IDERA PHARMACEUTICALS, INC.
Form 10-Q
November 09, 2012
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

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

**For the quarterly period ended September 30, 2012**

**or**

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

**For transition period from to .**

**Commission File Number: 001-31918**

# IDERA PHARMACEUTICALS, INC.

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

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

**(617) 679-5500**

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

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

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

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

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

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

| Common Stock, par value $.001 per share | 27,641,229 |
|---|---|
| **Class** | **Outstanding as of October 31, 2012** |

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**IDERA PHARMACEUTICALS, INC.**

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

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**PART I FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS.**

**IDERA PHARMACEUTICALS, INC.**

**CONDENSED BALANCE SHEETS**

**(UNAUDITED)**

| (In thousands, except per share amounts) | September 30, 2012 | December 31, 2011 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 8,352 | $ 24,571 |
| Prepaid expenses and other current assets | 144 | 255 |
| Total current assets | 8,496 | 24,826 |
| Property and equipment, net | 268 | 458 |
| Restricted cash | 311 | 311 |
| Total assets | $ 9,075 | $ 25,595 |
| **LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS (DEFICIT) EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,377 | $ 1,203 |
| Accrued expenses | 2,870 | 4,882 |
| Total current liabilities | 4,247 | 6,085 |
| Warrant and other liabilities | 1,172 | 1,565 |
| Total liabilities | 5,419 | 7,650 |
| Commitments and contingencies | | |
| Series D Redeemable Convertible Preferred Stock, $0.01 par value, Authorized, issued and outstanding 1,124 shares; Redemption amount $9,149; Liquidation preference $9,309 | 5,921 | 5,921 |
| Non-redeemable preferred stock, common stock, and other stockholders (deficit) equity: | | |
| Preferred stock, $0.01 par value, Authorized 5,000 shares Series A convertible preferred stock, Designated 1,500 shares, Issued and outstanding 1 share | | |
| Common stock, $0.001 par value, Authorized 140,000 and 70,000 shares at September 30, 2012 and December 31, 2011, respectively Issued and outstanding 27,641 and 27,637 shares at September 30, 2012 and December 31, 2011, respectively | 28 | 28 |
| Additional paid-in capital | 388,567 | 387,414 |
| Accumulated deficit | (390,860) | (375,418) |
| Total stockholders (deficit) equity | (2,265) | 12,024 |
| Total liabilities, redeemable preferred stock and stockholders (deficit) equity | $ 9,075 | $ 25,595 |

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

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**IDERA PHARMACEUTICALS, INC.**

**CONDENSED STATEMENTS OF COMPREHENSIVE LOSS**

**(UNAUDITED)**

| (In thousands, except per share amounts) | Three Months Ended September 30, 2012 | Three Months Ended September 30, 2011 | Nine Months Ended September 30, 2012 | Nine Months Ended September 30, 2011 |
|---|---|---|---|---|
| Alliance revenue | $ 3 | $ 4 | $ 40 | $ 45 |
| Operating expenses: | | | | |
| Research and development | 3,278 | 3,574 | 10,595 | 12,269 |
| General and administrative | 1,477 | 1,948 | 5,014 | 6,400 |
| Total operating expenses | 4,755 | 5,522 | 15,609 | 18,669 |
| Loss from operations | (4,752) | (5,518) | (15,569) | (18,624) |
| Other income (expense): | | | | |
| Decrease in fair value of warrant liability | 109 | | 106 | |
| Investment income, net | 2 | 2 | 8 | 28 |
| Foreign currency exchange (loss) gain | (28) | 27 | 13 | (20) |
| Net loss | (4,669) | (5,489) | (15,442) | (18,616) |
| Preferred stock dividends | 160 | | 480 | |
| Net loss applicable to common stockholders | $ (4,829) | $ (5,489) | $ (15,922) | $ (18,616) |
| Net loss per common share applicable to common stockholders (Note 10): | | | | |
| Basic | $ (0.17) | $ (0.20) | $ (0.58) | $ (0. 67) |
| Diluted | $ (0.17) | $ (0.20) | $ (0.58) | $ (0.67) |
| Shares used in computing net loss per common share applicable to common stockholders: | | | | |
| Basic | 27,640 | 27,632 | 27,639 | 27,618 |
| Diluted | 27,640 | 27,632 | 27,639 | 27,618 |
| Net loss | $ (4,669) | $ (5,489) | $ (15,442) | $ (18,616) |
| Other comprehensive loss: | | | | |
| Decrease in unrealized gain on available-for-sale securities | | | | (13) |
| Other comprehensive loss | | | | (13) |
| Comprehensive loss | $ (4,669) | $ (5,489) | $ (15,442) | $ (18,629) |

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

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**IDERA PHARMACEUTICALS, INC.**

**CONDENSED STATEMENTS OF CASH FLOWS**

**(UNAUDITED)**

| (In thousands) | Nine Months Ended September 30, 2012 | 2011 |
|---|---|---|
| **Cash Flows from Operating Activities:** | | |
| Net loss | $ (15,442) | $ (18,616) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Loss from disposition of assets | 4 | 1 |
| Non-employee stock option expense | 2 | 1 |
| Stock-based compensation | 1,628 | 2,094 |
| Decrease in fair value of warrant liability | (106) | |
| Issuance of common stock for services rendered | 1 | 38 |
| Amortization of investment premiums | | 59 |
| Depreciation expense | 201 | 373 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 111 | 424 |
| Accounts payable, accrued expenses, and other liabilities | (2,194) | 16 |
| Net cash used in operating activities | (15,795) | (15,610) |
| **Cash Flows from Investing Activities:** | | |
| Purchases of available-for-sale securities | | (1,025) |
| Proceeds from maturity of available-for-sale securities | | 17,585 |
| Decrease in restricted cash | | 102 |
| Purchases of property and equipment | | (21) |
| Net cash provided by investing activities | | 16,641 |
| **Cash Flows from Financing Activities:** | | |
| Dividends paid | (423) | |
| Proceeds from employee stock purchases | 3 | 47 |
| Payments on capital lease | (4) | (8) |
| Net cash (used in) provided by financing activities | (424) | 39 |
| Net (decrease) increase in cash and cash equivalents | (16,219) | 1,070 |
| Cash and cash equivalents, beginning of period | 24,571 | 17,008 |
| Cash and cash equivalents, end of period | $ 8,352 | $ 18,078 |

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

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**IDERA PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

**September 30, 2012**

**(UNAUDITED)**

(1) Organization

Idera Pharmaceuticals, Inc. ( Idera or the Company ) is a clinical stage biotechnology company engaged in the discovery and development of novel synthetic DNA- and RNA- based drug candidates. The Company is developing drug candidates that are designed to modulate immune responses mediated through Toll-like Receptors, or TLRs. The Company believes that the modulation of immune responses through TLRs provides a rationale for the development of drug candidates to treat a broad range of diseases. The Company also has created gene silencing oligonucleotides, or GSOs, which inhibit the production of disease-associated proteins by targeting RNA. The Company believes that its GSO technology provides it with a platform from which drug candidates for diverse disease indications can be developed.

TLRs are specific receptors present in immune system cells. Using a chemistry-based approach, the Company has created synthetic DNA- and RNA-based compounds that are targeted to TLRs 3, 7, 8, and 9. A TLR agonist is a compound that stimulates an immune response through the targeted TLR. A TLR antagonist is a compound that blocks activation of an immune response through the targeted TLR. Drug candidates are compounds that the Company is developing and that have not been approved for any commercial use.

The Company is focusing its internal development efforts on IMO-3100 and IMO-8400, its two TLR-targeted candidates for autoimmune and inflammatory diseases. The Company also is collaborating with Merck Sharp & Dohme Corp. (formerly Merck & Co., Inc.), which is referred to herein as Merck, for the use of agonists of TLRs 7, 8, and 9 as vaccine adjuvants for cancer, infectious diseases, and Alzheimer s disease. The Company is seeking to enter into collaborative alliances with pharmaceutical companies to advance its TLR-targeted programs in oncology, infectious diseases, respiratory diseases and the use of TLR3 agonists as vaccine adjuvants, as well as applications of its GSO technology platform.

At September 30, 2012, the Company had an accumulated deficit of $390,860,000. The Company expects to incur substantial operating losses in future periods. The Company does not expect to generate significant funds or product revenue until it successfully completes development and obtains marketing approval for 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 address a number of technological challenges and to comply with comprehensive regulatory requirements.

The Company had cash and cash equivalents of $8,352,000 at September 30, 2012. The Company believes that its existing cash and cash equivalents, together with the proceeds raised from a private placement of its securities in November 2012 (see Note 13), will be sufficient to fund its operations at least into the third quarter of 2013 based on its current operating plan, including the completion of its ongoing Phase 2 clinical trial of IMO-3100 in patients with psoriasis that it initiated in April 2012, the completion of the Phase 1 clinical trial of IMO-8400 in healthy subjects, which the Company expects to announce the initiation of in the fourth quarter of 2012, and preparations for the further advancement of its autoimmune disease program in at least two indications. The Company will need to raise additional funds in order to conduct any additional clinical development or to operate its business beyond such time. Additional financing may not be available to the Company in this time frame in the amounts the Company needs or on terms that are acceptable to the Company.

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

(2) 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 United States Generally Accepted Accounting Principles ( 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, 2012 are not necessarily indicative of results that may be expected for the year ended December 31, 2012. 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, 2011, which was filed with the SEC on March 14, 2012.

(3) Cash and Cash Equivalents

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, 2012 and December 31, 2011 consisted of cash and money market funds.

## Fair Value of Assets and Liabilities

(4) Fair Value of Assets and Liabilities

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

Effective January 1, 2012, the Company adopted, on a prospective basis, 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 U.S. GAAP and International Financial Reporting Standards. ASU No. 2011-04 is generally consistent with the Company s previous fair value measurement policies but includes additional disclosure requirements, particularly for assets and liabilities that require the use of Level 3 inputs to measure fair value. The adoption of ASU No. 2011-04 did not have a material impact on the Company s financial position or results of operations.

The table below presents the assets and liabilities measured and recorded in the financial statements at fair value on a recurring basis at September 30, 2012 and December 31, 2011 categorized by the level of inputs used in the valuation of each asset and liability.

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| (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) |
|---|---|---|---|---|
| **September 30, 2012** | | | | |
| Assets | | | | |
| Money market fund | $ 8,284 | $ 8,284 | $ | $ |
| Total assets | $ 8,284 | $ 8,284 | $ | $ |
| Liabilities | | | | |
| Warrant liability | $ 1,072 | $ | $ | $ 1,072 |
| Total liabilities | $ 1,072 | $ | $ | $ 1,072 |
| **December 31, 2011** | | | | |
| Assets | | | | |
| Money market fund | $ 24,532 | $ 24,532 | $ | $ |
| Total assets | $ 24,532 | $ 24,532 | $ | $ |
| Liabilities | | | | |
| Warrant liability | $ 1,178 | $ | $ | $ 1,178 |
| Total liabilities | $ 1,178 | $ | $ | $ 1,178 |

The Level 1 assets consist of money market funds, which are actively traded daily. Although the Company did not have any Level 2 assets at September 30, 2012 or December 31, 2011, Level 2 assets typically 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 any investments are classified as available-for-sale securities, any unrealized gains or losses are recorded in accumulated other comprehensive income or loss within stockholders (deficit) equity on the balance sheet. The Company did not elect to measure any other financial assets or liabilities at fair value.

In connection with the sale of its Series D preferred stock in November 2011, the Company issued warrants which contained a provision for price protection in the event that the Company issues other equity securities at a price below $1.46 per share of common stock. Because of the potential adjustment to the warrant exercise price that could result from this provision, the warrants do not meet the criteria set forth in Accounting Standards Codification 815-40, Derivatives and Hedging Contracts in Entity s own Stock to be considered indexed to the Company s own stock. Accordingly, the Company has recorded the fair value of these warrants as a liability. The Company estimated the fair value of these warrants at the issuance date using the Black-Scholes Model as the result was not significantly different than the use of a lattice or binomial model because the price protection provision is subject to a floor of $1.46 per share and the initial exercise price is $1.63. The Company characterized this warrant liability as a Level 3 liability because its fair value measurement is based, in part, on significant inputs not observed in the market and reflects the Company s assumptions as to the expected warrant exercise price, the expected volatility of the Company s common stock, the expected dividend yield, the expected term of the warrant instrument and the expected percentage of warrants to be exercised.

The warrants are revalued at the end of each quarter using the Black-Scholes Model and the change in the fair value of the warrants is recognized in the statement of comprehensive loss as other income (expense). The following assumptions and other inputs were used to compute the fair value of the warrant liability as of September 30, 2012, June 30, 2012 and December 31, 2011:

| | September 30, 2012 | June 30, 2012 | December 31, 2011 |
|---|---|---|---|
| Common stock price | $ 1.03 | $ 1.06 | $ 1.05 |
| Expected warrant exercise price | $ 1.46 | $ 1.46 | $ 1.46 |
| Remaining term of warrant (years) | 4.1 | 4.4 | 4.8 |
| Expected volatility | 60% | 61% | 58% |
| Average risk free interest rate | 0.5% | 0.6% | 0.8% |
| Expected dividend yield | | | |
| Expected percentage of warrants to be exercised | 100% | 100% | 100% |

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The closing price of the Company s common stock is readily determinable since it is publicly traded. The exercise price of the warrant was initially set at $1.63 and may be adjusted to as low as the $1.46 minimum exercise price per share for diluting effects such as if in specified circumstances the Company sells its common stock at a price below $1.46 per share. The Company used the $1.46 minimum exercise price as an assumption in computing the fair value of the warrant at September 30, 2012, June 30, 2012 and December 31, 2011 because the Company s common stock was trading below the $1.63 maximum exercise price as of such dates. The estimated remaining term of the warrant is readily determinable from the warrant agreement as it is the remaining contractual term. The expected volatility is based on the actual stock-price volatility over a period equal to the greater of the remaining term of the warrant or three years. The assumed risk-free interest rate is based on the U.S. Treasury security rate with a term equal to the remaining term of the warrant. The assumed dividend yield of zero is based on the fact that the Company has never paid cash dividends to common stockholders and has no present intention to pay cash dividends to common stockholders. The Company assumed that future financings would dilute the warrant holder s ownership in the Company such that the 19.99% ownership limitation would not prevent the warrant holder from exercising all of the warrants during the term of the warrants.

The Company expects that the closing price and expected volatility of its common stock will be the most significant inputs in determining the fair value of the warrants at the end of each quarter. The Company expects that fluctuations in the other unobservable input assumptions, including the expected warrant exercise price, the expected dividend yield and the expected percentage of warrants to be exercised, will generally have less significant effects on the fair value of the warrants than the closing price of the Company s common stock and expected volatility at the end of each quarter. For example, the Company expects 100% of the warrants to be exercised based on the assumption that future financings will dilute the warrant holder s ownership in the Company such that the 19.99% ownership limitation will not prevent the warrant holder from exercising all of the warrants during the term of the warrants. The Company does not expect that this assumption will change over the next few years given the Company s reliance on equity financings to fund its research and development programs. The Company may change the expected percentage of warrants to be exercised assumption if the warrants remain unexercised and are out of the money with a remaining term of less than six months.

Changes in the warrant liability from December 31, 2011 to September 30, 2012 were as follows:

| (In thousands) | Fair Value of Warrant Liability |
|---|---|
| Balance, December 31, 2011 | $ 1,178 |
| Increase (decrease) in fair value: | |
| Three months ended March 31, 2012 | 1,321 |
| Three months ended June 30, 2012 | (1,318) |
| Three months ended September 30, 2012 | (109) |
| Nine months ended September 30, 2012 | (106) |
| Balance, September 30, 2012 | $ 1,072 |

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The fair value of the warrants decreased from $1,181,000 at June 30, 2012 to $1,072,000 at September 30, 2012 primarily due to decreases in the market price of the Company s common stock and the remaining term of the warrants resulting in the recognition of $109,000 in non-operating income during the three months ended September 30, 2012. The fair value of the warrants decreased from $1,178,000 at December 31, 2011 to $1,072,000 at September 30, 2012 primarily due to decreases in the market price of the Company s common stock and the remaining term of the warrants resulting in the recognition of $106,000 of non-operating income during the nine months ended September 30, 2012. The Company expects that the fair value of the warrants will vary significantly in the future resulting in material non-operating charges and credits in some periods.

(5) Property and Equipment

At September 30, 2012 and December 31, 2011, net property and equipment at cost consisted of the following:

| (In thousands) | September 30, 2012 | December 31, 2011 |
|---|---|---|
| Leasehold improvements | $ 525 | $ 525 |
| Laboratory equipment and other | 2,856 | 2,898 |
| Total property and equipment, at cost | 3,381 | 3,423 |
| Less: accumulated depreciation | (3,113) | (2,965) |
| Property and equipment, net | $ 268 | $ 458 |

Depreciation expense was approximately $51,000 and $120,000 in the three months ended September 30, 2012 and 2011, respectively, and approximately $201,000 and $373,000 in the nine months ended September 30, 2012 and 2011, respectively.

(6) Restricted Cash

As part of the Company s lease arrangement for its office and laboratory facility, the Company is required to restrict cash for a security deposit. As of September 30, 2012, the restricted cash amounted to $311,000 held in certificates of deposit securing a line of credit for the lessor.

## Change in Accumulated Balance of Component of Other Comprehensive Loss

(7) Change in Accumulated Balance of Component of Other Comprehensive Loss

Effective January 1, 2012, the Company adopted Accounting Standard Update No. 2011-05, Comprehensive Income ( ASU No. 2011-05 ), which requires 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 is applied retroactively to all periods presented. ASU No. 2011-05 eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders (deficit) 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. The adoption of ASU No. 2011-05 did not have a material impact on the Company s financial position or results of operations.

The following table includes the changes in the accumulated balance of the component of other comprehensive loss for the nine months ended September 30, 2011:

| (In thousands) | Nine months ended September 30, 2011 |
|---|---|
| | $ 13 |

| | |
|---|---|
| Accumulated unrealized gain on available-for-sale securities at beginning of period | |
| Decrease during the period | (13) |
| Accumulated unrealized gain on available-for-sale securities at end of period | $ |

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There was no accumulated unrealized gain or loss on available-for-sale securities during the nine months ended September 30, 2012 and the three months ended September 30, 2011.

(8) 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, including IMO-2055, for the treatment of cancer, excluding cancer vaccines. 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, and Merck KGaA agreed to reimburse costs for the Company s IMO-2055 clinical trials for the period in which the Company continued to conduct the trials on behalf of Merck KGaA. In February 2009, the agreement was amended so that the Company could initiate and conduct on behalf of Merck KGaA additional clinical trials of IMO-2055, and Merck KGaA agreed to reimburse the Company for costs associated with any additional trials that the Company initiated and conducted. As of March 2010, Merck KGaA assumed sponsorship of all ongoing clinical trials of IMO-2055 for the treatment of cancer, and responsibility for all further clinical development of IMO-2055 in the treatment of cancer, excluding vaccines.

The Company recognized the $40.0 million upfront payment as revenue over the twenty-eight month term that ended in June 2010, which was the Company s period of continuing involvement under the research collaboration. The Company has recognized a total of $12.1 million of milestone revenue related to the initiation of clinical trials of IMO-2055.

In November 2011, the Company and Merck KGaA entered into a termination agreement terminating the license agreement. Under the termination agreement:

- the license agreement was terminated and the Company regained all rights for developing TLR9 agonists for the treatment of cancer, including all rights to IMO-2055 and any follow-on TLR9 agonists;

- Merck KGaA agreed to continue to conduct the Phase 2 trial of IMO-2055 in combination with cetuximab that was then ongoing and other specified related activities;

- Merck KGaA agreed to complete and analyze all clinical trials that Merck KGaA had initiated or for which Merck KGaA had assumed sponsorship and to finalize clinical study reports;

- the Company gained rights to the data from the Phase 2 trial of IMO-2055 in combination with cetuximab, as well as to the data from the Phase 1 trials conducted in other cancer indications;

- the Company agreed to reimburse Merck KGaA a maximum of 1.8 million ($2.3 million using a September 30, 2012 exchange rate) of Merck KGaA s costs for the third party contract research organization that is coordinating the Phase 2 trial of IMO-2055 in combination with cetuximab, payable in eleven installments comprised of ten monthly installments to be invoiced by Merck KGaA to the Company commencing on March 1, 2012 and a final payment payable by the Company to Merck KGaA upon Merck KGaA s completion of certain specified activities;

- the Company agreed to pay to Merck KGaA one-time 1.0 million ($1.3 million using a September 30, 2012 exchange rate) milestone payments upon occurrence of each of the following milestones: (i) partnering of IMO-2055 between the Company and any third party, (ii) initiation of any Phase 2 or Phase 3 clinical trial for IMO-2055 and (iii) regulatory submission of IMO-2055 in any country; and

Merck KGaA granted the Company an option to obtain a license to certain manufacturing and formulation know-how owned or developed by Merck KGaA under the License Agreement and to Merck KGaA s IMOxine trademark. The Company s option to license the IMOxine trademark has expired. If the Company elects to exercise its option with respect to the manufacturing and formulation know-how, the Company has agreed to pay a low single digit royalty on net sales of IMO-2055, with respect to such license.

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The Company recorded the 1.8 million ($2.4 million using a November 30, 2011 exchange rate) that it has agreed to reimburse Merck KGaA in installment payments as research and development expense in its Statement of Operations for the fourth quarter of 2011 as such amount represented the cost of regaining the Company s rights to IMO-2055 and follow-on compounds for use in the treatment of cancer, excluding cancer vaccines. As of September 30, 2012, 1.0 million ($1.3 million using a September 30, 2012 exchange rate) of these installments remained payable under the termination agreement and is recorded under accrued expenses in the condensed balance sheet.

(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 the Company s 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.

The Company has recognized a total of $1.0 million of milestone revenue under the license and collaboration agreement, which related to the achievement of a preclinical milestone with one of its TLR9 agonists used as an adjuvant in cancer vaccines.

(9) 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. Generally, the vesting of all of the Company s stock options was based on the passage of time and the employees continued service. In December 2011 and January 2012, the Company granted performance-based stock options to purchase

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a total of 697,500 shares of common stock to employees. Of this amount, options to purchase 174,375 shares will vest immediately upon the achievement of various performance conditions and options to purchase 523,125 shares will begin to vest over a three year service period upon the achievement of the same performance conditions. During the nine months ended September 30, 2012 one of the specified performance conditions was achieved and options to purchase 87,189 shares began vesting over a three-year period in accordance with the terms of the performance-based options. The Company recognizes expense over the implicit and explicit service periods for awards with performance conditions when the Company determines the achievement of the performance conditions to be probable.

The Company recorded charges of $505,000 and $655,000 in its statements of comprehensive loss for the three months ended September 30, 2012 and 2011, respectively, and $1,628,000 and $2,094,000 in its statements of comprehensive loss for the nine months ended September 30, 2012 and 2011, respectively, for 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. The following assumptions apply to the options to purchase 157,500 and 160,750 shares of common stock granted to employees and directors during the nine months ended September 30, 2012 and 2011, respectively:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2012 | 2011 |
| Average risk free interest rate | 0.9% | 3.0% |
| Expected dividend yield | | |
| Expected lives (years) | 5.6 | 9.7 |
| Expected volatility | 63% | 62% |
| Weighted average grant date fair value of options granted during the period (per share) | $ 0.54 | $ 1.55 |
| Weighted average exercise price of options granted during the period (per share) | $ 0.97 | $ 2.18 |

The expected lives and the expected volatility of the options are based on historical experience. All options granted during the nine months ended September 30, 2012 and 2011 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant.

(10) Net Loss per Common Share Applicable to Common Stockholders

For the three and nine months ended September 30, 2012 and 2011, basic and diluted net loss per common share applicable to common stockholders is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net loss per common share applicable to common stockholders is the same as basic net loss per common share applicable to common stockholders as the effects of the Company s potential common stock equivalents are antidilutive. Total antidilutive securities were 16,021,649 and 6,266,804 for the nine months ended September 30, 2012 and 2011, respectively, and consist of stock options, preferred stock and warrants.

For the three and nine months ended September 30, 2012, net loss per common share applicable to common stockholders reflects $160,000 and $480,000, respectively, in dividends payable on shares of our Series D redeemable convertible preferred stock that were issued in November 2011.

(11) Common Stock Issuances

(a) Cowen Sales Agreement

On April 12, 2012, the Company entered into a sales agreement (the Sales Agreement ) with Cowen and Company, LLC ( Cowen ) pursuant to which the Company may issue and sell shares of its common stock, having an aggregate

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offering price of up to $10,000,000 from time to time through Cowen as its sales agent. Cowen may sell the Company s common stock by methods deemed to be an at-the-market offering (the Offering ), as defined under the Securities Act of 1933, as amended, including sales made directly on the Nasdaq Global Market, on any other existing trading market for the common stock or to or through a market maker other than on an exchange. With the Company s prior written approval, Cowen may also sell the Company s common stock by any other method permitted by law, including in privately negotiated transactions.

Cowen has agreed to offer the common stock subject to the terms and conditions of the Sales Agreement on a daily basis or as otherwise agreed upon by the Company and Cowen. The Company will designate the maximum amount of common stock to be sold through Cowen on a daily basis or otherwise determine such maximum amount together with Cowen. Subject to the terms and conditions of the Sales Agreement, Cowen has agreed to use its commercially reasonable efforts to sell on the Company s behalf all of the shares of common stock requested to be sold by the Company. The Company may instruct Cowen not to sell common stock if the sales cannot be effected at or above the price designated by the Company in any such instruction. The Company or Cowen may suspend the offering of the common stock being made through Cowen under the Sales Agreement upon proper notice to the other party. The Company and Cowen each have the right, by giving written notice as specified in the Sales Agreement, to terminate the sales agreement in each party s sole discretion at any time.

The Sales Agreement provides that Cowen will be entitled to aggregate compensation for its services equal to 3.0% of the gross sales price per share of all shares sold through Cowen under the Sales Agreement. The Company has no obligation to sell any shares under the Sales Agreement. The Company has agreed in the Sales Agreement to provide indemnification and contribution to Cowen against certain liabilities, including liabilities under the Securities Act. In addition, the Company has agreed, under certain circumstances, to reimburse a portion of the expenses of Cowen in connection with the Offering up to a maximum of $50,000. The shares will be issued pursuant to the Company s shelf registration statement on Form S 3 (File No. 333-169060).

The Company has not sold any shares under the Sales Agreement as of September 30, 2012.

(b) Employee Stock Purchases

During the nine months ended September 30, 2012 and 2011, the Company issued 3,006 shares and 23,537 shares, respectively, of common stock in connection with employee stock purchases under the Company s 1995 Employee Stock Purchase Plan, which resulted in total proceeds to the Company of $3,000 and $47,000, respectively.

(12) Related Party Transactions

The Company paid certain directors consulting fees of approximately $12,000 in the three months ended September 30, 2011 and $1,000 and $30,000 in the nine months ended September 30, 2012 and 2011, respectively. The $1,000 paid in the 2012 period was associated with services performed in 2011. The Company did not pay consulting fees to directors during the three months ended September 30, 2012. The Company issued 1,216 and 14,932 shares of common stock in lieu of Director board and committee fees of approximately $1,000 and $38,000 during the nine months ended September 30, 2012 and 2011, respectively.

(13) Subsequent Event

On November 9, 2012, the Company raised approximately $7.0 million in gross proceeds from a private financing with Pillar Pharmaceuticals II L.P., an investment partnership managed by one of the directors of the Company and one of the limited partners of Pillar. In the financing, the Company sold 424,242 shares of its Series E convertible preferred stock, par value $0.01 per share, ( Series E preferred stock ) and warrants to purchase up to 8,484,840 shares of its common stock, $0.001 par value per share, (the warrants ). The initial conversion price of the Series E preferred stock and the initial exercise price of the warrants are $0.70 per share. The Company has agreed to pay to the holders of the Series E preferred stock quarterly dividends payable in cash in arrears at the rate of 4.6% per annum with the first dividend payment being due on March 31, 2013. Under the terms of the Series D preferred stock, any dividends paid to the holders of Series E preferred stock will also be paid to the holders of the Series D preferred stock on an as-converted to common stock basis. The Company has proposed an amendment to the Certificate of Designations of the Series D preferred stock to, among other things, modify the terms of the Series D preferred stock that require additional dividends. If such amendment is approved by the Company s stockholders, the holders of the Series E preferred stock will become entitled to receive dividends payable in cash quarterly in arrears at the rate of 8% per annum and the holders of the Series D preferred stock would cease to be entitled to corresponding dividends.

The net proceeds to Idera, excluding the proceeds of any exercise of the warrants, are expected to total approximately $6.2 million. The Company intends to use these funds for research and clinical development activities, the manufacturing of its product candidates, working capital and general corporate purposes, including the analysis of the data from the Company s ongoing Phase 2 trial of IMO-3100, the conduct of

a Phase 1 trial of IMO-8400 and the preparation for the further advancement of the Company s autoimmune disease program in at least two indications.

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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 E 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 synthetic DNA- and RNA- based drug candidates. We are developing drug candidates that are designed to modulate immune responses mediated through Toll-like Receptors, or TLRs. We believe that the modulation of immune responses through TLRs provides a rationale for the development of drug candidates to treat a broad range of diseases. We also have created gene silencing oligonucleotides, or GSOs, which inhibit the production of disease-associated proteins by targeting RNA. We believe that our GSO technology provides us with a platform from which drug candidates for diverse disease indications can be developed.

TLRs are specific receptors present in immune system cells. Using a chemistry-based approach, we have created synthetic DNA- and RNA-based compounds that are targeted to TLRs 3, 7, 8, and 9. A TLR agonist is a compound that stimulates an immune response through the targeted TLR. A TLR antagonist is a compound that blocks activation of an immune response through the targeted TLR. Drug candidates are compounds that we are developing and that have not been approved for any commercial use.

We are focusing our internal development efforts on IMO-3100 and IMO-8400, our two TLR-targeted candidates for autoimmune and inflammatory diseases. We are also collaborating with Merck Sharp & Dohme Corp. (formerly Merck & Co., Inc.), which is referred to herein as Merck, for the use of agonists of TLRs 7, 8, and 9 as vaccine adjuvants for cancer, infectious diseases, and Alzheimer s disease. We are seeking to enter into collaborative alliances with pharmaceutical companies to advance our TLR-targeted programs in oncology, infectious diseases, respiratory diseases, and the use of TLR3 agonists as vaccine adjuvants, as well as applications of our GSO technology platform.

We had cash and cash equivalents of $8,352,000 at September 30, 2012. We believe that our existing cash and cash equivalents, together with the proceeds raised from a private placement of our securities in November 2012, will be sufficient to fund our operations at least into the third quarter of 2013 based on our current operating plan, including the completion of our ongoing Phase 2 clinical trial of IMO-3100 in patients with psoriasis that we initiated in April 2012, the completion of the Phase 1 clinical trial of IMO-8400 in healthy subjects, which we expect to announce the initiation of in the fourth quarter of 2012, and preparations for the further advancement of our autoimmune disease program in at least two indications. We will need to raise additional funds in order to conduct any additional clinical development or to operate our business beyond such time. Additional financing may not be available to us in this time frame in the amounts that we need or on terms that are acceptable to us.

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*Autoimmune and Inflammatory Disease Program.* We have two drug candidates in clinical development in our autoimmune and inflammatory disease program. We are conducting a Phase 2 clinical trial of IMO-3100, an antagonist of TLR7 and TLR9 in adult patients with moderate to severe plaque psoriasis. We initiated the trial in the second quarter of 2012 and completed enrollment of the trial in October 2012 with a total enrollment of 44 patients. We anticipate that we will have top-line data for some of the endpoints in this Phase 2 study by the end of 2012 and complete data during the first quarter of 2013.

In addition, we have selected IMO-8400, an antagonist of TLRs 7, 8, and 9, as a second candidate for development in the treatment of autoimmune disease, with lupus as our initial indication. We submitted an Investigational New Drug application, or IND, for IMO-8400 to the United States Food and Drug Administration, or FDA, in the third quarter of 2012. We have received a safe-to-proceed notification from FDA to conduct a Phase 1 clinical trial of IMO-8400 in healthy subjects, which we expect to announce the initiation of in the fourth quarter of 2012. If the results of the Phase 1 study are favorable, then subject to obtaining the required funding, we would expect to initiate a Phase 2 clinical trial of IMO-8400 in patients with lupus. If we do not raise additional funding, we will not be able to initiate the planned Phase 2 trial of IMO-8400 in patients with lupus.

We have evaluated IMO-3100 and IMO-8400 in preclinical models of several autoimmune diseases including psoriasis, lupus, rheumatoid arthritis, and multiple sclerosis. In these models, treatment with IMO-3100 or IMO-8400 was associated with inhibition of Th1, Th17, and inflammasome pathways and improvement in a number of disease parameters.

*Vaccine Adjuvant Collaboration.* In January 2012, we announced that Merck had selected several of our novel agonists of TLR7, TLR8 or TLR9 for evaluation and use as vaccine adjuvant candidates in the fields of cancer, infectious diseases, and Alzheimer s disease.

*Cancer Program.* In November 2011, we reacquired rights to IMO-2055, an agonist of TLR9 in clinical development for the treatment of cancer, from Merck KGaA, Darmstadt, Germany, our former collaborator. We believe that IMO-2055 can be developed for use as an immune modifier in combination with targeted anticancer agents in certain cancer indications and are seeking to enter into collaborations with pharmaceutical companies to advance the use of IMO-2055 in the treatment of cancer.

*Gene Silencing Oligonucleotide Technology Platform.* Our GSOs are single-stranded RNA or DNA constructs that are complementary to targeted mRNA sequences of therapeutic interest. In preclinical studies, our GSOs have inhibited in vivo gene expression without requiring a delivery enhancement technology. We are seeking to enter into collaborations with pharmaceutical companies to advance applications of our GSO technology platform.

*Additional Programs.* In addition to our collaboration with Merck, our TLR programs in autoimmune and inflammatory diseases and cancer, and our GSO technology, we have identified TLR drug candidates for applications in the treatment of infectious diseases, respiratory diseases and hematological malignancies, and we have created TLR3 agonists for use as vaccine adjuvants. We are seeking to enter into collaborations with pharmaceutical companies to advance these additional applications.

At September 30, 2012, we had an accumulated deficit of $390.9 million. We expect to incur substantial operating losses in future periods. We do not expect to generate significant product revenue, sales-based milestones 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. We expect that our research and development expenses in 2012 will be lower than our research and development expenses in 2011.

**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

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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, stock-based compensation and our Series D redeemable convertible preferred stock and related warrants. 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, 2011. 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, stock-based compensation and our Series D redeemable convertible preferred stock and related warrants, 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, 2011, fit the description of critical accounting estimates and judgments. There were no changes in these policies during the nine months ended September 30, 2012.

**RESULTS OF OPERATIONS**

***Three and Nine Months Ended September 30, 2012 and 2011***

*Alliance Revenue*

Alliance revenue consisted of reimbursement by licensees of costs associated with patent maintenance, amounting to $3,000 and $4,000 in the three months ended September 30, 2012 and 2011, respectively, and $40,000 and $45,000 in the nine months ended September 30, 2012 and 2011, respectively. We did not recognize any revenue from collaborations in the three and nine months ended September 30, 2012 and 2011.

*Research and Development Expenses*

Research and development expenses decreased by $296,000, or 8%, from $3,574,000 for the three months ended September 30, 2011, to $3,278,000 for the three months ended September 30, 2012 and decreased by $1,674,000 or 14% from $12,269,000 for the nine months ended September 30, 2011 to $10,595,000 for the nine months ended September 30, 2012. In the following table, research and development expense is set forth in the following five 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 |
|---|---|---|---|---|---|---|
| | 2012 | 2011 | (Decrease) | 2012 | 2011 | (Decrease) |
| IMO-3100 external development expense | $ 761 | $ 463 | 64% | $ 1,809 | $ 1,543 | 17% |
| IMO-2055 external development expense | 1 | | % | 5 | 4 | 25% |
| IMO-2125 external development expense | 72 | 466 | (85)% | 223 | 2,233 | (90)% |
| Other drug development expense | 1,255 | 869 | 44% | 4,439 | 2,958 | 50% |
| Basic discovery expense | 1,189 | 1,776 | (33)% | 4,119 | 5,531 | (26)% |

| | | | | | |
|---|---|---|---|---|---|
| $ 3,278 | $ 3,574 | (8)% | $ 10,595 | $ 12,269 | (14)% |

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*IMO-3100 External Development Expenses.* These expenses include external expenses that we have incurred in connection with IMO-3100 since November 2009, when we commenced clinical development of IMO-3100. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-3100 clinical development but exclude internal costs such as payroll and overhead expenses. We incurred approximately $9,241,000 in external development expenses from November 2009 through September 30, 2012, 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 increases in IMO-3100 expenses in the three and nine months ended September 30, 2012, as compared to the three and nine months ended September 30, 2011, were primarily attributable to costs incurred in the 2012 periods in connection with the preparation for and conduct of our ongoing Phase 2 clinical trial of IMO-3100 that we initiated in April 2012. These increases were partially offset by lower costs associated with nonclinical studies during the nine months ended September 30, 2011, costs incurred during the first quarter of 2011 for the manufacture of IMO-3100 drug supply, other costs incurred in the 2011 periods in preparation for a planned Phase 2 clinical trial and costs incurred in the 2011 periods in connection with data analysis of the Phase 1 clinical trials of IMO-3100 that we had conducted.

The ongoing Phase 2 trial of IMO-3100 is a randomized, double-blind, and placebo-controlled study in patients with psoriasis. The trial is designed to evaluate the safety and clinical activity of IMO-3100 as a monotherapy. In October 2012 we announced completion of patient enrollment in the trial. In accordance with the study protocol, 44 patients with moderate to severe plaque psoriasis were randomized on a 1:1:1 basis to receive IMO-3100 at 0.16 or 0.32 mg/kg or placebo by subcutaneous injection once weekly for four weeks. Assessments of safety will be performed throughout the treatment and four-week follow-up periods. The primary outcome measure in the trial is change in epidermal thickness from treatment initiation to the end of treatment as assessed in biopsy samples of psoriatic lesions. Secondary outcome measures of clinical activity include Psoriasis Area Severity Index (PASI), mean focal psoriasis severity, and Physician Global Assessment (PGA) scores. This trial is being conducted at multiple sites in the United States, and skin biopsies will be analyzed at a central laboratory. We anticipate that we will have top-line data for some of the endpoints from the Phase 2 study by the end of 2012 and complete data during the first quarter of 2013.

*IMO-2055 External Development Expenses.* These expenses include external expenses that we have incurred in connection with IMO-2055. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-2055 clinical development, but exclude internal costs such as payroll and overhead expenses. We commenced clinical development of IMO-2055 in 2003 and from 2003 through September 30, 2012 we incurred approximately $19,879,000 in external development expenses, including costs associated with our clinical trials, manufacturing, process development activities related to the production of IMO-2055, additional nonclinical toxicology studies, and the cost of regaining our rights to IMO-2055 and follow-on compounds for use in the treatment of cancer, excluding cancer vaccines, under the termination agreement discussed below.

Under our collaboration with Merck KGaA, Merck KGaA was responsible for developing IMO-2055 for the treatment of cancer excluding vaccines. Merck KGaA refers to IMO-2055 as EMD 1201081. From December 2007 to March 2010, we conducted clinical trials of IMO-2055 under the collaboration and Merck KGaA reimbursed us. As of March 2010, Merck KGaA assumed sponsorship of all ongoing clinical trials of IMO-2055 for the treatment of cancer and responsibility for all further clinical development of IMO-2055 in the treatment of cancer. As a result of Merck KGaA s assumption of sponsorship of the trials, we did not incur significant expenses for IMO-2055 development during the three and nine months ended September 30, 2011.

On November 30, 2011, we entered into an agreement to terminate our collaboration with Merck KGaA and to regain rights for developing TLR9 agonists for the treatment of cancer. In connection with the termination agreement, we agreed to

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reimburse Merck KGaA for up to 1,816,000 ($2,336,000 using a September 30, 2012 exchange rate) of Merck KGaA s costs for the third party contract research organization that was coordinating Merck KGaA s Phase 2 trial of IMO-2055 in combination with cetuximab, payable in eleven installments commencing on March 1, 2012 including a final payment payable upon Merck KGaA s completion of certain specified activities. We also agreed to pay to Merck KGaA one-time 1,000,000 ($1,286,000 using a September 30, 2012 exchange rate) milestone payments upon the occurrence of each of the following milestones: (i) partnering of IMO-2055 with any third party, (ii) initiation of any Phase 2 or Phase 3 clinical trial for IMO-2055 and (iii) regulatory submission of IMO-2055 in any country. We recorded, in research and development expense during the three months ended December 31, 2011, 1,816,000 ($2,423,000 using a November 30, 2011 exchange rate) in installment payments which represents the cost of regaining our rights to IMO-2055 and our follow-on compounds for use in the treatment of cancer, excluding cancer vaccines. Under the agreement, Merck KGaA agreed to continue to conduct the Phase 2 trial of IMO-2055 in combination with cetuximab and other specified related activities and to complete and analyze all clinical trials that Merck KGaA had initiated or for which Merck KGaA had assumed sponsorship and to finalize clinical study reports. As a result, we did not incur significant expenses for IMO-2055 development during the three and nine months ended September 30, 2012. Any milestone payments will be recorded at the time that any milestones are achieved.

Merck KGaA conducted a Phase 1b clinical trial of IMO-2055 in combination with erlotinib and bevacizumab in patients with advanced non-small cell lung cancer. In the trial, progression-free survival was 5.6 months, median overall survival was 16 months, and the disease control rate, which is the percentage of patients who experience a response of stable disease or better, was 79%. The primary objective of the trial was to identify a recommended Phase 2 dosage of IMO-2055 for evaluation in combination with erlotinib and bevacizumab, which was established as 0.32 mg/kg/week. Data from this trial were reported in an abstract included in the 2012 American Society of Clinical Oncology Annual Meeting.

Merck KGaA conducted a Phase 1b clinical trial of IMO-2055 in combination with cetuximab and the chemotherapy regimen FOLFIRI in patients with advanced or metastatic colorectal cancer. The primary objective of this study was to determine the recommended Phase 2 dose of IMO-2055 when combined with cetuximab and FOLFIRI. Fifteen patients were enrolled in the dose escalation portion of the study and received IMO-2055 at 0.16, 0.32, or 0.48 mg/kg/week in combination with weekly cetuximab and FOLFIRI once every two weeks. The combination of IMO-2055, cetuximab, and FOLFIRI was generally well tolerated, and 0.48 mg/kg/week was identified as the recommended Phase 2 dose of IMO-2055 in this setting.

Merck KGaA conducted a Phase 2 clinical trial of IMO-2055 in combination with cetuximab in second-line cetuximab-naïve patients with recurrent or metastatic squamous cell carcinoma of the head and neck, or SCCHN, who previously progressed on chemotherapy. The primary endpoint of the study was progression-free survival. In the study, the combination of IMO-2055 and cetuximab did not meet the primary endpoint. The median progression-free survival based on investigator assessments was 2.9 months in both arms; based on independent radiology review it was 1.9 months in the cetuximab arm and 1.5 months in the combination arm.

We are seeking to enter into a collaboration with one or more pharmaceutical companies to advance the use of IMO-2055 in the treatment of cancer.

*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 from May 2007 through September 30, 2012 we incurred approximately $16,578,000 in external development, including costs associated with our clinical trials manufacturing, process development activities related to the production of IMO-2125, and additional nonclinical toxicology studies.

The decreases in IMO-2125 external development expenses in the three and nine months ended September 30, 2012, as compared to the corresponding 2011 periods, reflect our determination to discontinue further development of IMO-2125 in the treatment of chronic hepatitis C virus infection, or HCV, in the third quarter of 2011. IMO-2125 external development

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expenses during the three and nine months ended September 30, 2011 included costs associated with the conduct of nonclinical toxicology studies, costs associated with two Phase 1 clinical trials, and costs incurred during the first half of 2011 that were associated with preparation for a Phase 2 clinical trial. IMO-2125 external development expenses during the 2012 periods were related primarily to costs associated with the completion of nonclinical studies during the first half of 2012, costs associated with data analysis of a Phase 1 clinical trial, and costs associated with the maintenance of the clinical drug supply. We expect that IMO-2125 external development expenses will be lower in future periods.

*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. Internal expenses associated with products in clinical development include costs associated with our Autoimmune Disease Scientific Advisory Board.

The increases in other drug development expenses in the three and nine months ended September 30, 2012, as compared to the corresponding 2011 periods, were primarily due to costs of preclinical studies and manufacturing activities to support the IND for IMO-8400, which we submitted to the FDA in the third quarter of 2012, and were partially offset by the cost of obtaining nonclinical and clinical trial data from studies conducted by our former collaborative partner of IMO-2134, a TLR9 agonist, which cost we accrued in the second quarter of 2011, costs associated with nonclinical studies and manufacturing of preclinical research compounds in 2011, and lower employee compensation during 2012.

*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, 2012, as compared to the corresponding 2011 periods, were primarily due to decreases in the cost of laboratory supplies and employee compensation reflecting reduced activity and reduced headcount resulting from our September 2011 re-assessment and prioritization of our drug development programs.

We do not know if we will be successful in developing any drug candidate from our research and development programs. At this time, without knowing the results of the ongoing Phase 2 clinical trial of IMO-3100 or the Phase 1 clinical trial of IMO-8400, which we expect to announce the initiation of in the fourth quarter of 2012, and without an established plan for future clinical tests of drug candidates, we cannot reasonably estimate or know the nature, timing, and costs of the efforts that will be necessary to complete the remainder of the development of, or the period, if any, in which material net cash inflows may commence from, any drug candidate from our research and development programs. Moreover, the clinical development of any drug candidate from our research and development programs is subject to numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of unanticipated events arising during clinical development.

*General and Administrative Expenses*

General and administrative expenses decreased by $471,000, or 24%, from $1,948,000 in the three months ended September 30, 2011, to $1,477,000 in the three months ended September 30, 2012 and decreased by $1,386,000, or 22%, from $6,400,000 in the nine months ended September 30, 2011 to $5,014,000 in the nine months ended September 30, 2012. 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 administration expenses during the three and nine months ended September 30, 2012, as compared to the corresponding 2011 periods, were primarily due to lower legal costs associated with patent matters and lower employee compensation due to decreases in stock based compensation and the number of employees during the 2012 periods. These decreases were partially offset by higher corporate legal expenses associated with pursuing financing alternatives, including the financing arrangement we entered into with Cowen and Company LLC in April 2012.

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*Decrease in Fair Value of Warrant Liability*

During November 2011 we recorded a warrant liability reflecting the fair value of the warrants issued in our November 2011 financing. We determined the warrant to be a derivative instrument because it contains a specified anti-dilution provision that does not meet the indexed to the company s own stock exemption requirements in Accounting Standards Codification 815-40, Derivatives and Hedging Contracts in an Entity s own Stock. The warrant was classified as a liability, recorded at fair value as of the transaction date and is being marked to fair value through earnings each quarter. The fair value of the warrants decreased from $1,181,000 at June 30, 2012 to $1,072,000 at September 30, 2012 primarily due to decreases in the market price of our common stock and the remaining term of the warrants resulting in the recognition of $109,000 in non-operating income during the three months ended September 30, 2012. The fair value of the warrants decreased from $1,178,000 at December 31, 2011 to $1,072,000 at September 30, 2012 primarily due to decreases in the market price of our common stock and the remaining term of the warrants, which resulted in the recognition of $106,000 of non-operating income during the nine months ended September 30, 2012. We expect that the fair value of the warrants will vary significantly in the future resulting in material non-operating charges and credits in some periods.

*Investment Income, net*

Investment income, net amounted to $2,000 in both the three months ended September 30, 2012 and 2011 and $8,000 and $28,000 in the nine months ended September 30, 2012 and 2011, respectively. Investment income has been lower during 2012 because in 2012 all of our invested funds have been deposited in a money market fund which pays minimal interest and because of lower invested funds during 2012.

*Foreign Currency Exchange (Loss) Gain*

Our foreign currency exchange loss amounted to $28,000 in the three months ended September 30, 2012 primarily due to the impact that the decreasing value of the U.S. dollar had on our Euro-denominated accrued liabilities, including our liabilities associated with the cost of re-gaining the rights to our cancer program under our agreement with Merck KGaA and the cost of our clinical trial obligations. Our foreign currency exchange gain amounted to $13,000 in the nine months ended September 30, 2012 primarily due to the impact that the increasing value of the U.S. dollar had on our Euro-denominated accrued liabilities. Our foreign currency exchange gain amounted to $27,000 in the three months ended September 30, 2011 primarily due to the impact that the increasing value of the U.S. Dollar had on our Euro-denominated accrued liabilities associated with our clinical trial obligations. Our foreign currency exchange loss amounted to $20,000 in the nine months ended September 30, 2011, primarily due to the impact that the decreasing value of the U.S. dollar had on our Euro-denominated accrued liabilities.

*Preferred Stock Dividends*

The $160,000 and $480,000 in preferred stock dividends in the three and nine months ended September 30, 2012, respectively, consists of dividends payable on shares of our Series D preferred stock that we issued in November 2011.

*Net Loss Applicable to Common Stockholders*

As a result of the factors discussed above, our net loss applicable to common stockholders was $4,829,000 for the three months ended September 30, 2012, compared to $5,489,000 for the three months ended September 30, 2011 and $15,922,000 for the nine months ended September 30, 2012 compared to $18,616,000 for the nine months ended September 30, 2011. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through September 30, 2012, we incurred losses of $130,667,000. 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 $390,860,000 through September 30, 2012. We expect to continue to incur substantial operating losses in the future.

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**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.

*Series E Preferred Stock and Warrant Financing*

In November 2012, we raised approximately $7,000,000 in gross proceeds from a private financing with Pillar Pharmaceuticals II L.P., an investment partnership managed by one of our directors and one of the limited partners of Pillar. In the financing, we sold 424,242 shares of Series E convertible preferred stock and warrants to purchase up to 8,484,840 shares of common stock. The initial conversion price of the preferred stock and the initial exercise price of the warrants are $0.70 per share. The warrants to purchase common stock are exercisable immediately, and will expire if not exercised on or prior to November 9, 2017. We have agreed to pay to the Series E preferred stockholders quarterly dividends payable in cash in arrears at the rate of 4.6% per annum with the first dividend payment being due on March 31, 2013. Under the terms of the Series D preferred stock, any dividends that we pay to the Series E preferred stockholders will also be paid to the Series D preferred stockholders on an as-converted to common stock basis. We have proposed an amendment to the Certificate of Designations of the Series D preferred stock to, among other things, modify the terms of the Series D preferred stock that require additional dividends. If such amendment is approved by our stockholders, the Series E preferred stockholders will become entitled to receive dividends payable in cash quarterly in arrears at the rate of 8% per annum and the Series D preferred stockholders would cease to be entitled to corresponding dividends.

We expect that the net proceeds to us from the offering, excluding the proceeds of any future exercise of the warrants, will total approximately $6,200,000.

*Cowen Sales Agreement*

On April 12, 2012, we entered into a sales agreement with Cowen and Company, LLC pursuant to which we may issue and sell shares of our common stock, having an aggregate offering price of up to $10,000,000 from time to time through Cowen as our sales agent. Cowen may sell our common stock by methods deemed to be an at-the-market offering, as defined under the Securities Act of 1933, as amended, including sales made directly on the Nasdaq Global Market, on any other existing trading market for our common stock or to or through a market maker other than on an exchange. With our prior written approval, Cowen may also sell our common stock by any other method permitted by law, including in privately negotiated transactions.

Cowen has agreed to offer the common stock subject to the terms and conditions of the sales agreement on a daily basis or as otherwise agreed upon by us and Cowen. Under the arrangement, we will designate the maximum amount of our common stock to be sold through Cowen on a daily basis or otherwise determine such maximum amount together with Cowen. Subject to the terms and conditions of the sales agreement, Cowen has agreed to use its commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us. We may instruct Cowen not to sell common stock if the sales cannot be effected at or above the price designated by us in any such instruction. We or Cowen may suspend the offering of the common stock being made through Cowen under the sales agreement upon proper notice to the other party. We and Cowen each have the right, by giving written notice as specified in the sales agreement, to terminate the sales agreement in each party s sole discretion at any time.

The sales agreement provides that Cowen will be entitled to aggregate compensation for its services equal to 3.0% of the gross sales price per share of all shares sold through Cowen under the sales agreement. We have no obligation to sell any shares under the sales agreement. We have agreed in the sales agreement to provide indemnification and contribution to

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Cowen against certain liabilities, including liabilities under the Securities Act. In addition, we have agreed, under certain circumstances, to reimburse a portion of the expenses of Cowen in connection with the offering of common stock up to a maximum of $50,000. The shares will be issued pursuant to our shelf registration statement on Form S 3 (File No. 333-169060).

We have not sold any shares under the sales agreement as of September 30, 2012.

*Series D Preferred Stock and Warrant Financing*

In November 2011, we entered into a Convertible Preferred Stock and Warrant Purchase Agreement, or Purchase Agreement, with Pillar Pharmaceuticals I L.P., or the purchaser, an investment partnership managed by one of our directors. Pursuant to the Purchase Agreement, we issued and sold to the purchaser, for an aggregate purchase price of $9.5 million, 1,124,260 shares of our Series D Preferred Stock convertible, subject to the limitation, into 5,621,300 shares of our common stock, and warrants to purchase 2,810,650 shares of our common stock. The net proceeds to us from the offering, excluding the proceeds of any future exercise of the warrants, were approximately $9.1 million.

The conversion price of the Series D Preferred Stock is subject to adjustment in the event that we issue at any time shares of common stock without consideration or for a consideration per share that is less than $1.46, subject to appropriate adjustment, provided that the Series D Preferred Stock conversion price may not be reduced to a price that is less than $1.46. No holder of the Series D Preferred Stock may convert its shares to the extent such conversion would result in the holder and its affiliates beneficially owning more than 19.99% of the common stock outstanding.

The holder of the Series D Preferred Stock is 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, except that we may not pay any dividends to a holder of Series D Preferred Stock in shares of common stock to the extent the issuance of such shares would result in the holder of Series D Preferred Stock and its affiliates beneficially owning more than 19.99% of the common stock outstanding or the combined voting power of our securities outstanding immediately after giving effect to the issuance of such shares of common stock.

After November 4, 2013 and following written notice by us, we may redeem, for a cash payment equal to the $8.1375 original Series D Preferred Stock issue price per share plus any accrued or declared but unpaid dividends thereon, all or a portion of the Series D Preferred Stock if the closing price of our common stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to 200% of the Series D Preferred Stock conversion price. In addition, the holders of shares of Series D Preferred Stock then outstanding are entitled to require us to purchase the shares of Series D Preferred Stock at a price equal to the original Series D Preferred Stock purchase price per share plus all accrued or declared but unpaid dividends thereon upon the occurrence of specified fundamental changes such as mergers, consolidations, business combinations, stock purchases or similar transactions resulting in a person or group unaffiliated with any holder of Series D Preferred Stock owning 66.67% or more our outstanding voting securities of the Company or successor entity.

The warrants have an exercise price of $1.63 per common share, subject to adjustment therein, and may be exercised at the purchaser s option at any time on or before November 4, 2016. The exercise price of the warrants is subject to adjustment in the event that we issue shares of common stock without consideration or for a price per share that is lower than $1.46, subject to adjustment, provided that the exercise price of the warrants may not be reduced below $1.46. The warrants provide that we will not effect any exercise of the warrants, and the warrants may not be exercised with respect to any portion of the warrants, to the extent that such exercise would result in the purchaser and its affiliates beneficially owning more than 19.99% of the number of shares of common stock outstanding or the combined voting power of our securities outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of the warrant. After November 4, 2013, we may redeem the warrants for $0.01 per share of common stock issuable on exercise of the warrants following notice to the purchaser if the closing price of the common stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to $6.51, subject to adjustment.

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Under the terms of the Purchase Agreement, we granted the purchaser participation rights in future financings and the purchaser agreed that for so long as the purchaser and its affiliates beneficially own more than 15% of our outstanding common stock, the purchaser and its affiliates will vote any shares held by them in excess of the number of shares equal to 15% of the outstanding common stock (including the shares of common stock issuable upon conversion of the Series D preferred stock) with respect to any matter put to a vote of the holders of common stock in the same manner and percentage as the holders of the common stock (other than the purchaser) vote on such matter. The purchaser has also agreed to be subject to a standstill provision that continues for so long as the purchaser and its affiliates beneficially own more than 15% of the outstanding common stock. In connection with the Purchase Agreement, we also filed a registration statement 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.

*Collaboration Agreements*

Under the terms of our collaboration with Merck KGaA, which was terminated in November 2011, we received in February 2008 a $40.0 million upfront license fee in Euros of which we received $39.7 million due to foreign currency exchange rates and approximately $12.1 million in milestone payments and we have been reimbursed $4.5 million for expenses related to the development of IMO-2055.

Under the terms of our collaboration with Merck, Merck paid us a $20.0 million license fee in December 2006 and purchased 1,818,182 shares of our common stock for a price of $5.50 per share for an aggregate purchase price of $10.0 million. Since entering this agreement, we have also received $1.0 million in milestone payments and $3.4 million in research and development payments.

*Cash Flows*

*Nine Months Ended September 30, 2012*

As of September 30, 2012, we had approximately $8,352,000 in cash and cash equivalents, a net decrease of approximately $16,219,000 from December 31, 2011. Net cash used in operating activities totaled $15,795,000 during the nine months ended September 30, 2012, reflecting our $15,442,000 net loss for the nine months ended September, 30, 2012, as adjusted for non-cash income and expenses, including stock-based compensation, depreciation and the decrease in the warrant liability. It also reflects changes in our prepaid expenses and accounts payable, accrued expenses and a liability associated with recording rent expense on a straight-line basis over the term of our facility lease. The net cash used in financing activities totaled $424,000 during the nine months ended September 30, 2012 representing the dividends paid on our Series D preferred stock and payments on our capital lease less the proceeds received from employee stock purchases under our employee stock purchase plan.

*Nine Months Ended September 30, 2011*

Net cash used in operating activities totaled $15,610,000 during the nine months ended September 30, 2011. The $15,610,000 reflects our $18,816,000 net loss for the period, as adjusted for non-cash expenses, including stock-based compensation, depreciation and amortization of investment premiums. 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.

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*Funding Requirements*

We have incurred operating losses in all fiscal years except 2002, 2008 and 2009, and we had an accumulated deficit of $390,860,000 at September 30, 2012. 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 (deficit) 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 and cash equivalents of $8,352,000 at September 30, 2012. We believe that our existing cash and cash equivalents, together with the proceeds raised from a private placement of our securities in November 2012, will be sufficient to fund our operations at least into the third quarter of 2013 based on our current operating plan, including the completion of our ongoing Phase 2 clinical trial of IMO-3100 in patients with psoriasis that we initiated in April 2012, the completion of the Phase 1 clinical trial of IMO-8400 in healthy subjects, which we expect to announce the initiation of in the fourth quarter of 2012, and preparations for the further advancement of our autoimmune disease program in at least two indications. We will need to raise additional funds in order to conduct any additional clinical development or to operate our business beyond such time. Additional financing may not be available to us in this time frame in the amounts that we need or on terms that are acceptable to us.

We expect that we will require substantial additional funds to conduct research and development, including preclinical testing and clinical trials of our drug candidates and to fund our operations. We are seeking and expect to continue 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 funding are:

- the results of our clinical and preclinical development programs, including the results of the ongoing Phase 2 trial of IMO-3100 and the Phase 1 clinical trial of IMO-8400, which we expect to announce the initiation of in the fourth quarter of 2012;
- developments relating to our existing strategic collaboration with 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;
- our ability to enter into new strategic collaborations with biotechnology and pharmaceutical companies and the success of such collaborations; and
- our ability to maintain the listing of our common stock on the Nasdaq Global Market or an alternative national securities exchange.

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In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require additional funds or further cost reductions. Financing may not be available to us when we need it or may not be available to us on favorable or acceptable 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. An equity financing that involves existing stockholders may cause a concentration of ownership. 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 terminate, modify or delay preclinical or clinical trials of one or more of our drug candidates, significantly curtail or terminate discovery or development programs for new drug candidates, or relinquish rights to portions of our technology, drug candidates and/or products.

Our common stock is currently listed on the Nasdaq Global Market. In order to maintain our listing, we are required to meet specified financial requirements, including requirements that we maintain a minimum closing bid price of at least $1.00 per share for our common stock and that we maintain a minimum stockholders equity of $10,000,000 or a minimum market value of $50,000,000.

On June 7, 2012, we received a notification letter from the Nasdaq Listing Qualifications staff of The Nasdaq Stock Market advising us that we were not in compliance with the $50,000,000 minimum market value requirement for continued listing on The Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(b)(2)(A). Nasdaq also noted in its letter that we were no longer in compliance with Nasdaq Listing Rule 5450(b)(1)(A), which requires registrants to maintain a minimum of $10,000,000 in stockholders equity.

Nasdaq stated in its letter that in accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have been provided a compliance period of 180 calendar days, or until December 4, 2012, to regain compliance with the minimum market value continued listing requirement. The Nasdaq letter stated that if, at any time before December 4, 2012, the Market Value of Listed Securities of our common stock closes at $50,000,000 or more for a minimum of 10 consecutive business days, the Nasdaq staff will provide us with written notification that we have achieved compliance with the minimum market value continued listing requirements and the matter will be closed. We could also regain compliance with Nasdaq s continued listing requirements by reporting stockholders equity of $10 million or more.

As of September 30, 2012, our stockholders deficit was $2,265,000 and as of October 31, 2012, the aggregate market value for our common stock was $25,154,000. If we do not regain compliance with the minimum market value or the stockholders equity requirements by December 4, 2012, the Nasdaq staff will provide us with written notification that our common stock is subject to delisting from The Nasdaq Global Market. In such event, we would have the right to request a hearing before the Nasdaq Listing Qualifications Hearings Panel to seek a delay in any determination of delisting and a period of time to regain compliance. If such an effort were unsuccessful, our common stock would be delisted.

*Contractual Obligations*

During the nine months ended September 30, 2012, there were no material changes outside the ordinary course of our business to our contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011.

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

Foreign currency exchange gains and losses may result from amounts to be paid under our Merck KGaA collaboration and termination agreements and payments under our clinical trial agreements that are denominated in Euros. As of September 30, 2012, we had net accrued obligations of 1.0 million, or $1.3 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. At September 30, 2012, all of our invested funds were invested in a money market fund classified in cash and cash equivalents on the accompanying balance sheet.

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 principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of September 30, 2012. In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our chief executive officer and chief financial officer concluded that as of September 30, 2012, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our chief executive officer and chief financial officer by others, particularly during the period in which this report was prepared, and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms.

(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, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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## PART II OTHER INFORMATION

**Item 1A. RISK FACTORS.**

### RISK FACTORS

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

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

***We 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 had cash and cash equivalents of $8.4 million at September 30, 2012. We believe that our existing cash and cash equivalents, together with the proceeds raised from a private placement of our securities in November 2012, will be sufficient to fund our operations at least into the third quarter of 2013 based on our current operating plan, including the completion of our ongoing Phase 2 clinical trial of IMO-3100 in patients with psoriasis that we initiated in April 2012, the completion of the Phase 1 clinical trial of IMO-8400 in healthy subjects, which we expect to announce the initiation of in the fourth quarter of 2012, and preparations for the further advancement of our autoimmune disease program in at least two indications. We will need to raise additional funds in order to conduct any additional clinical development or to operate our business beyond such time. Additional financing may not be available to us in this time frame in the amounts that we need or on terms that are acceptable to us.

We expect that we will require substantial additional funds to conduct research and development, including preclinical testing and clinical trials of our drug candidates and to fund our operations. We are seeking and expect to continue 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 funding are:

- the results of our clinical and preclinical development programs, including the results of the ongoing Phase 2 trial of IMO-3100 and the Phase 1 clinical trial of IMO-8400, which we expect to announce the initiation of in the fourth quarter of 2012;
- developments related to our existing strategic collaboration with Merck;
- the cost, timing, and outcome of regulatory reviews;
- competitive and potentially competitive products and technologies and investors receptivity to our drug candidates and the technology underlying them in light of competitive products and technologies;

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

our ability to enter into additional 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.

Financing may not be available to us when we need it or may not be available to us on favorable or acceptable 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. An equity financing that involves existing stockholders may cause a concentration of ownership. 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, significantly curtail or terminate discovery or development programs for new drug candidates, or relinquish rights to portions of our technology, drug candidates and/or products.

***We must meet the Nasdaq Global Market continued listing requirements or we risk delisting, which could result in a decrease in our stock price and make it harder for us to sell securities in a financing and for our stockholders to trade our stock.***

Our common stock is currently listed on the Nasdaq Global Market. In order to maintain our listing, we are required to meet specified financial requirements, including requirements that we maintain a minimum closing bid price of at least $1.00 per share for our common stock and that we maintain a minimum stockholders equity of $10,000,000 or a minimum market value of $50,000,000.

On June 7, 2012, we received a notification letter from the Nasdaq Listing Qualifications staff of The Nasdaq Stock Market advising us that we were not in compliance with the $50,000,000 minimum market value requirement for continued listing on The Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(b)(2)(A). Nasdaq also noted in its letter that we were no longer in compliance with Nasdaq Listing Rule 5450(b)(1)(A), which requires registrants to maintain a minimum of $10,000,000 in stockholders equity.

Nasdaq stated in its letter that in accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have been provided a compliance period of 180 calendar days, or until December 4, 2012, to regain compliance with the minimum market value continued listing requirement. The Nasdaq letter stated that if, at any time before December 4, 2012, the minimum market value of our common stock closed at $50,000,000 or more for a minimum of 10 consecutive business days, the Nasdaq staff will provide us with written notification that we have achieved compliance with the minimum market value continued listing requirements and the matter will be closed. We could also regain compliance with Nasdaq s continued listing requirements by reporting stockholders equity of $10 million or more.

As of September 30, 2012, our stockholders deficit was $2,265,000 and as of October 31, 2012, the aggregate market value for our common stock was $25,154,000. If we do not regain compliance with the minimum market value or the stockholders equity requirements by December 4, 2012, the Nasdaq staff will provide us with written notification that our common stock is subject to delisting from The Nasdaq Global Market. In such event, we would have the right to request a hearing before the Nasdaq Listing Qualifications Hearings Panel to seek a delay in any determination of delisting and a period of time to regain compliance. If such an effort were unsuccessful, our common stock would be delisted.

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In addition, our common stock recently traded as low as $0.73 per share on October 23, 2012 and had a closing bid price of $0.89 per share on October 31, 2012. If we fail to maintain the $1.00 minimum closing bid price for 30 consecutive business days, we may also be at risk of delisting. Upon receipt of a deficiency notice from Nasdaq with respect to our share price, we would have 180 days to attempt to regain compliance, such as through a reverse stock split. If we did not regain compliance during this initial period, we could be eligible for an additional 180 day compliance period.

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.

***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, 2012, we had an accumulated deficit of $390.9 million. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 through September 30, 2012, we incurred losses of $130.7 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 (deficit) 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.

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

***We are depending heavily on the development of IMO-3100 and IMO-8400 and on our collaborative alliance with Merck. If we or our collaborator decides to terminate the development of any of our drug candidates, are unable to successfully develop and commercialize any of our drug candidates, or experience significant delays in doing so, our business may be materially harmed.***

We have invested a significant portion of our time and financial resources in the development of our clinical stage lead drug candidates, IMO-3100 and IMO-8400, as part of our autoimmune disease program. We expect that the next steps in our autoimmune disease program will be to advance the clinical development of IMO-8400 by completing the Phase 1 clinical trial in healthy subjects, which we expect to announce the initiation of in the fourth quarter of 2012, preparations for the further advancement of our autoimmune disease program in at least two indications, and if the results of the IMO-8400 Phase 1 study are favorable, then subject to obtaining the required funding, we would expect to initiate a Phase 2 clinical trial in patients with lupus. As such, we anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of IMO-3100 and/or IMO-8400. Our ability to generate product revenues will also depend on the development and commercialization of the drug candidates being developed under our collaboration with Merck. Our efforts, and the efforts of Merck, to develop and commercialize these compounds are at an early stage and are subject to many challenges. We have experienced setbacks with respect to our programs for IMO-3100, IMO-2125, and IMO-2055, including:

During the fourth quarter of 2010, we commenced additional nonclinical studies of IMO-3100 in light of some reversible immune responses that were observed in the 13-week nonclinical toxicology studies and that were inconsistent with observations made in our other nonclinical studies of IMO-3100. In June 2011, we submitted a Phase 2 protocol to the FDA to conduct a 12-week clinical trial of IMO-3100 in patients with psoriasis. In July 2011, the FDA placed a clinical hold on the protocol that we had submitted. In October 2011, we submitted to FDA a new Phase 2 protocol to evaluate IMO-3100 in adult patients with moderate to severe plaque psoriasis, over a four-week treatment period. In December 2011, the FDA removed

the clinical hold. We subsequently initiated in the second quarter of 2012 the four-week Phase 2 clinical trial that we are currently conducting. The outcome of this trial could negatively impact our ability or willingness to proceed with the further development and commercialization of our TLR candidates for the treatment of autoimmune disease, or our ability to license such compounds to a third party. Moreover, with respect to IMO-3100, we cannot be certain that the FDA will allow us to conduct further clinical trials of IMO-3100 for treatment periods of more than four weeks or at all without additional clinical or preclinical data.

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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. We subsequently completed a 39-week chronic nonclinical toxicology study of IMO-2125 in non-human primates in which there were no similar observations. During the third quarter of 2011, we re-assessed and prioritized our drug development programs, and determined to discontinue further investment of internal resources on the development of IMO-2125 for the treatment of HCV.

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 in patients with first-line SCCHN and subsequent re-evaluation of its clinical development program, Merck KGaA had determined that it would not conduct further clinical development of IMO-2055. In November 2011, we and Merck KGaA entered into a termination agreement terminating our collaboration and we reacquired the rights to IMO-2055 for the treatment of cancer. In May 2012, we announced that in the Phase 2 trial of IMO-2055 in combination with cetuximab in patients with second-line SCCHN, the combination of IMO-2055 and cetuximab did not meet the primary endpoint of the trial.

We intend to seek to enter into collaborations with pharmaceutical companies to advance the use of our TLR candidates. Our setbacks with respect to our programs for IMO-3100, IMO-2125 and IMO-2055 could negatively impact our ability to license any of such compounds to a third party.

Our ability to successfully develop and commercialize these drug candidates, or other potential candidates, will depend on our ability to overcome these recent challenges and on several factors, including the following:

- the drug candidates demonstrating activity in clinical trials;
- the drug candidates demonstrating an acceptable safety profile in nonclinical toxicology studies and during clinical trials;
- timely enrollment in clinical trials of IMO-8400 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;

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

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

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 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 International Pharmaceutical, Ltd. (Novartis) announced that they had decided to discontinue the

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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;

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- 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: