

IDERA PHARMACEUTICALS, INC.

Form 10-Q

November 13, 2006

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

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

For the quarterly period ended September 30, 2006,

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  
Number)*

**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**

**18,195,614**

Class

Outstanding as of November 7, 2006

**IDERA PHARMACEUTICALS, INC.**  
**FORM 10-Q**  
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Idera, Amplivax, IMO and Targeted Immune Therapy are our trademarks. IMOXIME GEM® are our registered trademarks. All other trademarks and service marks appearing in this quarterly report are the property of their respective owners.

**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 facts, included or incorporated in this report regarding our strategy, future operations, 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 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.

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**PART I FINANCIAL STATEMENTS**  
**ITEM 1. UNAUDITED FINANCIAL STATEMENTS**  
**IDERA PHARMACEUTICALS, INC.**  
**BALANCE SHEETS**  
**(UNAUDITED)**

	<b>SEPTEMBER</b>	<b>PRO FORMA</b>	<b>DECEMBER</b>
	<b>30,</b>	<b>SEPTEMBER</b>	<b>31,</b>
	<b>2006</b>	<b>30,</b>	<b>2005</b>
		<b>2006</b>	
		Note 16	
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 1,764,012	\$ 5,144,461	\$ 984,766
Short-term investments	6,298,087	6,298,087	7,390,903
Receivables	168,922	168,922	175,905
Prepaid expenses and other current assets	373,548	373,548	498,347
Total current assets	8,604,569	11,985,018	9,049,921
Property and equipment, net	365,852	365,852	418,684
Deferred financing costs	353,327	353,327	520,692
Restricted Cash		619,551	
Total Assets	\$ 9,323,748	\$ 13,323,748	\$ 9,989,297
<b>Liabilities and Stockholders Equity</b>			
Current liabilities:			
Accounts payable	\$ 1,126,932	\$ 1,126,932	\$ 536,371
Accrued expenses	1,114,052	1,114,052	1,338,048
Current portion of capital lease	6,519	6,519	6,519
Current portion of deferred revenue	1,502,537	1,502,537	2,171,287
Total current liabilities	3,750,040	3,750,040	4,052,225
Long term 4% convertible notes payable	5,032,750	5,032,750	5,032,750
Capital lease	4,889	4,889	10,321
Deferred revenue, net of current portion	300,464	300,464	1,229,451
Stockholders equity:			
Preferred stock, \$0.01 par value			
Authorized 5,000,000 shares Series A convertible			
preferred stock Designated 1,500,000 shares			
Issued and outstanding 655 shares	7	7	7
Common stock, \$0.001 par value			
Authorized 40,000,000 shares			
Issued and outstanding 17,412,328, 18,193,578			
and 13,927,631 shares at September 30, 2006			
actual, September 30, 2006 pro forma and			
December 31, 2005 actual, respectively	17,412	18,194	13,928
Additional paid-in capital	325,015,277	329,014,495	312,729,992
Accumulated deficit	(324,797,017)	(324,797,017)	(313,000,200)

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Accumulated other comprehensive loss	(74)	(74)	(11,341)
Deferred compensation			(67,836)
Total stockholders' equity (deficit)	235,605	4,235,605	(335,450)
Total Liabilities and Stockholders' Equity (Deficit)	\$ 9,323,748	\$ 13,323,748	\$ 9,989,297

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

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

	<b>THREE MONTHS ENDED</b>		<b>NINE MONTHS ENDED</b>	
	<b>SEPTEMBER 30,</b>		<b>SEPTEMBER 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Alliance revenue	\$ 572,144	\$ 544,778	\$ 1,829,523	\$ 1,027,528
Operating expenses:				
Research and development	3,008,696	2,260,584	9,659,283	7,182,326
General and administrative	1,395,497	1,232,920	3,975,003	3,781,934
Total operating expenses	4,404,193	3,493,504	13,634,286	10,964,260
Loss from operations	(3,832,049)	(2,948,726)	(11,804,763)	(9,936,732)
Other income (expense):				
Investment income, net	119,676	106,793	326,373	257,088
Interest expense	(106,529)	(107,816)	(317,935)	(145,533)
Net loss	(3,818,902)	(2,949,749)	(11,796,325)	(9,825,177)
Accretion of preferred stock dividends	(164)	(164)	(492)	(492)
Net loss applicable to common stockholders	\$ (3,819,066)	\$ (2,949,913)	\$ (11,796,817)	\$ (9,825,669)
Basic and diluted net loss per share (Note 5)	\$ (0.22)	\$ (0.21)	\$ (0.74)	\$ (0.71)
Basic and diluted net loss per share applicable to common stockholders (Note 5)	\$ (0.22)	\$ (0.21)	\$ (0.74)	\$ (0.71)
Shares used in computing basic and diluted loss per common share (see Note 4 regarding the reverse stock split)	17,222,795	13,889,380	16,043,086	13,880,346

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

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

	<b>NINE MONTHS ENDED</b>	
	<b>SEPTEMBER 30,</b>	
	<b>2006</b>	<b>2005</b>
<b>Cash Flows From Operating Activities:</b>		
Net loss	\$ (11,796,325)	\$ (9,825,177)
Adjustments to reconcile net loss to net cash used in operating activities		
Loss on disposal of property and equipment		2,134
Stock-based compensation	696,576	149,236
Depreciation and amortization expense	283,266	212,652
Issuance of common stock for services rendered	18,824	27,352
Non-cash interest expense	84,385	71,148
Changes in operating assets and liabilities		
Accounts receivable	6,983	117,833
Prepaid expenses and other current assets	124,799	(412,168)
Accounts payable and accrued expenses	282,179	(382,767)
Deferred revenue	(1,597,737)	3,256,430
Net cash used in operating activities	(11,897,050)	(6,783,327)
<b>Cash Flows From Investing Activities:</b>		
Purchase of available for sale securities	(15,746,839)	(9,908,536)
Proceeds from sale of available-for-sale securities	5,545,000	7,600,000
Proceeds from maturity of available-for-sale securities	11,325,000	5,000,000
Purchase of property and equipment	(82,146)	(206,512)
Net cash provided by investing activities	1,041,015	2,484,952
<b>Cash Flow From Financing Activities:</b>		
Proceeds from issuance of convertible notes payable		5,032,750
Sale of common stock and warrants, net of issuance costs	11,547,819	
Issuance costs from financing		(386,480)
Payments on capital lease	(5,432)	(1,630)
Proceeds from exercise of common stock options and warrants	92,894	72,348
Net cash provided by financing activities	11,635,281	4,716,988
Net increase in cash and cash equivalents	779,246	418,613
Cash and cash equivalents, beginning of period	984,766	5,021,860
Cash and cash equivalents, end of period	\$ 1,764,012	\$ 5,440,473
<b>Supplemental Disclosure of Non-cash Financing and Investing Activities:</b>		
Issuance of warrants for financing	\$	\$ 219,385

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Deferred compensation relating to issuance of stock options	\$		\$	72,000
Accretion of Series A convertible preferred stock dividends	\$	(492)	\$	(492)
Issuance of stock for services	\$	18,824	\$	27,352
Cash paid for interest	\$	92,106	\$	

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

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**IDERA PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
**SEPTEMBER 30, 2006**  
**(UNAUDITED)**

(1) Organization

Idera Pharmaceuticals, Inc. ( Idera or the Company ) (AMEX: IDP) is a biotechnology company engaged in the discovery and development of novel therapeutics that modulate immune responses through Toll-like Receptors (TLRs) for the treatment of multiple diseases. The Company is developing proprietary DNA- and RNA- based compounds that modulate TLRs and are targeted to TLR7, TLR8 or TLR9. The Company believes that these immune modulatory oligonucleotides, or IMO compounds, are broadly applicable to large and growing markets where significant unmet medical needs exist, including oncology, asthma and allergies, infectious diseases, autoimmune diseases and vaccine adjuvants. The Company's lead drug candidate is IMO-2055, which is also referred to as HYB2055 or IMOXine<sup>®</sup>. IMO-2055 is a synthetic DNA-based compound, which acts as an agonist for TLR9 and triggers the activation and modulation of the immune system. IMO-2055 is currently in a Phase 2 clinical trial as a monotherapy for renal cell carcinoma and a Phase 1/2 clinical trial in combination with chemotherapy agents for solid tumors. The Company has selected another TLR9 agonist, IMO-2125, as a lead compound for development for the treatment of infectious diseases. Idera is also collaborating with Novartis International Pharmaceuticals, Ltd., or Novartis, to develop treatments for asthma and allergies using other of the Company's TLR9 agonist compounds. Idera is also developing a new class of compounds which act as antagonists to TLRs. The Company's IMO compounds targeted to TLR7 and TLR8 and the Company's new class of compounds are in the discovery stage.

Based on its current operating plan, the Company believes that its existing cash, cash equivalents and short-term investments, including the proceeds from its November 2006 sale of common stock, which resulted in \$4.0 million in gross proceeds, will be sufficient to fund operations through June 2007. As more fully described in Note 13(b), in March 2006, the Company secured a purchase commitment from an investor to purchase up to a total of \$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 its discretion, at a minimum price of \$5.12 per share (see Note 13(b) and 16). The Company received \$3.5 million in July 2006 and \$4.0 million in November 2006 in gross proceeds from the sale of common stock under the purchase commitment. If the Company elects to sell the remaining \$2.3 million of its common stock in the remaining drawdown, the Company expects that the proceeds from such sales would enable the Company to pursue its clinical and preclinical development programs and continue operations through August 2007. The Company's actual cash requirements will depend on many factors, including particularly the scope and pace of its research and development efforts and its success in entering into strategic alliances. On June 29, 2006, the Company effected a one-for-eight reverse stock split of its issued and outstanding common stock. All share and per share information herein reflects this reverse stock split.

The Company does not expect to generate significant additional 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 addition, it has no other committed external sources of funds. As a result, in order for the Company to continue to pursue its clinical and preclinical development programs and continue its operations beyond June 2007, or August 2007 if it draws down all of the funds pursuant to the purchase commitment described above, the Company must raise additional funds from debt or equity financings or from collaborative arrangements with biotechnology or pharmaceutical companies. There can be no assurance that the requisite funds will be available in the necessary time frame or on terms acceptable to the Company. If the Company is unable to raise sufficient funds, the Company may be required to delay, scale back or significantly curtail its operating plans and possibly relinquish rights to portions of the Company's technology or products. In addition, increases in expenses or delays in clinical development may adversely impact the Company's cash position and require further cost reductions. No assurance can be given that the Company will be able to operate profitably on a consistent basis, or at all, in the future.

(2) Unaudited Interim Financial Statements

The accompanying unaudited consolidated condensed 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

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rules and regulations. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of interim period results have been included. The Company believes that its disclosures are adequate to make the information presented not misleading. Interim results for the three-month and nine-month periods ended September 30, 2006 are not necessarily indicative of results that may be expected for the year ended December 31, 2006. 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, 2005, which was filed with the Securities and Exchange Commission on March 31, 2006.

**(3) Reclassification and Additional Disclosures**

Prior to the third quarter of 2006, patent costs have been classified as research and development expense. Commencing with this quarterly report of Form 10-Q, these costs will be included in general and administrative expense. In addition, prior to 2006, stock compensation expense was shown separately in the statement of operations. Beginning in 2006, stock compensation expense is included in research and development expense and general and administrative expense. The prior period consolidated 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 reduced the number of outstanding shares of common stock from approximately 133.8 million shares to approximately 16.7 million shares, subject to reduction for fractional shares that were paid for in cash. Additionally, the reverse stock split resulted in proportionate adjustments to (i) the number of shares of common stock issuable upon conversion of the Company's Series A convertible preferred stock, (ii) the number of shares of common stock issuable upon conversion of the Company's 4% convertible subordinated notes due April 30, 2008, (iii) the number of shares of common stock issuable upon the exercise of options and warrants outstanding on June 29, 2006 and the exercise price of such options and warrants, and (iv) the number of shares issuable under the Company's stock incentive plans, including the Company's 2005 Stock Incentive Plan, 1997 Stock Incentive Plan, 1995 Director Stock Option Plan, and 1995 Employee Stock Purchase Plan. 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.

Pursuant to the Rights Agreement, dated as of December 10, 2001, between the Company and Mellon Investor Services LLC, as Rights Agent, as amended (the Rights Agreement), as a result of the reverse stock split, the number of Rights (as defined in the Rights Agreement) associated with each share of common stock was automatically proportionately adjusted so that (i) eight Rights were then associated with each outstanding share of common stock and (ii) so long as the Rights are attached to the common stock, eight Rights (subject to further adjustment pursuant to the provisions of the Rights Agreement) shall be deemed to be delivered for each share of common stock issued or transferred by the Company in the future.

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

The following table sets forth the computation of basic and diluted loss per share:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Numerator:				
Net loss	\$ (3,818,902)	\$ (2,949,749)	\$ (11,796,325)	\$ (9,825,177)
Accretion of preferred stock dividends	(164)	(164)	(492)	(492)

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Numerator for basic and diluted loss per share applicable to common shareholders	\$ (3,819,066)	\$ (2,949,913)	\$ (11,796,817)	\$ (9,825,669)
Denominator for basic and diluted loss per share (Note 4)	17,222,795	13,889,380	16,043,086	13,880,346
Loss per share basic and diluted:				
Net loss per share	\$ (0.22)	\$ (0.21)	\$ (0.74)	\$ (0.71)
Accretion of preferred stock dividends				
Net loss per share applicable to common stockholders	\$ (0.22)	\$ (0.21)	\$ (0.74)	\$ (0.71)

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Basic net loss per common share is computed using the weighted average number of shares of common stock outstanding during the period. For the three and nine months ended September 30, 2006 and 2005, 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 7,542,234 and 4,930,245 at September 30, 2006 and 2005, respectively. These antidilutive securities include stock options, warrants, convertible debt instruments and convertible preferred stock and are not included in the Company's calculation of diluted net loss per common share.

**(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 September 30, 2006 and December 31, 2005 consisted of cash and money market funds. On September 30, 2006, certain certificates of deposit which had maturity dates of less than 90 days at the time of purchase were also 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*. 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 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 consolidated balance sheet. 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 are included in Investment income, net on the accompanying consolidated statement of operations for all available-for-sale securities. The Company had no held-to-maturity investments, as defined by SFAS No. 115, at September 30, 2006 and December 31, 2005. The cost of securities sold is based on the specific identification method. The Company had no realized gains or losses for the three and nine months ended September 30, 2006 and 2005. There were no losses or permanent declines in value included in investment income for any securities in the three and nine months ended September 30, 2006 and 2005.

The Company had no long-term investments as of September 30, 2006 and December 31, 2005. Available-for-sale securities are classified as short-term regardless of their maturity date as if the Company considers them available 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. These securities can either be debt or preferred shares. The Company's short-term available-for-sale investments at market value consisted of the following at September 30, 2006 and December 31, 2005:

	<b>September 30, 2006</b>	<b>December 31, 2005</b>
Corporate bonds due in one year or less	\$ 299,121	\$ 2,102,432
Government bonds due in one year or less	1,068,726	2,484,975
Short term notes		901,820
Certificates of deposit	300,240	
Auction securities	4,630,000	1,901,676
Total	\$ 6,298,087	\$ 7,390,903

**(7) Property and Equipment**

At September 30, 2006 and December 31, 2005, net property and equipment at cost consisted of the following:

<b>September 30,</b>	<b>December 31,</b>
--------------------------	-------------------------

	<b>2006</b>	<b>2005</b>
Leasehold improvements	\$ 444,186	\$ 424,500
Laboratory equipment and other	1,990,410	1,927,950
Total property and equipment, at cost	2,434,596	2,352,450
Less: Accumulated depreciation and amortization	2,068,744	1,933,766
Property and equipment, net	\$ 365,852	\$ 418,684

Depreciation expense, which includes amortization of assets recorded under capital leases, was approximately \$31,000 and \$42,000 for the three months ended September 30, 2006 and 2005, respectively, and \$135,000 and \$114,000 for the nine months

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ended September 30, 2006 and 2005, respectively. In the first half of 2005, the Company wrote off unused property and equipment that had a cost of approximately \$109,000 resulting in a loss of approximately \$2,000.

**(8) Stock-Based Compensation**

The Company adopted SFAS No. 123R, *Share-Based Payment*, on January 1, 2006. This statement 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 has elected to adopt SFAS No. 123R on a modified prospective basis; accordingly, the financial statements for periods prior to January 1, 2006, will not include compensation cost calculated under the fair value method. 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.

Prior to January 1, 2006, the Company applied Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and therefore, recorded the intrinsic value of stock-based compensation as an expense. The following table illustrates the pro forma effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation for the three and nine months ended September 30, 2005.

	<b>Three months ended September 30, 2005</b>	<b>Nine months ended September 30, 2005</b>
Net loss applicable to common stockholders, as reported	\$ (2,949,913)	\$ (9,825,669)
Less: stock-based compensation expense included in reported net loss	121,198	149,236
Add: stock-based employee compensation expense determined under fair value based method for all awards	(266,851)	(719,595)
Pro forma net loss applicable to common stockholders, as adjusted for the effect of applying SFAS No. 123	\$ (3,095,566)	\$ (10,396,028)
Basic and diluted net loss per share applicable to common stockholders		
As reported	\$ (0.21)	\$ (0.71)
Pro forma	\$ (0.22)	\$ (0.75)

As explained in Note 9, prior to adopting SFAS 123R on January 1, 2006, the Company recorded changes in the intrinsic value of its repriced options in its Statement of Operations, including approximately \$121,000 and \$149,000 of stock compensation expense for the three and nine months ended September 30, 2005, which is shown in the above table. In accordance with SFAS 123R, the Company no longer includes changes in the intrinsic value of its repriced options in its Statement of Operations.

During the three and nine months ended September 30, 2006, the Company included charges of approximately \$213,000 and \$697,000, respectively, in its Statement of Operations. These charges represent the stock compensation expense computed in accordance with SFAS 123R. There were no corresponding charges included in the Statement of Operations during the three and nine months ended September 30, 2005. The adoption of SFAS 123R had no effect on cash flows during the first nine months of 2006. The adoption of SFAS 123R decreased basic and diluted earnings per share by \$0.01 and \$0.05, respectively, during the three and nine months ended September 30, 2006.

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. Pursuant to the terms of the plan, no additional options are

being granted under the 1995 Stock Option Plan. Options to purchase a total of 3,037,500 shares of common stock may be granted under the other stockholder approved plans. The Company has also granted options to purchase shares of Common Stock pursuant to agreements that were not approved by stockholders.

Under the Company's stock option and incentive plans, options may be granted to directors, officers and employees. Stock option grants generally vest ratably over three to four years and expire within ten years after the date of grant. Stock options granted under the 1995 Director Stock Option Plan vest in one year.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model and expensed over the requisite service period on a straight-line basis. The following assumptions apply to the options granted for the nine months ended September 30, 2006 and 2005:



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	<b>September 30,</b>	
	<b>2006</b>	<b>2005</b>
Weighted average expected term (years)	5.9	6.0
Weighted average expected volatility	88.3%	75.0%
Weighted average dividend per share		
Weighted average risk free interest rate	4.5%	3.9%
Weighted average fair value of options granted per share	\$3.53	\$3.33

Effective January 1, 2006, the Company modified the assumptions used to determine the fair value of options granted in accordance with SFAS No. 123R and SEC Staff Accounting Bulletin (SAB) No. 107. The assumptions used to determine the fair values of options granted after January 1, 2006 are based on the following:

- (i) The expected term represents the period of time that the options are expected to be outstanding. Where appropriate in accordance with SAB 107, the Company utilized the midpoint between the vesting date and the contractual term in determining the expected term of options that met the criteria for using this method under SAB 107. The expected term of options that do not meet the SAB 107 criteria is based on historical experience with exercise and post-vesting employment termination behavior.
- (ii) The expected volatility is based on the historical volatility of the Company's closing stock price on the last trading day of each calendar month for a period equal to the expected term of the option.
- (iii) The risk-free interest rate is based on the U.S. Treasury rate with a maturity date that corresponds with the expected term of the option.

Stock option activity for the nine months ended September 30, 2006 is summarized as follows:

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Life in Years</b>	<b>Aggregate Intrinsic Value</b>
Outstanding, December 31, 2005	2,548,180	\$ 5.71		
Granted	84,000	4.71		
Exercised	(13,878)	4.00		
Terminated	(571,720)	6.34		
Outstanding, September 30, 2006	2,046,582	5.51	5.99	\$28,026
Exercisable, September 30, 2006	1,474,815	5.87	4.89	26,089

As of September 30, 2006, there was \$1.7 million of total unrecognized compensation cost related to unvested stock-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 2.5 years.

Additional information on option activity for the nine months ended September 30, 2006 is as follows:

	<b>Nine Months ended September 30, 2006</b>
Total fair value of shares vested	\$709,262
Total intrinsic value of options exercised	11,989

**(9) Stock-Based Compensation Related to Repriced Options**

In September 1999, the Company's Board of Directors authorized the repricing of options to purchase 656,478 shares of common stock to \$4.00 per share, which represented the market value of the common stock on the date of the repricing. Prior to the adoption of SFAS 123R, these options were subject to variable plan accounting which required the Company to re-measure the intrinsic value of the repriced options, through the earlier of the date of exercise, cancellation or expiration, at each reporting date. For the three months and nine months ended September 30, 2005, the Company recognized an expense of approximately \$121,000 and \$149,000, respectively, as stock compensation relating to these repriced options as a result of an increase in the intrinsic value of these options between December 31, 2004 and September 30, 2005. In accordance with SFAS 123R, the Company no longer includes changes in the intrinsic value of repriced options in its statement of operations.

**Table of Contents****(10) Related Party Transactions**

During the nine months ended September 30, 2006 and in connection with the purchase commitment discussed in Note 13, the Company paid one of the its directors a commission of \$487,500 which represented 5% of the amount available to the Company under the purchase commitment.

In the nine months ended September 30, 2005, the Company paid Pillar Investment Limited, which is controlled by a director of the Company, approximately \$264,000 in cash and issued warrants to purchase 70,684 shares of common stock at an exercise price of \$7.12 per share as fees in connection with Pillar Investment Limited acting as the placement agent for the sale of the 4% convertible subordinated notes in May 2005 discussed in Note 12. The warrants have a Black-Scholes value of approximately \$219,000.

**(11) Comprehensive Income**

The following table includes the components of comprehensive income for the three and nine months ended September 30, 2006 and 2005.

	<b>Three months ended September</b>		<b>Nine months ended September</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Net loss	\$ (3,818,902)	\$ (2,949,749)	\$ (11,796,325)	\$ (9,825,177)
Other comprehensive income	3,903	173	11,267	12,982
Total comprehensive loss	\$ (3,814,999)	\$ (2,949,576)	\$ (11,785,058)	\$ (9,812,195)

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

**(12) Notes Payable**

On May 24, 2005, the Company sold approximately \$5.0 million in principal amount of 4% convertible subordinated notes due April 30, 2008 (the 4% Notes). Interest on the 4% Notes is payable semi-annually in arrears on April 30 and October 30 and at maturity or conversion. The Company has the option to pay interest on the 4% Notes in cash or in shares of the Company's common stock at the then current market value of the Company's common stock. Holders of the 4% Notes may convert, at any time prior to maturity, the principal amount of the 4% Notes (or any portion thereof) into shares of the Company's common stock at a conversion price of \$7.12 per share. The Company may cause the principal amount of the 4% Notes to be converted into shares of the Company's common stock at the then current conversion price if the volume weighted average of the closing sales prices of the Company's common stock for 10 consecutive trading days is equal to at least \$8.96 per share. If the Company conducts a financing resulting in greater than \$10.0 million in gross proceeds, the Company may elect to convert the 4% Notes into shares of the Company's common stock at the then current conversion price if the purchase price paid by the new investors in the financing (on a common stock equivalent basis) is greater than the then current conversion price of the 4% Notes. Holders of the 4% Notes may demand that the Company redeem the 4% Notes upon a change in control, a merger with an independent company, or a change in the Company's listing status.

The Company capitalized its financing costs associated with the sale of the 4% Notes and is amortizing them over the term of the notes. These costs include the Black-Scholes value of the warrants, legal expenses and miscellaneous costs attributable to the placement of the notes.

**(13) Private Financing***(a) Private Financing*

On March 24, 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 and will expire if not exercised on or prior to September 24, 2011. The warrants may be exercised by cash payment only and are exercisable any time on or after September 24, 2006. 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, total approximately \$8.9 million. The Company has filed a

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registration statement covering the resale of the common stock and the common stock issuable upon exercise of the warrants, which has been declared effective.

*(b) Financing Commitment*

On March 24, 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. In July 2006, the Company accessed \$3.5 million of this purchase commitment and sold 683,593 shares of common stock at a price of \$5.12 per share and in November 2006, the Company accessed \$4.0 million of this purchase commitment and sold 781,250 shares of common stock at a price of \$5.12 per share. If the Company elects to draw down any of the remaining \$2.3 million in exchange for newly-issued shares of the Company's common stock, the price at which such shares shall be issued will be equal to the greater of (a) 80% of the volume weighted average closing price during a five-day pricing period preceding the date that the Company notifies the investor of the sale and (b) a floor price of \$5.12 per share. No drawdown may occur within 45 days of any other drawdown, and no single drawdown may exceed \$4.0 million. Based on the floor price, a maximum of 439,453 additional shares of common stock could be issued under the purchase commitment. The Company is not obligated to sell any of the remaining \$2.3 million of common stock available under the purchase commitment and there are no minimum commitments or minimum use penalties. The purchase commitment does not contain any restrictions on the Company's operating activities, automatic pricing resets or minimum market volume restrictions. The agent fees and other costs directly related to securing the commitment amounted to approximately \$0.9 million. If the Company sells the entire \$9.8 million of its common stock pursuant to the purchase commitment, the net proceeds to the Company, excluding the proceeds of any future exercise of the warrants, will be approximately \$8.9 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, Idera 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.

*(c) Amendment to Rights Agreement*

On March 24, 2006, in connection with the private financing described above, the Company entered into an amendment ( Amendment No. 2 ) to the Rights Agreement, dated as of December 10, 2001, as amended (the Rights Agreement ), between the Company and Mellon Investor Services LLC, as Rights Agent. Amendment No. 2 modifies the definition of Exempted Persons that are excluded from the definition of Acquiring Person under the Rights Agreement to provide that Baker Brothers Investments, together with its affiliates and associates (the Baker Entities ), will be an Exempted Person under the Rights Agreement until such time as the Baker Entities beneficially own more than 4,375,000 shares of the Company's common stock (subject to adjustment) or less than 14% of the common stock then outstanding.

*(14) Novartis Collaboration*

On May 31, 2005, the Company entered into a research collaboration and option agreement and a license, development and commercialization agreement with Novartis International Pharmaceutical Ltd. 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 the Company a \$4.0 million license fee in July 2005. In addition to the \$4.0 million upfront payment, Novartis agreed to fund substantially all research activities and make milestone payments to Idera upon the achievement of clinical development, regulatory approval and cumulative net sales milestones. If Novartis elects to exercise its option to develop and commercialize licensed IMOs in the initial collaboration disease areas, Novartis is potentially obligated to pay the Company up to \$132.0 million in milestone payments. Novartis is also obligated to pay the Company a royalty on net sales of all products, if any, commercialized by Novartis, its affiliates and sublicensees. The Company is recognizing the \$4.0 million upfront payment as revenue over the two-year term of the research collaboration. If specific conditions are met, Novartis may choose to expand the collaboration to use identified immune modulatory

oligonucleotides for additional human diseases, other than oncology and infectious diseases, which will be subject to agreed upon milestone payments.

(15) Subsequent Event

On October 31, 2006, the Company entered into a lease agreement for laboratory and office space located in Cambridge, MA. The term of the lease commences on May 15, 2007 and expires on June 1, 2014, with one five-year renewal option exercisable by the

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Company. The Company intends to move its operations from its current facility to the new facility in May 2007. As part of the lease, the Company was required to restrict approximately \$620,000 for a security deposit. The initial annual rent expense will amount to \$1.2 million, subject to escalation during each year of the lease term. Total payments over the seven year term of the lease are approximately \$9.0 million.

### **(16) Pro Forma Balance Sheet**

In November 2006, the Company drew down \$4.0 million of the purchase commitment through the sale of 781,250 shares of common stock at a price of \$5.12 per share (see Note 13(b)). The unaudited pro forma balance sheet as of September 30, 2006 reflects the receipt on November 6, 2006 of approximately \$4.0 million of gross proceeds from the second drawdown under the commitment.

The \$620,000 facility lease security deposit discussed in Note 15 is included in non-current assets in the accompanying pro forma balance sheet at September 30, 2006.

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

### **GENERAL**

We are engaged in the discovery and development of novel therapeutics that modulate immune responses through Toll-like Receptors, or TLRs, for the treatment of multiple diseases. We are developing proprietary DNA- and RNA-based compounds that modulate TLRs and are targeted to TLR7, TLR8 or TLR9. We believe that these immune modulatory oligonucleotide, or IMO, compounds are broadly applicable to large and growing markets where significant unmet medical needs exist, including oncology, asthma and allergies, infectious diseases, autoimmune diseases and vaccine adjuvants. IMO-2055, our lead drug candidate, is a synthetic DNA-based compound, which acts as an agonist for TLR9 and triggers the activation and modulation of the immune system. IMO-2055 is currently in a Phase 2 clinical trial as a monotherapy for renal cell carcinoma and a Phase 1/2 clinical trial in combination with chemotherapy agents for solid tumors. We have selected another TLR9 agonist, IMO-2125, as a lead compound for development for the treatment of infectious diseases. We are also collaborating with Novartis to develop treatments for asthma and allergies using other of our TLR9 agonist compounds. We are also developing a new class of compounds which act as antagonists to TLRs. Our IMO compounds targeted to TLR7 and TLR8 and our new class of compounds which act as antagonists to TLRs are in the discovery stage.

Since 2003, we have devoted substantially all of our research and development efforts to our IMO technology and products and expect to continue that focus in future years. These IMO research and development efforts have resulted in over 150 patents and patent applications world wide. Although we are no longer developing our antisense technologies in-house, we have maintained over 300 key patents and patent applications in this area and will continue to seek additional collaborators to develop our antisense technologies. In order to commercialize our therapeutic products, we need to address a number of technological challenges and to comply with comprehensive regulatory requirements.

### **APPLICATION OF CRITICAL ACCOUNTING POLICIES**

This management's discussion and analysis of financial condition and results of operations is based on our consolidated 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.





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Our significant accounting policies are described in Note 2 of the Notes to Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2005. 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, 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, 2005, fit the definition of critical accounting estimates and judgments.

**STOCK BASED COMPENSATION**

On January 1, 2006, we adopted Statement of Financial Accounting Standards (SFAS) No. 123R, *Share-Based Payment*. This statement requires us to recognize all share-based payments to employees in the financial statements based on their fair values. We have chosen to adopt SFAS 123R on a modified prospective basis and the statement of operations does not include compensation costs calculated under the fair value method of SFAS 123R in the first nine months of 2005. Since the adoption of this new guidance there have been no significant changes in the quantity or types of instruments used in stock-based compensation programs, nor have there been any significant changes in the terms of existing stock-based compensation arrangements and no material cumulative adjustments were recorded in the first nine months of 2006.

During the three and nine months ended September 30, 2006, we included charges of approximately \$213,000 and \$697,000, respectively, in our statement of operations, which represent the stock compensation expense computed in accordance with SFAS 123R. There were no corresponding charges included in the statement of operations during the three and nine months ended September 30, 2005. We expect that the stock based compensation charges in our statement of operations for the remainder of 2006 will be similar to the charges included in the first nine months of 2006 with no corresponding charges in 2005. However, the amount of future charges cannot be forecasted precisely since it is dependent, in part, on future stock option grants and other factors which cannot be accurately predicted at this time.

Prior to adopting SFAS 123R on January 1, 2006, we recorded changes in the intrinsic value of our repriced options in our Statement of Operations, including charges of \$121,000 in the three months ended September 30, 2005 and \$149,000 in the nine months ended September 30, 2005 as a result of increases in the intrinsic value of the repriced options during these periods. In accordance with SFAS 123R, we no longer include changes in the intrinsic value of our repriced options in our statement of operations.

As of September 30, 2006, there was \$1.7 million of total unrecognized compensation cost related to unvested stock-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 2.5 years.

**RESULTS OF OPERATIONS*****Three and Nine Months Ended September 30, 2006 and 2005******Alliance Revenue***

Total alliance revenue increased by \$27,000, or 5%, from \$545,000 for the three months ended September 30, 2005 to \$572,000 for the three months ended September 30, 2006 and increased by \$802,000, or 78%, from \$1,028,000 for the nine months ended September 30, 2005 to \$1,830,000 for the nine months ended September 30, 2006. The increase in revenues between the nine months ended September 30, 2006 and the nine months ended September 30, 2005 was primarily due to license fees we recognized under our collaboration agreement with Novartis, which we entered into in May 2005. In July 2005, we received from Novartis a \$4,000,000 upfront fee in connection with the execution of the agreement. We are recognizing this \$4,000,000 fee over two years that commenced on the date that we entered into the agreement with the balance being recorded as deferred revenue. Our revenues for both periods were comprised of revenue earned under various collaboration and licensing agreements for research and development, including reimbursement of third-party expenses, license fees, sublicense fees, and royalty payments.

***Research and Development Expenses***

Research and development expenses increased by \$748,000, or 33%, from \$2,261,000 for the three months ended September 30, 2005 to \$3,009,000 for the three months ended September 30, 2006 and increased by 2,477,000 or 34%, from \$7,182,000 for the nine months ended September 30, 2005 to \$9,659,000 for the nine months ended September 30, 2006. The increase in the three months ended September 30, 2006 was primarily attributable to

manufacturing and IND-enabling safety study expenses associated with our

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pre-IND lead infectious disease compound, IMO-2125, increased expenditures for our Phase 1/2 clinical trial of IMO-2055 in combination with chemotherapy agents started in October 2005, costs associated with the formation of our Oncology Clinical Advisory Board, and increased compensation expense attributable, in part, to our adoption of SFAS 123R. These increases were partially offset by decreases in research and other IMO-2055 expenses. The increase in the nine months ended September 30, 2006 was primarily attributable to costs relating to manufacturing and IND-enabling safety study costs associated with IMO-2125, Phase 1/2 clinical trial expenses for IMO-2055, Phase 2 clinical trial expenses for IMO-2055 and related nonclinical safety study costs, costs associated with the formation of our Oncology Clinical Advisory Board and increased stock-based compensation attributable, in part, to our adoption of SFAS 123R. In the nine months ended September 30, 2005, we had expenses for manufacturing IMO-2055 that led to a corresponding decrease in expenses in the nine months ended September 30, 2006. This is because IMO-2055 manufactured and expensed during the 2005 period was utilized during the 2006 period and there was no IMO-2055 manufactured and expensed in 2006.

(In thousands)	Three months ended September 30,			Nine months ended September 30,		
	2006	2005	Percentage Increase (Decrease)	2006	2005	Percentage Increase (Decrease)
IMO-2055 External Development Expense	\$ 839	\$ 853	(2%)	\$ 2,624	\$ 2,770	(5%)
Other Drug Development Expense	1,213	298	307%	3,708	1,140	225%
Basic Discovery Expense	957	1,110	(14%)	3,327	3,272	2%
Total Research and Development Expense	\$ 3,009	\$ 2,261	33%	\$ 9,659	\$ 7,182	34%

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 connection with IMO-2055, our lead compound being developed for oncology applications under the name IMOxine. 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 the date we commenced clinical development of IMO-2055, we have incurred approximately \$9.8 million in external expenses in connection with IMO-2055. The decrease in IMO-2055 expenses in the three months ended September 30, 2006 compared to the same period in 2005 was primarily attributable to lower Phase 2 trial expenses as we approach full enrollment of Stage A of our Phase 2 clinical trial and to a decrease in drug supply expenses as a result of the manufacture and expense recognition of IMO-2055 during the third quarter of 2005 but not during the third quarter of 2006. These decreases were partially offset by an increase in our Phase 1/2 clinical trial expenses and an increase in additional nonclinical safety studies of IMO-2055. The decrease in IMO-2055 expenses in the nine months ended September 30, 2006 was primarily attributable to our manufacture of IMO-2055 in the nine months ended September 30, 2005, as explained above, partially offset by increases in 2006 of nonclinical studies of IMO-2055 and our Phase 1/2 clinical trial expenses of IMO-2055.

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 carcinoma. The primary endpoint of the trial is to determine the tumor response, measured by the increase or decrease in size, by a standard approach referred to as RECIST, which stands for Response Evaluation Criteria in Solid Tumors. Secondary objectives include safety, duration of response, time to progression, survival through 12 months after the last dose, and the effect of the treatment on quality of life. The trial was designed as a two-stage trial. Stage A of the trial provided for the evaluation of IMO-2055 at two dose levels, 0.16 mg/kg and 0.64 mg/kg, administered by weekly subcutaneous injection. Based

on tumor response rates experience with drugs in clinical use for kidney cancer as of the initiation date for our Phase 2 trial, the statistical design for Stage A of the trial required 23 patients for each dose level. We originally planned to recruit a minimum of 46 patients who had previously failed one prior therapy for the treatment of metastatic or recurrent clear cell renal carcinoma, who we refer to as second-line patients. We expected a low number of treatment-naïve patients, and the original protocol did not specify a target enrollment for treatment-naïve patients. In October 2005, in response to a higher than expected enrollment rate of treatment-naïve patients in the Phase 2 trial, we submitted to the FDA a protocol amendment that provides for enrollment of up to 46 treatment-naïve patients in the first stage of the trial, in addition to the 46 second-line patients provided for by the original study design. In November 2006, we further amended the protocol to allow us to study additional immune system parameters. Recruitment has been slower than projected because of the recent approval of the two new therapies, Sutent® and Nexavar®, for treatment of the same patient population. We expect to complete enrollment for Stage A of the trial by the

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end of 2006. Since we cannot predict how long patients will remain on IMO-2055 treatment, we cannot estimate when we will have final results for Stage A of the trial. Decisions with regard to Stage B of the trial will depend on Stage A results.

In October 2005, we initiated a Phase 1/2 clinical trial of IMO-2055 in combination with the chemotherapy agents Gemzar® and carboplatin at the Lombardi Comprehensive Cancer Center at Georgetown University Medical Center. We enrolled eight refractory solid tumor patients in the original Phase 1 part of the trial. We are seeking to enroll 12 to 18 additional refractory solid tumor patients in the amended Phase 1 portion of the trial to evaluate the safety of the combination. If successful, we plan to use Phase 1 data for dose selection for the subsequent Phase 2 portion of the trial as first-line treatment of non-small cell lung cancer patients.

*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. The internal expenses associated with products in clinical development include costs associated with our Oncology Clinical Advisory Board, payroll and overhead. The increase in these expenses in the three and nine months ended September 30, 2006 was primarily attributable to manufacturing and IND-enabling safety study costs associated with our pre-IND lead infectious disease compound, IMO-2125, costs associated with the formation of our Oncology Clinical Advisory Board and an increase in compensation costs attributable to the hiring of additional employees and our adoption of SFAS 123R.

Our Oncology Clinical Advisory Board, which we referred to above, was recently formed to advise us on the IMO-2055 clinical program. We plan to consider the recommendations of the advisory board and determine which cancer indications to pursue based on the IMO-2055 mechanism of action and clinical and preclinical data. Once we make this determination, we plan to develop additional protocols for FDA review and plan to initiate one or more new trials commencing at the earliest in 2007. If we were to commence such a trial or trials in 2007, our IMO-2055 expenses would increase significantly commencing in 2007.

*Basic Discovery Expense.* These expenses include our internal and external expenses relating to the continuing development of our IMO technology and research to identify additional compounds. These expenses reflect payments for lab supplies, external research, professional fees, as well as, payroll and overhead. The decrease in these expenses in the three months ended September 30, 2006 was primarily attributable to a decrease in external research as some of our collaborative agreements were completed. This decrease was partially offset by an increase in compensation costs attributable, in part, to our adoption of SFAS 123R. The increase in these expenses in the nine months ended September 30, 2006 was primarily attributable to an increase in lab supplies and an increase in allocation of overhead costs, as well as, an increase in compensation costs attributable, in part, to our adoption of SFAS 123R. These decreases are partially offset by a decrease in external research as some of our collaborative agreements were completed.

We do not know if we will be successful in developing IMO-2055 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 agreed upon a development strategy and pathway with the FDA, 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. Moreover, the clinical development of IMO-2055 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 \$162,000, or 13%, from \$1,233,000 in the three months ended September 30, 2005 to \$1,395,000 in the three months ended September 30, 2006 and increased by \$193,000, or 5%, from \$3,782,000 in the nine

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months ended September 30, 2005 to \$3,975,000 in the nine months ended September 30, 2006. The increase in the three and nine months ended September 30, 2006 primarily reflects higher compensation attributable, in part, to our adoption of SFAS 123R. The increase in the nine-month period is partially offset by a decrease in corporate legal expenses.

*Investment Income, net*

Investment income increased by approximately \$13,000, or 12%, from \$107,000 in the three months ended September 30, 2005 to \$120,000 in the three months ended September 30, 2006 and increased by \$69,000, or 27%, from \$257,000 in the nine months ended September 30, 2005 to \$326,000 in the nine months ended September 30, 2006. These increases resulted from higher interest rates. The increases are also attributable to changes to our portfolio to include instruments with shorter maturities resulting in lower premium amortization offsetting interest income in the three and nine months ended September 30, 2006.

*Interest Expense*

Interest expense decreased by \$1,000, or 1%, from \$108,000 in the three months ended September 30, 2005 to \$107,000 in the three months ended September 30, 2006 and increased by \$172,000, or 118%, from \$146,000 in the nine months ended September 30, 2005 to \$318,000 in the nine months ended September 30, 2006. The increase for the nine months ended September 30, 2006 reflect interest on our 4% convertible subordinated notes issued in May 2005 and amortization of deferred financing costs associated with these notes.

*Net Loss Applicable to Common Stockholders*

As a result of the factors discussed above, our net loss applicable to common stockholders amounted to \$3,819,000 for the three months ended September 30, 2006, as compared to \$2,950,000 for the three months ended September 30, 2005 and \$11,797,000 for the nine months ended September 30, 2006, as compared to \$9,826,000 for the nine months ended September 30, 2005. We have incurred losses of \$64.6 million since January 1, 2001 and losses of \$260.2 million prior to December 31, 2000 for a total of \$324.8 million in losses through September 30, 2006. 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 service our debt. Historically, we have funded our cash requirements primarily through the following means: equity and debt financing, license fees and research funding under collaborative and license agreements, interest income and lease financings.

In March 2006, we raised approximately \$9.8 million in gross proceeds from a private placement to institutional investors. In the private placement, we sold for a purchase price of \$3.52 per share 2,769,886 shares of common stock and warrants to purchase 2,077,414 shares of common stock. The warrants 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. 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. In July 2006, we drew down \$3.5 million of this commitment through the sale of 683,593 shares of common stock at a price of \$5.12 per share and on November 6, 2006, we drew down \$4.0 million of this commitment through the sale of 781,250 shares of common stock at a price of \$5.12 per share. If we elect to draw down the remaining \$2.3 million of newly-issued shares of our common stock, the price will be equal to the greater of a) 80% of the volume weighted average closing price during a five-day pricing period preceding the date that we notify the investor of the sale and b) \$5.12 per share. No drawdown may occur within 45 days of any other drawdown. Based on the floor price, a maximum of 439,453 additional shares of common stock could be issued under the purchase commitment. We are not obligated to sell any of the remaining \$2.3 million available under the purchase commitment and there are no minimum commitments or minimum use penalties. The purchase commitment does not contain any restrictions on our operating activities, automatic pricing resets or minimum market volume restrictions. The agent fees and other costs directly related to securing the purchase commitment total approximately \$0.9 million, which we paid in the nine months ended September 30, 2006. If we elect to sell the entire \$9.8 million of our common

stock pursuant to the purchase commitment, the net proceeds to us, excluding the proceeds of any future exercise of the warrants, will be approximately \$8.9 million. As part of the arrangement, we issued warrants to the investor to purchase 761,718 shares of our common stock at an exercise price of \$5.92 per share.



**Table of Contents***Cash Flows*

As of September 30, 2006, we had approximately \$8,062,000 in cash, cash equivalents and short-term investments, a decrease of approximately \$314,000 from December 31, 2005.

We used approximately \$11,897,000 of cash for operating activities during the nine months ended September 30, 2006, principally to fund our research and development expenses and our general and administrative expenses. The \$11,897,000 primarily consists of our net loss of \$11,796,000 for the period, as adjusted for non-cash stock-based compensation, the increase in our accrued expenses and decreases in deferred revenue and prepaid expenses.

The net cash provided by investing activities during the first three quarters of 2006 of \$1,041,000 reflects our purchase of approximately \$15,747,000 in securities offset by our sale of \$5,545,000 of securities and the proceeds of approximately \$11,325,000 from securities that matured between January 1, 2006 and September 30, 2006.

The net cash of approximately \$11,635,000 provided by financing activities during the first three quarters of 2006 reflects the approximately \$9,750,000 in gross proceeds that we received from the private placement to institutional investors in March 2006 and the \$3,500,000 in gross proceeds from the sale of common stock in July 2006 under our March 2006 purchase commitment offset by the expenses associated with both the March 2006 private placement and the purchase commitment. Net cash provided by financing activities also reflects approximately \$93,000 we received from the exercise of stock options during the nine months ended September 30, 2006.

*Funding Requirements*

We believe that, based on our current operating plan, our existing cash, cash equivalents and short-term investments, including the proceeds from our November 2006 sale of common stock under the March 2006 purchase commitment, which resulted in \$4.0 million in gross proceeds, are sufficient to fund our operations through June 2007. If we sell the remaining \$2.3 million under the purchase commitment, we expect to have sufficient cash and investments to be able to pursue our clinical and preclinical development programs and continue operations through August 2007.

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. As a result, in order for us to continue to pursue our clinical and preclinical development programs and continue operations beyond June 2007, or August 2007 if we draw down all of the funds pursuant to the purchase commitment, we must raise additional funds in 2007 from debt, equity financings or from collaborative arrangements with biotechnology or pharmaceutical companies. There can be no assurance that the requisite funds will be available in the necessary time frame or on terms acceptable to us. Should we be unable to raise sufficient funds, 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 receptivity of the capital markets to financings by biotechnology companies; and

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

*Contractual Obligations*

We have contractual obligations in the form of employment agreements, operating leases and consulting and collaboration agreements. On October 31, 2006, we entered into a lease agreement for laboratory and office space located in Cambridge, MA. The term of the lease commences on May 15, 2007 and expires on June 1, 2014, with one five-year renewal option exercisable by the Company. As part of the lease, we were required to restrict approximately \$620,000 for a security deposit. The initial annual rent

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expense will amount to \$1.2 million, subject to escalation during each year of the lease term. Total payments over the seven year term of the lease are approximately \$9.0 million. We have specified rights to sublease this facility. The Company intends to move its operations from its current facility to the new facility in May 2007

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

As of September 30, 2006, we have no assets and liabilities related to non-dollar-denominated currencies.

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

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

**ITEM 4. CONTROLS AND PROCEDURES**

(a) *Evaluation of Disclosure Controls and Procedures.* Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2006. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2006, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(b) *Changes in Internal Controls.* No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act) occurred during the fiscal quarter ended September 30, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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**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 in this quarterly report on Form 10-Q before purchasing our common stock. If any of the following risks actually occurs, our business, financial condition or results of operations would likely suffer, possibly materially. In that case, the trading price of our common stock could fall, and you may lose all or part of the money you paid to buy our common stock.*

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

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

We have incurred losses in every year since our inception, except for 2002 when our recognition of revenues under a license and collaboration agreement resulted in us reporting net income for that year. As of September 30, 2006, we had incurred operating losses of approximately \$324.8 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 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 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 discovery and development programs and other operations.***

We will require substantial funds to conduct research and development, including preclinical testing and clinical trials of our drugs. 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, including the proceeds from our November 6, 2006 sale of common stock at a price of \$5.12 per share under a purchase commitment, which resulted in \$4.0 million in gross proceeds, will be sufficient to fund our operations through June 2007. In March 2006, we secured the purchase commitment from an investor to purchase from us up to a total of \$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, at a minimum price of \$5.12 per share. If we draw down the \$2.3 million remaining under this purchase commitment, we expect to have sufficient cash and investments to be able to pursue our clinical and preclinical development programs and continue operations through August 2007.

We will need to raise additional funds to operate our business beyond such time. 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 receptivity of the capital markets to financings by biotechnology companies; and

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

Additional financing may not be available to us when we need it or may not be available to us on favorable terms. We could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, drug candidates or drugs which 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. 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.

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

***We are depending heavily on the success of our lead drug candidate, IMO-2055, which is in clinical development. If we are unable to 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 drug 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 the trial and during commercial use;

successful completion of clinical trials;

receipt of marketing approvals from the U.S. Food and Drug Administration, or the FDA, and equivalent foreign regulatory authorities;

establishing commercial manufacturing arrangements with third-party manufacturers;

launching commercial sales of the product, whether alone or in collaboration with others; and

acceptance of the product in the medical community and with third-party payors.

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 carcinoma. 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 drug candidates. 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. In addition, we may not be able to obtain authority from any regulatory agency to complete these trials or complete any other clinical trials. The FDA and other regulatory authorities may not approve any of our potential products for any indication.

The results from preclinical testing of a drug candidate that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger scale, advanced stage clinical trials. A failure of any of our clinical trials can occur at any stage of testing. Further, 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:

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we may not be able to supply an adequate quantity of drug candidate meeting the required quality standards for use in clinical trials or other materials necessary for conducting our clinical trials;

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;

the cost of our clinical trials may be greater than we currently anticipate and/or we may lack sufficient funding to continue clinical trials; and

the effects of our products may not be the desired effects or may include undesirable side effects or the products may have other unexpected characteristics.

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

The rate of completion of clinical trials is dependent in part upon the rate of enrollment of patients. We originally planned to recruit a minimum of 46 patients who had previously failed one prior therapy, who we refer to as second-line patients, into the first stage of our Phase 2 trial of IMO-2055 in renal cell carcinoma. As of October 2005, our enrollment of second-line patients was less than anticipated, whereas the enrollment of treatment-naïve patients was more than expected. As a result, we amended the trial protocol in October 2005 to accommodate statistical endpoints for both treatment-naïve and second-line patients, thus extending the completion of the trial beyond the time we expected. As a result, we are now seeking to enroll up to 92 patients in the first stage of the trial, and we plan to continue patient recruitment into the fourth quarter of 2006. Recruitment has been slower than projected because of the recent approval of two new therapies, Sutent<sup>®</sup> and Nexavar<sup>®</sup>, for treatment of the same patient population. 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.

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

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

Our drug candidates and our collaborators' drug candidates will require preclinical and other, nonclinical testing and extensive clinical trials prior to submission of any regulatory application for commercial sales. We are currently conducting clinical trials with IMO-2055 in oncology and plan to commence clinical trials of IMO-2125 in infectious disease 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 costs, delay any potential revenues and reduce the probability that a potential product will receive regulatory approval.

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

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

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

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

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

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

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

enrolling patients in order to commence the clinical trial.

***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 organizations such as 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 Sutent<sup>®</sup> and Nexavar<sup>®</sup> for use in renal cell carcinoma, which is the indication for which we are evaluating IMO-2055 monotherapy in our Phase 2 trial. Two of our competitors are currently evaluating TLR9 agonists in Phase 3 clinical trials.

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.

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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 to secure sufficient capital resources for the period between technological conception and commercial sales.

***Because the products that we may develop will be based on new technologies and therapeutic approaches, the market may not be receptive to these products upon their introduction.***

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. Many of the products that we are developing are based upon technologies or therapeutic approaches that are relatively new and unproven. The FDA has not granted marketing approval to any products based on IMO technology or TLR9 agonists, and no such products are currently being marketed. As a result, it may be more difficult for us to achieve regulatory approval or market acceptance of our products. In addition, if products based upon TLR technology being developed by our competitors have negative preclinical or clinical trial results or otherwise are viewed negatively, such events could negatively impact the perception of our TLR technology and market acceptance of our products. 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.

***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 Sudhir Agrawal and 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 IMO Technology. He is named as an inventor on over 230 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 for a term ending on October 19, 2008, subject to annual renewals. 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 for a term ending on December 5, 2007, subject to annual renewals. 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.

Our future growth will require hiring a significant number of qualified technical and management personnel. 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. In 1997, we determined not to continue clinical development of GEM91, our lead product candidate at the time. Currently, we are conducting clinical trials of IMO-2055.





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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, with which compliance is costly and time-consuming; if we fail to comply with these requirements, we could be subject to adverse consequences and penalties.***

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

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

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

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

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

restrictions on such products or the manufacturing of such products;

withdrawal of the 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.



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**Risks Relating to Collaborators**

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

An important element of our business strategy includes entering into collaborative relationships for the development and commercialization of products based on our discoveries. We face significant competition in seeking appropriate collaborators. Moreover, these arrangements are complex to negotiate and time-consuming to document. We may not be successful in our efforts to establish collaborative relationships or other alternative arrangements.

The success of collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations. The risks that we face in connection with these collaborations include the following:

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

disagreements with 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;

collaborators have considerable discretion in electing whether to pursue the development of any additional drugs and may pursue technologies or products either on their own or in collaboration with our competitors that are similar to or competitive with our technologies or products that are the subject of the collaboration with us; and

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.

Given these risks, it is possible that any collaborative arrangements into which we enter may not be successful. In May 2005, we entered into collaborative arrangements with Novartis involving our IMO technology for application in asthma and allergies. Previous collaborative arrangements to which we were a party with F. Hoffmann-La Roche and G.D. Searle & Co., involving our antisense technology, were terminated prior to the development of any product. The failure of any of our collaborative relationships could delay our drug development or impair commercialization of our products.

**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.



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We do not know whether any of our patent applications or those patent applications that we in-license will result in the issuance of any patents. Our issued patents and those that may issue 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 six license agreements in the field of antisense technology under which we have acquired rights to patents, patent applications and technology of third parties. Under these licenses we are obligated to pay royalties on net sales by us of products or processes covered by a valid claim of a patent or patent application licensed to us. We also are required in some cases to pay a specified percentage of any sublicense income that we may receive. These licenses impose various commercialization, sublicensing, insurance and other obligations on us. Our failure to comply with these requirements could result in termination of the licenses. These licenses generally will otherwise remain in effect until the expiration of all valid claims of the patents covered by such licenses or upon earlier termination by the parties. The issued patents covered by these licenses expire at various dates ranging from 2006 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 in which 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.

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

We have limited manufacturing experience and no 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.

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

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

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

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

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

- the potential that any such third-party manufacturer 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.

We purchased oligonucleotides for preclinical and clinical testing from Avecia Biotechnology at a preferential price under a supply agreement, which expired in March 2004. We have continued to purchase all of the oligonucleotides we are using in our ongoing clinical trials and preclinical testing from Avecia. The terms of the agreement have been extended until such time as a new agreement is negotiated. If Avecia determines not to accept any purchase order for oligonucleotides or we are unable to enter into a new manufacturing arrangement with Avecia or a new contract manufacturer on a timely basis or at all, our ability to supply the product needed for our clinical trials could be materially impaired. The services of multiple third-party manufacturers are utilized to accomplish the final portion of the manufacturing process.

***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.

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***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 PAREXEL International to manage our Phase 2 clinical trial of IMO-2055 in renal cell carcinoma. We rely heavily on these parties for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our products. If we seek to conduct any of these activities ourselves in the future, we will need to recruit appropriately trained personnel and add to our infrastructure.

***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 will 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 recently enacted a limited prescription drug benefit for Medicare recipients in the Medicare Prescription Drug and Modernization Act of 2003. While the program established by this statute may increase demand for our products, if we participate in this program, our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than we might otherwise obtain. Non-Medicare third-party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries.

A primary trend in the United States healthcare industry is toward cost containment. In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve 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.

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. 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.



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

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

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

a classified board of directors;

limitations on the removal of directors;

limitations on stockholder proposals at meetings of stockholders;

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

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

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 September 30, 2006, 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 \$6.48 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;

developments or disputes concerning patents or other proprietary rights;

the departure of key personnel;

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

our cash resources;

the terms of any financing conducted by us;

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changes in the structure of healthcare payment systems;

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

general economic, industry and market conditions.

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

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

***We may be unable to repay our 4% convertible subordinated notes when due or to repurchase the convertible subordinated notes if we are required to do so under the terms of our agreement with the holders of the 4% convertible subordinated notes.***

In May 2005, we sold approximately \$5.0 million in principal amount of 4% convertible subordinated notes. On April 30, 2008, the entire outstanding principal amount of our 4% convertible subordinated notes will become due and payable, unless the notes are converted to common stock prior to expiration. In addition, we may be required to redeem all or part of the convertible subordinated notes prior to the final maturity date if specified events occur. We may not have sufficient funds or may be unable to arrange for additional financing to pay the amount due under the convertible subordinated notes at maturity or to pay the price to repurchase the convertible subordinated notes. Any future borrowing arrangements or debt agreements to which we may become a party may restrict or prohibit us from repaying or repurchasing the convertible subordinated notes. If we are prohibited from repaying or repurchasing the convertible subordinated notes, we could try to obtain the consent of lenders under those arrangements, or we could attempt to refinance the indebtedness that contains the restrictions. If we could not obtain the necessary consents or refinance the indebtedness, we would be unable to repay or repurchase the convertible subordinated notes. Any such failure would constitute an event of default under the agreement with the holders of the 4% convertible subordinated notes, which could, in turn, constitute a default under the terms of any future indebtedness.

***You may suffer additional dilution if we issue additional shares to the investor under the Common Stock Purchase Agreement.***

In March 2006, we entered into a Common Stock Purchase Agreement with an investor. Under this agreement, we secured a purchase commitment from the investor to purchase from us up to a total of \$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. In July 2006, we drew down \$3.5 million and in November 2006, we drew down \$4.0 million of this commitment through the sale of 683,593 and 781,250 shares of common stock, respectively. It is anticipated that we will draw down the remaining \$2.3 million in December 2006 through the sale of additional shares of common stock. In each drawdown, the shares of common stock will be sold at a price equal to 80% of the volume weighted average of the closing prices of the common stock on the five trading days preceding the drawdown notice, but such purchase price in no event will be less than a floor price of \$5.12 per share. Based on this floor price, a maximum of 439,453 additional shares of common stock could be issued with respect to the remaining \$2.3 million of common stock available under the purchase commitment. We are not obligated to sell any of the remaining \$2.3 million of common stock available under the purchase commitment and there are no minimum commitments or minimum use penalties. If we issue shares of our common stock to the investor pursuant to the purchase commitment, our then existing stockholders will experience dilution.

**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.



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**SIGNATURES**

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

**IDERA PHARMACEUTICALS, INC**

Date: November 13, 2006

/s/ Sudhir Agrawal

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

Date: November 13, 2006

/s/ Robert G. Andersen

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

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**Exhibit Index**

**Exhibit No.**

- 10.1 Amendment No. 1 to Purchase Agreement between the Company and Biotech Shares Ltd., dated July 10, 2006.
- 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.