

IDERA PHARMACEUTICALS, INC.

Form 10-Q

May 14, 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 March 31, 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.)*

**345 Vassar 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**

**21,253,492**

Class

Outstanding as of April 30, 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 Balance Sheets as of March 31, 2007 and December 31, 2006</u>	4
<u>Unaudited Statements of Operations for the Three Months ended March 31, 2007 and 2006</u>	5
<u>Unaudited Statements of Cash Flows for the Three Months ended March 31, 2007 and 2006</u>	6
<u>Notes to 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>	19
<u>Item 4T Controls and Procedures</u>	20
<b><u>PART II OTHER INFORMATION</u></b>	21
<u>Item 1A. Risk Factors</u>	21
<u>Item 6 Exhibits</u>	36
<u>Signatures</u>	36
<u>EX-31.1 Section 302 Certification of CEO</u>	
<u>EX-31.2 Section 302 Certification of CFO</u>	
<u>EX-32.1 Section 906 Certification of CEO</u>	
<u>EX-32.2 Section 906 Certification of CFO</u>	

IMO<sup>tm</sup> is our trademark. Idera<sup>®</sup> is our registered trademark. 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, projects, will, and would and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth below under Part II, Item 1A Risk Factors. These factors and the other cautionary statements made in this quarterly report 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.  
BALANCE SHEETS**

<b>(in thousands, except per share amounts)</b>	<b>March 31, 2007 (unaudited)</b>	<b>December 31, 2006</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 3,482	\$ 24,596
Short-term investments	30,026	13,591
Receivables	1,572	398
Prepaid expenses and other current assets	466	417
 Total current assets	 35,546	 39,002
Property and equipment, net	1,433	622
Deferred financing costs		298
Restricted cash	619	619
 Total assets	 \$ 37,598	 \$ 40,541
 <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,010	\$ 1,155
Accrued expenses	921	864
Current portion of capital lease	7	7
Current portion of deferred revenue	6,631	5,992
 Total current liabilities	 8,569	 8,018
 Long term 4% convertible notes payable		 5,033
Capital lease obligation, excluding current portion	2	3
Deferred revenue, net of current portion	13,918	15,250
 Total liabilities	 22,489	 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		

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

Issued and outstanding	21,203 and 20,458 shares at March 31, 2007 and December 31, 2006, respectively	21	20
Additional paid-in capital		347,150	341,743
Accumulated deficit		(332,054)	(329,526)
Accumulated other comprehensive loss		(8)	
Total stockholders' equity		15,109	12,237
Total liabilities and stockholders' equity		\$ 37,598	\$ 40,541

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

4

---

**Table of Contents**

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

<b>(in thousands, except per share amounts)</b>	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2007</b>	<b>2006</b>
Alliance revenue	\$ 1,829	\$ 636
Operating expenses:		
Research and development	2,819	2,985
General and administrative	1,953	1,268
Total operating expenses	4,772	4,253
Loss from operations	(2,943)	(3,617)
Other income (expense):		
Investment income, net	477	73
Interest expense	(62)	(106)
Net loss	\$ (2,528)	\$ (3,650)
Basic and diluted net loss per share (Note 5)	\$ (0.12)	\$ (0.26)
Shares used in computing basic and diluted loss per common share	20,787	14,154

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

**Table of Contents**

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

(in thousands)	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>Cash Flows From Operating Activities:</b>		
Net loss	\$ (2,528)	\$ (3,650)
Adjustments to reconcile net loss to net cash used in operating activities -		
Gain on disposal of property and equipment	(3)	
Stock-based compensation	435	247
Depreciation and amortization	86	109
Issuance of common stock for services rendered	14	3
Non-cash interest expense		50
Changes in operating assets and liabilities -		
Accounts receivable	(174)	(7)
Prepaid expenses and other current assets	(49)	(52)
Accounts payable and accrued expenses	(88)	485
Deferred revenue	(1,693)	(551)
Net cash used in operating activities	(4,000)	(3,366)
<b>Cash Flows From Investing Activities:</b>		
Purchase of available-for-sale securities	(26,206)	(1,990)
Proceeds from sale of available-for-sale securities	8,275	600
Proceeds from maturity of available-for-sale securities	1,500	3,200
Purchase of property and equipment	(874)	(5)
Net cash (used in) provided by investing activities	(17,305)	1,805
<b>Cash Flow From Financing Activities:</b>		
Sale of common stock and warrants, net of issuance costs		8,122
Proceeds from exercise of common stock options and warrants and employee stock purchases	192	69
Payments on capital lease	(1)	(2)
Net cash provided by financing activities	191	8,189
Net (decrease) increase in cash and cash equivalents	(21,114)	6,628
Cash and cash equivalents, beginning of period	24,596	985
Cash and cash equivalents, end of period	\$ 3,482	\$ 7,613
<b>Supplemental disclosure of non-cash financing and investing activities:</b>		
Issuance of common stock for services rendered	\$ 14	\$ 3
Automatic conversion of 4% convertible subordinated notes into common stock	\$ 5,033	\$



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

**Table of Contents**

**IDERA PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
**MARCH 31, 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/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 is currently conducting a Phase 2 trial of IMO-2055 in oncology and a Phase 1/2 trial of IMO-2055 in combination with chemotherapy in oncology. The Company has selected a second TLR9 agonist, IMO-2125, as a lead product candidate for treating infectious diseases and recently submitted an Investigational New Drug application, or IND, to the U.S. Food and Drug Administration, or FDA, for this product candidate. 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 TLR9 agonists for the treatment of asthma/allergy indications and 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.

The Company has incurred operating losses in all fiscal years except 2002 and had an accumulated deficit of \$332.1 million at March 31, 2007. 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 a number of 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 no 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**

(2) Unaudited Interim Financial Statements

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

At the close of business on June 29, 2006, the Company effected a one-for-eight reverse stock split of its issued and outstanding common stock and fixed the number of authorized shares of its common stock at 40,000,000. As a result of the reverse stock split, each share of common stock outstanding at the close of business on June 29, 2006 automatically converted into one-eighth of one share of common stock. All share and per share information herein reflects this reverse stock split. The reverse stock split did not alter the par value of the common stock, which is \$0.001 per share, or modify any voting rights or other terms of the common stock.

(5) 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 months ended March 31, 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 7,475,086 and 8,085,338 for the three months ended March 31, 2007 and 2006, respectively, and consist of stock options, warrants and convertible preferred stock. Antidilutive securities for the three months ended March 31, 2006 also includes convertible debt instruments on an as-converted basis. Net loss is the same as net loss applicable to common stockholders for the three months ended March 31, 2007 and 2006.

(6) 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 March 31, 2007 and December 31, 2006 consisted of cash and money market funds. On March 31, 2007, certain certificates of deposit 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 positive intent to hold to maturity are classified as

**Table of Contents**

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 loss on the accompanying balance sheets. The amortization of premiums and accretion of discounts, and any realized gains and losses and declines in value judged to be other than temporary, and interest and dividends for all available-for-sale securities are included in Investment income, net on the accompanying statements of operations. The Company had no held-to-maturity investments, as defined by SFAS No. 115, at March 31, 2007 and December 31, 2006. The cost of securities sold is based on the specific identification method.

The Company had no realized gains or losses for the three-months ended March 31, 2007 and 2006. There were no losses or permanent declines in value included in investment income for any securities in the three months ended March 31, 2007 and 2006.

The Company had no long-term investments as of March 31, 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 March 31, 2007 and December 31, 2006:

<b>(in thousands)</b>	<b>March 31, 2007</b>	<b>December 31, 2006</b>
Certificates of deposit	\$ 5,501	\$ 300
Corporate bonds due in one year or less	1,674	301
Government bonds due in one year or less	8,460	1,595
Government bonds - long term	2,772	
Auction securities	10,620	11,395
Foreign bonds - long term	999	
<b>Total</b>	<b>\$ 30,026</b>	<b>\$ 13,591</b>

**(7) Property and Equipment**

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

<b>(in thousands)</b>	<b>March 31, 2007</b>	<b>December 31, 2006</b>
Leasehold improvements	\$ 598	\$ 444
Laboratory equipment and other	2,848	2,175
<b>Total property and equipment, at cost</b>	<b>3,446</b>	<b>2,619</b>
Less: Accumulated depreciation and amortization	2,013	1,997
<b>Property and equipment, net</b>	<b>\$ 1,433</b>	<b>\$ 622</b>

As of March 31, 2007 and December 31, 2006, laboratory equipment and other includes approximately \$20,000 of office equipment financed under a capital lease with total accumulated depreciation of approximately \$7,000 and \$6,000, respectively. Depreciation expense, which includes amortization of assets recorded under capital leases, was approximately \$66,000 and \$51,000 for the three months ended March 31, 2007 and 2006, respectively. In the first quarter of 2007, the Company wrote off unused property and equipment that had a cost of approximately \$49,000 resulting in a gain of approximately \$3,000.

(8) Restricted Cash

As part of a new operating lease, which is expected to commence in the second quarter of 2007, the Company was required to restrict approximately \$620,000 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

**Table of Contents**

\$103,000 upon each of the second, third and fourth anniversaries of the commencement date, subject to certain conditions.

**(9) 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 at the date of grant. The Company's policy is to charge the fair value of stock options as an expense on a straight-line basis over the vesting period. The Company included charges of \$345,000 and \$247,000 in its statements of operations for the three months ended March 31, 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 options 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 option 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 options granted for the three months ended March 31, 2007 and 2006:

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
Average risk free interest rate	4.7%	4.3%
Expected dividend yield		
Expected lives	6 years	6 years
Expected volatility	70.6%	90.7%
Weighted average grant date fair value of options granted during the period (per share)	\$ 4.91	\$ 3.67

**(10) Related Party Transactions**

In the three months ended March 31, 2006 and in connection with the purchase commitment described in Note (12), the Company agreed to pay \$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. The Company paid approximately \$263,000 of this amount during the first quarter of 2006. In the three months ended March 31, 2006, the Company paid another director of the Company \$5,000 for consulting services.

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

The following table includes the components of comprehensive income (loss) for the three months ended March 31, 2007 and 2006.

<b>(in thousands)</b>	<b>March 31, 2007</b>	<b>March 31, 2006</b>
Net loss	\$ (2,528)	\$ (3,650)
Other comprehensive (loss) income	(8)	11
Total comprehensive loss	\$ (2,536)	\$ (3,639)

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

**Table of Contents****(12) 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.

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 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.

**(13) 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 were paid approximately \$61,000, which represented 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 was reclassified to additional paid-in-capital in connection with the automatic conversion of the 4% Notes.

**(14) 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 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

**Table of Contents**

result of such extension, Novartis paid the Company an additional \$1.0 million in May 2007. In connection with this extension, the Company extended the time period over which it is amortizing the upfront payment.



**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/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 are currently conducting a Phase 2 trial of IMO-2055 in oncology and a Phase 1/2 trial of IMO-2055 in combination with chemotherapy in oncology. We have selected a second TLR9 agonist, IMO-2125, as a lead product candidate for treating infectious diseases and recently submitted an Investigational New Drug application, or IND, to the U.S. Food and Drug Administration, or FDA, for this product candidate. 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 TLR9 agonists for the treatment of asthma/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.

As of March 31, 2007, we had an accumulated deficit of \$332.1 million. 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. In 2007, we expect that our research and development expenses will be higher than our research and development expenses in 2006 as we commence new clinical trials of IMO-2055 and, subject to our IMO-2125 IND becoming effective, begin clinical trials of IMO-2125.

**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.

**Table of Contents**

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, 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 Months Ended March 31, 2007 and 2006***Revenue*

Total alliance revenue increased by \$1,193,000, or 188%, from \$636,000 for the three months ended March 31, 2006 to \$1,829,000 for the three months ended March 31, 2007. This increase was primarily due to license fees we recognized under our collaboration agreement with Merck, which we entered into in December 2006. We are recognizing the \$20.0 million upfront payment we received from Merck in December 2006 over the expected research term under the collaboration agreement. As a result, we recognized \$1.3 million of the upfront payment from Merck as revenue in the first quarter of 2007. In February 2007, Novartis elected to extend our research collaboration with them by an additional year. As a result of such extension, Novartis paid us an additional \$1.0 million in May 2007. In connection with this extension, we extended the time period over which we are amortizing the \$4.0 million upfront payment received from Novartis in 2005. Under our Novartis research collaboration, we recognized \$0.3 million as revenue in the first quarter of 2007 and \$0.5 million as revenue in the first quarter of 2006.

Our revenues for both periods were comprised of revenue earned under various collaboration and licensing agreements for research and development, including reimbursement of internal and third-party expenses, and license fees, sublicense fees, and royalty payments.

*Research and Development Expenses*

Research and development expenses decreased by \$166,000, or 6%, from \$2,985,000 for the three months ended March 31, 2006 to \$2,819,000 for the three months ended March 31, 2007. The decrease in research and development expenses from March 31, 2006 to March 31, 2007 was primarily due to decreased clinical costs associated with IMO-2055 and decreased IND-enabling safety study costs associated with IMO-2125. These decreased expenses were offset, in part, by increased manufacturing costs associated with IMO-2125, higher payroll costs associated with the addition of employees, and increased stock-based compensation.

	<b>Three Months Ended March 31, (In thousands)</b>		<b>Percentage Increase (Decrease)</b>
	<b>2007</b>	<b>2006</b>	
IMO-2055 External Development Expense	\$ 375	\$ 993	(62%)
Other Drug Development Expense	1,183	964	23%
Basic Discovery Expense	1,261	1,028	23%
Total Research and Development Expense	\$ 2,819	\$ 2,985	(6%)

In 2006, we included patent related costs in research and development expenses but have reclassified them to general and administrative expenses for all periods displayed above. In the preceding table, research and development expense is set forth in the following three categories:

*IMO-2055 External Development Expenses.* These expenses include external expenses that we have incurred in

**Table of Contents**

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 trials and studies 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 \$11.0 million in external expenses in connection with IMO-2055. The decrease in IMO-2055 development expenses in the first quarter of 2007 compared to the first quarter of 2006 was primarily attributable to lower Phase 2 trial expenses as we approached full enrollment of our Phase 2 clinical trial and slower enrollment due to the recent approval of two new therapies developed by other companies for treatment of the same patient populations and to a decrease in non-clinical studies of IMO-2055. These decreases were partially offset by an increase in expenses associated with the Phase 1/2 clinical trial initiated in October 2005.

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. The trial is a two-stage, multi-center, open label study of IMO-2055. Under the protocol for the trial, we are seeking to enroll a total of up to 92 patients in the first stage of the trial, 46 who have failed one prior therapy and 46 who are treatment-naïve. We have completed enrollment of the 46 treatment-naïve patients and enrolled 44 patients out of the target of 46 patients who have failed one prior therapy. We have informed investigators that we will cease enrollment in this trial on June 29, 2007 or earlier if the remaining two patients are recruited prior to that date. 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 such time as all patients have ceased to receive treatment in the trial.

In October 2005, we initiated a Phase 1/2 clinical trial of IMO-2055 in combination with the chemotherapy agents gemcitabine and carboplatin. We are seeking to enroll up to 26 refractory solid tumor patients in the Phase 1 portion of the trial to evaluate the safety of the combination. As of May 4, 2007, we had enrolled 20 patients in the trial and we expect to complete enrollment in the second quarter of 2007. We expect to announce initial results of the Phase 1 portion of this study by the end of 2007.

We plan to initiate additional studies with IMO-2055 in combination with approved, targeted anti-cancer agents. We intend to initiate clinical trials to investigate IMO-2055 in combination with Tarceva<sup>®</sup> and in triple combination with Tarceva<sup>®</sup> and Avastin<sup>®</sup> in patients with non-small cell lung cancer who have failed one prior therapy. We expect to initiate a Phase 1b trial to assess the safety of the combinations in the third quarter of 2007 and, following an analysis of the results of the Phase 1b trial, to conduct a four-arm randomized, placebo controlled Phase 2 trial of the combinations. We are currently discussing the protocols for both trials with the FDA.

We also plan to initiate clinical trials to investigate IMO-2055 in combination with Erbitux<sup>®</sup> and Camptosar<sup>®</sup> in patients with colorectal cancer who have failed one prior therapy. We expect to initiate a Phase 1b trial to assess safety of this combination in the fourth quarter of 2007 and, following an analysis of the results of the Phase 1b trial, to conduct a randomized, placebo controlled Phase 2 trial of the combination. We plan to discuss the protocols for both trials with the FDA.

*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, payroll and overhead.

For the three months ended March 31, 2007 and 2006, our direct external expenses related to IMO-2125 were approximately \$266,000 and \$254,000, respectively. The increase in other drug development expenses in the first quarter of 2007 compared with the first quarter of 2006 was primarily attributable to manufacturing of IMO-2125 offset by a decrease in IND-enabling safety study costs associated with IMO-2125. We recently submitted an IND

**Table of Contents**

application for IMO-2125 and plan to initiate a Phase 1 trial in hepatitis C patients in the second half of 2007. We have formed a Hepatitis C Clinical Advisory Board, consisting of experienced hepatitis C investigators, which has been advising us on the development of IMO-2125 in hepatitis C. The increase in other drug development expenses was also attributable to an increase in compensation costs as a result of hiring additional employees and higher stock based compensation expense.

*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. The increase in these expenses in the first quarter of 2007 compared to the first quarter of 2006 was primarily attributable to an increase in payroll expenses as we began work under our Merck collaboration and an increase in expenses for laboratory supplies.

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, without knowing the results of our ongoing clinical trials of IMO-2055 and, without having finalized the protocols for future clinical tests 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 \$685,000, or 54%, from \$1,268,000 in the three months ended March 31, 2006 to \$1,953,000 in the three months ended March 31, 2007. General and administrative expenses consisted primarily of salary expense, stock compensation expense, consulting fees and professional legal fees associated with our patent applications and maintenance, our regulatory filing requirements, and our business development initiatives.

The increase in general and administrative expenses from March 31, 2006 to March 31, 2007 was primarily due to increased professional fees associated with marketing research and legal services. The increase also reflects higher payroll expenses associated with a higher number of non-research employees and higher compensation expense related to employee and consultant stock options. These increased expenses were offset, in part, by lower patent preparation costs resulting from a consolidation of our patent portfolio and greater efficiencies in maintaining our patents.

*Investment Income, net*

Investment income increased by approximately \$404,000, or 553%, from \$73,000 in the three months ended March 31, 2006 to \$477,000 in the three months ended March 31, 2007. This increase resulted from higher cash and investment balances in the three months ended March 31, 2007.

*Interest Expense*

Interest expense decreased by approximately \$44,000, or 42%, from \$106,000 in the three months ended March

**Table of Contents**

31, 2006 to \$62,000 in the three months ended March 31, 2007. This decrease resulted from the conversion of all our 4% notes in the aggregate principal amount of approximately \$5,033,000 issued in May 2005 into 706,844 shares of common stock on February 20, 2007. The first quarter of 2006 included a full quarter 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 \$2,528,000 for the three months ended March 31, 2007 compared to \$3,650,000 for the three months ended March 31, 2006. We have incurred losses of \$71.9 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 had an accumulated deficit of \$332.1 million through March 31, 2007. We expect to continue to incur substantial operating losses in the future.

**LIQUIDITY AND CAPITAL RESOURCES**

*Sources of Liquidity*

We require cash to fund our operating expenses, 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 by one year until May 2008 and, in connection with the extension, paid us \$1.0 million in May 2007.

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 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.

In March 2006, we raised approximately \$9.8 million in gross proceeds from a private placement to institutional

**Table of Contents**

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.

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.

*Cash Flows*

As of March 31, 2007, we had approximately \$33.5 million in cash and cash equivalents and investments, a net decrease of approximately \$4.7 million from December 31, 2006. We used \$4.0 million of cash for operating activities during the first quarter of 2007. The \$4.0 million primarily reflects our \$2.5 million net loss for the period, as adjusted for non-cash revenue and expenses, including depreciation and amortization, stock-based compensation, and changes in deferred revenue associated with payments under our collaborative arrangements and our accounts receivable and payable.

The net cash used in investing activities during the first quarter of 2007 of \$17.3 million reflects our purchase of approximately \$26.2 million in securities offset by our sale of \$8.3 million of securities and the proceeds of approximately \$1.5 million from securities that matured in the first quarter of 2007. The net cash used in investing activities also reflects our purchases of laboratory and computer equipment in the first quarter of 2007.

The net cash provided by financing activities during the first quarter of 2007 of \$0.2 million reflects proceeds received from the exercise of stock options and warrants during the first quarter of 2007.

*Funding Requirements*

We have incurred operating losses in all fiscal years except 2002 and had an accumulated deficit of \$332.1 million at March 31, 2007. 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 \$33.5 million at March 31, 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 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

**Table of Contents**

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

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. 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.

*Contractual Obligations*

We have contractual obligations in the form of operating and capital leases.

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

As of March 31, 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.

**Table of Contents**

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 Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 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 procedures as of March 31, 2007, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(b) *Changes in Internal Controls.* No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act) occurred during the fiscal quarter ended March 31, 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 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 March 31, 2007, we had an accumulated deficit of \$332.1 million. 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 commence the clinical development of 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 Phase 2 trials involving IMO-2055. 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;

- the cost, timing and outcome of regulatory reviews;

**Table of Contents**

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 candidate, IMO-2055, which is in clinical development. If we are unable to successfully develop and commercialize this product, 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 candidate, IMO-2055. We anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of this product. The commercial success of this product 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 product, whether alone or in collaboration with others;

acceptance of the product 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 this product are at an early stage, as we are currently conducting a Phase 2 clinical trial in patients with metastatic or recurrent clear cell renal cancer and a Phase 1/2 clinical trial in patients with refractory solid tumors. If we are not successful in commercializing this product, 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. A 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. Furthermore, interim results of a clinical trial do not necessarily predict final results.

There is to date little 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;

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

**Table of Contents**

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 have determined to close enrollment of the trial as of June 29, 2007 if the remaining two patients are not recruited prior to that date. 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 are currently conducting clinical trials with IMO-2055 in oncology and plan to commence clinical trials of IMO-2125 for hepatitis C in 2007. 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;

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;

**Table of Contents**

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 hepatitis C virus for IMO-2125 and have recently submitted an IND for this product candidate. Coley Pharmaceutical Group, or Coley, and Anadys Pharmaceuticals, Inc., have performed early clinical trials of immune stimulatory compounds for the treatment of hepatitis C, and both programs currently are on hold. 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® and Nexavar®, for use in 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 multiple Phase 3 and Phase 2 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.

**Table of Contents**

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 300 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 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, 2009, 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 has an initial term ending on December 5, 2007, and that 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.

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

***We are subject to comprehensive regulatory requirements, which are costly and time consuming to comply with; if***

**Table of Contents**

***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.***

**Table of Contents**

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 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.

**Table of Contents**

**Risks Relating to Intellectual Property**

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

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

obtain patents;

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

operate without infringing upon the proprietary rights of others;

prevent others from infringing on our proprietary rights; and

protect trade secrets.

We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may be issued in the future, or those licensed to us, may be challenged, invalidated or circumvented, and the rights granted thereunder may not provide us proprietary protection or competitive advantages against competitors with similar technology. 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.

**Table of Contents**

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 2007 to 2022. If one or more of these licenses is terminated, we may be delayed in our efforts, or be unable, to develop and market the products that are covered by the applicable license or licenses.

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

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the biotechnology industry. We may become a party to various types of patent litigation or other proceedings regarding intellectual property rights from time to time even under circumstances where we are not practicing and do not intend to practice any of the intellectual property involved in the proceedings. For instance, in 2002, 2003, and 2005, we became involved in interference proceedings declared by the United States Patent and Trademark Office, 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

**Table of Contents**

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;

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. For example, we have contracted with a contract research organization to manage our Phase 2 clinical trial of IMO-2055 in renal cell cancer. 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

## **Table of Contents**

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:

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

**Table of Contents**

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 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***

**Table of Contents**

***consider desirable.***

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

a classified board of directors,

limitations on the removal of directors,

limitations on stockholder proposals at meetings of stockholders,

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

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

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

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

Our stock price has been volatile. During the period from January 1, 2005 to March 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 \$9.45 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;



**Table of Contents**

our cash resources;

the terms of any financing conducted by us;

changes in the structure of healthcare payment systems;

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

general economic, industry and market conditions.

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

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

**ITEM 6. EXHIBITS.**

The list of Exhibits filed as part of this Quarterly Report on Form 10-Q 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: May 14, 2007

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

Date: May 14, 2007

/s/ Robert G. Andersen  
Robert G. Andersen  
Chief Financial Officer and Vice President  
of Operations (Principal Financial and  
Accounting Officer)

36

---

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

37