

IDERA PHARMACEUTICALS, INC.

Form 10-Q

November 13, 2007

**Table of Contents**

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

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

**For the quarterly period ended September 30, 2007**

**or**

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

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

**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)*

**(617) 679-5500**

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No   
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

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

**21,464,439**

Class

Outstanding as of October 31, 2007

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

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<u>Item 1 - Financial Statements</u>	4
<u>Unaudited Condensed Balance Sheets as of September 30, 2007 and December 31, 2006</u>	4
<u>Unaudited Condensed Statements of Operations for the Three and Nine Months ended September 30, 2007 and 2006</u>	5
<u>Unaudited Condensed Statements of Cash Flows for the Nine Months ended September 30, 2007 and 2006</u>	6
<u>Notes to Condensed Financial Statements</u>	7
<u>Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3 Quantitative and Qualitative Disclosures About Market Risk</u>	20
<u>Item 4T Controls and Procedures</u>	20
<b><u>PART II OTHER INFORMATION</u></b>	22
<u>Item 1 Legal Proceedings</u>	22
<u>Item 1A Risk Factors</u>	22
<u>Item 2 Unregistered Sales of Equity Securities and Use of Proceeds</u>	37
<u>Item 3 Defaults Upon Senior Securities</u>	37
<u>Item 4 Submission of Matters to a Vote of Security Holders</u>	37
<u>Item 5 Other Information</u>	37
<u>Item 6 Exhibits</u>	37
<u>Signatures</u>	37
<u>Ex-31.1 Certification of CEO</u>	
<u>Ex-31.2 Certification of CFO</u>	
<u>Ex-32.1 Certification of CEO</u>	
<u>Ex-32.2 Certification of CFO</u>	

IMO<sup>tm</sup> and Idera are our trademarks. All other trademarks and service marks appearing in this quarterly report are the property of their respective owners.

**Table of Contents**

**FORWARD-LOOKING STATEMENTS**

This quarterly report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this report regarding our strategy, future operations, collaborations, intellectual property, financial position, future revenues, projected costs, prospects, plans, and objectives of management are forward-looking statements. The words believes, anticipates, estimates, plans, expects, intends, may, could, should, potential, likely, projects, continue, will, and would and similar expressions are used 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 should be read as being applicable to all related forward-looking statements whenever they appear in this quarterly report. In addition, any forward-looking statements represent our estimates only as of the date that this quarterly report is filed with the SEC and should not be relied upon as representing our estimates as of any subsequent date. We do not assume any obligation to update any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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

<b>(in thousands, except per share amounts)</b>	<b>September 30, 2007 (unaudited)</b>	<b>December 31, 2006</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 11,963	\$ 24,596
Short-term investments	16,055	13,591
Receivables	386	398
Prepaid expenses and other current assets	622	417
Total current assets	29,026	39,002
Property and equipment, net	1,904	622
Deferred financing costs		298
Non-current portion of prepaid expenses	104	
Restricted cash	619	619
Total assets	\$ 31,653	\$ 40,541
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,018	\$ 1,155
Accrued expenses	1,546	864
Current portion of capital lease	23	7
Current portion of note payable	259	
Current portion of deferred revenue	6,260	5,992
Total current liabilities	9,106	8,018
4% convertible notes payable		5,033
Capital lease obligation, net of current portion	55	3
Note payable, net of current portion	952	
Deferred revenue, net of current portion	11,134	15,250
Other liabilities	43	
Total liabilities	21,290	28,304
Commitments and contingencies		
Stockholders equity:		
Preferred stock, \$0.01 par value, authorized 5,000 shares Series A convertible preferred stock, designated 1,500 shares, issued and outstanding 1 share		
Common stock, \$0.001 par value, authorized 40,000 shares issued and outstanding 21,382 and 20,458 shares at September 30, 2007 and December 31, 2006, respectively	21	20

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-Q

Additional paid-in capital	348,564	341,743
Accumulated deficit	(338,227)	(329,526)
Accumulated other comprehensive income	5	
Total stockholders' equity	10,363	12,237
Total liabilities and stockholders' equity	\$ 31,653	\$ 40,541

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

4

---

**Table of Contents**

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

<b>(in thousands, except per share amounts)</b>	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Alliance revenue	\$ 1,970	\$ 572	\$ 5,748	\$ 1,829
Operating expenses:				
Research and development	3,479	3,009	9,288	9,659
General and administrative	2,033	1,395	6,369	3,975
Total operating expenses	5,512	4,404	15,657	13,634
Loss from operations	(3,542)	(3,832)	(9,909)	(11,805)
Other income (expense):				
Investment income, net	416	120	1,322	326
Interest expense	(40)	(107)	(114)	(318)
Net loss	\$ (3,166)	\$ (3,819)	\$ (8,701)	\$ (11,797)
Basic and diluted net loss per share (Note 14)	\$ (0.15)	\$ (0.22)	\$ (0.41)	\$ (0.74)
Shares used in computing basic and diluted loss per common share	21,346	17,223	21,132	16,043

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

**Table of Contents**

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

(in thousands)	<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>Cash Flows From Operating Activities:</b>		
Net loss	\$ (8,701)	\$ (11,797)
Adjustments to reconcile net loss to net cash used in operating activities		
Loss on disposal of property and equipment	6	
Stock-based compensation	1,434	697
Depreciation and amortization	252	283
Issuance of common stock for services rendered	35	19
Non-cash interest expense		84
Changes in operating assets and liabilities		
Accounts receivable	12	7
Prepaid expenses and other assets	(143)	125
Accounts payable and accrued expenses	420	282
Deferred revenue	(3,848)	(1,598)
Net cash used in operating activities	(10,533)	(11,898)
<b>Cash Flows From Investing Activities:</b>		
Purchase of available-for-sale securities	(49,752)	(15,747)
Proceeds from sale of available-for-sale securities	36,215	5,545
Proceeds from maturity of available-for-sale securities	11,105	11,325
Purchase of property and equipment	(1,455)	(82)
Net cash (used in) provided by investing activities	(3,887)	1,041
<b>Cash Flows From Financing Activities:</b>		
Sale of common stock and warrants, net of issuance costs		11,548
Net proceeds from issuance of note payable	1,278	
Proceeds from exercise of common stock options and warrants and employee stock purchases	586	93
Payments on note	(67)	
Payments on capital lease	(10)	(5)
Net cash provided by financing activities	1,787	11,636
Net (decrease) increase in cash and cash equivalents	(12,633)	779
Cash and cash equivalents, beginning of period	24,596	985
Cash and cash equivalents, end of period	\$ 11,963	\$ 1,764
<b>Supplemental disclosure of non-cash financing and investing activities:</b>		
Cash paid for interest	\$ 114	\$ 92





**Table of Contents**

**IDERA PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2007**  
**(UNAUDITED)**

(1) (a) Organization

Idera Pharmaceuticals, Inc., or the Company, is a biotechnology company engaged in the discovery and development of synthetic DNA- and RNA-based compounds for the treatment of cancer, infectious diseases, autoimmune diseases and asthma and allergies, and for use as vaccine adjuvants. The Company has designed proprietary product candidates to modulate immune responses through Toll-like Receptors, or TLRs. TLRs are specific receptors present in immune system cells that direct the immune system to respond to potential disease threats. Relying on its expertise in DNA and RNA chemistry, the Company identifies product candidates targeted to TLRs 7, 8 or 9 for its internal development programs and for collaborative alliances. It is developing both agonists and antagonists of TLRs 7, 8 and 9. The Company has three internal programs, in oncology, infectious diseases, and autoimmune diseases, and two collaborative alliances relating to the development of treatments for asthma and allergies and the development of adjuvants for vaccines.

The Company's most advanced product candidate, IMO-2055, is an agonist of TLR9. The Company closed enrollment of a Phase 2 trial of IMO-2055 in oncology in June 2007 and a Phase 1/2 trial of IMO-2055 in combination with chemotherapy in oncology in July 2007. The Company plans to initiate additional studies with IMO-2055 in combination with approved, targeted anti-cancer agents in the fourth quarter of 2007 and the first quarter of 2008. The Company is developing a second TLR9 agonist, IMO-2125, for the treatment of infectious diseases. In September 2007, the Company initiated a Phase 1 clinical trial of IMO-2125 in patients with chronic hepatitis C virus infection. In its autoimmune disease program, which is in earlier stages of research, the Company is evaluating TLR antagonists in preclinical models. The Company is collaborating with Novartis International Pharmaceutical, Ltd., or Novartis, for the discovery, development, and commercialization of its TLR9 agonists for the treatment of asthma and allergy indications and with Merck & Co., Inc., or Merck, for the use of its TLR7, 8 and 9 agonists in combination with Merck's therapeutic and prophylactic vaccines in the areas of oncology, infectious diseases and Alzheimer's disease.

The Company has incurred operating losses in all fiscal years except 2002 and had an accumulated deficit of \$338.2 million at September 30, 2007. The Company has losses of \$78.0 million incurred since January 1, 2001 and incurred losses of \$260.2 million prior to December 31, 2000 when it was involved in the development of antisense technology. The Company expects to incur substantial operating losses in the future and does not expect to generate significant funds internally until it successfully completes development and obtains marketing approval for products, either alone or in collaborations with third parties, which the Company expects will take a number of years. In order to commercialize its therapeutic products, the Company needs to address many technological challenges and to comply with comprehensive regulatory requirements.

(b) Recently Adopted Accounting Pronouncement

The Company adopted the Financial Accounting Standards Board's Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109 (FIN 48), effective January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in financial statements and requires the impact of a tax position to be recognized in the financial statements if that position is more likely than not of being sustained by the taxing authority. The adoption of FIN 48 did not have a material effect on the Company's financial position or results of operations.

The Company files income tax returns in the U.S. federal and Massachusetts jurisdictions. The Company is no longer subject to tax examinations for years before 2003, except to the extent that it utilizes net operating losses or tax credit carryforwards that originated before 2003. The Company does not believe there will be any material changes in its unrecognized tax positions over the next 12 months. The Company has not incurred any interest or penalties. In the event that the Company is assessed interest or penalties at some point in the future, they will be classified in the financial statements as general and administrative expense.



**Table of Contents**

In July 2007, the Emerging Issues Task Force ( EITF ) issued EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities* ( EITF 07-3 ). EITF 07-3 clarifies the accounting for nonrefundable advance payments for goods or services that will be used or rendered for research and development activities. EITF 07-3 states that such payments should be capitalized and recognized as an expense as the goods are delivered or the related services are performed. If an entity does not expect the goods to be delivered or the services rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. The Company is currently evaluating the effect of EITF 07-3 on its financial statements but does not expect the adoption of EITF 07-3 to have a material effect on the Company's financial position or results of operations.

**(2) Unaudited Interim Financial Statements**

The accompanying unaudited financial statements included herein have been prepared by the Company in accordance with accounting principles generally accepted in the United States for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of interim period results have been included. The Company believes that its disclosures are adequate to make the information presented not misleading. Interim results for the three-month and nine-month periods ended September 30, 2007 are not necessarily indicative of results that may be expected for the year ended December 31, 2007. The unaudited interim financial statements should be read in conjunction with the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006.

**(3) Reclassification and Additional Disclosures**

Prior to the third quarter of 2006, the Company classified patent costs as research and development expense. The Company now includes these costs in general and administrative expense. The prior period financial statements have been reclassified in order to conform with the current presentation.

**(4) Cash Equivalents and Investments**

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be cash equivalents. Cash and cash equivalents at September 30, 2007 and December 31, 2006 consisted of cash and money market funds. On September 30, 2007, commercial paper that had maturity dates of less than 90 days at the time of purchase were included as cash equivalents. On December 31, 2006, certain corporate bonds that had maturity dates of less than 90 days at the time of purchase were included as cash equivalents.

The Company accounts for investments in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 115, *Accounting for Certain Investments in Debt and Equity Securities* ( SFAS No. 115 ). Management determines the appropriate classification of marketable securities at the time of purchase. In accordance with SFAS No. 115, investments that the Company does not have the intent to hold to maturity are classified as available-for-sale and reported at fair market value. Unrealized gains and losses associated with available-for-sale investments are recorded in Accumulated other comprehensive income on the accompanying balance sheets. The amortization of premiums and accretion of discounts, and any realized gains and losses and declines in value judged to be other than temporary, and interest and dividends for all available-for-sale securities are included in Investment income, net on the accompanying statements of operations. The Company had no held-to-maturity investments, as defined by SFAS No. 115, at September 30, 2007 and December 31, 2006. The cost of securities sold is based on the specific identification method.

For the three and nine months ended September 30, 2007, the Company had de minimis realized gains. The Company had no realized gains or losses for the three or nine months ended September 30, 2006. There were no losses or permanent declines in value included in investment income for any securities in the three or nine months ended September 30, 2007 and 2006. Interest receivable related to the Company's securities was \$288,000 at September 30, 2007 and \$158,000 at December 31, 2006 and is recorded within receivables on the Company's balance sheets.



**Table of Contents**

The Company had no long-term investments as of September 30, 2007 and December 31, 2006. Available-for-sale securities are classified as short-term regardless of their maturity date as the Company considers them available for use to fund operations within one year of the balance sheet date. Auction securities are highly liquid securities that have floating interest or dividend rates that reset periodically through an auctioning process that sets rates based on bids. Issuers include municipalities, closed-end bond funds and corporations. The Company's short-term available-for-sale investments at market value consisted of the following at September 30, 2007 and December 31, 2006:

<b>(in thousands)</b>	<b>September 30, 2007</b>	<b>December 31, 2006</b>
Certificates of deposit	\$ 4,601	\$ 300
Corporate bonds due in one year or less	1,662	301
Euro bonds due in one year or less	499	
Government bonds due in one year or less	7,693	1,595
Auction securities	1,600	11,395
<b>Total</b>	<b>\$ 16,055</b>	<b>\$ 13,591</b>

**(5) Property and Equipment**

At September 30, 2007 and December 31, 2006, net property and equipment at cost consists of the following:

<b>(in thousands)</b>	<b>September 30, 2007</b>	<b>December 31, 2006</b>
Leasehold improvements	\$ 412	\$ 444
Laboratory equipment and other	2,426	2,175
<b>Total property and equipment, at cost</b>	<b>2,838</b>	<b>2,619</b>
Accumulated depreciation and amortization	(934)	(1,997)
<b>Property and equipment, net</b>	<b>\$ 1,904</b>	<b>\$ 622</b>

As of September 30, 2007 and December 31, 2006, laboratory equipment and other included approximately \$98,000 and \$20,000, respectively, of laboratory and office equipment financed under capital leases with total accumulated amortization of approximately \$13,000 and \$6,000, respectively. Depreciation expense, which includes amortization of assets recorded under capital leases, was approximately \$119,000 and \$31,000 for the three months ended September 30, 2007 and 2006, respectively, and \$247,000 and \$135,000 for the nine months ended September 30, 2007 and 2006, respectively. The Company vacated its previous facility in the second quarter of 2007. Consequently as of September 30, 2007, the Company wrote off fully amortized leasehold improvements that had a cost of approximately \$445,000. In addition as of September 30, 2007, the Company wrote off unused furniture, and obsolete software, computers and other equipment that had an aggregate cost of approximately \$874,000 resulting in a loss of \$5,600. During the second quarter of 2007, the Company changed its method of computing depreciation expense to depreciate assets based on the actual periods held rather than the half year convention that was previously used for additions and disposals. This change in method of accounting for depreciation did not have a material impact on depreciation expense or the net loss per share for the nine month period ended September 30, 2007, compared to the previous method.

**(6) Restricted Cash**

As part of the operating lease described in Note 9, which commenced in the second quarter of 2007, the Company was required to restrict approximately \$619,000 of cash for a security deposit. These funds are held in certificates of deposit securing a line of credit for the lessor. The restricted cash amount is expected to be reduced by approximately \$103,000 upon each of the second, third and fourth anniversaries of the lease commencement date, subject to certain conditions.

**Table of Contents**

(7) Note Payable

On June 12, 2007, the Company executed a promissory note in the aggregate principal amount of \$1.3 million (the Note ) in favor of General Electric Capital Corporation ( GE ). The Note is secured by specific laboratory, manufacturing, office and computer equipment and is subject to the terms of a master security agreement dated April 23, 2007 by and between the Company and GE. The Note bears interest at a fixed rate of 11% per annum, and is payable in 48 consecutive monthly installments of principal and accrued interest, with the first installment having been paid out of the proceeds of the borrowing on June 12, 2007.

The obligations of the Company under the Note and the master security agreement may be accelerated upon the occurrence of an event of default, which includes customary events of default, including without limitation payment defaults, defaults in the performance of covenants and obligations, the inaccuracy of representations or warranties and bankruptcy and insolvency related defaults.

(8) 4% Convertible Notes Payable

In 2005, the Company sold approximately \$5,033,000 in aggregate principal amount of 4% convertible subordinated notes due April 30, 2008 (the 4% Notes ). In February 2007, the Company elected to automatically convert these 4% Notes into 706,844 shares of the Company s common stock effective on February 20, 2007. In accordance with the terms of the 4% Notes and an agreement dated May 20, 2005, among the Company and the holders of the 4% Notes, the Company was entitled to exercise this right of automatic conversion because the volume-weighted average of the closing prices of the Company s common stock for a period of ten consecutive trading days ending February 8, 2007 exceeded \$8.90 per share, which represented 125% of the conversion price of the 4% Notes. As of February 20, 2007, the 4% Notes were no longer considered outstanding and interest ceased to accrue. Holders of the 4% Notes were paid cash in lieu of any fractional shares and \$61,000 in accrued interest through February 19, 2007.

The Company capitalized its financing costs associated with the sale of the 4% Notes and amortized them as interest expense through February 19, 2007. The unamortized balance of the deferred financing costs of \$266,000 was reclassified to additional paid-in-capital in connection with the automatic conversion of the 4% Notes.

(9) Lease Commitment.

In June 2007, the Company relocated its operations to a newly leased facility. The Company entered into a lease arrangement on October 31, 2006 and the term of the lease commenced on June 1, 2007 and will terminate on May 31, 2014, with one five-year renewal option exercisable by the Company. Rent expense, including real estate taxes and net of sublease income that ended in January 2007, was \$321,000 and \$901,000 for the three and nine months ended September 30, 2007, respectively, and \$96,000 and \$238,000 for the three and nine months ending September 30, 2006, respectively. The rent expense for the nine months ended September 30, 2007 includes approximately \$155,000 in one-time charges resulting from vacating the Company s previous location.

(10) Equity Offerings

In March 2006, the Company raised approximately \$9.8 million in gross proceeds from a private placement to institutional investors. In the private placement, the Company sold for a purchase price of \$3.52 per share 2,769,886 shares of common stock and warrants to purchase 2,077,414 shares of common stock. The warrants to purchase common stock have an exercise price of \$5.20 per share, are fully exercisable, and will expire if not exercised on or prior to September 24, 2011. The warrants may be exercised by cash payment only. After March 24, 2010, the Company may redeem the warrants for \$0.08 per warrant share following notice to the warrant holders if the volume weighted average of the closing sales price of the common stock exceeds 300% of the warrant exercise price for the 15-day period preceding the notice. The Company may exercise its right to redeem the warrants by providing 20 days prior written notice to the holders of the warrants. The net proceeds to the Company from the offering, excluding the proceeds of any future exercise of the warrants, were approximately \$8.9 million. The agent fees and other costs directly related to securing the commitment amounted to approximately \$0.9 million. As of September 30, 2007, these warrants have not been exercised.

In March 2006, the Company secured a purchase commitment from an investor to purchase from the Company up to \$9.8 million of the Company s common stock during the period from June 24, 2006 through December 31, 2006 in up to three drawdowns made by the Company at the Company s discretion. Prior to December 31, 2006, the





**Table of Contents**

Company drew down the full \$9.8 million through the sale of 1,904,296 shares of common stock at a price of \$5.12 per share resulting in net proceeds to the Company, excluding the proceeds of any future exercise of the warrants, described below, of approximately \$8.9 million. The agent fees and other costs directly related to securing the commitment amounted to approximately \$0.9 million. As part of the arrangement, the Company issued warrants to the investor to purchase 761,718 shares of common stock at an exercise price of \$5.92 per share. The warrants are exercisable by cash payment only. The warrants are exercisable at any time on or prior to September 24, 2011. On or after March 24, 2010, the Company may redeem the warrants for \$0.08 per warrant share following notice to the warrant holders if the closing sales price of the common stock exceeds 250% of the warrant exercise price for 15 consecutive trading days prior to the notice. The Company may exercise its right to redeem the warrants by providing at least 30 days prior written notice to the holders of the warrants. As of September 30, 2007, these warrants have not been exercised.

**(11) Comprehensive Income (Loss)**

The following table includes the components of comprehensive income (loss) for the three and nine months ended September 30, 2007 and 2006.

<b>(in thousands)</b>	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Net loss	\$ (3,166)	\$ (3,819)	\$ (8,701)	\$ (11,797)
Other comprehensive income	26	4	5	12
Total comprehensive loss	\$ (3,140)	\$ (3,815)	\$ (8,696)	\$ (11,785)

Other comprehensive income represents the net unrealized gains on available-for-sale investments.

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

In May 2005, the Company entered into a research collaboration and option agreement and a separate license, development and commercialization agreement with Novartis to discover, develop and potentially commercialize TLR9 agonists that are identified as potential treatments for asthma and allergies. The Company and Novartis agreed that the term of the research and collaboration phase would be two years commencing in May 2005. The Company initially was recognizing the \$4.0 million upfront payment paid under the collaboration as revenue over the two-year term of the research collaboration. In February 2007, Novartis elected to extend the research collaboration by an additional year. As a result of such extension, Novartis paid the Company an additional \$1.0 million in May 2007. The Company amortizes the upfront payment and the extension payment over the expected research term.

**(13) Stock-Based Compensation**

The Company adopted SFAS No. 123R, *Share-Based Payment*, ( SFAS No. 123R ) on January 1, 2006. SFAS No. 123R requires the Company to recognize all share-based payments to employees in the financial statements based on their fair values. Under SFAS No. 123R, the Company is required to record compensation expense over an award's vesting period based on the award's fair value on the date of grant. The Company's policy is to expense the fair value of stock awards on a straight-line basis over the vesting period. The Company incurred charges in its statements of operations of \$385,000 and \$213,000 for the three months ended September 30, 2007 and 2006, respectively, and \$1,139,000 and \$697,000 for the nine months ended September 30, 2007 and 2006, respectively, representing the stock compensation expense computed in accordance with SFAS No. 123R.

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

The fair value of each stock award is estimated on the date of grant using the Black-Scholes option-pricing model and expensed over the requisite vesting period on a straight-line basis. The following assumptions apply to the stock

awards granted for the nine months ended September 30, 2007 and 2006:

11

---

**Table of Contents**

	<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
Risk free interest rate	4.8%	4.5%
Expected dividend yield		
Expected lives	5.9 years	5.9 years
Expected volatility	70.2 %	88.3 %
Weighted average grant date fair value of options granted during the period	\$ 4.86	\$ 3.53

**(14) Net Loss per Common Share**

Basic and diluted net loss per common share is computed using the weighted average number of shares of common stock outstanding during the period. For the three and nine months ended September 30, 2007 and 2006, diluted net loss per share of common stock is the same as basic net loss per share of common stock, as the effects of the Company's potential common stock equivalents are antidilutive. Total antidilutive securities were 7,325,066 and 7,542,234 at September 30, 2007 and 2006, respectively, and consist of stock options, warrants and convertible preferred stock. Antidilutive securities at September 30, 2006 also include convertible debt instruments on an as-converted basis. Net loss applicable to common stockholders is the same as net loss for the three and nine months ended September 30, 2007 and 2006.

**(15) Related Party Transactions**

The Company has had no related party transactions in the three and nine months ended September 30, 2007. During the nine months ended September 30, 2006 and in connection with the purchase commitment described in Note 10, the Company paid \$487,000 in commissions to one of the Company's directors, which represented 5% of the amount available to the Company under the purchase commitment. In the nine months ended September 30, 2006, the Company paid another director of the Company \$10,000 for consulting services.

**Table of Contents**

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

**GENERAL**

We are engaged in the discovery and development of synthetic DNA- and RNA-based compounds for the treatment of cancer, infectious diseases, autoimmune diseases and asthma and allergies, and for use as vaccine adjuvants. We have designed proprietary product candidates to modulate immune responses through Toll-like Receptors, or TLRs. TLRs are specific receptors present in immune system cells that direct the immune system to respond to potential disease threats. Relying on our expertise in DNA and RNA chemistry, we are identifying product candidates targeted to TLRs 7, 8 or 9 for our internal development programs and for collaborative alliances. We are developing both agonists and antagonists of TLRs 7, 8 and 9. We have three internal programs, in oncology, infectious diseases, and autoimmune diseases, and two collaborative alliances relating to the development of treatments for asthma and allergies and the development of adjuvants for vaccines.

Our most advanced product candidate, IMO-2055, is an agonist of TLR9. We closed enrollment of a Phase 2 trial of IMO-2055 in oncology in June 2007 and a Phase 1/2 trial of IMO-2055 in combination with chemotherapy in oncology in July 2007. We plan to initiate additional studies with IMO-2055 in combination with approved, targeted anti-cancer agents in the fourth quarter of 2007 and the first quarter of 2008. We are developing a second TLR9 agonist, IMO-2125, for the treatment of infectious diseases. In September 2007, we initiated a Phase 1 clinical trial of IMO-2125 in patients with chronic hepatitis C virus infection. In our autoimmune disease program, which is in earlier stages of research, we are evaluating TLR antagonists in preclinical models. We are collaborating with Novartis International Pharmaceutical, Ltd., or Novartis, for the discovery, development, and commercialization of our TLR9 agonists for the treatment of asthma and allergy indications. We also are collaborating with Merck & Co., Inc., or Merck, for the use of our TLR7, 8 and 9 agonists in combination with Merck's therapeutic and prophylactic vaccines in the areas of oncology, infectious diseases, and Alzheimer's disease.

We have given formal notice to Isis Pharmaceuticals, Inc., or Isis, that we believe that Isis has materially breached certain provisions of the Collaboration and License Agreement, or the Collaboration Agreement, between us and Isis dated May 24, 2001. We believe that Isis improperly expanded the scope of our Collaboration Agreement by sublicensing rights to our intellectual property for use outside the licensed field. In accordance with the dispute resolution provision terms of our Collaboration Agreement, we and Isis submitted the dispute to arbitration. On October 16, 2007, we and Isis held our initial meeting with the arbitrator and are proceeding with the arbitration. In the arbitration, we are seeking to have the scope of the Collaboration Agreement clarified and Isis determined to be in breach. We do not believe that an adverse result to this action will be material to us.

As of September 30, 2007, we had an accumulated deficit of \$338.2 million. We incurred losses of \$78.0 million since January 1, 2001. We also incurred net losses of \$260.2 million prior to December 31, 2000 during which time we were involved in the development of antisense technology. We expect to incur substantial operating losses in the future and do not expect to generate significant funds internally until we successfully complete development and obtain marketing approval for products, either alone or in collaborations with third parties, which we expect will take a number of years. In order to commercialize our therapeutic products, we need to address a number of technological challenges and to comply with comprehensive regulatory requirements. We expect that our research and development expenses in the fourth quarter of 2007 will be higher than our research and development expenses in the corresponding period of 2006 due to the new clinical trial of IMO-2055 that we plan to initiate in the fourth quarter of 2007 and the clinical trial of IMO-2125, which we commenced in the third quarter of 2007.

**CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

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

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

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

Our significant accounting policies are described in Note 2 of the Notes to Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2006. Not all of these significant accounting policies,

**Table of Contents**

however, fit the definition of critical accounting estimates. We believe that our accounting policies relating to revenue recognition and stock-based compensation, as described under the caption Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies in our Annual Report on Form 10-K for the year ended December 31, 2006, fit the definition of critical accounting estimates and judgments.

**RESULTS OF OPERATIONS****Three and Nine Months Ended September 30, 2007 and 2006***Revenue*

Our revenues are comprised of revenue earned under various collaboration and licensing agreements, including reimbursement of internal and third-party expenses, license fees, sublicense fees, and royalty payments. Total alliance revenue increased by \$1.4 million, or 233%, from \$0.6 million for the three months ended September 30, 2006 to \$2.0 million for the three months ended September 30, 2007 and increased by \$3.9 million, or 217%, from \$1.8 million for the nine months ended September 30, 2006 to \$5.7 million for the nine months ended September 30, 2007. These increases were primarily due to license fees recognized under our collaboration agreement with Merck, which was entered into in December 2006. The \$20.0 million upfront payment received from Merck in December 2006 is being recognized over the expected research term under the agreement. As a result, \$1.3 million of the upfront payment from Merck was recognized as revenue in the third quarter of 2007 and \$3.8 million was recognized as revenue in the nine months ended September 30, 2007. In February 2007, Novartis elected to extend our research collaboration with them. As a result of such extension, Novartis paid us an additional \$1.0 million in May 2007. We are amortizing the \$4.0 million upfront payment and the extension payment over the expected research term with \$0.3 million recognized as revenue in the three months ended September 30, 2007 as compared to \$0.5 million for the same period in 2006 and \$1.0 million recognized as revenue in the nine months ended September 30, 2007 as compared to \$1.5 million for the same period in 2006.

*Research and Development Expenses*

Research and development expenses increased by \$470,000, or 16%, from \$3,009,000 for the three months ended September 30, 2006 to \$3,479,000 for the three months ended September 30, 2007 and decreased by \$371,000 or 4%, from \$9,659,000 for the nine months ended September 30, 2006 to \$9,288,000 for the nine months ended September 30, 2007. The increase in the three months ended September 30, 2007 was primarily due to increases in IMO-2125 clinical development costs incurred in preparation for the launch of the trial, discovery employee costs associated with the Merck collaboration, which are reimbursed, payroll costs associated with the hiring of additional employees, stock-based compensation, and allocated rent expense resulting from the move to a new laboratory and office facility. These increases were offset, in part, by decreases in costs incurred for IMO-2125 pharmacology studies, manufacturing costs and IMO-2055 nonclinical development costs.

The decrease in the nine months ended September 30, 2007 was primarily due to the completion in 2006 of Investigational New Drug, or IND, enabling safety and pharmacology studies for IMO-2125, lower manufacturing costs for IMO-2125 in 2007 and a decrease in non-clinical and clinical costs associated with IMO-2055. These decreases were offset, in part, by increases in costs related to the clinical and non-clinical trials of IMO-2125, discovery employee costs associated with the Merck collaboration, which are reimbursed, and payroll costs associated with the hiring of additional drug development employees and stock-based compensation.

	Three Months Ended September 30, (In thousands)			Nine Months Ended September 30, (In thousands)		
	2007	2006	Percentage Increase (Decrease)	2007	2006	Percentage Increase (Decrease)
IMO-2055 External Development Expenses	\$ 615	\$ 839	(27%)	\$ 1,375	\$ 2,624	(48%)
IMO-2125 External Development Expenses	472			707		

Edgar Filing: IDERA PHARMACEUTICALS, INC. - Form 10-Q

Other Drug Development Expenses	1,073	1,213	(12%)	3,162	3,708	(15%)
Basic Discovery Expenses	1,319	957	38%	4,044	3,327	22%
Total Research and Development Expenses	\$ 3,479	\$ 3,009	16%	\$ 9,288	\$ 9,659	(4%)



**Table of Contents**

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

*IMO-2055 External Development Expenses.* These expenses include external expenses that we have incurred in connection with IMO-2055, our lead compound that we are developing for oncology applications. These external expenses reflect payments to independent contractors and vendors for drug development studies, including clinical trials, conducted after the initiation of IMO-2055 clinical trials and drug manufacturing and related costs but exclude internal costs such as payroll and overhead. Since 2003, when we commenced clinical development of IMO-2055, we have incurred approximately \$12.0 million in external expenses in connection with IMO-2055. IMO-2055 external development expenses decreased by \$224,000, or 27%, from \$839,000 for the three months ended September 30, 2006 to \$615,000 for the three months ended September 30, 2007 and decreased by \$1,249,000, or 48%, from \$2,624,000 for the nine months ended September 30, 2006 to \$1,375,000 for the nine months ended September 30, 2007. The decrease in IMO-2055 development expenses in the third quarter of 2007 compared to the third quarter of 2006 and the nine months ended September 30, 2007 compared to the nine months ended September 30, 2006 was primarily attributable to lower clinical trial expenses as we closed enrollment of a Phase 2 trial in June 2007 and a Phase 1/2 trial in July 2007 and to a decrease in non-clinical studies of IMO-2055. These decreases were partially offset by an increase in expenses associated with the planning activities for the two Phase 1b trials we intend to initiate in the fourth quarter of 2007 and first quarter of 2008.

In October 2004, we commenced patient recruitment for an open label, multi-center Phase 2 clinical trial of IMO-2055 as a monotherapy in patients with metastatic or recurrent clear cell renal cancer. Under the protocol for the trial, we were seeking to enroll a total of up to 92 patients in the first stage of the trial, 46 who had failed one prior therapy and 46 who were treatment-naïve. We closed enrollment in this trial on June 29, 2007. As of that date, we had completed enrollment of the target 46 treatment-naïve patients and enrolled 45 patients out of the target of 46 patients who had failed one prior therapy. We expect that when final data are available, we will report the results at an appropriate scientific meeting and will decide on the next steps for evaluation of IMO-2055 in metastatic or recurrent clear cell renal cancer. We will not be able to obtain a complete set of data from the trial until all patients have ceased to receive treatment in the trial. At present, one patient continues to receive treatment in this Phase 2 trial. We expect that final data from this trial will be available in the second or third quarter of 2008.

In October 2005, we initiated a Phase 1/2 clinical trial of IMO-2055 in combination with the chemotherapy agents gemcitabine and carboplatin in patients with refractory solid tumors. The purpose of the Phase 1 portion of the trial was to evaluate the safety of the combination. Three dose levels of IMO-2055 and three treatment schedules of IMO-2055 were investigated in this trial. We enrolled twenty-two patients in this trial and closed enrollment in July 2007. We reported initial results from this trial at the 12<sup>th</sup> World Conference on Lung Cancer in Seoul, Korea, in September 2007.

We plan to initiate additional studies with IMO-2055 in combination with approved, targeted anti-cancer agents. We intend to initiate a clinical trial to investigate IMO-2055 in combination with Tarceva<sup>®</sup>, a small molecule designed to inhibit the activity of the tyrosine kinase epidermal growth factor receptor (EGFR), and in triple combination with Tarceva<sup>®</sup> and Avastin<sup>®</sup>, a recombinant, humanized antibody to vascular endothelial growth factor (VEGF), in patients with non-small cell lung cancer who have failed one prior therapy. We expect to initiate a Phase 1b trial in the fourth quarter of 2007 to assess the safety of the combinations with multiple doses of IMO-2055. Investigational sites for this Phase 1b trial have been initiated and screening of patients is underway. Following an analysis of the results of the Phase 1b trial, we plan to conduct a four-arm randomized, placebo controlled Phase 2 trial of the combinations.

We also intend to initiate clinical trials to investigate IMO-2055 in combination with Erbitux<sup>®</sup>, a recombinant, humanized antibody to EGFR, and Camptosar<sup>®</sup>, a cytotoxic, chemotherapeutic agent that inhibits topoisomerase I function, in patients with colorectal cancer. We expect to initiate a Phase 1b trial to assess the safety of this combination with multiple doses of IMO-2055 in the first quarter of 2008. Following an analysis of the results of the Phase 1b trial, we plan to conduct a randomized, placebo controlled Phase 2 trial of the combination.

*IMO-2125 External Development Expenses.* These expenses include external expenses that we have incurred in connection with IMO-2125, our lead compound that we are developing for infectious disease applications, since we submitted our IND application for IMO-2125. These external expenses include payments to independent contractors and vendors for drug development trials and studies, drug manufacturing and related costs but exclude internal costs

such as payroll and overhead. We incurred \$472,000 in the three months ended September 30, 2007 and \$707,000 in

**Table of Contents**

the nine months ended September 30, 2007 of external development expenses associated with the initiation of our Phase 1 clinical trial of IMO-2125 and related non-clinical studies and manufacturing process development.

In May 2007, we submitted an IND to the U.S. Food and Drug Administration, or FDA, for evaluation of IMO-2125 in patients with chronic hepatitis C virus infection. We initiated a Phase 1 clinical trial of IMO-2125 in the third quarter of 2007.

The Phase 1 trial is being conducted in patients with chronic hepatitis C virus infection who have failed to respond to combination therapy with ribavirin and pegylated IFN-a, the current standard of care. We expect to enroll up to 40 patients in this trial with ten patients per cohort. Of the ten patients per cohort, 8 will be randomized to receive IMO-2125 treatment and two will be randomized to receive placebo treatment. Four dose levels of IMO-2125 will be investigated. The planned treatment is four weeks for each cohort. The trial is designed to assess safety and tolerability of IMO-2125 at each dose level as well as to determine the effect of IMO-2125 on hepatitis C virus RNA levels and parameters of immune system activation. We plan to conduct the trial at five or more sites.

*Other Drug Development Expenses.* These expenses include internal and external expenses associated with preclinical development of identified compounds in anticipation of advancing these compounds into clinical development in addition to internal costs associated with products in clinical development.

The internal and 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, as well as payroll and overhead. Expenses associated with products in clinical development include costs associated with our Oncology Clinical Advisory Board and our Hepatitis C Clinical Advisory Board, payroll and overhead.

Other drug development expenses decreased by \$140,000, or 12%, from \$1,213,000 for the three months ended September 30, 2006 to \$1,073,000 for the three months ended September 30, 2007 and decreased by \$546,000, or 15%, from \$3,708,000 for the nine months ended September 30, 2006 to \$3,162,000 for the nine months ended September 30, 2007.

The \$140,000 and \$546,000 decreases in other drug development expenses for the three and nine months ended September 30, 2007, as compared to the corresponding 2006 periods, are primarily attributable to decreases in manufacturing and pre-IND direct external expenses related to IMO-2125. The pre-IND direct external expenses related to IMO-2125 were approximately zero and \$629,000 for the three months ended September 30, 2007 and 2006, respectively, and \$352,000 and \$1,997,000 for the nine months ended September 30, 2007 and 2006, respectively. The preceding 2007 amounts only include costs incurred through April 2007 with respect to IMO-2125 since costs incurred after the May 2007 submission of the IMO-2125 IND have been shown separately in the above table. The decreases in these pre-IND IMO-2125 expenses are primarily attributable to decreases in IND-enabling safety and pharmacology study costs and lower manufacturing costs in the three and nine months ended September 30, 2007.

The decrease in other drug development expenses in both periods was partially offset by an increase in compensation costs as a result of hiring additional employees and higher stock based compensation expense and allocated costs associated with the move to our new facility during the second quarter of 2007.

*Basic Discovery Expenses.* These expenses include our internal and external expenses relating to the continuing discovery and development of our TLR-targeted programs, including agonists and antagonists of TLRs 7, 8 and 9. These expenses reflect payments for laboratory supplies, external research, and professional fees, as well as payroll and overhead. Basic discovery expenses increased by \$362,000, or 38%, from \$957,000 for the three months ended September 30, 2006 to \$1,319,000 for the three months ended September 30, 2007 and increased by \$717,000, or 22%, from \$3,327,000 for the nine months ended September 30, 2006 to \$4,044,000 for the nine months ended September 30, 2007. The increase in these expenses in the three and nine months ending September 30, 2007 compared to the three and nine months ending September 30, 2006 is primarily attributable to an increase in payroll expenses relating to work under our Merck collaboration, an increase in expenses for laboratory supplies and allocated costs associated with the move to our new facility during the second quarter of 2007.

**Table of Contents**

We do not know if we will be successful in developing IMO-2055, IMO-2125 or any of our other product candidates. At this time, given the current status of our clinical trials of IMO-2055 and IMO-2125, 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, IMO-2055 or IMO-2125. Moreover, the clinical development of IMO-2055 and IMO-2125 or any of our other product candidates 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, including with respect to:

the number of clinical sites included in the trials;

the length of time required to enroll suitable subjects;

the number of subjects that ultimately participate in the trials; and

the efficacy and safety results of our clinical trials and the number of additional required clinical trials.

*General and Administrative Expenses*

General and administrative expenses increased by \$638,000, or 46%, from \$1,395,000 in the three months ended September 30, 2006 to \$2,033,000 in the three months ended September 30, 2007 and increased by \$2,394,000, or 60%, from \$3,975,000 in the nine months ended September 30, 2006 to \$6,369,000 in the nine months ended September 30, 2007. 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 regulatory filing requirements, and our business development initiatives.

The increases in general and administrative expenses for both periods reflect increased employee costs, higher stock-based compensation expense for employees and consultants, implementation of Sarbanes-Oxley Section 404 requirements, costs associated with the move to our new facility and costs accrued in anticipation of payments to be made to our former Chief Financial Officer under the transition agreement entered into with him in May 2007. We expect costs relating to the facility move, the transition agreement and certain of the costs associated with Sarbanes-Oxley compliance to be non-recurring. The increase during the nine months ended September 30, 2007 also reflects higher professional fees associated with marketing research and legal services. These increased expenses were offset, in part, by lower patent and trademark preparation and maintenance costs in the three and nine months ended September 30, 2007.

*Investment Income, net*

Investment income increased by \$296,000, or 247%, from \$120,000 in the three months ended September 30, 2006 to \$416,000 in the three months ended September 30, 2007 and increased by \$996,000, or 306%, from \$326,000 in the nine months ended September 30, 2006 to \$1,322,000 in the nine months ended September 30, 2007. These increases resulted from higher cash and investment balances in 2007.

*Interest Expense*

Interest expense decreased by \$67,000, or 63%, from \$107,000 in the three months ended September 30, 2006 to \$40,000 in the three months ended September 30, 2007 and decreased by \$204,000, or 64%, from \$318,000 in the nine months ended September 30, 2006 to \$114,000 in the nine months ended September 30, 2007. These decreases resulted from the conversion of our 4% notes in the aggregate principal amount of approximately \$5,033,000 into 706,844 shares of common stock on February 20, 2007. The three and nine months ended September 30, 2006 included full periods of interest and amortization of deferred financing costs associated with our 4% notes.

*Net Loss*

As a result of the factors discussed above, our net loss was \$3,166,000 for the three months ended September 30, 2007 compared to \$3,819,000 for the three months ended September 30, 2006 and \$8,701,000 for the nine months ended September 30, 2007 compared to \$11,797,000 for the nine months ended September 30, 2006. We have incurred losses of \$78.0 million since January 1, 2001. We also incurred net losses of \$260.2 million prior to December 31, 2000 during which time we were involved in the development of antisense technology. Since our

inception, we have accumulated a deficit of \$338.2 million through September 30, 2007. We expect to continue to incur substantial operating losses in the future.

**Table of Contents**

**LIQUIDITY AND CAPITAL RESOURCES**

*Sources of Liquidity*

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

equity and debt financing;

license fees and research funding under collaborative and license agreements;

interest income; and

lease financings.

In May 2005, we issued approximately \$5.0 million in principal amount of 4% convertible subordinated notes due April 30, 2008 to overseas investors. Interest on the 4% convertible subordinated notes was payable in arrears semi-annually on April 30 and October 30 and at maturity or upon conversion. We had the option to pay interest on the 4% convertible subordinated notes in cash or in shares of common stock at the then current market value of the common stock. In February 2007, we elected to automatically convert the 4% convertible subordinated notes in the aggregate principal amount of \$5.0 million into 706,844 shares of our common stock effective on February 20, 2007. We were entitled to exercise the right of automatic conversion because the volume-weighted average of the closing prices of our common stock for the ten consecutive trading days ending February 8, 2007 exceeded \$8.90 per share, which represented 125% of the conversion price of the notes.

In May 2005, we entered into a research collaboration and option agreement and a license, development and commercialization agreement with Novartis to discover, develop and potentially commercialize immune modulatory oligonucleotides that are TLR9 agonists and that are identified as potential treatments for asthma and allergies. Under the terms of the agreements, Novartis paid us a \$4.0 million license fee in July 2005. In February 2007, Novartis elected to extend the research phase of the collaboration and paid us an additional \$1.0 million in May 2007.

In March 2006, we raised approximately \$9.8 million in gross proceeds from a private placement to institutional investors. In the private placement, we sold for a purchase price of \$3.52 per share 2,769,886 shares of common stock and warrants to purchase 2,077,414 shares of common stock. The warrants have an exercise price of \$5.20 per share, are fully exercisable and will expire if not exercised on or prior to September 24, 2011. The warrants may be exercised by cash payment only. After March 24, 2010, we may redeem the warrants for \$0.08 per warrant share following notice to the warrant holders if the volume weighted average of the closing sales price of the common stock exceeds 300% of the warrant exercise price for the 15-day period preceding the notice. We may exercise our right to redeem the warrants by providing 20 days prior written notice to the holders of the warrants. The net proceeds to us from the offering, excluding the proceeds of any future exercise of the warrants, totaled approximately \$8.9 million. None of these warrants has been exercised to date.

In March 2006, we secured a purchase commitment from an investor to purchase from us up to \$9.8 million of our common stock during the period from June 24, 2006 through December 31, 2006 in up to three drawdowns made by us at our discretion. Prior to December 31, 2006, we drew down the full \$9.8 million through the sale of 1,904,296 shares of common stock at a price of \$5.12 per share resulting in net proceeds to us, excluding the proceeds of any future exercise of the warrants, described below, of approximately \$8.9 million. The agent fees and other costs directly related to securing the commitment amounted to approximately \$0.9 million. As part of the arrangement, we issued warrants to the investor to purchase 761,718 shares of common stock at an exercise price of \$5.92 per share. The warrants are exercisable by cash payment only. The warrants are exercisable at any time on or prior to September 24, 2011. On or after March 24, 2010, we may redeem the warrants for \$0.08 per warrant share following notice to the warrant holders if the closing sales price of the common stock exceeds 250% of the warrant exercise price for 15 consecutive trading days prior to the notice. We may exercise our right to redeem the warrants by providing at least 30 days prior written notice to the holders of the warrants. None of these warrants has been exercised to date.

In December 2006, we entered into an exclusive license and research collaboration agreement with Merck to research, develop, and commercialize vaccine products containing our TLR7, 8 and 9 agonists in the fields of

**Table of Contents**

oncology, infectious diseases and Alzheimer's disease. Under the terms of the agreement, Merck paid us a \$20.0 million license fee in December 2006. In addition, in connection with the execution of the license and collaboration agreement, we issued and sold to Merck 1,818,182 shares of our common stock for a price of \$5.50 per share resulting in an aggregate purchase price of \$10.0 million.

*Cash Flows*

As of September 30, 2007, we had approximately \$28.0 million in cash and cash equivalents and investments, a net decrease of approximately \$10.2 million from December 31, 2006. We used \$10.5 million of cash for operating activities during the first three quarters of 2007. The \$10.5 million primarily reflects our \$8.7 million net loss for the period, as adjusted for non-cash revenue and expenses, including stock-based compensation, depreciation and amortization. It also reflects the changes in deferred revenue associated with payments under our collaborative arrangements and changes in our accounts payable and accrued expenses.

The net cash used in investing activities during the nine months ended September 30, 2007 of \$3.9 million reflects our purchase of approximately \$49.8 million in securities offset by our sale of \$36.2 million of securities and the proceeds of approximately \$11.1 million from securities that matured in the nine months ended September 30, 2007. The net cash used in investing activities also reflects our purchase of laboratory, office and computer equipment in the first three quarters of 2007.

The net cash provided by financing activities during the first three quarters of 2007 of \$1.8 million primarily reflects the net proceeds from the issuance of a \$1.3 million promissory note and the \$0.6 million in proceeds received from the exercise of stock options and warrants during the first three quarters of 2007.

*Funding Requirements*

We have incurred operating losses in all fiscal years except 2002 and had an accumulated deficit of \$338.2 million at September 30, 2007. We have incurred losses of \$78.0 million since January 1, 2001. We also incurred losses of \$260.2 million prior to December 31, 2000 during which time we were involved in the development of antisense technology. We expect to continue to incur substantial operating losses in future periods. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital. We had cash, cash equivalents and short-term investments of \$28.0 million at September 30, 2007. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our operations at least through December 31, 2008. We will need to raise additional funds to operate our business beyond such time, including completing any Phase 2 trials involving IMO-2055.

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

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

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

the success of our clinical and preclinical development programs;

the success of our existing strategic collaborations with Novartis and Merck;

the cost, timing and outcome of regulatory reviews;

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





**Table of Contents**

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

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

***Contractual Obligations***

We have contractual obligations in the form of operating and capital leases. In June 2007, we borrowed \$1.3 million from GE Capital Corporation pursuant to a promissory note in order to finance the purchase of new laboratory, office, and computer equipment to be used in our new office and laboratory facility in Cambridge, Massachusetts. The note is secured by specific laboratory, manufacturing, office and computer equipment and is subject to the terms of a master security agreement dated April 23, 2007 by and between us and GE. The note bears interest at a fixed rate of 11% per annum, and is payable in 48 consecutive monthly installments of principal and accrued interest, with the first installment having been paid out of the proceeds of the borrowing on June 12, 2007.

Our obligations under the note and the master security agreement may be accelerated upon the occurrence of an event of default, which includes customary events of default, including without limitation payment defaults, defaults in the performance of covenants and obligations, the inaccuracy of representations or warranties and bankruptcy and insolvency related defaults.

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

As of September 30, 2007, we had no assets and liabilities related to non-dollar-denominated currencies.

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 investments. We do not own derivative financial investment instruments in our investment portfolio. Based on a hypothetical ten percent adverse movement in interest rates, the potential losses in future earnings, fair value of risk sensitive financial instruments, and cash flows are immaterial, although the actual effects may differ materially from the hypothetical analysis.

**ITEM 4T. CONTROLS AND PROCEDURES**

(a) *Evaluation of Disclosure Controls and Procedures.* Our management, with the participation of our Chief Executive Officer and our Interim Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2007. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and



**Table of Contents**

procedures as of September 30, 2007, our Chief Executive Officer and Interim Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(b) *Changes in Internal Controls*. No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act) occurred during the fiscal quarter ended September 30, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents**

**IDERA PHARMACEUTICALS, INC.  
PART II OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS.**

We are not aware of any current or pending litigation to which we are or may be a party that we believe could materially adversely affect our results of operations or financial condition or net cash flows.

**ITEM 1A. RISK FACTORS.**

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

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

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

We have incurred losses in every year since our inception, except for 2002 when our recognition of revenues under a license and collaboration agreement resulted in us reporting net income for that year. As of September 30, 2007, we had an accumulated deficit of \$338.2 million. We have incurred losses of \$78.0 million since January 1, 2001. We also incurred losses of \$260.2 million prior to December 31, 2000 during which time we were involved in the development of antisense technology. We expect to continue to incur substantial operating losses in future periods. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital.

We have never had any products of our own available for commercial sale and have received no revenues from the sale of drugs. To date, almost all of our revenues have been from collaborative and license agreements. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any drugs. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our products will become commercially available, or when we will become profitable, if at all. We expect to continue to incur significant and increasing operating losses for at least the next several years. We anticipate that our expenses will increase as we continue the clinical development of IMO-2055 and IMO-2125.

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

We will require substantial funds to conduct research and development, including preclinical testing and clinical trials of our product candidates. We will also require substantial funds to conduct regulatory activities and to establish commercial manufacturing, marketing and sales capabilities. We believe that, based on our current operating plan, our existing cash, cash equivalents and short-term investments, will be sufficient to fund our operations at least through December 31, 2008.

We will need to raise additional funds to operate our business beyond such time, including completing any on-going clinical trials involving IMO-2055 or IMO-2125. We believe that the key factors that will affect our ability to obtain additional funding are:

the success of our clinical and preclinical development programs;

the success of our existing strategic collaborations with Novartis and Merck;

**Table of Contents**

the cost, timing and outcome of regulatory reviews;

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

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

If we cannot obtain adequate funds, we may terminate, modify or delay preclinical or clinical trials of one or more of our product candidates, fail to establish or delay the establishment of manufacturing, sale or marketing capabilities, or curtail research and development programs for new product candidates.

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

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

***We are depending heavily on the success of our lead product candidates, IMO-2055 and IMO-2125, which are in clinical development. If we are unable to successfully develop and commercialize these products, or experience significant delays in doing so, our business will be materially harmed.***

We are investing a significant portion of our time and financial resources in the development of our lead product candidates, IMO-2055 and IMO-2125. We anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of one or both of these products. The commercial success of these products will depend on several factors, including the following:

acceptable safety profile during clinical trials;

demonstration of statistically recognized efficacy in clinical trials;

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

establishment of commercial manufacturing arrangements with third-party manufacturers;

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

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

competition from other companies and their therapies;

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

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



## **Table of Contents**

Our efforts to commercialize these products are at an early stage, as we are currently conducting Phase 1 and Phase 2 clinical trials of these products in defined patient populations. If we are not successful in commercializing these products, or are significantly delayed in doing so, our business will be materially harmed. ***If our clinical trials are unsuccessful, or if they are delayed or terminated, we may not be able to develop and commercialize our products.***

In order to obtain regulatory approvals for the commercial sale of our products, we are required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of our product candidates. Clinical trials are lengthy, complex and expensive processes with uncertain results. We may not be able to complete any clinical trial of a potential product within any specified time period. Moreover, clinical trials may not show our potential products to be both safe and efficacious. The FDA and other regulatory authorities may not approve any of our potential products for any indication. We may not be able to obtain authority from the FDA or other equivalent foreign regulatory agencies to complete these trials or commence and complete any other clinical trials.

The results from preclinical testing of a product 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. For example in June 2007, Coley Pharmaceutical Group, Inc. announced that its partner, Pfizer Inc., had discontinued four clinical trials in lung cancer for PF-3512676, its investigational TLR9 agonist compound, in combination with cytotoxic chemotherapy. This discontinuation included two Phase 3 clinical trials and two Phase 2 clinical trials. In addition, in January 2007, Coley Pharmaceuticals Group, Inc. announced that it had suspended its development of a TLR9 agonist, Actilon<sup>®</sup>, for hepatitis C. In addition, in July 2007, Anadys Pharmaceuticals, Inc. and its partner Novartis announced that they had decided to discontinue the development of ANA975, the investigational TLR7 agonist compound that was previously evaluated in a Phase 1b trial for the treatment of hepatitis C virus infection. The parties determined that the results of preclinical toxicology studies do not support further clinical evaluation of chronic daily dosing of ANA975 in hepatitis C patients.

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

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

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

- our preclinical 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 preclinical 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 less than expected;

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

- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements, including any issues identified through inspections of manufacturing or clinical trial operations or clinical trial sites;



**Table of Contents**

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

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

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

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

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

The rate of completion of clinical trials is dependent in part upon the rate of enrollment of patients. For example, in the first stage of our Phase 2 trial of IMO-2055 in renal cell cancer, enrollment was slower than projected due to the recent approval of two new therapies developed by other companies, Sutent® and Nexavar®, for treatment of the same patient populations and as a result we closed enrollment of the trial in June 2007. Patient accrual is a function of many factors, including:

the size of the patient population,

the proximity of patients to clinical sites,

the eligibility criteria for the study,

the nature of the study,

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 product candidates and our collaborators' product candidates will require preclinical and other nonclinical testing and extensive clinical trials prior to submission of any regulatory application for commercial sales. We recently closed enrollment in two clinical trials with IMO-2055 in oncology and commenced a clinical trial of IMO-2125 for chronic hepatitis C virus infection in the third quarter of 2007. We plan to commence new clinical trials of IMO-2055 in oncology in the fourth quarter of 2007 and the first quarter of 2008. In conducting clinical trials, we cannot be certain that any planned clinical trial will begin on time, if at all. Delays in commencing clinical trials of potential products could increase our product development costs, delay any potential revenues and reduce the probability that a potential product will receive regulatory approval.

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

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



**Table of Contents**

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

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

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

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

obtaining institutional review board approval for conducting a clinical trial at a prospective site; and

enrolling patients in order to commence the clinical trial.

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

The product candidates that we are developing are based upon technologies or therapeutic approaches that are relatively new and unproven. We have focused our efforts on the research and development of RNA- and DNA-based compounds targeted to TLRs. Neither we nor any other company have obtained regulatory approval to market such compounds as therapeutic drugs, and no such products currently are being marketed. It is unknown whether the results of preclinical studies with TLR-targeted compounds will be indicative of results that may be obtained in clinical trials, and results we have obtained in the initial small-scale clinical trials we have conducted to date may not be predictive of results in subsequent large-scale trials. Further, the chemical and pharmacological properties of RNA- and DNA-based compounds targeted to TLRs may not be fully recognized in preclinical and small-scale clinical trials, and such compounds may interact with human biological systems in unforeseen, ineffective, or harmful ways that we have not yet identified. As a result of these factors, we may never succeed in obtaining a regulatory approval to market any product. Furthermore, the commercial success of any of our products for which we may obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance by the medical community and third party payors as clinically useful, cost-effective and safe. In addition, if products based upon TLR technology being developed by our competitors have negative clinical trial results or otherwise are viewed negatively, the perception of our TLR technology and market acceptance of our products could be impacted negatively. For example, we are pursuing an indication for treatment of chronic hepatitis C virus infection for IMO-2125 and commenced a Phase 1 clinical trial of IMO-2125 in patients with chronic hepatitis C virus infection in the third quarter of 2007. Coley Pharmaceutical Group, Inc. and Anadys Pharmaceuticals, Inc. have performed early clinical trials of immune stimulatory compounds for the treatment of hepatitis C, and both programs have been discontinued. We cannot be certain whether such actions will negatively impact the perception of our TLR technology.

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

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

The biotechnology industry is highly competitive and characterized by rapid and significant technological change. We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies. Some of these organizations are pursuing products based on technologies similar to our technologies. Other of these organizations have developed and are marketing products, or are pursuing other technological approaches designed to produce products, that are competitive with our product candidates in the therapeutic effect these competitive products have on diseases targeted by our product candidates. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than any that we are developing. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. As examples, the FDA recently

approved drugs developed by other companies, Sutent<sup>®</sup> and Nexavar<sup>®</sup>, for use in

## **Table of Contents**

renal cell cancer, which is the indication for which we are evaluating IMO-2055 monotherapy in our Phase 2 trial. Pfizer Inc., in collaboration with Coley has two clinical trials on-going with a TLR9 agonist for treating cancer. In addition, Dynavax has announced initiation of a clinical trial for its TLR9 agonist for cancer.

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

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

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

Our success is highly dependent on the retention of principal members of our technical and management staff, including Dr. Sudhir Agrawal and Dr. Robert Karr. Dr. Agrawal serves as our Chief Executive Officer and Chief Scientific Officer. Dr. Karr serves as our President. Dr. Agrawal has made significant contributions to the field of antisense technology, and has led the development of our compounds targeted to TLRs. He is named as an inventor on over 380 patents and patent applications worldwide. Dr. Karr has extensive experience in the pharmaceutical industry. Drs. Agrawal and Karr provide us leadership for management, research and development activities. The loss of either Dr. Agrawal's or Dr. Karr's services would be detrimental to our ongoing scientific progress and the execution of our business plan.

We are a party to an employment agreement with Dr. Agrawal that expires on October 19, 2010, but may be renewed for additional one-year terms. This agreement may be terminated by us or Dr. Agrawal for any reason or no reason at any time upon notice to the other party. We do not carry key man life insurance for Dr. Agrawal.

We are a party to an employment agreement with Dr. Karr that expires on December 5, 2008, but may be renewed for additional one-year terms. This agreement may be terminated by us or Dr. Karr for any reason or no reason at any time upon notice to the other party. We do not carry key man life insurance for Dr. Karr.

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

### **Regulatory Risks**

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

All of the products that we are developing or may develop in the future will require additional research and development, extensive preclinical studies and clinical trials and regulatory approval prior to any commercial sales. This process is lengthy, often taking a number of years, is uncertain and is expensive. Since our inception, we have conducted clinical trials of a number of compounds. Currently, we are conducting clinical trials of IMO-2055 and IMO-2125.

We may need to address a number of technological challenges in order to complete development of our products. Moreover, these products may not be effective in treating any disease or may prove to have undesirable or

## **Table of Contents**

unintended side effects, unintended alteration of the immune system over time, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

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

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

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

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

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

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

restrictions on our products or the manufacturing of our products;

withdrawal of our products from the market;

warning letters;

voluntary or mandatory recall;

finest;

suspension or withdrawal of regulatory approvals;

product seizure;

refusal to permit the import or export of our products;

injunctions or the imposition of civil penalties; and

criminal penalties.

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

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

**Table of Contents**

**Risks Relating to Collaborators**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

An important element of our business strategy includes entering into strategic collaborations with corporate collaborators, primarily large pharmaceutical companies, for the development, commercialization, marketing and distribution of some of our product candidates. In May 2005, we entered into a collaborative arrangement with Novartis involving our TLR9 agonists for application in asthma and allergies. In December 2006, we entered into a





**Table of Contents**

collaborative agreement with Merck involving our TLR7, 8 and 9 agonists for application in vaccine products for oncology, infectious diseases and Alzheimer's disease. The failure of these collaborative relationships or any others we enter into in the future could delay our drug development or impair commercialization of our products and could materially harm our business and might accelerate our need for additional capital.

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

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

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

we may have difficulty enforcing the contracts if one of our collaborators fails to perform;

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

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

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

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

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

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

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

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

**Risks Relating to Intellectual Property**

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

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



**Table of Contents**

obtain patents;

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

operate without infringing upon the proprietary rights of others;

prevent others from infringing on our proprietary rights; and

protect trade secrets.

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

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

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

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

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

We are party to five royalty-bearing license agreements in the field of antisense technology under which we have acquired rights to patents, patent applications and technology of third parties. Under these licenses we are obligated to pay royalties on net sales by us of products or processes covered by a valid claim of a patent or patent application licensed to us. We also are required in some cases to pay a specified percentage of any sublicense income that we may receive. These licenses impose various commercialization, sublicensing, insurance and other obligations on us.

Our failure to comply with these requirements could result in termination of the licenses. These licenses generally will otherwise remain in effect until the expiration of all valid claims of the patents covered by such licenses or upon earlier termination by the parties. The issued patents covered by these licenses expire at various dates ranging from 2010 to 2022. If one or more of these licenses is terminated, we may be delayed in our efforts, or be unable, to develop and market the products that are covered by the applicable license or licenses.

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

## **Table of Contents**

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

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

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

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

*Because we have limited manufacturing experience, facilities or infrastructure, we are dependent on third-party manufacturers to manufacture products for us. If we cannot rely on third-party manufacturers, we will be required to incur significant costs and devote significant efforts to establish our own manufacturing facilities and capabilities.*

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

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

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

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

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

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

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

**Table of Contents**

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

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

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

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

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

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

We do not have the ability to independently conduct the clinical trials required to obtain regulatory approval for our products. We depend on independent clinical investigators, contract research organizations and other third party service providers in the conduct of the clinical trials of our products and expect to continue to do so. We have contracted with contract research organizations to manage all of our current clinical trials of IMO-2055 and IMO-2125. We rely heavily on these parties for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our products. If we seek to conduct any of these activities ourselves in the future, we will need to recruit appropriately trained personnel and add to our infrastructure.

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

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



**Table of Contents**

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

the efficacy and potential advantages over alternative treatments;

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

relative convenience and ease of administration;

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

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

publicity concerning our products or competing products and treatments.

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

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

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

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

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

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

Our business exposes us to the risk of product liability claims that is inherent in the manufacturing, testing and marketing of human therapeutic drugs. We face an inherent risk of product liability exposure related to the testing of



**Table of Contents**

our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products. Regardless of merit or eventual outcome, liability claims and product recalls may result in:

decreased demand for our product candidates and products;

damage to our reputation;

regulatory investigations that could require costly recalls or product modifications;

withdrawal of clinical trial participants;

costs to defend related litigation;

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

loss of revenue;

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

the inability to commercialize any products that we may develop.

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

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

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

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

a classified board of directors,

limitations on the removal of directors,

limitations on stockholder proposals at meetings of stockholders,

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

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

**Table of Contents**

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

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

Our stock price has been volatile. During the period from January 1, 2006 to October 31, 2007, the closing sales price of our common stock, as adjusted to reflect the one-for-eight reverse split of our common stock effected on June 29, 2006, ranged from a high of \$12.20 per share to a low of \$2.36 per share. The stock market has also experienced significant price and volume fluctuations, and the market prices of biotechnology companies in particular have been highly volatile, often for reasons that have been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

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

the regulatory status of our product candidates;

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

the success of competitive products or technologies;

regulatory developments in the United States and foreign countries;

our success in entering into collaborative agreements;

developments or disputes concerning patents or other proprietary rights;

the departure of key personnel;

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

our cash resources;

the terms of any financing conducted by us;

changes in the structure of healthcare payment systems;

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

general economic, industry and market conditions.

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

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

stock and the risk that the value of their investment in our stock could decline.

**Table of Contents**

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES.**

None.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.**

None.

**ITEM 5. OTHER INFORMATION.**

None.

**ITEM 6. EXHIBITS.**

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

**SIGNATURES**

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

**IDERA PHARMACEUTICALS, INC**

Date: November 9, 2007

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

Date: November 9, 2007

/s/ Donna A. Lopolito  
Donna A. Lopolito  
Interim Chief Financial Officer (Principal  
Financial and Accounting Officer)

**Table of Contents**

**Exhibit Index**

**Exhibit No.**

- 31.1 Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Interim Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Interim Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

38