IDERA PHARMACEUTICALS, INC.
Form 10-Q
November 09, 2011

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

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

**For the quarterly period ended September 30, 2011**

**or**

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

**For transition period from _____to_____ .**

**Commission File Number: 001-31918**

**IDERA PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

| **Delaware** | **04-3072298** |
|---|---|
| *(State or other jurisdiction of incorporation or organization)* | *(I.R.S. Employer Identification No.)* |
| **167 Sidney Street**<br>**Cambridge, Massachusetts**<br>*(Address of principal executive offices)* | **02139**<br>*(zip code)* |

**(617) 679-5500**

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes þ No o

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

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

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

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

| | |
|---|---|
| **Common Stock, par value $.001 per share** | 27,634,389 |
| Class | Outstanding as of October 15, 2011 |

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

**FORWARD-LOOKING STATEMENTS**

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

**PART I FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS.**

**IDERA PHARMACEUTICALS, INC.**
**CONDENSED BALANCE SHEETS**
**(UNAUDITED)**

| **(In thousands, except per share amounts)** | **September 30, 2011** | **December 31, 2010** |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 18,078 | $ 17,008 |
| Short-term investments | 1,003 | 17,635 |
| Prepaid expenses and other current assets | 471 | 997 |
| Total current assets | 19,552 | 35,640 |
| Property and equipment, net | 577 | 930 |
| Restricted cash | 311 | 311 |
| Total assets | $ 20,440 | $ 36,881 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,048 | $ 1,757 |
| Accrued expenses | 2,544 | 1,783 |
| Total current liabilities | 3,592 | 3,540 |
| Other liabilities | 195 | 240 |
| Total liabilities | 3,787 | 3,780 |
| Commitments and contingencies | | |
| Stockholders equity: | | |
| Preferred stock, $0.01 par value per share, Authorized 5,000 shares | | |
| Series A convertible preferred stock, Designated 1,500 shares, Issued and outstanding 1 share | | |
| Common stock, $0.001 par value per share, Authorized 70,000 shares Issued and outstanding 27,634 and 27,596 shares at September 30, 2011 and December 31, 2010, respectively | 28 | 28 |
| Additional paid-in capital | 386,883 | 384,702 |
| Accumulated deficit | (370,258) | (351,642) |
| Accumulated other comprehensive income | | 13 |
| Total stockholders equity | 16,653 | 33,101 |
| Total liabilities and stockholders equity | $ 20,440 | $ 36,881 |

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

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

| (In thousands, except per share amounts) | Three Months Ended September 30, 2011 | Three Months Ended September 30, 2010 | Nine Months Ended September 30, 2011 | Nine Months Ended September 30, 2010 |
|---|---|---|---|---|
| Alliance revenue | $ 4 | $ 5,089 | $ 45 | $ 15,052 |
| Operating expenses: | | | | |
| Research and development | 3,574 | 7,786 | 12,269 | 19,333 |
| General and administrative | 1,948 | 2,193 | 6,400 | 7,709 |
| Total operating expenses | 5,522 | 9,979 | 18,669 | 27,042 |
| Loss from operations | (5,518) | (4,890) | (18,624) | (11,990) |
| Other income (expense): | | | | |
| Investment income, net | 2 | 31 | 28 | 86 |
| Foreign currency exchange gain (loss) | 27 | 148 | (20) | (46) |
| Net loss | $ (5,489) | $ (4,711) | $ (18,616) | $ (11,950) |
| Basic net loss per common share (Note 12) | $ (0.20) | $ (0.18) | $ (0.67) | $ (0.49) |
| Diluted net loss per common share (Note 12) | $ (0.20) | $ (0.18) | $ (0.67) | $ (0.49) |
| Shares used in computing basic net loss per common share | 27,632 | 25,980 | 27,618 | 24,314 |
| Shares used in computing diluted net loss per common share | 27,632 | 25,980 | 27,618 | 24,314 |

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

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

| | Nine Months Ended September 30, | |
|---|---|---|
| **(In thousands)** | **2011** | **2010** |
| **Cash Flows from Operating Activities:** | | |
| Net loss | $ (18,616) | $ (11,950) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Loss from disposition of assets | 1 | 3 |
| Stock-based compensation expense | 2,094 | 2,929 |
| Non-employee stock option expense | 1 | 6 |
| Depreciation expense | 373 | 417 |
| Amortization of investment premiums | 59 | 190 |
| Issuance of common stock for services rendered | 38 | 1 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | | 4,471 |
| Prepaid expenses and other current assets | 424 | (601) |
| Accounts payable, accrued expenses and other liabilities | 16 | 4,346 |
| Deferred revenue | | (11,115) |
| Net cash used in operating activities | (15,610) | (11,303) |
| **Cash Flows from Investing Activities:** | | |
| Purchases of available-for-sale securities | (1,025) | (8,309) |
| Proceeds from maturity of available-for-sale securities | 17,585 | |
| Decrease in restricted cash | 102 | 103 |
| Purchases of property and equipment | (21) | (88) |
| Net cash provided by (used in) investing activities | 16,641 | (8,294) |
| **Cash Flows from Financing Activities:** | | |
| Sale of common stock and warrants, net of issuance costs | | 14,089 |
| Proceeds from exercise of common stock options and employee stock purchases | 47 | 104 |
| Payments on capital lease | (8) | (15) |
| Net cash provided by financing activities | 39 | 14,178 |
| Net increase (decrease) in cash and cash equivalents | 1,070 | (5,419) |
| Cash and cash equivalents, beginning of period | 17,008 | 25,471 |
| Cash and cash equivalents, end of period | $ 18,078 | $ 20,052 |

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

**IDERA PHARMACEUTICALS, INC.**
**NOTES TO CONDENSED FINANCIAL STATEMENTS**
**September 30, 2011**
**(UNAUDITED)**

(1) Organization

Idera Pharmaceuticals, Inc. ( Idera or the Company ) is a clinical stage biotechnology company engaged in the discovery and development of novel DNA- and RNA- based drug candidates. The Company is developing drug candidates that are designed to modulate immune responses mediated through Toll-like Receptors (TLRs). TLRs are specific receptors present in immune system cells. Using its chemistry-based approach, Idera has created synthetic nucleic acid-based compounds that are targeted to TLRs 3, 7, 8, and 9. The Company believes that by modulating immune responses mediated through TLRs, it can develop compounds to treat a broad range of diseases.

The Company is focusing its internal development efforts on TLR-targeted compounds for autoimmune and inflammatory diseases. The Company s TLR research and development pipeline also includes partnered programs for the treatment of cancer, with Merck KGaA, and for vaccine adjuvants, with Merck Sharp & Dohme Corp., which is referred to herein as Merck, as well as proprietary programs for the treatment of infectious diseases, respiratory diseases, hematologic oncology, and additional vaccine adjuvants. Merck KGaA and Merck are not related.

The Company is also evaluating gene silencing oligonucleotides, or GSOs, for the purpose of inhibiting the production of disease-associated proteins. GSOs are novel chemical structures that Idera has shown in preclinical models selectively bind to targeted messenger RNA and microRNA and thereby inhibit protein production.

During the third quarter of 2011, the Company re-assessed and prioritized its drug development programs. Based on this prioritization, Idera is focusing its internal development efforts on TLR-targeted compounds for autoimmune and inflammatory diseases and advancing its GSO technology. In addition, Idera has discontinued further development of IMO-2125, which had been its lead drug candidate for the treatment of hepatitis C virus (HCV), and decided to advance its TLR-targeted programs in infectious diseases, respiratory diseases, hematologic oncology, and additional vaccine adjuvant applications only through partnerships with third parties.

At September 30, 2011, the Company had an accumulated deficit of $370.3 million. The Company expects to incur substantial operating losses in future periods. The Company does not expect to generate significant product revenue or royalties until it successfully completes development and obtains marketing approval for drug candidates, either alone or in collaborations with third parties, which it expects will take a number of years. In order to commercialize its drug candidates, the Company needs to complete clinical development and to comply with comprehensive regulatory requirements. In 2011, the Company expects that its research and development expenses will be lower than its research and development expenses in 2010 reflecting the completion of multiple Phase 1 clinical trials in 2010, delays in initiating clinical trials planned for 2011, and the discontinuation of the development of IMO-2125 and other compounds in the Company s research and development pipeline.

The Company had cash, cash equivalents, and investments of $19.1 million at September 30, 2011. The Company believes that its existing cash, cash equivalents, and investments, together with the proceeds raised from a private placement of its securities on November 4, 2011 (see note 16), will be sufficient to fund its operations at least into the second quarter of 2013 based on its current operating plan. The Company will need to raise additional funds in order to operate its business beyond such time. Additional financing may not be available to the Company when it needs it or may not be available on favorable terms.

The Company is subject to a number of risks and uncertainties similar to those of other companies of the same size within the biotechnology industry, such as uncertainty of success and timeliness of development, including clinical trial outcomes in internal and collaborative programs, uncertainty of funding, and history of operating losses.

(2) New Accounting Pronouncements

The Company adopted Financial Accounting Standards Board, or FASB, Accounting Standard Update No. 2009-13, Multiple-Element Revenue Arrangements ( ASU No. 2009-13 ) on January 1, 2011. ASU No. 2009-13 updates the existing multiple-element revenue arrangements guidance currently included in Accounting Standards Codification No. 605-25 in two ways. The first change relates to the determination of when the individual deliverables included in multiple-element arrangements may be treated as separate units of accounting. This is significant since it may result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. Since the Company is applying ASU No. 2009-13 prospectively to arrangements entered into or materially modified after the adoption date and since there were no new collaborations or material modifications to existing collaborations in the nine months ended September 30, 2011, the adoption of ASU No. 2009-13 had no effect on the Company s financial position and results of operations through September 30, 2011. The effect that ASU No. 2009-13 may have on the Company s policy for recognizing revenue under any future collaboration agreements will depend upon the terms of those future collaboration agreements, if any.

The Company adopted FASB Accounting Standard Update No. 2010-17, Milestone Method of Revenue Recognition ( ASU No. 2010-17 ) on January 1, 2011. ASU No. 2010-17 provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. The Company is applying ASU No. 2010-17 prospectively to arrangements entered into or materially modified after the adoption date. Since the Company did not earn any milestones during the first nine months of 2011, the adoption of ASU No. 2010-17 has had no effect on the Company s financial position and results of operations through September 30, 2011. Since the Company used a similar method of recognizing milestone revenue prior to adopting ASU No. 2010-17, the Company does not expect that the adoption of ASU No. 2010-17 will have a significant effect on its policy for recognizing revenue on any milestones that it receives in future periods.

In May 2011, the FASB issued Accounting Standards Update No. 2011-04, Fair Value Measurement (Topic 820) ( ASU No. 2011-04 ), which updates the existing fair value measurement guidance currently included in the Accounting Standards Codification to achieve common fair value measurement and disclosure requirements in United States Generally Accepted Accounting Principles ( U.S. GAAP ) and International Financial Reporting Standards. ASU 2011-04 is effective on a prospective basis to interim and annual periods beginning after December 15, 2011. The Company is currently evaluating the effect that ASU 2011-04 may have on its fair value measurement policy.

In June 2011, the FASB issued Accounting Standard Update No. 2011-05, Comprehensive Income ( ASU No. 2011-05 ), which will require companies to present the components of net income and other comprehensive income either as one continuous statement or as two consecutive statements. ASU No. 2011-05 eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders equity. The update does not change the items which must be reported in other comprehensive income, how such items are measured or when they must be reclassified to net income. ASU No. 2011-05 is effective for interim and annual periods beginning after December 15, 2011. The Company does not expect ASU No. 2011-05 to have a material impact on its financial position or results of operations.

(3) Unaudited Interim Financial Statements

The accompanying unaudited financial statements included herein have been prepared by the Company in accordance with U.S. GAAP for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC ). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustments, and disclosures considered necessary for a fair presentation of interim period results have been included. Interim results for the three and nine months ended September 30, 2011 are not necessarily indicative of results that may be expected for the year ended December 31, 2011. For further information, refer to the financial statements and footnotes thereto included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2010, which was filed with the SEC on March 10, 2011.

(4) Cash, Cash Equivalents and Short-Term Investments

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be cash equivalents. Cash and cash equivalents at September 30, 2011 and December 31, 2010 consisted of cash and money market funds.

Management determines the appropriate classification of marketable securities at the time of purchase. Investments that the Company does not have the positive intent to hold to maturity are classified as available-for-sale and reported at fair market value. Unrealized gains and losses associated with available-for-sale investments are recorded in Accumulated other comprehensive income on the accompanying balance sheets. The amortization of premiums and accretion of discounts, and any realized gains and losses and declines in value judged to be other-than-temporary, and interest and dividends for all available-for-sale securities are included in Investment income, net on the accompanying statements of operations. Investments that the Company intends to hold to maturity are classified as held-to-maturity investments. The Company had no held-to-maturity investments at either September 30, 2011 or December 31, 2010. The cost of securities sold is based on the specific identification method.

The Company had no realized gains or losses from available-for-sale securities in the three or nine months ended September 30, 2011 and 2010. There were no losses or other-than-temporary declines in value included in Investment income, net for any securities for the three or nine months ended September 30, 2011 and 2010. The Company had no auction rate securities as of September 30, 2011 and December 31, 2010.

The Company s available-for-sale short-term investments consisted of the following at September 30, 2011 and December 31, 2010:

| | September 30, 2011 | | | |
|---|---|---|---|---|
| **(In thousands)** | **Cost** | **Gross Unrealized (Losses)** | **Gross Unrealized Gains** | **Estimated Fair Value** |
| Corporate bonds due in one year or less | $ 1,003 | $ | $ | $ 1,003 |
| Total | $ 1,003 | $ | $ | $ 1,003 |

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

(5) Fair Value of Assets and Liabilities

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

The table below presents the assets and liabilities measured at fair value on a recurring basis at September 30, 2011 categorized by the level of inputs used in the valuation of each asset and liability.

| (In thousands) | Total | Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
|---|---|---|---|---|
| Assets | | | | |
| Money market fund | $ 18,035 | $ 18,035 | $ | $ |
| Short-term investments | 1,003 | | 1,003 | |
| Total | $ 19,038 | $ 18,035 | $ 1,003 | $ |
| Liabilities | $ | $ | $ | $ |

The Level 1 assets consist of money market funds, which are actively traded daily. The Level 2 assets consist of corporate bond investments whose fair value is generally determined from quoted market prices received from pricing services based upon quoted prices from active markets and/or other significant observable market transactions at fair value. Since these prices may not represent actual transactions of identical securities, they are classified as Level 2. Since all investments are classified as available-for-sale securities, any unrealized gains or losses are recorded in accumulated other comprehensive income or loss within stockholders equity on the balance sheet. The Company did not elect to measure any other financial assets or liabilities at fair value. See Note (4).

(6) Property and Equipment

At September 30, 2011 and December 31, 2010, net property and equipment at cost consisted of the following:

| (In thousands) | September 30, 2011 | December 31, 2010 |
|---|---|---|
| Leasehold improvements | $ 525 | $ 515 |
| Laboratory equipment and other | 2,896 | 2,889 |

| | | |
|---|---|---|
| Total property and equipment, at cost | 3,421 | 3,404 |
| Less: accumulated depreciation | (2,844) | (2,474) |
| Property and equipment, net | $ 577 | $ 930 |

As of September 30, 2011 and December 31, 2010, laboratory equipment and other included approximately $79,000 of office equipment financed under capital leases with accumulated depreciation of approximately $68,000 and $56,000, respectively.

Depreciation expense, which includes amortization of assets recorded under capital leases, was approximately $120,000 and $130,000 in the three months ended September 30, 2011 and 2010, respectively, and approximately $373,000 and $417,000 in the nine months ended September 30, 2011 and 2010, respectively.

(7) Restricted Cash

As part of the Company s lease arrangement for its office and laboratory facility, the Company was required to restrict $619,000 of cash for a security deposit. The restricted cash was reduced by a total of approximately $308,000 upon the second, third and fourth anniversaries of the June 2007 lease commencement date. As a result, at September 30, 2011, restricted cash was $311,000. The restricted cash is held in certificates of deposit securing a line of credit for the lessor.

(8) Comprehensive Loss

The following table includes the components of comprehensive loss for the three and nine months ended September 30, 2011 and 2010.

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| **(In thousands)** | **2011** | **2010** | **2011** | **2010** |
| Net loss | $ (5,489) | $ (4, 711) | $ (18,616) | $ (11,950) |
| Other comprehensive income (loss) | | 5 | (13) | 45 |
| Total comprehensive loss | $ (5,489) | $ (4,706) | $ (18,629) | $ (11,905) |

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

(9) Revenue Recognition

An important part of the Company s business strategy is to enter into research and development collaborations with biotechnology and pharmaceutical corporations that bring expertise and resources to the potential research and development and commercialization of drugs based on the Company s technology. Under the Company s research and development collaborations, the Company has generally licensed specified portions of its intellectual property and provided research and development services to the collaborator during the period of continued involvement in the early portion of the collaborations. The collaborators have generally been responsible for drug development activities initiated after the collaboration is effective. The collaborators are also generally responsible for any commercialization activities that may be initiated if any of the drug candidates receive marketing approval from the appropriate regulatory authority.

Under the Company s existing collaborative arrangements, the Company has received non-refundable license fees, milestone payments, reimbursements of certain internal and external research and development expenses and patent-related expenses. The Company is also entitled to receive royalties on product sales. The Company classifies all of these amounts as revenue in its statement of operations since it considers licensing intellectual property and providing research and development and patent-related services to be part of its central business operations. In the three and nine months ended September 30, 2010, alliance revenue consisted primarily of revenue recognized under the Merck KGaA and Merck collaborations. Since the Company completed the research portions of these collaborations during 2010, all of the upfront license fee payments were fully amortized and recognized by December 2010. Consequently, the Company did not recognize any revenue under the Merck KGaA and Merck collaborations during the three and nine months ended September 30, 2011. Alliance revenue for the three and nine months ended September 30, 2011 and 2010, including revenue recognized under the Company s collaborative arrangements with Merck KGaA and Merck during the 2010 period, was as follows:

| (In thousands) | Three Months Ended September 30, 2011 | 2010 | Nine Months Ended September 30, 2011 | 2010 |
|---|---|---|---|---|
| Collaboration revenue | | | | |
| Merck KGaA | $ | $ 3,822 | $ | $ 11,173 |
| Merck | | 1,250 | | 3,796 |
| | | 5,072 | | 14,969 |
| Other revenue | 4 | 17 | 45 | 83 |
| Total alliance revenue | $ 4 | $ 5,089 | $ 45 | $ 15,052 |

During the three and nine months ended September 30, 2010, the Company incurred approximately $8,000 and $24,000, respectively, in third-party expenses in connection with its collaborative arrangements. The Company did not incur any such expenses in the corresponding 2011 periods. These third party expenses are classified as research and development and general and administrative expenses in the Company s statement of operations.

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

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

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

The Company recognizes revenue from reimbursements earned in connection with research and development collaboration agreements as related research and development costs are incurred, and contractual services are performed. The Company includes amounts contractually owed to it under these research and development collaboration agreements, including any earned but unbilled receivables, in receivables in its balance sheets. The Company s principal costs under these agreements are generally for its personnel and related expenses of conducting research and development, as well as for research and development performed by outside contractors or consultants or related research and development materials provided by third parties or for clinical trials it conducts on behalf of a collaborator.

For payments that are contingent upon milestone events or achieving a specific result from the research and development efforts the Company recognizes these milestone payments as revenue in their entirety upon achieving the related milestone provided the milestone meets the criteria specified below. Milestones typically consist of significant events in the development life cycle of the related technology, such as initiating clinical trials, filing for approval with regulatory agencies, and obtaining approvals from regulatory agencies. The Company recognizes revenue from milestone payments received under collaboration agreements in their entirety upon achieving the related milestone, provided that the milestone event is substantive, its achievability was not reasonably assured at

the inception of the agreement, the amount attributed to the milestone is reasonable in relation to the Company s performance and to the amounts attributed to the other deliverables in the arrangement and the Company has no further performance obligations relating to the milestone event. In the event that the agreement provides for payment to be made subsequent to the Company s standard payment terms, the Company recognizes revenue when payment becomes due.

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

Although the Company follows detailed guidelines in measuring revenue, certain judgments affect the application of its revenue policy. For example, in connection with its existing collaboration agreements, whenever the Company has deferred revenue recorded on its balance sheet it is classified as short-term or long-term deferred revenue based on the Company s best estimate of when such amounts would be recognized. However, these estimates are based on the Company s collaboration agreements and its then current operating plan and, if either should change, the Company could recognize a different amount of deferred revenue over the subsequent twelve-month period.

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

Additional information on the Company s collaborative arrangements is included in Note (10).

(10) Collaboration and License Agreements

(a) Collaboration and License Agreement with Merck KGaA

In December 2007, the Company entered into an exclusive, worldwide license agreement with Merck KGaA to research, develop and commercialize products containing its TLR9 agonists for the treatment of cancer, excluding cancer vaccines, which agreement became effective February 4, 2008. Under the terms of the agreement, the Company granted Merck KGaA worldwide exclusive rights to its lead TLR9 agonists, IMO-2055 and IMO-2125, and to a specified number of novel, follow-on TLR9 agonists to be identified by Merck KGaA and the Company under a research collaboration, for use in the treatment, cure and/or delay of the onset or progression of cancer in humans. Under the terms of the agreement: Merck KGaA paid the Company in February 2008 a $40.0 million upfront license fee in Euros of which $39.7 million was received due to foreign currency exchange rates in effect at that time; Merck KGaA agreed to reimburse future development costs for certain of the Company s IMO-2055 clinical trials for the period in which the Company continued to conduct the trials on behalf of Merck KGaA; Merck KGaA agreed to pay up to 264 million in development, regulatory approval, and commercial success milestone payments if products containing the Company s TLR9 agonist compounds are successfully developed and marketed for treatment, cure and/or delay of the onset or progression of cancer in humans; and Merck KGaA agreed to pay mid single-digit to low double-digit royalties on net sales of products containing the Company s TLR9 agonists that are marketed. Merck KGaA refers to IMO-2055 as EMD 1201081. In February 2009, the agreement was amended so that the Company could initiate and conduct on behalf of Merck KGaA additional clinical trials of EMD 1201081 until such time as Merck KGaA had filed an Investigational New Drug ( IND ) application with the U.S. Food and Drug Administration ( FDA ) and assumed sponsorship of these trials. Under the amendment, Merck KGaA agreed to reimburse the Company for costs associated with any additional trials that the Company initiated and conducted. Merck KGaA filed an IND and, as of March 2010, Merck KGaA assumed sponsorship of all ongoing clinical trials of EMD 1201081 for the treatment of cancer, and has assumed responsibility for all further clinical development of EMD 1201081 in the treatment of cancer, excluding vaccines.

The Company recognized the $40.0 million upfront payment as revenue over the twenty-eight month term that ended in June 2010, which was the Company s period of continuing involvement under the research collaboration. Through September 30, 2011, the Company has recognized a total of $12.1 million of milestone revenue related to the initiation of clinical trials of EMD 1201081.

(b) Collaboration and License Agreement with Merck Sharp & Dohme Corp.

In December 2006, the Company entered into an exclusive, worldwide license and research collaboration agreement with Merck to research, develop, and commercialize vaccine products containing the Company s TLR7, 8, and 9 agonists in the fields of cancer, infectious diseases, and Alzheimer s disease. Under the terms of the agreement, the Company granted Merck exclusive rights to a number of the Company s TLR7, 8, and 9 agonists for use in combination with Merck s therapeutic and prophylactic vaccines under development in the fields of cancer, infectious diseases, and Alzheimer s disease. The Company also agreed with Merck to engage in a two-year research collaboration to generate novel agonists targeting TLR7 and TLR8 incorporating both Merck and Idera chemistry for use in vaccines in the defined fields, which collaboration was extended by Merck for two additional one-year periods. Under the terms of the agreement: Merck paid the Company a $20.0 million upfront license fee; Merck purchased $10.0 million of the Company s common stock at $5.50 per share; and Merck agreed to fund the research and development collaboration. Merck also agreed to pay the Company milestone payments as follows: up to $165.0 million if vaccines containing the Company s TLR9 agonist compounds are successfully developed and marketed in each of the oncology, infectious disease, and Alzheimer s disease fields; up to $260.0 million if vaccines containing the Company s TLR9 agonist compounds are successfully developed and marketed for follow-on indications in the oncology field and if vaccines containing the Company s TLR7 or TLR8 agonists are successfully developed and marketed in each of the oncology, infectious disease, and Alzheimer s disease fields; and if Merck develops and commercializes additional vaccines using the Company s agonists, the Company would be entitled to receive additional milestone payments. In addition, Merck agreed to pay the Company mid- to upper single-digit royalties on net product sales of vaccines using the Company s TLR agonist technology that are developed and marketed.

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

In December 2006, in connection with the execution of the license and collaboration agreement, the Company entered into a stock purchase agreement with Merck. Pursuant to such stock purchase agreement, the Company issued and sold to Merck 1,818,182 shares of the Company s common stock for a price of $5.50 per share resulting in aggregate gross proceeds of $10.0 million.

In 2008, the Company recognized $1.0 million of milestone revenue that it received from Merck relating to achieving a preclinical milestone with one of its TLR9 agonists used as an adjuvant in cancer vaccines.

(11) Stock-Based Compensation

The Company recognizes all share-based payments to employees and directors in the financial statements based on their fair values. The Company records compensation expense over an award s requisite service period, or vesting period, based on the award s fair value at the date of grant. The Company s policy is to charge the fair value of stock options as an expense on a straight-line basis over the vesting period, which is generally four years for employees and three years for directors. The Company included charges of $655,000 and $782,000 in its statements of operations for the three months ended September 30, 2011 and 2010, respectively, and $2,094,000 and $2,929,000 in its statements of operations for the nine months ended September 30, 2011 and 2010, respectively, representing the stock-based compensation expense attributable to share-based payments made to employees and directors.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model and expensed over the requisite service period on a straight-line basis. The following assumptions apply to the options to purchase 160,750 and 135,500 shares of common stock granted to employees and directors during the nine months ended September 30, 2011 and 2010, respectively:

| | Nine Months Ended September 30, 2011 | Nine Months Ended September 30, 2010 |
|---|---|---|
| Average risk free interest rate | 3.0% | 2.4% |
| Expected dividend yield | | |
| Expected lives (years) | 9.7 | 5.6 |
| Expected volatility | 62.0% | 66.4% |
| Weighted average grant date fair value of options granted during the period (per share) | $ 1.55 | $ 2.65 |
| Weighted average exercise price of options granted during the period (per share) | $ 2.18 | $ 4.45 |

The Company s adoption of policies with respect to the treatment of stock options in the event of director or employee retirement during 2010 resulted in the modification of stock options by accelerating the vesting of nonvested stock options held by, and by extending the post-retirement period during which stock options may be exercised by, those directors and employees whose retirement qualifies under the terms of the policy. The stock option modifications increased the fair value of those options by $111,000 when modified, of which $1,000 and $5,000 was expensed during the three months ended September 30, 2011 and 2010, respectively, and $5,000 and $84,000 was expensed during the nine months ended September 30, 2011 and 2010, respectively.

As a result of the stock option modifications, the Company recognized $237,000 more of stock-based compensation expense during the nine months ended September 30, 2010 than it would have recognized if the stock options had not been modified. Of that amount, $84,000 was attributable to the increase in fair value of the modified options and $153,000 was attributable to the accelerated recognition of the original fair value of options held by directors who were or would become eligible for retirement prior to the completion of the option vesting period, which amount would otherwise have been expensed over the vesting period on a straight line basis. As a result of the stock option modifications, the Company did not recognize $55,000, $10,000 and $60,000 of stock-based compensation expense during the three months ended September 30, 2010 and the three and nine months ended September 30, 2011, respectively, than it otherwise would have recognized if the stock options had not been modified, which amounts consisted of $61,000, $10,000 and $64,000 that resulted from the accelerated recognition of the original fair value of options held by directors who were or will become eligible for retirement prior to the completion of the option vesting period, offset, in the three months ended September 30, 2010 and the nine months ended September 30, 2011, by $6,000 and $4,000 increases in expense attributable to the increase in fair value.

During prior periods, the Company awarded stock options to purchase shares of common stock to persons who were neither employees nor directors. The fair value of the nonvested portion of the non-employee, non-director options is remeasured each quarter. This remeasured fair value is partially expensed each quarter based upon the percentage of the nonvested portion of the option s vesting period that has elapsed to date, less the amount expensed in prior periods. The remeasurement as of September 30, 2011 resulted in a (credit) charge to operations for non-employee, non-director options of $(5,000) and $1,000 for the three and nine months ended September 30, 2011, respectively. The remeasurement as of September 30, 2010 resulted in charges to operations for non-employee, non-director options of $17,000 and $6,000 for the three and nine months ended September 30, 2010, respectively.

(12) Net Loss per Common Share

Basic and diluted net loss per common share is computed using the weighted average number of shares of common stock outstanding during the period. For the three and nine months ended September 30, 2011 and 2010,

diluted net loss per share is the same as basic net loss per common share, as the effects of the Company s potential common stock equivalents are antidilutive. Total antidilutive securities were 6,266,804 and 8,608,354 for the nine months ended September 30, 2011 and 2010, respectively, and consist of stock options and warrants. Net loss applicable to common stockholders is the same as net loss for all periods presented.

(13) Stockholders Equity

During the nine months ended September 30, 2011 and 2010, the Company issued 23,537 and 30,852 shares, respectively, of common stock in connection with stock option exercises and employee stock purchases, which resulted in total proceeds to the Company of $47,000 and $104,000, respectively. During the nine months ended September 30, 2011, pursuant to its director compensation program, the Company issued 14,932 shares of common stock to a director in lieu of cash fees of approximately $38,000. See note (15) for information about additional stock issuances.

(14) Related Party Transactions

The Company paid certain directors consulting fees of approximately $12,000 and $16,000 in the three months ended September 30, 2011 and 2010, respectively, and $30,000 and $48,000 in the nine months ended September 30, 2011 and 2010, respectively.

(15) 2010 Financing

In August, 2010, the Company raised $15.1 million in gross proceeds from a registered direct offering of common stock to institutional investors. In the offering, the Company sold 4,071,005 shares of common stock and warrants to purchase 1,628,402 shares of common stock. The common stock and the warrants were sold in units at a price of $3.71 per unit, with each unit consisting of one share of common stock and warrants to purchase 0.40 shares of common stock. The warrants to purchase common stock have an exercise price of $3.71 per share, were exercisable immediately, and will expire if not exercised on or prior to August 5, 2015. The net proceeds to the Company from the offering, excluding the proceeds of any future exercise of the warrants, were approximately $14.1 million.

(16) Subsequent Event

On November 4, 2011, Idera Pharmaceuticals, Inc. ( the Company ) raised approximately $9.5 million in gross proceeds from a private financing with Pillar Pharmaceuticals I L.P., an investment partnership managed by one of the directors of Idera. In the financing, the Company sold 1,124,260 shares of Series D convertible preferred stock, par value $0.01 per share, of the Company ( Series D preferred stock ) and warrants to purchase up to 2,810,650 shares of common stock, $0.001 par value per share, of the Company (the warrants ). The initial conversion price of the Series D preferred stock and the initial exercise price of the warrants are $1.6275 per share. The holders of the Series D preferred stock are entitled to receive dividends payable quarterly in arrears at the rate of 7% per annum. Such dividends shall be paid in cash through December 31, 2014 and thereafter in cash or with shares of common stock, as determined by the Company in its sole discretion, subject to certain limitations as defined.

The net proceeds to Idera, excluding the proceeds of any exercise of the warrants, are expected to total approximately $9.1 million. The Company intends to use these funds for research and product development activities, including costs of conducting preclinical studies and clinical trials, and for general corporate purposes.

The securities offered by Idera in the private placement were not registered under the Securities Act of 1933, as amended, and cannot be offered or sold in the United States absent registration or an applicable exemption from registration requirements. The Company has agreed to file a registration statement with the Securities and Exchange Commission registering the resale of the shares of common stock issuable upon conversion of the Series D preferred stock and the shares of common stock issuable upon exercise of the warrants issued in the private placement.

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

**GENERAL**

We are a clinical stage biotechnology company engaged in the discovery and development of novel DNA- and RNA- based drug candidates. We are developing drug candidates that are designed to modulate immune responses mediated through Toll-like Receptors (TLRs). TLRs are specific receptors present in immune system cells. Using our chemistry-based approach, we have created synthetic nucleic acid-based compounds that are targeted to TLRs 3, 7, 8, and 9. We believe that by modulating immune responses mediated through TLRs, we can develop compounds to treat a broad range of diseases.

We also are evaluating gene silencing oligonucleotides, or GSOs, for the purpose of inhibiting the production of disease-associated proteins. GSOs are novel chemical structures that we have shown in preclinical models selectively bind to targeted messenger RNA and microRNA and thereby inhibit protein production.

During the third quarter of 2011, we re-assessed and prioritized our drug development programs. Based on this prioritization, we are focusing our internal development efforts on TLR-targeted compounds for autoimmune and inflammatory diseases and advancing our GSO technology. In addition, we have discontinued further development of IMO-2125, which had been our lead drug candidate for the treatment of hepatitis C virus (HCV), and decided to advance our TLR-targeted programs in infectious diseases, respiratory diseases, hematologic oncology, and additional vaccine adjuvant applications only through partnerships with third parties.

Our lead drug candidate for autoimmune and inflammatory diseases is IMO-3100, an antagonist of TLR7 and TLR9. We are also evaluating additional follow-on antagonist compounds for further development in autoimmune diseases. A TLR antagonist is a compound that blocks activation of an immune response mediated through the targeted TLR. IMO-3100 has shown activity in preclinical models of various autoimmune and inflammatory disease models, including psoriasis, lupus, and rheumatoid arthritis. We have completed two Phase 1 clinical trials of IMO-3100 in healthy subjects and data from these trials have been presented at scientific meetings. In June 2011, we submitted a Phase 2 protocol to the U.S. Food and Drug Administration, or FDA, to conduct a clinical trial of IMO-3100 in patients with psoriasis. In July 2011, the FDA placed the proposed Phase 2 clinical trial on clinical hold. We continue to communicate with the FDA regarding the clinical development of IMO-3100 in patients with psoriasis. Our goal is to initiate a clinical trial of IMO-3100 in 2012 to establish proof of concept.

Our TLR research and development pipeline also includes partnered programs for the treatment of cancer, with Merck KGaA, and for vaccine adjuvants, with Merck Sharp & Dohme Corp., which is referred to herein as Merck, as well as proprietary programs for the treatment of infectious diseases, respiratory diseases, hematologic oncology, and additional vaccine adjuvants. Merck KGaA and Merck are not related.

We are collaborating with Merck KGaA for the use of TLR9 agonists in cancer treatment, excluding cancer vaccines. A TLR agonist is a compound that stimulates immune responses through the targeted TLR. Merck KGaA has conducted clinical trials of IMO-2055, which Merck KGaA refers to as EMD 1201081, in combination with other cancer therapy agents. These studies include a Phase 2 clinical trial of IMO-2055 in combination with Erbitux® in the treatment of second-line squamous cell carcinoma of the head and neck (SCCHN), a Phase 1b clinical trial of IMO-2055 in combination with Tarceva® and Avastin® in the treatment of non-small cell lung cancer, and a Phase 1b clinical trial of IMO-2055 in combination with Erbitux® and FOLFIRI, a chemotherapy regimen, in the treatment of colorectal cancer. Merck KGaA also had initiated a Phase 1 clinical trial of IMO-2055 in combination with cisplatin, 5-fluorouracil, and Erbitux® in patients with first-line SCCHN, which Merck KGaA has terminated. In this terminated trial, the incidence of neutropenia and electrolyte imbalances was higher than published data from a trial of cisplatin, 5-fluorouracil, and Erbitux® without IMO-2055. In July 2011, Merck KGaA informed us that, based on the observations in this terminated trial, Merck KGaA had re-evaluated its clinical development program and decided that it would not conduct further clinical development of IMO-2055. Merck

KGaA also informed us that it planned to complete the ongoing Phase 2 trial of IMO-2055 in combination with Erbitux® in second-line patients with SCCHN. There have been no serious safety concerns observed to date in the Phase 2 trial of IMO-2055 in combination with Erbitux®. Merck KGaA has informed us that patient recruitment for the two Phase 1b trials has ended. Merck KGaA has the right to continue evaluating follow-on TLR9 agonists created by Idera under the collaboration.

We also are collaborating with Merck for the use of TLR7, TLR8, and TLR9 agonists as vaccine adjuvants in the fields of cancer, infectious diseases, and Alzheimer s disease.

At September 30, 2011, we had an accumulated deficit of $370,258,000. We expect to incur substantial operating losses in future periods. We do not expect to generate significant product revenue or royalties until we successfully complete development and obtain marketing approval for drug candidates, either alone or in collaborations with third parties, which we expect will take a number of years. In order to commercialize our drug candidates, we need to complete clinical development and to comply with comprehensive regulatory requirements. In 2011, we expect that our research and development expenses will be lower than our research and development expenses in 2010, reflecting the completion of multiple Phase 1 clinical trials in 2010, delays in the initiation of clinical trials that were planned for 2011, and the discontinuation of the development of IMO-2125 and other compounds in our research and development pipeline.

**CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

This management s discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgments, including those related to revenue recognition and stock-based compensation. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We regard an accounting estimate or assumption underlying our financial statements as a critical accounting estimate where:

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

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

Our significant accounting policies are described in Note 2 of the notes to our financial statements in our Annual Report on Form 10-K for the year ended December 31, 2010. Not all of these significant policies, however, fit the definition of critical accounting policies and estimates. We believe that our accounting policies relating to revenue recognition and stock-based compensation, as described under the caption Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates in our Annual Report on Form 10-K for the year ended December 31, 2010, fit the description of critical accounting estimates and judgments. There were no changes to these policies in the nine months ended September 30, 2011 other than the adoption of ASU No. 2009-13 and ASU No. 2010-17 that impacted our revenue recognition policy as discussed in Note 2 in the notes to the financial statements in this Quarterly Report on Form 10-Q.

**RESULTS OF OPERATIONS**

***Three and Nine Months Ended September 30, 2011 and 2010***

*Alliance Revenue*

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

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

| | Three Months Ended September 30, (in thousands) | | Percentage Increase | Nine Months Ended September 30, (in thousands) | | Percentage Increase |
|---|---|---|---|---|---|---|
| | 2011 | 2010 | (Decrease) | 2011 | 2010 | (Decrease) |
| License fees | $ | $ 1,263 | (100)% | $ | $ 11,130 | (100)% |
| Research and development | | 26 | (100)% | | 89 | (100)% |
| Milestones | | 3,797 | (100)% | | 3,797 | (100)% |
| Other | 4 | 3 | 33% | 45 | 36 | 25% |
| Total alliance revenue | $ 4 | $ 5,089 | (100)% | $ 45 | $ 15,052 | (100)% |

*License Fees.* License fees primarily include license fee revenue recognized under our collaborations with Merck KGaA and Merck. License fee revenue during the nine months ended September 30, 2010 was comprised of amortization of the upfront license fee payments under these collaborations. License fee revenue during the three months ended September 30, 2010 was comprised primarily of amortization of the upfront license fee payments under the Merck collaboration. We recognized license fee revenue ratably over the expected period of our continuing involvement in the collaborations, which has generally represented the estimated research period of the agreement.

We received a $40,000,000 upfront payment from Merck KGaA in Euros in February 2008 of which we received $39,733,000 due to foreign currency exchange rates in effect at the time. We recognized the $40,000,000 upfront payment as revenue over the twenty eight-month research term that ended in June 2010. We received a $20,000,000 upfront payment from Merck in December 2006. We recognized the $20,000,000 upfront payment as revenue over the two-year initial research term and the two-year extension period that ended in December 2010. Since we completed the research portions of these collaborations during 2010, all of the upfront license fee payments were fully amortized by December 2010. Consequently, we did not recognize any license fee revenue under the Merck KGaA and Merck collaborations during the three and nine months ended September 30, 2011.

*Research and Development Revenue.* Research and development revenue was $26,000 and $89,000 in the three and nine months ended September 30, 2010 and consisted of research reimbursements by Merck during the second quarter of 2010 and reimbursement by Merck KGaA of costs associated with clinical trials of IMO-2055 during the first quarter of 2010 and the manufacture of other compounds for research during the third quarter of 2010. Merck KGaA assumed sponsorship of the IMO-2055 trials by March 2010, and consequently we did not recognize any research and development revenue in the three and nine months ended September 30, 2011. We do not expect to have research and development revenue in future periods under our agreements with Merck KGaA and Merck.

*Milestones.* Milestone revenue decreased by $3,797,000 in the three and nine months ended September 30, 2011, as compared to the comparable 2010 periods, reflecting our recognition of a milestone payment under our

collaboration with Merck KGaA in the third quarter of 2010. The third quarter 2010 milestone payment resulted from the initiation by Merck KGaA of the Phase 1b clinical trial of EMD 1201081 in treatment of patients with SCCHN.

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

*Research and Development Expenses*

Research and development expenses decreased by $4,212,000, or 54%, from $7,786,000 for the three months ended September 30, 2010, to $3,574,000 for the three months ended September 30, 2011 and decreased by $7,064,000 or 37% from $19,333,000 for the nine months ended September 30, 2010 to $12,269,000 for the nine months ended September 30, 2011. In the following table, research and development expense is set forth in the following four categories which are discussed beneath the table:

| | Three Months Ended September 30, (in thousands) | | Percentage Increase | Nine Months Ended September 30, (in thousands) | | Percentage Increase |
|---|---|---|---|---|---|---|
| | **2011** | **2010** | **(Decrease)** | **2011** | **2010** | **(Decrease)** |
| IMO-2125 External Development Expense | $ 466 | $ 2,979 | (84)% | $ 2,233 | $ 6,220 | (64)% |
| IMO-3100 External Development Expense | 463 | 1,818 | (75)% | 1,543 | 4,399 | (65)% |
| Other Drug Development Expense | 869 | 1,008 | (14)% | 2,962 | 2,944 | 1% |
| Basic Discovery Expense | 1,776 | 1,981 | (10)% | 5,531 | 5,770 | (4)% |
| Total Research and Development Expense | $ 3,574 | $ 7,786 | (54)% | $ 12,269 | $ 19,333 | (37)% |

*IMO-2125 External Development Expenses.* These expenses include external expenses that we have incurred in connection with IMO-2125. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-2125 clinical development, but exclude internal costs such as payroll and overhead expenses. We commenced clinical development of IMO-2125 in May 2007 and since then we have incurred approximately $16,466,000 in external development expenses through September 30, 2011, including costs associated with our clinical trials, manufacturing and process development activities related to the production of IMO-2125, and additional nonclinical toxicology studies.

The decreases in IMO-2125 expenses in the three and nine months ended September 30, 2011 as compared to the corresponding 2010 periods were attributable to decreases in costs associated with two Phase 1 clinical trials of IMO-2125, manufacturing which occurred in 2010 but not in 2011, the preparation in 2010 for a Phase 2 clinical trial of IMO-2125 in non-responder HCV patients, and a decrease in the cost of conducting additional nonclinical safety studies of IMO-2125. The decrease in the nine months ended September 30, 2011 was partially offset by costs in the first half of 2011 associated with preparation for the Phase 2 clinical trial of IMO-2125 in treatment-naïve HCV patients that we had planned to initiate in the second quarter of 2011. Costs attributable to IMO-2125 during the three months ended September 30, 2011 were associated primarily with nonclinical safety studies and with the analysis of data from the Phase 1 clinical trial of IMO-2125 in treatment-naïve HCV patients.

As part of our third quarter 2011 strategic assessment, we discontinued further development of IMO-2125 in the treatment of HCV. As a result, we expect that IMO-2125 external development expenses will be lower in future periods.

*IMO-3100 External Development Expenses.* These expenses include external expenses that we have incurred in connection with IMO-3100 since November 2009, when we commenced clinical development of IMO-3100. These external expenses include payments to independent contractors and vendors for drug development activities

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conducted after the initiation of IMO-3100 clinical development but exclude internal costs such as payroll and overhead expenses. Since November 2009, we have incurred approximately $7,325,000 in external development expenses through September 30, 2011, including costs associated with our clinical trials, manufacturing and process development activities related to the production of IMO-3100, and additional nonclinical toxicology studies.

The decreases in IMO-3100 expenses in the three and nine months ended September 30, 2011 as compared to the corresponding 2010 periods were primarily attributable to higher costs associated with nonclinical safety studies and the initiation and progression of our Phase 1 multiple dose clinical trial during the 2010 periods and $569,000 associated with the cancellation of two previously scheduled nonclinical chronic toxicology studies during the third quarter of 2010, partially offset by costs associated with the preparation for the planned Phase 2 clinical trial in psoriasis. The decrease in IMO-3100 expenses in the nine months ended September 30, 2011 is also attributable to expenses associated with the manufacture of additional IMO-3100 drug supplies in the nine months ended September 30, 2010.

In November 2009, we submitted to the FDA an IND for the clinical evaluation of IMO-3100 in autoimmune diseases. In January 2010, we initiated a Phase 1 clinical trial of IMO-3100 in healthy subjects. In this single-dose, dose escalation Phase 1 trial, IMO-3100 was administered by subcutaneous injection at dose levels of 0.04, 0.08, 0.16, 0.32, and 0.64 mg/kg to a total of 36 subjects. At each dose level, six subjects received IMO-3100. An additional six subjects received placebo treatment. The primary objective of the trial was to evaluate the safety and tolerability of IMO-3100. Secondary objectives were to characterize the pharmacokinetic profile of IMO-3100 and to assess the pharmacodynamic mechanism of action of IMO-3100. The pharmacodynamic mechanism of action is how IMO-3100 engages the immune system in the targeted manner, which we assessed through measurement of the inhibition of TLR7 and TLR9-mediated cytokine induction in peripheral blood mononuculear cells, or PBMCs. The trial was conducted at a single U.S. site. In October 2010 we announced results from the single-dose Phase 1 clinical trial of IMO-3100. IMO-3100 was well tolerated at all dose levels in the trial.

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

In June 2011, we submitted a Phase 2 protocol to the FDA to conduct a clinical trial of IMO-3100 in patients with psoriasis. In July 2011, the FDA placed the proposed Phase 2 clinical trial on clinical hold. We continue to communicate with the FDA regarding the clinical development of IMO-3100 in patients with psoriasis. Our goal is to initiate a clinical trial of IMO-3100 in 2012 to establish proof of concept.

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

Other drug development expenses decreased in the three months ended September 30, 2011, as compared to the three months ended September 30, 2010, primarily due to lower employee expenses partially offset by increases in the cost of nonclinical studies of preclinical compounds and manufacturing expenses in the 2011 period. Other drug development expenses increased in the nine months ended September 30, 2011, as compared to the nine months ended September 30, 2010, primarily due to increases in the cost of nonclinical studies of preclinical compounds, manufacturing expenses and consulting costs, partially offset by lower employee expenses in the 2011 period. The increase in other drug development expenses during the nine months ended September 30, 2011 also reflects the cost of obtaining nonclinical and clinical trial data from studies conducted by Novartis of IMO-2134, a TLR9 agonist.

*Basic Discovery Expenses.* These expenses include our internal and external expenses relating to our discovery efforts with respect to our TLR-targeted programs, including agonists and antagonists of TLRs 3, 7, 8 and 9, TLR antisense, and GSOs. These expenses reflect payments for laboratory supplies, external research, and professional fees, as well as payroll and overhead expenses. The decreases in basic discovery expenses in the three and nine months ended September 30, 2011, as compared to the corresponding 2010 periods, was primarily due to decreases in the cost of laboratory supplies and employee expenses.

We do not know if we will be successful in developing any drug candidate from our research and development programs. At this time, 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 $245,000, or 11%, from $2,193,000 in the three months ended September 30, 2010, to $1,948,000 in the three months ended September 30, 2011 and decreased by $1,309,000, or 17%, from $7,709,000 in the nine months ended September 30, 2010, to $6,400,000 in the nine months ended September 30, 2011. General and administrative expenses consist primarily of salary expense, stock compensation expense, consulting fees and professional legal fees associated with our patent applications and maintenance, our corporate regulatory filing requirements, our corporate legal matters, and our business development initiatives.

The decreases in general and administrative expenses in the three and nine months ended September 30, 2011, as compared to the corresponding 2010 periods, were primarily due to decreases in stock based compensation, employee cash compensation expenses and consulting fees associated with business and strategic initiatives in the 2011 periods. The decrease in stock compensation expense during the nine months ended September 30, 2011 was mainly due to higher recognized expense in 2010 associated with the modification of non-employee director stock options. The decreases in general and administrative expenses were partially offset by increases in legal costs associated with patent matters in the 2011 periods.

*Investment Income, net*

Investment income, net, decreased by approximately $29,000, or 94%, from $31,000 in the three months ended September 30, 2010 to $2,000 in the three months ended September 30, 2011 and decreased by approximately $58,000, or 67%, from $86,000 in the nine months ended September 30, 2010 to $28,000 in the nine months ended September 30, 2011. These decreases were primarily due to lower average investment balances and lower interest rates in both the three and nine months ended September 30, 2011.

*Foreign Currency Exchange Gain (Loss)*

Our foreign currency exchange gain was $27,000 in the three months ended September 30, 2011 compared to a gain of $148,000 in the three months ended September 30, 2010. These gains reflect the impact that fluctuations in U.S. Dollar/Euro currency exchange rates had on payments in all periods under our clinical trial agreements that are denominated in Euros and the gain in the three months ended September 30, 2010 reflects the receipt of a milestone payment in the third quarter of 2010 under our Merck KGaA collaboration. In the third quarter of 2010, we earned a $3,797,000 milestone under our Merck KGaA collaboration for which we received $4,077,000 based on foreign exchange rates in effect at the time of payment as a result of the weakening value of the U.S. dollar, resulting in a foreign currency exchange gain of $280,000 on the milestone payment received during the third quarter of 2010.

Our foreign currency exchange loss was $20,000 in the nine months ended September 30, 2011 compared to $46,000 in the nine months ended September 30, 2010. The decrease in the foreign currency exchange loss during the nine months ended September 30, 2011 is primarily due to the impact that fluctuations in U.S. Dollar/Euro currency exchange rates had on the receipt of milestone payments in the first and third quarters of 2010. In 2009, we earned a milestone under our Merck KGaA collaboration, for which we had a $4,300,000 receivable at December 31, 2009. Merck KGaA paid us for this milestone in February 2010 and we received $4,074,000 based on foreign exchange rates in effect at the time of payment as a result of the strengthening value of the U.S. dollar. Consequently, we incurred a foreign currency exchange loss of $226,000 on the milestone payment during the first quarter of 2010. The foreign currency exchange losses during the nine months ended September 30, 2011 and 2010 also reflect the impact that fluctuations in U.S. Dollar/Euro currency exchange rates have on the receipt of the milestone payment in the third quarter of 2010 under our Merck KGaA collaboration referred to above and on payments under our clinical trial agreements that are denominated in Euros.

*Net Loss*

As a result of the factors discussed above, our net loss was $5,489,000 for the three months ended September 30, 2011, compared to $4,711,000 for the three months ended September 30, 2010 and our net loss was $18,616,000 for the nine months ended September 30, 2011, compared to $11,950,000 for the nine months ended September 30, 2010. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through September 30, 2011, we incurred losses of $110,065,000. We also incurred net losses of $260,193,000 prior to December 31, 2000 during which time we were primarily involved in the development of non-TLR targeted antisense technology. Since our inception, we had an accumulated deficit of $370,258,000 through September 30, 2011. We expect to continue to incur substantial operating losses in the future.

**LIQUIDITY AND CAPITAL RESOURCES**

*Sources of Liquidity*

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

equity and debt financing;

license fees, research funding and milestone payments under collaborative and license agreements;

interest income; and

lease financings.

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

In November 2011, we raised $9,500,000 in gross proceeds from a private financing with Pillar Pharmaceuticals I L.P., an investment partnership managed by one of the directors of Idera. In the financing, we sold 1,124,260 shares of Series D convertible preferred stock and warrants to purchase up to 2,810,650 shares of common stock. The initial conversion price of the preferred stock and the initial exercise price of the warrants are $1.6275 per share. The warrants to purchase common stock are exercisable immediately, and will expire if not exercised on or prior to

November 4, 2016. The preferred stockholders are entitled to receive dividends payable quarterly in arrears at the rate of 7% per annum. Such dividends shall be paid in cash through December 31, 2014 and thereafter in cash or with shares of common stock, as determined by us in our sole discretion, subject to certain limitations as defined. The net proceeds to us from the offering, excluding the proceeds of any future exercise of the warrants, are expected to be approximately $9,100,000.

Under the terms of our collaboration with Merck KGaA, in February 2008 Merck KGaA paid us a $40,000,000 upfront license fee in Euros of which we received $39,733,000 due to foreign currency exchange rates. Since entering this agreement, we have received approximately $12,110,000 in milestone payments and have been reimbursed $4,542,000 for expenses related to the development of EMD 1201081.

In December 2006, we entered into an exclusive license and research collaboration agreement with Merck to research, develop and commercialize vaccine products containing our TLR7, 8 and 9 agonists in the fields of cancer, infectious diseases and Alzheimer s disease. Under the terms of the agreement, Merck paid us a $20,000,000 license fee in December 2006. In addition, in connection with the execution of the license and collaboration agreement, we issued and sold to Merck 1,818,182 shares of our common stock for a price of $5.50 per share resulting in an aggregate purchase price of $10,000,000. Since entering this agreement, we have received $1,000,000 in milestone payments and $3,408,000 in research and development payments.

*Cash Flows*

As of September 30, 2011, we had approximately $19,081,000 in cash and cash equivalents and investments, a net decrease of approximately $15,562,000 from December 31, 2010. Net cash used in operating activities totaled $15,610,000 during the nine months ended September 30, 2011, reflecting our $18,616,000 net loss for the period, as adjusted for non-cash expenses, including stock-based compensation, depreciation and amortization. It also reflects changes in our prepaid expenses and accounts payable, accrued expenses and other liabilities.

The net cash provided by investing activities during the nine months ended September 30, 2011 of $16,641,000 reflects the maturity of $17,585,000 in available-for-sale securities and a $102,000 decrease in restricted cash offset by the purchase of approximately $1,025,000 of securities and $21,000 of laboratory equipment and leasehold improvements during the period.

The $39,000 net cash provided by financing activities during the nine months ended September 30, 2011 reflects the proceeds of $47,000 received from employee stock purchases, offset, in part, by payments on our capital leases.

As of September 30, 2010, we had approximately $42,951,000 in cash and cash equivalents and investments, a net increase of approximately $2,744,000 from December 31, 2009. Net cash used in operating activities totaled $11,303,000 during the nine months ended September 30 2010, reflecting our $11,950,000 net loss for the period, as adjusted for non-cash revenue and expenses, including the reduction in deferred revenue associated with the recognition of deferred revenue under our collaboration agreements, stock-based compensation, depreciation and amortization. It also reflects changes in our accounts receivable, prepaid expenses and accounts payable, accrued expenses and other liabilities.

The net cash used in investing activities during the nine months ended September 30, 2010 of $8,294,000 reflects our purchase of $8,309,000 in available-for-sale securities in the nine months ended September 30, 2010 and our purchase of $88,000 of laboratory, office and computer equipment offset by a $103,000 decrease in restricted cash in the nine-month period.

The net cash provided by financing activities during the nine months ended September 30, 2010 of $14,178,000 reflects proceeds of $14,089,000 from the August 5, 2010 registered direct offering mentioned above and proceeds of $104,000 received from the exercise of common stock options and employee stock purchases during the nine-month period offset, in part, by payments on our capital leases.

*Funding Requirements*

We have incurred operating losses in all fiscal years except 2002, 2008, and 2009, and we had an accumulated deficit of $370,258,000 at September 30, 2011. We expect to incur substantial operating losses in future periods. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, total assets and working capital.

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

We do not expect to generate significant additional funds internally until we successfully complete development and obtain marketing approval for products, either alone or in collaboration with third parties, which we expect will take a number of years. In addition, we have no committed external sources of funds.

We had cash, cash equivalents, and investments of $19,081,000 at September 30, 2011. We believe that our existing cash, cash equivalents, and investments, together with the additional funds raised in the November 2011 financing, will be sufficient to fund our operations at least into the second quarter of 2013 based on our current operating plan. We will need to raise additional funds to operate our business beyond such time.

During the third quarter of 2011, we re-assessed and prioritized our drug development programs. Based on this prioritization, we are focusing our internal development efforts on TLR-targeted compounds for autoimmune and inflammatory diseases and advancing our GSO technology. In addition, we have discontinued further development of IMO-2125, which had been our lead drug candidate for the treatment of hepatitis C virus (HCV), and decided to advance our TLR-targeted programs in infectious diseases, respiratory diseases, hematologic oncology, and additional vaccine adjuvant applications only through partnerships with third parties. In July 2011, the FDA placed our proposed Phase 2 clinical trial of IMO-3100 in patients with psoriasis on clinical hold. We continue to communicate with the FDA regarding the clinical development of IMO-3100 in patients with psoriasis. Our goal is to initiate a clinical trial of IMO-3100 in 2012 to establish proof of concept.

If we proceed with the clinical development with any of our compounds, we expect that the period of time that our current resources will be able to fund our operations could be significantly reduced and we would need to seek additional funding through collaborations, the sale or license of assets or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain additional funding are:

- the results of our clinical and preclinical development programs;
- developments relating to our existing strategic collaborations with Merck KGaA and Merck;
- the cost, timing, and outcome of regulatory reviews;
- competitive and potentially competitive products and technologies and investors receptivity to our drug candidates and the technology underlying them in light of competitive products and technologies;
- the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies such as ours specifically; and
- our ability to enter into new strategic collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require additional funds or further cost reductions. Additional financing may not be available to us when we need it or may not be available to us on favorable terms. We could be required to seek funds through collaborative alliances or others that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing equity securities, our then existing stockholders will experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and are likely to include rights that are senior to the holders of our common stock. Any additional debt financing or equity that we raise may contain terms, such as liquidation and other preferences, or liens or other restrictions on our assets, which are not favorable to us or our stockholders. The terms of any financing may adversely affect the holdings or the rights of existing stockholders. If we are unable to obtain adequate funding on a timely basis or at all, we may be required to significantly curtail one or more of our discovery or development programs and possibly relinquish rights to portions of our technology or products.

*Contractual Obligations*

During the nine months ended September 30, 2011, there were no material changes outside the ordinary course of our business to our contractual obligations as disclosed in our Annual Report of Form 10-K for the year ended December 31, 2010.

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

Foreign currency exchange gains and losses may result from amounts received under our Merck KGaA collaboration agreement and payments under our clinical trial agreements that are denominated in Euros. As of September 30, 2011, we had net accrued obligations of 0.4 million, or $0.5 million. All other assets and liabilities are in U.S. dollars, which is our functional currency.

We maintain investments in accordance with our investment policy. The primary objectives of our investment activities are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. We regularly review our investment holdings in light of the then current economic environment. We do not own auction rate securities or derivative financial investment instruments in our investment portfolio.

Based on a hypothetical ten percent adverse movement in interest rates, the potential losses in future earnings, fair value of risk sensitive financial instruments, and cash flows are immaterial, although the actual effects may differ materially from the hypothetical analysis.

**ITEM 4. CONTROLS AND PROCEDURES.**

(a) *Evaluation of Disclosure Controls and Procedures.* Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the period covered by this report. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2011, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(b) *Changes in Internal Controls*. No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act) occurred during the fiscal quarter ended September 30, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II OTHER INFORMATION

**Item 1A. RISK FACTORS.**

### RISK FACTORS

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

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

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

We have incurred losses in every year since our inception, except for 2002, 2008, and 2009 when our recognition of revenues under license and collaboration agreements resulted in our reporting net income for those years. As of September 30, 2011, we had an accumulated deficit of $370.3 million. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through September 30, 2011, we incurred losses of $110.1 million. We incurred losses of $260.2 million prior to December 31, 2000 during which time we were primarily involved in the development of non-TLR targeted antisense technology. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity, total assets, and working capital.

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

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

We will require substantial funds to conduct research and development, including preclinical testing and clinical trials of our drug candidates. We will also require substantial funds to conduct regulatory activities and to establish commercial manufacturing, marketing, and sales capabilities. We had cash, cash equivalents, and investments of $19.1 million at September 30, 2011. We believe that our existing cash, cash equivalents, and investments, together with the funds raised in the November 2011 financing, will be sufficient to fund our operations at least into the second quarter of 2013 based on our current operating plan. We will need to raise additional funds in order to operate our business beyond such time.

During the third quarter of 2011, we re-assessed and prioritized our drug development programs. Based on this prioritization, we are focusing our internal development efforts on TLR-targeted compounds for autoimmune and inflammatory diseases and advancing our GSO technology. In addition, we have discontinued further development

of IMO-2125, which had been our lead drug candidate for the treatment of hepatitis C virus (HCV), and decided to advance our TLR-targeted programs in infectious diseases, respiratory diseases, hematologic oncology, and additional vaccine adjuvant applications only through partnerships with third parties.

In July 2011, the FDA placed our proposed Phase 2 clinical trial of IMO-3100 in patients with psoriasis on clinical hold. We continue to communicate with the FDA regarding the clinical development of IMO-3100 in patients with psoriasis. Our goal is to initiate a clinical trial of IMO-3100 in 2012 to establish proof of concept.

If we proceed with the clinical development with any of our compounds, we expect that the period of time that our current resources will be able to fund our operations could be significantly reduced and we would need to seek additional funding through collaborations, the sale or license of assets or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain additional funding are:

- the results of our clinical and preclinical development programs;
- developments related to our existing strategic collaborations with Merck KGaA and Merck;
- the cost, timing, and outcome of regulatory reviews;
- competitive and potentially competitive products and technologies and investors receptivity to our drug candidates and the technology underlying them in light of competitive products and technologies;
- the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies such as ours specifically; and
- our ability to enter into additional strategic collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

Additional financing may not be available to us when we need it or may not be available to us on favorable terms. We could be required to seek funds through collaborative alliances or through other means that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing equity securities, our then existing stockholders will experience dilution. The terms of any financing may adversely affect the holdings or the rights of existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and are likely to include rights that are senior to the holders of our common stock. Any additional debt financing or equity that we raise may contain terms, such as liquidation and other preferences, or liens or other restrictions on our assets, which are not favorable to us or our stockholders. If we are unable to obtain adequate funding on a timely basis or at all, we may be required to terminate, modify or delay preclinical or clinical trials of one or more of our drug candidates, fail to establish or delay the establishment of manufacturing, sale or marketing capabilities, curtail research and development programs for new drug candidates and/or possibly relinquish rights to portions of our technology, drug candidates and/or products. For example, we significantly curtailed expenditures on our research and development programs during 1999 and 2000 because we did not have sufficient funds available to advance these programs at planned levels.

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

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

We have invested a significant portion of our time and financial resources in the development of our clinical stage lead drug candidate for autoimmune and inflammatory diseases, IMO-3100. We anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of IMO-3100 and the other drug candidates being developed by our collaborators, including IMO-2055, which we have licensed to Merck KGaA for use in the treatment, cure and/or delay of the onset or progression of cancer in humans. Our efforts, and the efforts of our collaborators, to develop and commercialize these compounds are at an early stage and are subject to many challenges. Recently, we have experienced setbacks with respect to our programs for IMO-3100, IMO-2125, and our collaboration with respect to IMO-2055, including:

During the first half of 2011, we continued to conduct nonclinical studies of IMO-3100, which we commenced in the fourth quarter of 2010, in light of some reversible immune responses that were observed in the 13-week nonclinical toxicology studies and that were inconsistent with observations in our other nonclinical studies of IMO-3100. In June 2011, we submitted a Phase 2 protocol to the FDA to conduct a clinical trial of IMO-3100 in patients with psoriasis. In July 2011, the FDA placed the proposed Phase 2 clinical trial on clinical hold.

In April 2011, we chose to delay initiation of our planned 12-week Phase 2 randomized clinical trial of IMO-2125 plus ribavirin in treatment-naïve, genotype 1 HCV patients based on preliminary observations in an ongoing 26-week chronic nonclinical toxicology study of IMO-2125 in rodents. Histology analysis from the rodent study showed instances of atypical lymphocytic proliferation. No similar observations were made in the recently completed histology analysis from a 39-week chronic nonclinical toxicology study of IMO-2125 in non-human primates.

In July 2011, Merck KGaA informed us that, based on increased incidence of neutropenia and electrolyte imbalances reported in its Phase 1 trial of IMO-2055 in combination with cisplatin/5-FU and cetuximab (Erbitux(R)) in patients with first-line SCCHN and subsequent re-evaluation of its clinical development program, Merck KGaA determined that it will not conduct further clinical development of IMO-2055.

During the third quarter of 2011, we re-assessed and prioritized our drug development programs. Based on this prioritization, we are focusing our internal development efforts on TLR-targeted compounds for autoimmune and inflammatory diseases and advancing our GSO technology. In addition, we have discontinued further development of IMO-2125, which had been our lead drug candidate for the treatment of hepatitis C virus (HCV), and decided to advance our TLR-targeted programs in infectious diseases, respiratory diseases, hematologic oncology, and additional vaccine adjuvant applications only through partnerships with third parties.

We continue to communicate with the FDA regarding the clinical development of IMO-3100 in patients with psoriasis. Our goal is to initiate a clinical trial of IMO-3100 in 2012 to establish proof of concept. The outcome of our correspondence with FDA could negatively impact our ability or willingness to proceed with the further development and commercialization of IMO-3100. Additionally, our collaboration with Merck KGaA may be adversely affected by the increased incidence of neutropenia and electrolyte imbalances reported by Merck KGaA in its Phase 1 clinical trial of IMO-2055 combined with cisplatin and other anticancer drugs. We cannot be certain that Merck KGaA s right to continued evaluation of follow-on TLR9 agonists will result in the development and commercialization of any TLR9 agonists under the collaboration.

Even if we decide to proceed with the development of any of these drug candidates and are able to overcome these recent challenges, our ability to successfully develop and commercialize these drug candidates, or other potential candidates, will depend on several factors, including the following:

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

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

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

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

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

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

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

establishment of commercial manufacturing arrangements with third-party manufacturers;

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

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

competition from other companies and their therapies;

changes in treatment regimes;

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

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

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

In order to obtain regulatory approvals for the commercial sale of our products, we are required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of our drug candidates. Clinical trials are lengthy, complex, and expensive processes with uncertain results. We may not be able to complete any clinical trial of a potential product within any specified time period. Moreover, clinical trials may not show our potential products to be both safe and efficacious. The FDA or other equivalent foreign regulatory agencies may not allow us to complete these trials or commence and complete any other clinical trials. For example, in July 2011, the FDA placed a clinical hold on a protocol we had submitted for a proposed Phase 2 clinical trial of IMO-3100 in patients with psoriasis.

The results from preclinical testing of a drug candidate that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger scale, advanced stage clinical trials. Furthermore, interim results of a clinical trial do not necessarily predict final results, and failure of any of our clinical trials can occur at any stage of testing. Companies in the biotechnology and pharmaceutical industries, including companies with greater experience in preclinical testing and clinical trials than we have, have suffered significant setbacks in clinical trials, even after demonstrating promising results in earlier trials. Moreover, effects seen in nonclinical studies, even if not observed in clinical trials, may result in limitations or restrictions on clinical trials. Numerous unforeseen events

may occur during, or as a result of, preclinical testing, nonclinical testing or the clinical trial process that could delay or inhibit the ability to receive regulatory approval or to commercialize drug products.

In addition to the recent setbacks that we have experienced with respect to the clinical development of our TLR-targeted drug candidates, other companies developing drugs targeted to TLRs have experienced setbacks in clinical trials. For example in 2007, Coley Pharmaceutical Group, which since has been acquired by Pfizer, Inc., discontinued four clinical trials for PF-3512676, its investigational TLR9 agonist compound, in combination with cytotoxic chemotherapy in cancer, and suspended its development of a TLR9 agonist, Actilon®, for HCV infection. In July 2007, Anadys Pharmaceuticals, Inc. and its partner Novartis announced that they had decided to discontinue the development of ANA975, the investigational TLR7 agonist compound for HCV infection. Dynavax Technologies Corporation announced in May 2008 discontinuation of the clinical development program for TOLAMBA®, which comprises a TLR9 agonist covalently attached to a ragweed antigen. These setbacks with respect to TLR-targeted drug candidates may result in enhanced scrutiny by regulators or IRBs of clinical trials of TLR-targeted drug candidates, including our TLR-targeted drug candidates, which could result in regulators or IRBs prohibiting the commencement of clinical trials, requiring additional nonclinical studies as a precondition to commencing clinical trials or imposing restrictions on the design or scope of clinical trials that could slow enrollment of trials, increase the costs of trials or limit the significance of the results of trials. Such setbacks could also adversely impact the desire of investigators to enroll patients in, and the desire of patients to enroll in, clinical trials of TLR-targeted drug candidates.

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

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

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

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

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

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

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

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

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

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

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

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

the size of the patient population;

the proximity of patients to clinical sites;

the eligibility criteria for the study;

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

the existence of competitive clinical trials; and

the availability of alternative treatments.

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

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

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

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

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

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

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

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

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

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

enrolling patients in order to commence the clinical trial.

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

Our technologies or therapeutic approaches are relatively new and unproven. We have focused our efforts on the research and development of RNA- and DNA-based compounds targeted to TLRs and on GSOs. Neither we nor any other company have obtained regulatory approval to market such compounds as therapeutic drugs, and no such products currently are being marketed. It is unknown whether the results of preclinical studies with TLR-targeted compounds will be indicative of results that may be obtained in clinical trials, and results we have obtained in the 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 or of GSOs may not be fully recognized in preclinical studies and small-scale clinical trials, and such compounds may interact with human biological systems in unforeseen, ineffective or harmful ways that we have not yet identified.

As a result of these factors, we may never succeed in obtaining regulatory approval to market any product. Furthermore, the commercial success of any of our products for which we may obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance by patients, the medical community, and third-party payors as clinically useful, safe, and cost-effective. In addition, if products being developed by our competitors have negative clinical trial results or otherwise are viewed negatively, the perception of our technologies and market acceptance of our products could be impacted negatively.

Our recent setbacks with respect to our TLR-targeted compounds, together with the setbacks experienced by other companies developing TLR-targeted compounds, may result in a negative perception of our technology and our TLR-targeted compounds, impact our ability to obtain marketing approval of these drug candidates and adversely affect acceptance of our technology and our TLR-targeted compounds by patients, the medical community and third-party payors.

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

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

We are developing our TLR-targeted drug candidates for use in the treatment of autoimmune and inflammatory diseases and cancer, and as vaccine adjuvants. We are also advancing our gene silencing oligonucleotide, or GSO, technology for potential application as research reagents and as therapeutic agents. For all of the disease areas in which we are developing potential therapies, there are many other companies, public and private, that are actively engaged in discovering, developing, and commercializing products and technologies that may compete with our technologies and drug candidates and technology, including TLR targeted compounds as well as non-TLR targeted therapies.

Our principal competitors developing TLR-targeted compounds for autoimmune and inflammatory diseases include Dynavax Technologies Corporation, with its collaborator, GlaxoSmithKline plc. For our partnered programs, our principal competitors developing TLR-targeted compounds for cancer treatment include Pfizer, Inc., Anadys Pharmaceuticals, Inc., and VentiRx Pharmaceuticals. Merck s vaccines using our TLR7, 8 or 9 agonists as adjuvants may compete with vaccines being developed or marketed by GlaxoSmithKline plc, Novartis, Dynavax Technologies Corporation, VaxInnate, Inc., Intercell AG, Cytos Biotechnology AG, and Celldex Therapeutics, Inc.

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

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

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

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

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

We are a party to an employment agreement with Dr. Agrawal that expires on October 19, 2014, but automatically extends annually for an additional year. This agreement may be terminated by us or Dr. Agrawal for any reason or no reason at any time upon notice to the other party. We do not carry key man life insurance for Dr. Agrawal.

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

**Regulatory Risks**

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

All of the drug candidates that we are developing, or may develop in the future, will require additional research and development, extensive preclinical studies, nonclinical testing, clinical trials, and regulatory approval prior to any commercial sales. This process is lengthy, often taking a number of years, is uncertain, and is expensive. Since our inception, we have conducted clinical trials of a number of compounds and currently two of our compounds, IMO-3100 and IMO-2055, are in clinical development. The FDA and other regulatory authorities may not approve any of our potential products for any indication.

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

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

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

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

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

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

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

voluntary or mandatory product recalls;

fines;

suspension or withdrawal of regulatory approvals;

product seizure or detention;

refusal to permit the import or export of our products;

injunctions or the imposition of civil penalties; and

criminal penalties.

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

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

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

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

**Risks Relating to Collaborators**

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

We seek to advance some of our products through collaborative alliances with pharmaceutical companies. Collaborators provide the necessary resources and drug development experience to advance our compounds in their programs. During the third quarter of 2011, we re-assessed and prioritized our drug development programs and have decided to advance our TLR-targeted programs in infectious diseases, respiratory diseases, hematologic oncology, and additional vaccine adjuvant applications only through partnerships with third parties.

Upfront payments and milestone payments received from collaborations help to provide us with the financial resources for our internal research and development programs. Our internal programs are focused on developing TLR-targeted drug candidates for the potential treatment of autoimmune and inflammatory diseases and cancer. We are also advancing our GSO technology for potential application as research reagents and as therapeutic agents. We believe that additional resources will be required to advance compounds in all of these areas. If we do not reach agreements with additional collaborators in the future, we may not be able to obtain the expertise and resources necessary to achieve our business objectives, our ability to advance our compounds will be jeopardized and we may fail to meet our business objectives.

We may have difficulty establishing additional collaboration alliances, particularly with respect to our TLR-targeted drug candidates and technology. Potential partners may note that one of our TLR collaborations, with Novartis, was terminated by Novartis, and that Merck KGaA has informed us that it has determined not to conduct further clinical development of IMO-2055 at this stage. Potential partners may also be reluctant to establish collaborations with respect to IMO-2125, IMO-3100, and our other TLR-targeted drug candidates, given our recent setbacks with respect to IMO-2125 and IMO-3100. We also face, and will continue to face, significant competition in seeking appropriate collaborators.

Even if a potential partner were willing to enter into a collaborative alliance with respect to our TLR-targeted compounds or technology, the terms of such a collaborative alliance may not be on terms that are favorable to us. Moreover, collaborations are complex and time consuming to negotiate, document, and implement. We may not be successful in our efforts to establish and implement collaborations on a timely basis.

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

An important element of our business strategy includes entering into collaborative alliances with corporate collaborators, primarily large pharmaceutical companies, for the development, commercialization, marketing, and distribution of some of our drug candidates. In December 2007, we entered into an exclusive, worldwide license agreement with Merck KGaA to research, develop, and commercialize products containing our TLR9 agonists for treatment of cancer, excluding cancer vaccines. In December 2006, we entered into an exclusive license and research collaboration with Merck to research, develop, and commercialize vaccine products containing our TLR7, 8, and 9 agonists in the fields of cancer, infectious diseases, and Alzheimer s disease.

Any collaboration that we enter into may not be successful. For instance, Merck KGaA has informed us that it has determined not to conduct further clinical development of IMO-2055 at this stage. The success of our collaborative alliances, if any, will depend heavily on the efforts and activities of our collaborators. Our existing collaborations and any potential future collaborations have risks, including the following:

- our collaborators may control the development of the drug candidates being developed with our technologies and compounds including the timing of development;
- our collaborators may control the public release of information regarding the developments, and we may not be able to make announcements or data presentations on a schedule favorable to us;
- disputes may arise in the future with respect to the ownership of rights to technology developed with our collaborators;
- disagreements with our collaborators could delay or terminate the research, development or commercialization of products, or result in litigation or arbitration;
- we may have difficulty enforcing the contracts if any of our collaborators fail to perform;
- our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect the perception of us in the business or financial communities;
- our collaboration agreements are likely to be for fixed terms and subject to termination by our collaborators in the event of a material breach or lack of scientific progress by us;
- our collaborators may have the first right to maintain or defend our intellectual property rights and, although we would likely have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not, our ability to do so may be compromised by our collaborators acts or omissions;

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

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

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

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

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

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

**Risks Relating to Intellectual Property**

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

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

obtain patents;

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

operate without infringing upon the proprietary rights of others;

prevent others from infringing on our proprietary rights; and

protect our trade secrets.

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

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

As of October 15, 2011, we owned 78 U.S. patents and U.S. patent applications and 253 corresponding patents and patent applications throughout the rest of the world for our TLR-targeted immune modulation technologies. These patents and patent applications include novel chemical compositions of matter and methods of use of our IMO compounds, including IMO-2125, IMO-3100 and IMO-2055. With respect to IMO-2125, we have issued patents that cover the chemical composition of matter of IMO-2125 and methods of its use, with the earliest composition claims expiring in 2026. With respect to IMO-3100, we have patent applications that cover the chemical composition of matter of IMO-3100 and methods of its use that, if issued, would expire at the earliest in 2026. With respect to IMO-2055, we have issued patents that cover the chemical composition of matter of IMO-2055 and methods of its use, including in combination with marketed cancer products, with the earliest composition claims expiring in 2023. With respect to IMO-4200, we have patent applications that cover the chemical composition of matter of IMO-4200 and methods of its use that, if issued, would expire at the earliest in 2027.

As of October 15, 2011, we owned four U.S. patent applications and one worldwide patent application for our GSO compounds and methods of their use. Patents issuing from these patent applications, if any, would expire at the earliest in 2030.

In addition to our TLR-targeted and GSO patent portfolios, we are the owner or hold licenses of patents and patent applications related to antisense technology. As of October 15, 2011, our antisense patent portfolio included 101 U.S. patents and patent applications and 160 patents and patent applications throughout the rest of the world. These antisense patents and patent applications include novel compositions of matter, the use of these compositions for various genes, sequences and therapeutic targets, and oral and other routes of administration. Some of the patents and patent applications in our antisense portfolio were in-licensed. These in-licensed patents expire at various dates ranging from 2012 to 2022.

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

Although we have many issued patents and pending patent applications in the United States and other countries, we may not have rights under certain third party patents or patent applications related to our products. Third parties may own or control these patents and patent applications in the United States and abroad. In particular, we are aware of third party United States patents that contain broad claims related to the use of certain oligonucleotides for stimulating an immune response, although we do not believe that these claims are valid. In addition, there may be other patents and patent applications related to our products of which we are not aware. Therefore, in some cases, in order to develop, manufacture, sell or import some of our products, we or our collaborators may choose to seek, or be required to seek, licenses under third-party patents issued in the United States and abroad or under third party patents that might issue from 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 or our GSO compounds and methods of their use. However, we are party to seven royalty-bearing license agreements under which we have acquired rights to patents, patent applications, and technology of third parties in the field of antisense technology, which may be applicable to our TLR antisense. Under these licenses we are obligated to pay royalties on net sales by us of products or processes covered by a valid claim of a patent or patent application licensed to us. We also are required in some cases to pay a specified percentage of any sublicense income that we may receive. These licenses impose various commercialization, sublicensing, insurance, and other obligations on us.

Our failure to comply with these requirements could result in termination of the licenses. These licenses generally will otherwise remain in effect until the expiration of all valid claims of the patents covered by such licenses or upon earlier termination by the parties. The issued patents covered by these licenses expire at various dates ranging from 2012 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 some of our antisense and ribozyme patents. All of these interferences have since been resolved. We are neither practicing nor intending to practice the intellectual property that is associated with any of these interference proceedings.

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

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

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

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

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

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

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

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

- reliance on the third party for regulatory compliance and quality assurance;
- the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us;
- the potential that third-party manufacturers will develop know-how owned by such third party in connection with the production of our drug candidates that becomes necessary for the manufacture of our drug candidates; and
- reliance upon third-party manufacturers to assist us in preventing inadvertent disclosure or theft of our proprietary knowledge.

Any contract manufacturers with which we enter into manufacturing arrangements will be subject to ongoing periodic, unannounced inspections by the FDA, or foreign equivalent, and corresponding state and foreign agencies or their designees to ensure compliance with cGMP requirements and other governmental regulations and corresponding foreign standards. One of our contract manufacturers notified us that it had received a GMP warning letter from the FDA in February 2011. Any failure by our third-party manufacturers to comply with such requirements, regulations or standards could lead to a delay in the conduct of our clinical trials, or a delay in, or failure to obtain, regulatory approval of any of our drug candidates. Such failure could also result in sanctions being imposed, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, product seizures or recalls, imposition of operating restrictions, total or partial suspension of production or distribution, or criminal prosecution.

Additionally, contract manufacturers may not be able to manufacture our drug candidates at a cost or in quantities necessary to make them commercially viable. 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 substance or drug product is manufactured

or a change of a third-party manufacturer, may require prior FDA review and approval in accordance with the FDA s cGMP and NDA/BLA regulations. Contract manufacturers may also be subject to comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a drug candidate. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. If we or our contract manufacturers are unable to comply, we or they may be subject to regulatory action, civil actions or penalties.

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

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

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

We do not have the ability to independently conduct the clinical trials required to obtain regulatory approval for our drug candidates. We depend on independent clinical investigators, contract research organizations, and other third-party service providers in the conduct of the clinical trials of our drug candidates and expect to continue to do so. We contracted with contract research organizations to manage our Phase 1 clinical trials of IMO-2125 in patients with chronic HCV infection and our Phase 1 clinical trials of IMO-3100 in healthy subjects and expect to contract with such organizations for future clinical trials. We rely heavily on these parties for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and foreign regulatory agencies require us to comply with certain standards, commonly referred to as good clinical practices, and applicable regulatory requirements, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or at all, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval, and commercialization of our drug candidates. If we seek to conduct any of these activities ourselves in the future, we will need to recruit appropriately trained personnel and add to our infrastructure.

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

Any products that we ultimately bring to the market, if they receive marketing approval, may not gain market acceptance by physicians, patients, third-party payors or others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

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

the efficacy and potential advantages over alternative treatments;

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

relative convenience and ease of administration;

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

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

publicity concerning our products or competing products and treatments.

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

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

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

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

In March 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act became law. These health care reform laws are intended to broaden access to health insurance; reduce or constrain the growth of health care spending, especially Medicare spending; enhance remedies against fraud and abuse; add new transparency requirements for health care and health insurance industries; impose new taxes and fees on certain sectors of the health industry; and impose additional health policy reforms. Among the new fees is an annual assessment beginning in 2011 on makers of branded pharmaceuticals and biologics, under which a company s assessment is based primarily on its share of branded drug sales to federal health care programs. Such fees could affect our future profitability. Although it is too early to determine the effect of the new health care

legislation on our future profitability and financial condition, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

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

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

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

decreased demand for our drug candidates and products;

damage to our reputation;

regulatory investigations that could require costly recalls or product modifications;

withdrawal of clinical trial participants;

costs to defend related litigation;

substantial monetary awards to clinical trial participants or patients, including awards that substantially exceed our product liability insurance, which we would then have to pay using other sources, if available, and would damage our ability to 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, which expires in December 2011, 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, 2010 to October 15, 2011, the closing sales price of our common stock ranged from a high of $6.94 per share to a low of $1.00 per share. The stock market has also experienced significant price and volume fluctuations, particularly within the past three years, and the market prices of biotechnology companies in particular have been highly volatile, often for reasons that have been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

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

the regulatory status of our drug candidates;

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

the success of competitive products or technologies;

regulatory developments in the United States and foreign countries;

our success in entering into collaborative agreements;

developments or disputes concerning patents or other proprietary rights;

the departure of key personnel;

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.

***We must meet the NASDAQ Global Market continued listing requirements or we risk delisting, which may decrease our stock price and make it harder for our stockholders to trade our stock.***

Our common stock is currently listed on the NASDAQ Global Select Market and has recently traded as low as $1.00. We are required to meet specified financial requirements to maintain such listing, one of which is that we maintain a minimum closing price of at least $1.00 per share for our common stock. If we fail to maintain the $1.00 minimum closing price for 30 consecutive business days, we may be at risk of delisting. Upon receipt of a deficiency notice from NASDAQ we have 180 days to attempt to regain compliance, such as through a reverse stock split. If we do not regain compliance during this initial period, we may be eligible for an additional 180 day compliance period. To qualify, we would be required to transfer to the NASDAQ Capital Market, meet the listing requirements for that market (with the exception of the minimum closing price requirement) and present a plan to regain compliance with the $1.00 minimum closing price requirement. However, if it appears to the NASDAQ that we will not be able to cure the deficiency, or if we are otherwise not eligible, our common stock would be subject to delisting. While there is a right to appeal the NASDAQ s determination to delist our common stock, there can be no assurance they would grant our request for continued listing.

There can be no assurance that we will meet the continued listing requirements for the NASDAQ Global Market, or that our common stock will not be delisted from the NASDAQ Global Market in the future. If our common stock is delisted from NASDAQ, it may be eligible to trade on the over-the-counter market, which may be a less liquid market, or on the pink sheets. In such case, our stockholders ability to trade, or obtain quotations of the market value of, shares of our common stock would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our securities. There can be no assurance that our common stock, if delisted from the NASDAQ Global Market, will be listed on a national securities exchange, a national quotation service, the OTC Bulletin Board or the pink sheets. Delisting from NASDAQ, or even the issuance of a notice of potential delisting, would also result in negative publicity, make it more difficult for us to raise additional capital, adversely affect the market liquidity of our common stock, reduce security analysts coverage of us and diminish investor, supplier and employee confidence.

**ITEM 6. EXHIBITS.**

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

**SIGNATURES**

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

**IDERA PHARMACEUTICALS, INC.**

Date: November 9, 2011 /s/ Sudhir Agrawal

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

Date: November 9, 2011 /s/ Louis J. Arcudi, III

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

**Exhibit Index**

| **Exhibit No.** | |
|---|---|
| 31.1 | Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 | Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS* | XBRL Instance Document |
| 101.SCH* | XBRL Taxonomy Extension Schema |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB* | XBRL Taxonomy Extension Labels Linkbase Document |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document |

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