and

enrolling patients in order to commence the clinical trial.

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

Our technologies or therapeutic approaches are relatively new and unproven. We have focused our efforts on the research and development of RNA- and DNA-based compounds targeted to TLRs. Neither we nor any other company have obtained regulatory approval to market such compounds as therapeutic drugs, and no such products currently are being marketed. It is unknown whether the results of preclinical studies with TLR-targeted compounds will be indicative of results that may be obtained in clinical trials, and results we have obtained in the initial small-scale clinical trials we have conducted to date may not be predictive of results in subsequent large-scale clinical trials. Further, the chemical and pharmacological properties of RNA- and DNA-based compounds targeted to TLRs may not be fully recognized in preclinical studies and small-scale clinical trials, and such compounds may interact with human biological systems in unforeseen, ineffective, or harmful ways that we have not yet identified. As a result of these factors, we may never succeed in obtaining a regulatory approval to market any product. Furthermore, the commercial success of any of our products for which we may obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance by the medical community and third-party payors as clinically useful, safe, and cost-effective. In addition, if products based upon TLR technology being developed by our competitors have negative clinical trial results or otherwise are viewed negatively, the perception of our TLR technology and market acceptance of our products could be impacted negatively. For example, Dynavax Technologies 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 also announced in May 2008 discontinuation of the clinical development program for TOLAMBA, which comprises a TLR9 agonist covalently attached to a ragweed antigen. In addition, Pfizer, Inc. and Anadys Pharmaceuticals, Inc.

each have performed early clinical trials of TLR-targeted compounds for the treatment of chronic HCV infection, and both programs were discontinued. We cannot be certain whether such discontinuations will negatively impact the perception of our TLR technology.



## **Table of Contents**

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

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

The biotechnology industry is highly competitive and characterized by rapid and significant technological change. We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies. Some of these organizations are pursuing products based on technologies similar to our technologies. Other of these organizations have developed and are marketing products, or are pursuing other technological approaches designed to produce products, that are competitive with our drug candidates in the therapeutic effect these competitive products have on diseases targeted by our drug candidates. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than any that we are developing. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. As examples, the FDA recently approved drugs developed by other companies, Sutent and Nexavar for use in renal cell cancer, which is the indication for which we evaluated IMO-2055 monotherapy in our Phase 2 clinical trial. Pfizer, Inc. is conducting clinical trials of PF-3512676, a TLR9 agonist for treating cancer. In addition, Dynavax Technologies Corporation has announced initiation of a clinical trial for its TLR9 agonist 1018 ISS for cancer. Both Pfizer, Inc., and Dynavax Technologies Corporation have clinical programs, either independently or with collaborators, in therapeutic fields other than cancer, such as asthma and allergy treatments and for use as vaccine adjuvants, that also potentially compete with our drug candidates.

Many of our competitors are substantially larger than we are and have greater capital resources, research and development staffs and facilities than we have. In addition, many of our competitors are more experienced than we are in drug discovery, development and commercialization, obtaining regulatory approvals, and drug manufacturing and marketing.

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

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

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

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

Furthermore, our future growth will require hiring a number of qualified technical and management personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our

activities. If we are not able to continue to attract and retain, on acceptable terms, the qualified personnel necessary

**Table of Contents**

for the continued development of our business, we may not be able to sustain our operations or growth.

**Regulatory Risks**

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

All of the drug candidates that we are developing or may develop in the future will require additional research and development, extensive preclinical studies and clinical trials, and regulatory approval prior to any commercial sales. This process is lengthy, often taking a number of years, is uncertain, and is expensive. Since our inception, we have conducted clinical trials of a number of compounds. Currently, we are conducting clinical trials of IMO-2125 .

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

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

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

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

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

Both before and after approval is obtained, violations of regulatory requirements may result in:

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

restrictions on our products or the manufacturing of our products;

withdrawal of our products from the market;

warning letters;

voluntary or mandatory recall;

fines;

suspension or withdrawal of regulatory approvals;

product seizure;

refusal to permit the import or export of our products;

injunctions or the imposition of civil penalties; and

criminal penalties.

*We have only limited experience in regulatory affairs and our products are based on new technologies; these*

**Table of Contents**

***factors may affect our ability or the time we require to obtain necessary regulatory approvals.***

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

**Risks Relating to Collaborators**

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

If we do not reach agreements with additional collaborators in the future, we may fail to meet our business objectives. We believe collaborations can provide us with expertise and resources. If we cannot enter into additional collaboration agreements, we may not be able to obtain the expertise and resources necessary to achieve our business objectives. We face, and will continue to face, significant competition in seeking appropriate collaborators. Moreover, collaborations are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements. The terms of any collaborations or other arrangements that we establish, if any, may not be favorable to us.

The failure of these collaborative alliances could delay our drug development or impair commercialization of our products and could materially harm our business and might accelerate our need for additional capital.

Any collaboration that we enter into may not be successful. The success of our collaborative alliances, if any, will depend heavily on the efforts and activities of our collaborators. Possible future collaborations have risks, including the following:

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

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

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

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

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

future collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of our products to reach their potential could be limited if future collaborators decrease or fail to increase spending relating to such products;

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

future collaborators may develop alternative products either on their own or in collaboration with others, or encounter conflicts of interest or changes in business strategy or other business issues, which could adversely

affect their willingness or ability to fulfill their obligations to us.

Given these risks, it is possible that any collaborative alliance into which we enter may not be successful.

**Table of Contents**

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

An important element of our business strategy includes entering into collaborative alliances with corporate collaborators, primarily large pharmaceutical companies, for the development, commercialization, marketing, and distribution of some of our drug candidates. In December 2007, we entered into an exclusive, worldwide license agreement with Merck KGaA to research, develop, and commercialize products containing our TLR9 agonists for treatment of cancer, excluding cancer vaccines. In December 2006, we entered into an exclusive license and research collaboration with Merck & Co. to research, develop, and commercialize vaccine products containing our TLR7, 8, and 9 agonists in the fields of cancer, infectious diseases, and Alzheimer's disease. In May 2005, we entered into a collaboration with Novartis to discover, develop and potentially commercialize TLR9 agonists that are identified as potential treatments for asthma and allergies. The failure of these collaborations or any others we enter into in the future could delay our drug development or impair commercialization of our products and could materially harm our business and might accelerate our need for additional capital.

The success of our collaborative alliances, if any, will depend heavily on the efforts and activities of our collaborators. Our existing collaborations have risks, including the following:

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

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

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

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

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

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

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

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

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

our collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of our products to reach their potential could be limited if our collaborators decrease or fail to increase spending relating to such products;

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

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

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire



## **Table of Contents**

by the other party. Such terminations or expirations may adversely affect us financially and could harm our business reputation in the event we elect to pursue collaborations that ultimately expire or are terminated in such a manner.

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

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

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

obtain patents;

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

operate without infringing upon the proprietary rights of others;

prevent others from infringing on our proprietary rights; and

protect trade secrets.

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

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

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

We may not have rights under some patents or patent applications related to our products. Third parties may own or control these patents and patent applications in the United States and abroad. Therefore, in some cases, to develop, manufacture, sell or import some of our products, we or our collaborators may choose to seek, or be required to seek, licenses under third-party patents issued in the United States and abroad or under patents that might issue from United States and foreign patent applications. In such an event, we would be required to pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, we or our collaborators may not be able to develop, manufacture, sell or import these products.

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

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

sublicensing, insurance and other obligations on us.

Our failure to comply with these requirements could result in termination of the licenses. These licenses

## **Table of Contents**

generally will otherwise remain in effect until the expiration of all valid claims of the patents covered by such licenses or upon earlier termination by the parties. The issued patents covered by these licenses expire at various dates ranging from 2014 to 2022. If one or more of these licenses is terminated, we may be delayed in our efforts, or be unable, to develop and market the products that are covered by the applicable license or licenses.

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

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

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

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

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

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

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

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

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

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

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

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

**Table of Contents**

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

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

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

Additionally, contract manufacturers may not be able to manufacture our TLR-targeted drug candidates at a cost or in quantities necessary to make them commercially viable. To date, our third-party manufacturers have met our manufacturing requirements, but we cannot be assured that they will continue to do so. Furthermore, changes in the manufacturing process or procedure, including a change in the location where the drug is manufactured or a change of a third-party manufacturer, may require prior FDA review and approval in accordance with the FDA's cGMP regulations. There are comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a product. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. If we or our contract manufacturers are unable to comply, we or they may be subject to regulatory action, civil actions or penalties.

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

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

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

We do not have the ability to independently conduct the clinical trials required to obtain regulatory approval for our products. We depend on independent clinical investigators, contract research organizations and other third-party service providers in the conduct of the clinical trials of our products and expect to continue to do so. We have contracted with contract research organizations to manage our current Phase 1 clinical trials of IMO-2125 in patients with chronic HCV infection. We rely heavily on these parties for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our products. If we seek to conduct any of these activities ourselves in the future, we will need to recruit appropriately trained personnel and add to our infrastructure.

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

Any products that we ultimately bring to the market, if they receive marketing approval, may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become

profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

**Table of Contents**

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

the efficacy and potential advantages over alternative treatments;

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

relative convenience and ease of administration;

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

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

publicity concerning our products or competing products and treatments.

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

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

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

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

Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved healthcare products. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could decrease the price we might establish for products that we may develop, which would result in lower product revenues to us.

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

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

decreased demand for our drug candidates and products;

damage to our reputation;



**Table of Contents**

regulatory investigations that could require costly recalls or product modifications;

withdrawal of clinical trial participants;

costs to defend related litigation;

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

loss of revenue;

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

the inability to commercialize any products that we may develop.

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

**Risks Relating to an Investment in Our Common Stock**

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

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

a classified board of directors,

limitations on the removal of directors,

limitations on stockholder proposals at meetings of stockholders,

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

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

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

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

Our stock price has been volatile. During the period from January 1, 2008 to October 31, 2009, the closing sales price of our common stock ranged from a high of \$15.41 per share to a low of \$4.66 per share. The stock market has also experienced significant price and volume fluctuations, particularly within the past year, and the market prices of

biotechnology companies in particular have been highly volatile, often for reasons that have been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many

**Table of Contents**

factors, including:

results of clinical trials of our drug candidates or those of our competitors;

the regulatory status of our drug candidates;

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

the success of competitive products or technologies;

regulatory developments in the United States and foreign countries;

our success in entering into collaborative agreements;

developments or disputes concerning patents or other proprietary rights;

the departure of key personnel;

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

our cash resources;

the terms of any financing conducted by us;

changes in the structure of healthcare payment systems;

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

general economic, industry and market conditions.

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

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

**ITEM 6. EXHIBITS.**

The list of Exhibits filed as part of this Quarterly Report on Form 10-Q is set forth on the Exhibit Index immediately preceding such Exhibits, and is incorporated herein by this reference.

**Table of Contents**

**SIGNATURES**

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

**IDERA PHARMACEUTICALS, INC.**

Date: November 5, 2009

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

Date: November 5, 2009

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

41

---

**Table of Contents**

**Exhibit Index**

**Exhibit No.**

- 10.1 Offer letter by and between the Company and Dr. Alice Bexon, dated November 27, 2006, as amended.
- 31.1 Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.