

AMAG PHARMACEUTICALS INC.  
Form 10-Q  
August 08, 2007

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2007

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File #0-14732

**AMAG PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**04-2742593**

(IRS Employer  
Identification No.)

**125 CambridgePark Drive - 6th Floor**  
**Cambridge, Massachusetts**  
(Address of Principal Executive Offices)

**02140**  
(Zip Code)

**(617) 498-3300**

(Registrant's Telephone Number, Including Area Code)

**ADVANCED MAGNETICS, INC.**

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

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

As of August 1, 2007 there were 16,845,939 shares of the registrant's Common Stock, par value \$.01 per share, outstanding.

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**PART I**

FINANCIAL INFORMATION

**Item 1. Financial Statements.**

**AMAG PHARMACEUTICALS, INC.**

**CONDENSED BALANCE SHEETS**

**AS OF JUNE 30, 2007 AND DECEMBER 31, 2006**

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

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(Unaudited)

	June 30, 2007	December 31, 2006
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 9,750	\$ 114,460
Short-term investments	276,049	41,599
Accounts receivable - trade	419	349
Inventories	332	344
Prepaid expenses and interest receivable	1,857	1,098
Total current assets	288,407	157,850
Property, plant and equipment:		
Land	360	360
Building and improvements	4,967	4,947
Laboratory equipment	5,794	5,560
Furniture and fixtures	1,539	1,311
Total property, plant and equipment	12,660	12,178
Less - accumulated depreciation	(8,027	) (7,721 )
Net property, plant and equipment	4,633	4,457
Long-term investments	8,760	
Restricted cash	34	34
Total assets	\$ 301,834	\$ 162,341
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 639	\$ 3,851
Accrued expenses	3,925	3,550
Deferred revenue	738	976
Total current liabilities	5,302	8,377
Long-term liabilities:		
Deferred revenue and rent expense	1,239	1,688
Total liabilities	6,541	10,065
Commitments and contingencies (Note J)		
Stockholders' equity:		
Preferred stock, par value \$.01 per share, 2,000,000 shares authorized; none issued		
Common stock, par value \$.01 per share, 25,000,000 shares authorized; 16,771,764 shares issued and outstanding at June 30, 2007 and 14,065,663 shares issued and outstanding at December 31, 2006		
	168	141
Additional paid-in capital	395,121	234,930
Accumulated other comprehensive loss	(63	)
Accumulated deficit	(99,933	) (82,795 )
Total stockholders' equity	295,293	152,276
Total liabilities and stockholders' equity	\$ 301,834	\$ 162,341

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

**AMAG PHARMACEUTICALS, INC.**

**CONDENSED STATEMENTS OF OPERATIONS**



**FOR THE THREE- AND SIX-MONTH PERIODS ENDED**

**JUNE 30, 2007 AND 2006**

(IN THOUSANDS, EXCEPT PER SHARE DATA)

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**(Unaudited)**

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2007	2006	2007	2006
<b>Revenues:</b>				
License fees	\$ 184	\$ 238	\$ 726	\$ 467
Royalties	64	133	141	211
Product sales	497	574	791	980
Total revenues	745	945	1,658	1,658
<b>Costs and expenses:</b>				
Cost of product sales	101	90	258	141
Research and development	5,115	6,252	11,256	10,322
Selling, general and administrative	5,083	1,855	7,874	3,837
Total costs and expenses	10,299	8,197	19,388	14,300
Operating loss	(9,554 )	(7,252 )	(17,730 )	(12,642 )
<b>Other Income (Loss):</b>				
Interest income	2,619	584	4,592	839
Litigation settlement (Note J)			(4,000 )	
Net loss	\$ (6,935 )	\$ (6,668 )	\$ (17,138 )	\$ (11,803 )
Net loss per share - basic and diluted:	\$ (0.46 )	\$ (0.57 )	\$ (1.17 )	\$ (1.07 )
<b>Weighted average shares outstanding used to compute loss per share:</b>				
Basic and diluted	15,150	11,714	14,658	11,028

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

**AMAG PHARMACEUTICALS, INC.**

**CONDENSED STATEMENTS OF COMPREHENSIVE LOSS**

**FOR THE THREE- AND SIX-MONTH PERIODS ENDED**

**JUNE 30, 2007 AND 2006**

(IN THOUSANDS)



**(Unaudited)**

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	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2007	2006	2007	2006
Net loss	\$ (6,935 )	\$ (6,668 )	\$ (17,138 )	\$ (11,803 )
Other comprehensive loss:				
Unrealized (loss) gain on securities	(63 )		(63 )	19
Comprehensive net loss	\$ (6,998 )	\$ (6,668 )	\$ (17,201 )	\$ (11,784 )

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

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**AMAG PHARMACEUTICALS, INC.**

**CONDENSED STATEMENTS OF CASH FLOWS**

**FOR THE SIX-MONTH PERIODS ENDED**

**JUNE 30, 2007 AND 2006**

(IN THOUSANDS)

**(Unaudited)**



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	Six-Month Periods Ended June 30,	
	2007	2006
Net loss	\$ (17,138 )	\$ (11,803 )
Cash flows from operating activities:		
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	369	200
Non-cash expense associated with non-employee stock options		82
Non-cash expense associated with employee stock options and restricted stock units	3,787	1,880
Amortization of (discounts) premiums on purchased securities	(600 )	22
Loss on disposal of fixed assets		13
Changes in operating assets and liabilities:		
Accounts receivable - trade	(70 )	(39 )
Inventories	12	37
Prepaid expenses and interest receivable	(759 )	(6 )
Accounts payable and accrued expenses	(2,837 )	3,926
Deferred revenue and rent expense	(687 )	(464 )
Total adjustments	(785 )	5,651
Net cash used in operating activities	(17,923 )	(6,152 )
Cash flows from investing activities:		
Proceeds from sales or maturities of available-for-sale investments	74,308	
Proceeds from maturities of held-to-maturity investments	124,034	15,553
Purchase of available-for-sale investments	(330,229 )	
Purchase of held-to-maturity investments	(110,787 )	(31,535 )
Restricted cash		(16 )
Capital expenditures	(545 )	(782 )
Net cash used in investing activities	(243,219 )	(16,780 )
Cash flows from financing activities:		
Proceeds from the exercise of stock options	1,842	2,381
Proceeds from the exercise of warrants		650
Proceeds from the issuance of common stock pursuant to the Employee Stock Purchase Plan	111	94
Proceeds from the issuance of common stock, net of underwriting discount of \$8,143 and other expenses of issue of \$228 in May 2007 and net of underwriting discount of \$2,035 and other expenses of issue of \$173 in March 2006	154,479	31,659
Net cash provided by financing activities	156,432	34,784
Net (decrease) increase in cash and cash equivalents	(104,710 )	11,852
Cash and cash equivalents at beginning of the period	114,460	7,719
Cash and cash equivalents at end of the period	\$ 9,750	\$ 19,571
Supplemental data:		
Non-cash financing activities:		
Non-cash stock option exercises	\$ 516	\$ 446
Non-cash warrant exercises	\$	\$ 8,088

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

**AMAG PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

**JUNE 30, 2007**

**(Unaudited)**

A. Summary of Accounting Policies

*Business*

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AMAG Pharmaceuticals, Inc. (formerly Advanced Magnetics, Inc.), a Delaware corporation founded in 1981, is a biopharmaceutical company that utilizes its proprietary nanoparticle technology for the development and commercialization of therapeutic iron compounds to treat anemia and novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. We have two approved products, Feridex I.V.® and GastroMARK®, and we have two product candidates, ferumoxytol and Combidex®. Ferumoxytol, our key product candidate, is being developed for use as an intravenous, or IV, iron replacement therapeutic for the treatment of iron deficiency anemia in chronic kidney disease. *Combidex* is our investigational functional molecular imaging agent consisting of iron oxide nanoparticles for use in conjunction with magnetic resonance imaging, or MRI, to aid in the differentiation of cancerous from normal lymph nodes. *Feridex I.V.*, our liver contrast agent, is approved and marketed in Europe, the United States and other countries. *GastroMARK*, our oral contrast agent used for delineating the bowel in MRI, is approved and marketed in Europe, the United States and other countries.

### *Change in Fiscal Year End*

On May 14, 2007, our Board of Directors, or the Board, approved a change in our fiscal year end from September 30 to December 31. On June 14, 2007, we filed a transition report on Form 10-Q for the quarter ended December 31, 2006 pursuant to Rule 13a-10 of the Securities Exchange Act of 1934 for transition period reporting. Accordingly, these unaudited condensed financial statements reflect our new year end of December 31, and therefore, year-to-date amounts are for the six month periods ended June 30, 2007 and 2006.

### *Change in Corporate Name*

On July 24, 2007, we announced that we changed our corporate name from Advanced Magnetics, Inc. to AMAG Pharmaceuticals, Inc., effective immediately. The name change was effected pursuant to Section 253 of the Delaware General Corporate Law through a merger of a newly-created, wholly-owned subsidiary with and into Advanced Magnetics, Inc. The name change did not require stockholder approval.

### *Basis of Presentation*



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These condensed financial statements are unaudited and, in the opinion of management, include all adjustments necessary for a fair statement of such interim financial statements. Such adjustments consisted only of normal recurring items.

In accordance with accounting principles generally accepted in the United States of America for interim financial reports and the instructions for Form 10-Q and the rules of the Securities and Exchange Commission, or the SEC, certain information and footnote disclosures normally included in annual financial statements have been condensed or omitted. Our accounting policies are described in the Notes to the Financial Statements in our Annual Report on Form 10-K for the fiscal year ended September 30, 2006. Interim results are not necessarily indicative of the results of operations for the full year. These interim financial statements should be read in conjunction with our most recent Annual Report on Form 10-K for the fiscal year ended September 30, 2006.

### *Use of Estimates*

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The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial

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statements and the reported amounts of revenue and expenses during the reported period. Actual results could differ from those estimates.

#### *Cash and Cash Equivalents*

Cash equivalents consist principally of cash held in commercial bank accounts, money market funds and U.S. Treasury securities having an original maturity of less than three months. The U.S. Treasury securities were classified as cash equivalents in accordance with the provisions of Statement of Financial Accounting Standards, or SFAS, No. 95 Statement of Cash Flows .

#### *Investments*

We account for and classify our investments as either available-for-sale, trading, or held-to-maturity, in accordance with the guidance outlined in SFAS No. 115 Accounting for Certain Investments in Debt and Equity Securities, or SFAS 115. The determination of the appropriate classification by us is based on a variety of factors, including management's intent.

Held-to-maturity securities are those securities which we have the ability and intent to hold until maturity and are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method. At June 30, 2007, we had two investments which were classified as held-to-maturity.

Available-for-sale securities are those securities which we view as available for use in current operations. We have classified all of our available-for-sale securities as short-term investments, even though the stated maturity date may be one year or more beyond the current balance sheet date. Available-for-sale investments are stated at fair value with their unrealized gains and losses included as a separate component of stockholders' equity entitled Accumulated other comprehensive loss, until such gains and losses are realized.

The fair value of our investments is determined from quoted market prices. Investments are considered to be impaired when a decline in fair value below cost basis is determined to be other than temporary. We periodically employ a methodology in evaluating whether a decline in fair value below cost basis is other than temporary that considers available evidence regarding our marketable securities. In the event that the cost basis of a security exceeds its fair value, we evaluate, among other factors, the duration of the period that, and extent to which, the fair value is less than cost basis; the financial health of and business outlook for the investee, including industry and sector performance, changes in technology, and operational and financing cash flow factors; overall market conditions and trends; and our intent and ability to hold the investment. Once a decline in fair value is determined to be other than temporary, a write-down is either recorded in, or is transferred from accumulated other comprehensive loss to, the Statements of Operations, and a new cost basis in the security is established. There were no unrealized losses in our investments which were deemed to be other than temporary in the three- and six-month periods ended June 30, 2007 and 2006. Realized gains and losses are determined on the specific identification method and are included in interest income in the Statements of Operations. Interest income is accrued as earned.

#### *Equity-Based Compensation*

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On October 1, 2005, we adopted SFAS No. 123R, Share-Based Payment, or SFAS 123R, and its related implementation guidance as promulgated by both the Financial Accounting Standards Board, or the FASB, and the SEC Staff Accounting Bulletin 107, or SAB 107, in connection with accounting for the share-based compensation arrangements of our employees and certain directors. These pronouncements require that equity-based compensation cost be measured at the grant date (based upon an estimate of the fair value of the compensation granted) and recorded to expense over the requisite service period, which generally is the vesting period.

We estimate the fair value of equity-based compensation involving stock options based on the Black-Scholes option pricing model. This model requires the input of several factors such as the expected option term, expected volatility of our stock price over the expected option term, expected risk-free interest rate over the expected

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option term, expected dividend yield over the expected option term, and an expected forfeiture rate, and is subject to various assumptions. We believe this valuation methodology is appropriate for estimating the fair value of stock options we grant to employees and directors which are subject to SFAS 123R requirements. The valuation of equity-based compensation using this methodology is an estimate and thus may not be reflective of actual future results or amounts ultimately realized by recipients of these grants. These amounts, and the amounts applicable to future quarters, are also subject to future quarterly adjustments based upon a variety of factors, which include, but are not limited to, the issuance of new options. The fair value of restricted stock units granted to employees and directors is determined at the grant date and is computed based upon the estimated fair market value per share on the date of the grant.

*Fair Value of Financial Instruments*

The estimated fair value of certain financial instruments, including cash and cash equivalents, short- and long-term investments, accounts receivable, accounts payable and accrued expenses, approximates the carrying value due to their short maturities and varying interest rates. Any net unrealized gain (loss) on investments is recorded as a separate component of stockholders' equity entitled Accumulated other comprehensive loss.

*Reclassifications*

Certain amounts from the prior fiscal quarter have been reclassified to conform to the current quarter's presentation. The Company changed from the direct method presentation of cash flows to the indirect method presentation of cash flows in order to conform to comparable industry presentations.

**B. Investments**

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At June 30, 2007 and December 31, 2006, a portion of our investments consisted of U.S. government agency securities and corporate debt securities which were classified as held-to-maturity investments.

Held-to-maturity securities were as follows (in thousands):

	<b>June 30, 2007</b>			
	<b>Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
<b>U.S. treasury and government agency securities</b>				
Due in one year or less	\$	\$	\$	\$
Due in one to three years	8,760		(7 )	8,753
	\$ 8,760	\$	\$ (7 )	\$ 8,753
	<b>December 31, 2006</b>			
	<b>Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
<b>Corporate debt and preferred securities</b>				
Due in one year or less	\$ 9,599	\$ 1	\$	\$ 9,600
Due in one to three years				
<b>U.S. treasury and government agency securities</b>				
Due in one year or less	12,000		(4 )	11,996
Due in one to three years				
	\$ 21,599	\$ 1	\$ (4 )	\$ 21,596

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At June 30, 2007 and December 31, 2006, a portion of our investments consisted of corporate debt and preferred securities, U.S. treasury and government agency securities, commercial paper, and auction rate securities which were classified as available-for-sale investments. Our investments in auction rate securities are recorded at cost, which approximates fair market value due to their variable interest rates, which typically reset every 7 to 35 days, and, despite the long-term nature of their stated contractual maturities, we have the ability to quickly liquidate these securities.

The following is a summary of our available-for-sale securities (in thousands):

	<b>June 30, 2007</b>			
	<b>Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
<b>Corporate debt and preferred securities</b>				
Due in one year or less	\$ 13,879	\$	\$ (9 )	\$ 13,870
Due in one to three years	10,301	1	(39 )	10,263
<b>U.S. treasury and government agency securities</b>				
<b>Due in one year or less</b>				
Due in one to three years	2,999		(3 )	2,996
<b>Commercial paper</b>				
<b>Due in one year or less</b>				
Due in one to three years	19,533		(13 )	19,520
<b>Auction rate securities</b>				
<b>Due in one year or less</b>				
Due after five years	229,400			229,400
	<b>\$ 276,112</b>	<b>\$ 1</b>	<b>\$ (64 )</b>	<b>\$ 276,049</b>

	<b>December 31, 2006</b>			
	<b>Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
<b>Auction rate securities</b>				
Due in one year or less	\$ 20,000	\$	\$	\$ 20,000
Due after five years	\$ 20,000	\$	\$	\$ 20,000

The following is a summary of the gross unrealized losses and fair value of our investments with unrealized losses that are not deemed to be other-than-temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position (in thousands):

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	<b>June 30, 2007</b>		<b>12 Months or greater</b>		<b>Total Fair Value</b>	<b>Unrealized Losses</b>
	<b>Less than 12 Months Fair Value</b>	<b>Unrealized Losses</b>	<b>Fair Value</b>	<b>Unrealized Losses</b>		
Corporate debt securities	\$ 13,159	\$ (49 )	\$	\$	\$ 13,159	\$ (49 )
U.S. treasury and government agency securities	11,749	(10 )			11,749	(10 )
Commercial paper	19,519	(12 )			19,519	(12 )
	\$ 44,427	\$ (71 )	\$	\$	\$ 44,427	\$ (71 )

	<b>December 31, 2006</b>		<b>12 Months or greater</b>		<b>Total Fair Value</b>	<b>Unrealized Losses</b>
	<b>Less than 12 Months Fair Value</b>	<b>Unrealized Losses</b>	<b>Fair Value</b>	<b>Unrealized Losses</b>		
U.S. treasury and government agency securities	\$ 11,996	\$ (4 )	\$	\$	\$ 11,996	\$ (4 )

The unrealized losses on our investments at June 30, 2007 were caused by interest rate increases, and not credit quality issues. Since the decline in market value is attributable to changes in interest rates, and we have the ability and intent to hold these investments until a recovery of fair value, we do not consider these investments to be other-than-temporarily impaired at June 30, 2007.

The unrealized loss at December 31, 2006 on an investment in a U.S. treasury and government agency security was primarily caused by interest rate increases. Because we had the ability and intent to hold this investment until a recovery of fair value, we did not consider this investment to be other-than-temporarily impaired at December 31, 2006.

**C. Inventories**



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The major classes of inventories as of June 30, 2007 and December 31, 2006 were as follows (in thousands):

	<b>June 30, 2007</b>	<b>December 31, 2006</b>
Raw materials	\$ 259	\$ 289
Work in process	47	41
Finished goods	26	14
Total inventories	\$ 332	\$ 344

### D. Income Taxes

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There were no income tax provisions or benefits for the three- and six-month periods ended June 30, 2007 and 2006, as we incurred a net loss in all of those periods. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets as of June 30, 2007 and December 31, 2006.

Effective January 1, 2007, we adopted the provisions of FASB Interpretation No. 48 entitled Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109, or FIN 48. As a result of the implementation of FIN 48, we recognized no material adjustment for unrecognized income tax benefits. At the adoption date of January 1, 2007 and also at June 30, 2007, we had no unrecognized tax benefits.

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We recognize interest and penalties related to uncertain tax positions in income tax expense. As of January 1, 2007, the date of adoption of FIN 48, and June 30, 2007 and 2006, we had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in our Statements of Operations.

The statute of limitations for assessment by the IRS and state tax authorities is closed for fiscal years prior to September 30, 2004, although carryforward attributes that were generated prior to fiscal year 2004 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period. There are currently no federal or state audits in progress.

As of September 30, 2006, we had unused federal net operating losses, or NOLs, of approximately \$68.5 million, which begin to expire in 2010, unused state NOL carryforwards of approximately \$51.0 million, which began to expire in fiscal 2006, and unused research and development, or R&D, credit carryforwards of approximately \$3.6 million which began to expire in fiscal 2006. We also have approximately \$3.0 million of capital loss carryforwards which begin to expire in 2007.

Utilization of NOLs and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986, or Section 382, as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since our formation, we have raised capital through the issuance of capital stock on several occasions which, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in a change of control, as defined by Section 382, or could result in a change of control in the future upon subsequent disposition. We have not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since our formation due to the significant complexity and cost associated with such study. If we have experienced a change of control, as defined by Section 382, at any time since our formation, utilization of our NOL or R&D credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization. Further, until a study is completed and any limitation known, no amounts are being presented as an uncertain tax position under FIN 48.

**E.** Net Loss per Share

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We compute basic net loss per share by dividing net loss by the weighted average number of common shares outstanding during the relevant period. Options to purchase a total of 1,161,973 and 971,625 shares of common stock that were outstanding as of June 30, 2007 and 2006, respectively, were excluded from the computation of diluted net loss per share because such options were anti-dilutive as we incurred a net loss in those periods. In addition, 29,500 and 30,000 shares of common stock issuable upon the vesting of restricted stock units were outstanding as of June 30, 2007 and 2006, respectively, and were excluded from the computation of diluted net loss per share because such units were anti-dilutive as we incurred a net loss in those periods.

Warrants to purchase 261,780 shares of common stock, issued in July 2003 at an exercise price of \$15.50 per share (all of which were exercised in the six months ended June 30, 2006), were excluded from the computation of diluted net loss per share for the three- and six-month periods ended June 30, 2006 because such warrants were anti-dilutive as we incurred a net loss in those periods. In addition, warrants to purchase 359,999 shares of common stock, issued in June 2005 at an exercise price of \$13.00 per share (all of which were exercised in the six months ended June 30, 2006), were also excluded from the computation of diluted net loss per share for the three- and six-month periods ended June 30, 2006 because such warrants were anti-dilutive as we incurred a net loss in those periods. There were no warrants outstanding during the three- and six-month periods ended June 30, 2007.

The components of basic and diluted net loss per share were as follows (in thousands except per share data):

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	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2007	2006	2007	2006
Net loss (A)	\$ (6,935 )	\$ (6,668 )	\$ (17,138 )	\$ (11,803 )
Weighted average common shares outstanding (B)	15,150	11,714	14,658	11,028
Net loss per share:				
Basic and diluted (A/B)	\$ (0.46 )	\$ (0.57 )	\$ (1.17 )	\$ (1.07 )

**F.** Common Stock Transactions

**In May 2007, we sold an aggregate of 2,500,000 shares of our common stock, \$.01 par value per share, in an underwritten public offering at a price to the public of \$65.14 per common share, resulting in gross proceeds of approximately \$162.9 million. Net proceeds to us after deducting fees, commissions and other expenses related to the offering were approximately \$154.5 million. The shares were issued pursuant to a shelf registration statement on Form S-3 which became effective upon filing.**

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In December 2006, we sold an aggregate of 2,103,000 shares of our common stock, \$.01 par value per share, in an underwritten public offering at a price to the public of \$62.00 per common share, resulting in gross proceeds of \$130.4 million. Net proceeds to us after deducting fees, commissions and other expenses related to the offering were \$122.9 million. The shares were issued pursuant to a shelf registration statement on Form S-3 and a registration statement filed pursuant to Rule 462(b) promulgated under the Securities Act of 1933, as amended, or the Securities Act.

**In March 2006, we sold an aggregate of 1,233,214 shares of our common stock, \$.01 par value per share, in an underwritten public offering at a price to the public of \$27.46 per common share, resulting in gross proceeds of \$33.8 million. Net proceeds to us after deducting fees, commissions and other expenses related to the offering were \$31.7 million. The shares were issued pursuant to our then existing shelf registration statement on Form S-3 and a registration statement filed pursuant to Rule 462(b) promulgated under the Securities Act.**



**G.** Equity-Based Compensation

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We have several stock-based compensation plans. Our Amended and Restated 2000 Stock Plan, or the 2000 Stock Plan, which was approved by our stockholders, provides for the grant of options and other stock awards to our directors, officers, employees and consultants. The terms and conditions of each such grant, including, but not limited to, the number of shares, the exercise price, term of the option/award and vesting requirements, are determined by our Board or the Compensation Committee of our Board.

As of June 30, 2007, we have granted options and restricted stock units covering 1,869,650 shares of common stock under the 2000 Stock Plan, of which 195,575 stock options and no restricted stock units have expired or terminated, and 493,002 stock options and 7,500 restricted stock units have been exercised. The remaining number of outstanding options and restricted stock units pursuant to this plan as of June 30, 2007 was 1,144,073 and 29,500, respectively. The remaining number of shares available for future grants as of June 30, 2007 was 325,925. As previously disclosed and included above, during 2007 we granted 110,000 performance-based option awards. These awards become exercisable in full immediately upon the achievement of certain performance goals established by our Board. All outstanding options granted have an exercise price equal to the closing price of our common stock on the grant date and substantially all outstanding options have a ten year term.

Our standard stock option agreement allows for payment of the exercise price for vested stock options either through a cash remittance to us in exchange for newly issued shares, or through a non-cash exchange of previously issued shares held by the recipient in exchange for our newly issued shares. The latter method results in no cash being received by us, but also results in a lower number of total shares subsequently being outstanding (as compared

to a cash exercise), as a direct result of previously issued shares being exchanged in return for the issuance of new shares. Shares returned to us in this manner are retired.

At our Annual Meeting of Stockholders held on February 6, 2007, our stockholders approved our 2006 Employee Stock Purchase Plan. The plan authorizes the issuance of up to 100,000 shares of our common stock to eligible employees. Under the terms of the 2006 Employee Stock Purchase Plan, which began on June 1, 2007 and expires May 31, 2012, eligible employees may purchase shares (subject to certain plan and/or income tax limitations) in ten semi-annual offerings through payroll deductions of up to an annual maximum of 10% of the employee's total compensation, including base pay or salary and any overtime, bonuses or commissions. The first period of the plan commenced on June 1, 2007 and ends November 30, 2007. For the remainder of the plan, periods will consist of six-month periods commencing June 1 and ending November 30 and commencing December 1 and ending May 31. The purchase price per share is the lesser of 85% of the fair market value of the stock on the first or last day of the plan period. As of June 30, 2007, no shares have been issued under the 2006 Employee Stock Purchase Plan.

On November 7, 2006, the Board approved a revised plan of non-employee director compensation. As part of this plan it is intended that on the first Tuesday of each November, each non-employee director will be granted an option to purchase \$100,000 in value of shares of our common stock pursuant to our 2000 Stock Plan. On May 14, 2007, the Board approved an amendment to the foregoing plan to provide that on the first Tuesday of each November, the Chairman of the Board (provided that the Chairman is a non-employee director), will be granted an option to purchase \$200,000 in value of shares of common stock pursuant to our 2000 Stock Plan. These options will vest in full on the date of grant, have an exercise price equal to the fair market value of a share of our common stock as of the date of grant, and have a ten year term. The actual number of shares granted will be determined using a Black-Scholes option pricing model identical to that used by us for purposes of preparing our financial statements. In lieu of the foregoing annual grant for the first year of service on the Board, each newly-elected non-employee director will be granted an option to purchase \$250,000 in value of shares of our common stock pursuant to our 2000 Stock Plan on the date such director is elected to the Board. These options will vest in four equal annual installments beginning one year from the date of grant, have an exercise price equal to the fair market value of a share of our common stock as of the date of grant, and have a ten-year term. The actual number of shares granted will be determined using a Black-Scholes option pricing model.

For the three months ended June 30, 2007, we recorded stock-based compensation expense of approximately \$2.3 million for stock options granted under the 2000 Stock Plan, the Company's 2006 Employee Stock Purchase Plan and the Company's 2003 Employee Stock Purchase Plan, as amended (together, the ESPP Plans), of which \$0.4 million was included in research and development expenses and \$1.9 million was included in selling, general and administrative expenses. For the six months ended June 30, 2007, we recorded stock-based compensation expense of approximately \$3.8 million for stock options granted under the 2000 Stock Plan and the ESPP Plans, of which approximately \$0.8 million was included in research and development expenses and approximately \$3.0 million was included in selling, general and administrative expenses. The stock-based compensation expense for both the three months and six months ended June 30, 2007 included approximately \$0.5 million of expense associated with 25,000 options, issued at a weighted average exercise price of \$41.16 per share, whose vesting was accelerated in connection with the retirement of our former Executive Chairman of the Board of Directors.

The following table summarizes the weighted average of assumptions we utilized for calculating the expense associated with grants of options to differing groups of optionees for the six-month period ended June 30, 2007 in accordance with SFAS 123R:

	Employees	Directors
Risk-free interest rate %	4.7	N/A
Expected volatility %	68	N/A
Expected option term	5.60 years	N/A
Dividend yield	None	None

Risk free interest rates utilized are based upon published U.S. Treasury yield curves at the date of the grant for the expected option term. For stock options issued prior to the three-month period ended June 30, 2007,

we relied exclusively on the historical volatility of our own common stock price over the prior period equivalent to our expected option term. During the three-month period ended June 30, 2007, we estimated our expected stock price volatility by basing it on a blend of the historical volatility of our own common stock price with the historical volatility of other similar companies over the prior period equivalent to our expected option term to better reflect expected future volatility. For stock options issued prior to the three-month period ended June 30, 2007, we used the simplified method as promulgated by SAB 107 for estimating the expected option term. During the three-month period ended June 30, 2007, we used the calculated historical term of stock options in computing the expected option term.

At June 30, 2007, the amount of unrecorded expense associated with the adoption of SFAS 123R attributable to future periods for employee stock-based compensation was \$16.4 million, of which \$15.6 million was associated with stock options and \$0.8 million was associated with restricted stock units. Such amounts will be amortized, in varying amounts, to research and development or selling, general and administrative expense, on a straight line basis over a weighted average amortization period of approximately three years. These future estimates are subject to change based upon a variety of future events which include, but are not limited to, changes in estimated forfeiture rates, changes in whether a performance condition is considered probable, and the issuance of new options.

#### **H. Concentration of Credit Risk**

Our operations are located solely within the United States. We perform ongoing credit evaluations of our customers and generally do not require collateral. Three companies were responsible for approximately 89% of our revenue during the six months ended June 30, 2007. Bayer Healthcare Pharmaceuticals (formerly known as Berlex Laboratories, Inc.), or Bayer, represented approximately 43%, Guerbet S.A., or Guerbet, represented approximately 24%, and, Cytogen Corporation, or Cytogen, represented approximately 22% of our revenue during the six months ended June 30, 2007. Two companies were responsible for approximately 82% of our revenue during the six months ended June 30, 2006. Bayer represented approximately 43% and Guerbet represented approximately 39% of our revenue during the six months ended June 30, 2006. No other company accounted for more than 10% of our total revenues for the six months ended June 30, 2007.

Bayer represented approximately 76% and 0% of our trade receivables at June 30, 2007 and December 31, 2006, respectively. Revenues from customers and licensees outside of the United States, principally in Europe, South Korea and Japan, amounted to 26% and 42% of our total revenues for the six months ended June 30, 2007 and 2006, respectively.

#### **I. Recently Issued and Proposed Accounting Pronouncements**

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In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements, or SFAS 157. This statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, SFAS 157 does not require any new fair value measurements. However, for some entities, the application of this statement will change current practice. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Accordingly, we are in the process of evaluating the impact of SFAS 157, but we do not expect it to have a significant impact on our condensed financial statements.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities - Including an Amendment of FASB Statement No. 115, or SFAS 159. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value, thereby providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. The amendment to SFAS 115 applies to all entities with available-for-sale and trading securities. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Accordingly, we are in the process of evaluating the impact of SFAS 159, but we do not expect it to have a significant impact on our condensed financial statements.

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In June 2007, the Emerging Issues Task Force, or EITF, of the FASB reached a consensus on Issue 07-03, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities, or EITF 07-03, which addresses the diversity which exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under this EITF, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-03 is effective for fiscal years beginning after December 15, 2007 and interim periods within those years. Accordingly, we are in the process of evaluating the impact of EITF 07-03, but we do not expect it to have a significant impact on our condensed financial statements.

## **J. Commitments and Contingencies**

### *Legal Proceedings*

On January 25, 2006, Cytogen filed a lawsuit against us in Massachusetts Superior Court in connection with a license and marketing agreement entered into in August 2000 between us and Cytogen. We filed an answer to the complaint asserting numerous counterclaims. On February 15, 2007, we settled the lawsuit with Cytogen. As a result, on February 15, 2007, each party dropped all claims against the other, and all agreements between the parties were terminated. Under the terms of the settlement, we paid Cytogen \$4.0 million in cash and released to Cytogen 50,000 shares of Cytogen common stock held in escrow under the terms of the original license and marketing agreement.

### *Facility Lease and Related Letter of Credit*

On February 28, 2006, we entered into a lease agreement with CambridgePark 125 Realty Corporation, for certain real property located at 125 CambridgePark Drive, Cambridge, Massachusetts. The lease has a three year term, with an additional partial month at the beginning of the term and provides for one option to extend the lease for a two year period. Under the terms of the lease, we were required to pay the landlord approximately \$15,600 per calendar month for the first year of the term (plus the partial month at the beginning of the term), approximately \$16,300 per calendar month for the next year of the term and approximately \$17,000 per calendar month for the last year of the term. In addition to rent, we are also required to pay a proportionate share of the landlord's annual operating costs and electricity. The rent for any extension term will be determined at the time of the exercise of the option under terms set out in the lease.

On November 29, 2006, we entered into an amendment to our lease with CambridgePark 125 Realty Corporation, for the purpose of securing the rental of an additional 8,154 square feet of executive office space at 125 CambridgePark Drive on a coterminous basis with our existing lease. Under the terms of the lease amendment, we were required to pay the landlord approximately \$18,300 per calendar month for the first year of the amended lease for the additional space, approximately \$19,000 per calendar month for the second year of the amended lease for the additional space, and approximately \$19,700 per calendar month for the remaining term of the amended lease for the additional space. All of the other terms and conditions of the original lease apply to the additional rented space. In addition to rent, we are also required to pay a proportionate share of the landlord's annual operating costs and electricity. The rent for any extension term will be determined at the time of the exercise of the option under terms set out in the lease.

In accordance with FASB Technical Bulletin No. 85-3, Accounting for Operating Leases with Scheduled Rent Increases, rent expense is being recognized in the financial statements on a straight-line basis over the lease term, excluding extension periods. In accordance with FASB Technical Bulletin No. 88-13, Issues Relating to Accounting for Leases, and other related interpretations, lease incentives granted to us by the lessor pursuant to the lease amendment are being accounted for on a straight-line basis over the remaining term of the amended lease for the additional space. In addition, in fulfillment of a security deposit requirement for both the original space and the additional space, we issued a \$33,949 irrevocable letter of credit to the landlord. This amount is classified on the accompanying balance sheet as a long-term asset and is restricted in its use.

*Other*

We are a party to an agreement with FoxKiser Development Partners LLC, or FoxKiser, one of our regulatory consultants for *Combidex*, which provides for certain royalty payments to FoxKiser based on future commercial product sales of *Combidex*, if any.

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**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**



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*The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2006.*

*Except for the historical information contained herein, the matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q, words such as may, will, expects, intends, and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements. Any forward-looking statement should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q and those risks identified in our other Securities and Exchange Commission, or SEC, filings, including but not limited to our Annual Report on Form 10-K for the fiscal year ended September 30, 2006. We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in Company expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.*

### **Overview**

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AMAG Pharmaceuticals, Inc. (formerly Advanced Magnetics, Inc.), a Delaware corporation founded in 1981, is a biopharmaceutical company that utilizes its proprietary nanoparticle technology for the development and commercialization of therapeutic iron compounds to treat anemia and novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. We have two approved products, Feridex I.V.® and GastroMARK®, and two product candidates, ferumoxytol and Combidex®.

Ferumoxytol, our key product candidate, is being developed for use as an intravenous, or IV, iron replacement therapeutic for the treatment of iron deficiency anemia in chronic kidney disease, or CKD, patients. We have completed, and publicly announced the results of, all four of our planned pivotal Phase III clinical studies for ferumoxytol as an IV iron replacement therapeutic in CKD patients. Two of the studies were identical efficacy and safety studies each of which enrolled 304 non-dialysis dependent CKD patients comparing two doses of 510 mg ferumoxytol to daily oral iron. The third study was a safety study in 750 non-dialysis dependent CKD and dialysis-dependent CKD patients comparing a single dose of 510 mg ferumoxytol to placebo. The final study was a 230 patient multi-center efficacy and safety study in hemodialysis-dependent CKD patients comparing two doses of 510 mg ferumoxytol to daily oral iron. In July 2007 we announced preliminary positive results from this final study. The efficacy and safety study results demonstrated a statistically significant achievement of all primary and secondary endpoints.

The results from our final study were consistent with the previously reported data from the other three Phase III studies. Across all phases of the ferumoxytol clinical program, with approximately 2,800 total administered doses of ferumoxytol, there were no cases of anaphylaxis and no drug-related deaths. Three of the 1,722 ferumoxytol-treated patients, or 0.17%, experienced a drug-related serious adverse event, or SAE. Of those three patients, one experienced an anaphylactoid event with hypotension, one developed transient hypotension, and one who was previously assigned to oral iron in the randomized phase of the hemodialysis study experienced a drug-related SAE of transient hypotension in the readmission arm after ferumoxytol treatment. One of 289 oral iron treated patients, or 0.35%, experienced a drug-related SAE of severe gastritis. One of 781 IV saline (placebo) treated patients, or 0.13%, experienced a drug-related SAE of petechiae.

We have completed our pre-NDA meeting with the U.S. Food and Drug Administration, or the FDA, with respect to our proposed New Drug Application, or NDA, for ferumoxytol as an IV iron replacement therapeutic in CKD patients with iron deficiency anemia. Based on our current estimate of the timing of our efforts to prepare and

finalize our NDA submission, we currently plan to submit our NDA for ferumoxytol as an IV iron replacement therapeutic in CKD patients during the fourth calendar quarter of 2007.

*Combidex*, our other product under development, is an investigational functional molecular imaging agent consisting of iron oxide nanoparticles for use in conjunction with magnetic resonance imaging, or MRI, to aid in the differentiation of cancerous from normal lymph nodes. In March 2005, we received an approvable letter from the FDA with respect to *Combidex*, subject to certain conditions. In December 2006, Guerbet S.A., or Guerbet, our European partner, announced that it submitted a marketing authorization application to the European Agency for the Evaluation of Medicinal Products, the European equivalent of an NDA, seeking approval for *Combidex* under the tradename Sinerem™ as an aid in the differentiation of lymph nodes in patients with pelvic cancers, including prostate, bladder, cervical and uterine cancer. In February 2007, we announced that we had re-acquired all U.S. marketing rights to *Combidex* in connection with the settlement of a lawsuit with Cytogen Corporation. We are working to determine whether additional data from a Phase III study sponsored by Guerbet in Europe in patients with pelvic cancers, including prostate, bladder, cervical and uterine cancer, together with other additional analyses and information we intend to provide to the FDA will address the concerns raised in the March 2005 approvable letter. Based on our preliminary review of the data from the Guerbet trial, it remains uncertain whether the data from that trial will be sufficient to address the concerns raised by the FDA, and until our evaluation and analysis of the additional data is complete and we meet with the FDA to discuss our intended response to the March 2005 approvable letter, we cannot predict with certainty the timing or likelihood of our ability to satisfy the conditions specified by the FDA for approval of *Combidex*.

*Feridex I.V.*, our liver contrast agent, is currently approved and marketed in Europe, the United States and other countries. *GastroMARK*, our oral contrast agent used for delineating the bowel in MRI, is also approved and marketed in Europe, the United States and other countries.

On May 14, 2007, our Board of Directors, or the Board, approved a change in our fiscal year end from September 30 to December 31. On June 14, 2007, we filed a transition report on Form 10-Q for the quarter ended December 31, 2006 pursuant to Rule 13a-10 of the Securities Exchange Act of 1934, or the Exchange Act, for transition period reporting. Accordingly, our unaudited condensed financial statements reflect our new year end of December 31 and therefore, year-to-date amounts are for the six-month periods ended June 30, 2007 and 2006.

On July 24, 2007, we announced that we changed our corporate name from Advanced Magnetics, Inc. to AMAG Pharmaceuticals, Inc., effective immediately. The name change was effected pursuant to Section 253 of the Delaware General Corporate Law through a merger of a newly-created, wholly-owned subsidiary with and into Advanced Magnetics, Inc. The name change did not require stockholder approval.

**Results of Operations for the Three-Month Period Ended June 30, 2007 as Compared to the Three-Month Period Ended June 30, 2006**

*Revenues*

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Total revenues were \$0.7 million and \$0.9 million for the three months ended June 30, 2007 and 2006, respectively, representing a decrease of approximately 21%. The decrease in revenues was primarily the result of a decrease in the recognition of deferred license fee revenue from a license and marketing agreement covering *Combidex*, a decrease in royalty revenue, and a decrease in sales of *Feridex I.V.* by our marketing partner. Two companies were responsible for 92% of our revenue during the three months ended June 30, 2007. Bayer Healthcare Pharmaceuticals (formerly known as Berlex Laboratories, Inc.), or Bayer, represented approximately 70% and Guerbet represented approximately 22% of our revenue during the three months ended June 30, 2007. Two companies were responsible for approximately 89% of our revenue during the three months ended June 30, 2006. Bayer represented approximately 57% and Guerbet represented approximately 32% of our revenue for the three months ended June 30, 2006.

Our revenues for the three months ended June 30, 2007 and 2006 consisted of the following (in thousands):

	Three-Month Periods Ended June 30,		\$ Change	% Change		
	2007	2006				
License fees	\$ 184	\$ 238	\$ (54)	)	-23	%
Royalties	64	133	(69)	)	-52	%
Product sales	497	574	(77)	)	-13	%
Total revenues	\$ 745	\$ 945	\$ (200)	)	-21	%

*License Fee Revenue*

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All of our license fee revenue for the three months ended June 30, 2007 consisted of license fee revenue associated with a license and marketing agreement with Bayer signed in fiscal 1995. Our license fee revenue for the three months ended June 30, 2006 consisted of license fee revenue related to a license and marketing agreement signed with Cytogen in fiscal 2000 and license fee revenue associated with our license and marketing agreement with Bayer.

In August 2000, we entered into a license and marketing agreement with Cytogen in which, among other things, we granted Cytogen exclusive United States marketing rights to *Combidex*. At the time of signing that agreement, we received shares of common stock of Cytogen with a market value of \$13.5 million as a non-refundable licensing fee. Revenue associated with this fee was recognized over the development period of the products subject to the agreement as costs were incurred. The entire amount of the license fee was booked as deferred revenue upon signing the agreement. On February 15, 2007, as part of the settlement of a lawsuit with Cytogen, the license and marketing agreement with Cytogen was terminated and the remainder of the deferred revenue associated with this agreement, \$0.4 million, was recognized as income at that time.

In February 1995, we entered into a license and marketing agreement and a supply agreement with Bayer, granting Bayer a product license and exclusive marketing rights to *Feridex I.V.* in the United States and Canada. In 1996, the parties agreed to remove Canada from the territories subject to the agreement. Bayer paid us non-refundable license fees and other fees in connection with the agreements. We have determined to account for the revenue associated with this agreement on a straight-line basis over the term of the agreement due to the existence of an established contract period. The agreement expires in 2010 but can be terminated earlier upon the occurrence of certain specified events.

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Total license fee revenue for the three months ended June 30, 2007 and 2006 was recognized as follows (in thousands):

	Three-Month Periods Ended June 30,				
	2007	2006	\$ Change	% Change	
License fee revenue recognized in connection with the Cytogen agreement	\$	\$ 54	\$ (54)	) -100	%
License fee revenue recognized in connection with the Bayer agreement	184	184	0	0	%
Total	\$ 184	\$ 238	\$ (54)	) -23	%

*Product Sale Revenue*

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Product sale revenue for the three months ended June 30, 2007 and 2006 consisted of the following (in thousands):

	Three-Month Periods Ended June 30,		\$ Change	% Change
	2007	2006		
<i>Feridex I.V.</i>	\$ 343	\$ 574	\$ (231)	-40%
<i>GastroMARK</i>	154		154	N/A
<b>Total</b>	<b>\$ 497</b>	<b>\$ 574</b>	<b>\$ (77)</b>	<b>-13%</b>

The decrease in product sale revenue for the three months ended June 30, 2007 as compared to the three months ended June 30, 2006 was primarily the result of a decrease in sales of *Feridex I.V.* to one of our marketing partners, partially offset by an increase in sales of *GastroMARK* to one of our marketing partners. Product sales fluctuate from period to period largely as a result of unpredictable annual product demand by end users and the batch size in which our products are manufactured and shipped, which creates uneven purchasing patterns by our marketing partners. Due to the historically low volume of our product sales, the impact of inflation is immaterial. We expect revenue from product sales will continue to fluctuate from period to period as a result of these factors.

### *Costs and Expenses*

*Cost of Product Sales*

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We incurred costs of \$0.1 million associated with product sales during both the three months ended June 30, 2007 and 2006. This constituted approximately 20% and 16% of product sales during the three months ended June 30, 2007 and 2006, respectively. The cost of product sales and therefore our gross margins are dependent on the mix of customers, prices we charge for our products, product mix, changes in unit volume and production efficiencies.

### *Research and Development Expenses*

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Research and development expenses include external expenses, such as costs of clinical trials, contract research and development expenses, consulting and professional fees and expenses, and internal expenses, such as compensation of employees engaged in research and development activities, the manufacture of product needed to support research and development efforts, related costs of facilities, and other general costs related to research and development.

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Research and development expenses for the three months ended June 30, 2007 and 2006 consisted of the following (in thousands):

	Three-Month Periods Ended June 30,		\$ Change	% Change		
	2007	2006				
External Research and Development Expenses						
Ferumoxytol as an Iron Replacement						
Therapeutic	\$ 1,917	\$ 4,514	\$ (2,597)	)	-58	%
<i>Combidex</i>	149	10	139		>100	%
Other external costs	25	179	(154)	)	-86	%
<b>Total</b>	<b>\$ 2,091</b>	<b>\$ 4,703</b>	<b>\$ (2,612)</b>	<b>)</b>	<b>-56</b>	<b>%</b>
<b>Internal Research and Development Expenses</b>	<b>3,024</b>	<b>1,549</b>	<b>1,475</b>		<b>95</b>	<b>%</b>
<b>Total Research and Development Expenses</b>	<b>\$ 5,115</b>	<b>\$ 6,252</b>	<b>\$ (1,137)</b>	<b>)</b>	<b>-18</b>	<b>%</b>

Total research and development expenses incurred in the three months ended June 30, 2007 amounted to \$5.1 million, a decrease of \$1.1 million from the three months ended June 30, 2006. The decrease was attributable to a \$2.6 million decrease in external costs partially offset by a \$1.5 million increase in internal costs. We expect research and development expenses to generally remain at current levels for the remainder of 2007 as we wind down clinical activities and continue to prepare for our ferumoxytol NDA submission, continue expansion of the research and development function and activities in support of ferumoxytol, and finalize our plan for responding to the March 2005 approvable letter we received from the FDA with respect to *Combidex*.

The \$2.6 million decrease in external costs for the three months ended June 30, 2007 as compared to the three months ended June 30, 2006 was due primarily to a decrease in expenditures associated with the development program for ferumoxytol as an IV iron replacement therapeutic as we completed our Phase III clinical trials.

The \$1.5 million increase in internal costs for the three months ended June 30, 2007 as compared to the three months ended June 30, 2006 was due primarily to higher compensation-related costs as a result of hiring additional research and development personnel and the implementation of a company-wide bonus plan. There were no company-wide bonus plans in place during the three months ended June 30, 2006. For the three-month period ended June 30, 2007, the amount of stock-based compensation expense included in research and development was \$0.4 million, an increase of \$0.3 million compared to the same period in 2006.

Through the end of fiscal 2000, we incurred aggregate internal and external research and development expenses of \$6.5 million related to pre-clinical and toxicology studies of ferumoxytol. Since the end of fiscal 2000 and through the three months ended June 30, 2007, we incurred aggregate external research and development expenses of \$35.1 million related to pre-clinical activities and clinical trials in connection with ferumoxytol. We currently estimate that the future cost of the external efforts necessary to complete development prior to the submission of our NDA for ferumoxytol as an IV iron replacement therapeutic for the treatment of anemia in CKD patients in the U.S. will be in the range of approximately \$5.0 to \$7.0 million through the end of 2007. Our external costs could increase if we experience inadequate performance or errors by third party service providers, if we need to increase the scope and/or budget of the services provided by third parties, if there are deficiencies in the design or oversight by us of our studies, or if we need to conduct additional clinical trials or we otherwise experience a delay in the submission of our NDA for ferumoxytol as an IV iron replacement therapeutic.

We incurred total research and development expenses of \$13.5 million through the end of fiscal 2000 in connection with the development of *Combidex*. Since fiscal 2000 and through the three months ended June 30, 2007, we incurred additional external research and development expenses of \$1.8 million, as well as additional internal research and development costs related to our efforts to obtain FDA approval for *Combidex*. We cannot predict with certainty the timing or cost of the efforts that would be necessary to satisfy the conditions specified by the FDA for approval of *Combidex* or our ability to complete those efforts in a timely or cost-effective manner, if at all. However, our external research and development expenses with respect to *Combidex* may increase as we finalize our strategy for responding to the March 2005 approvable letter.

*Selling, General and Administrative Expenses*

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Selling, general and administrative expenses for the three months ended June 30, 2007 and 2006 consisted of the following (in thousands):

	Three-Month Periods Ended June 30,		\$ Change	% Change
	2007	2006		
Compensation, payroll taxes and benefits	\$ 3,309	\$ 1,279	\$ 2,030	>100%
Professional and consulting fees and other expenses	1,774	576	1,198	>100%
<b>Total</b>	<b>\$ 5,083</b>	<b>\$ 1,855</b>	<b>\$ 3,228</b>	<b>&gt;100%</b>

The increase in selling, general and administrative expenses for the three months ended June 30, 2007 as compared to the three months ended June 30, 2006 was due primarily to costs associated with the expansion of our commercial operations function, including the professional staff and consultants hired in preparation for the potential commercialization of ferumoxytol as an IV iron replacement therapeutic, and the implementation of a company-wide bonus plan. There were no company-wide bonus plans in place during the three months ended June 30, 2006. For the three-month period ended June 30, 2007, the amount of stock based compensation expense included in selling, general and administrative expenses was \$1.9 million, an increase of \$1.2 million compared to the same period in 2006. The increase in stock-based compensation expense was largely attributable to increased option grants as well as a modification which occurred in connection with the resignation of our former Executive Chairman of the Board.

We expect selling, general and administrative expenses to continue to increase over the remainder of 2007 as we continue our efforts to augment our operational infrastructure, by recruiting additional staff such as sales and marketing professionals, and hiring consultants in preparation for the potential commercialization of ferumoxytol as an IV iron replacement therapeutic.

*Other Income (Loss)*



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Other income (loss) consisted of \$2.6 million and \$0.6 million of interest income for the three months ended June 30, 2007 and 2006, respectively. The increase in other income (loss) for the three months ended June 30, 2007, as compared to the three months ended June 30, 2006, was primarily attributable to a higher average total dollar amount of invested funds in the three months ended June 30, 2007 as compared to the three months ended June 30, 2006 as a result of our December 2006 and May 2007 financings.

### *Income Taxes*

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We had no income tax provision for the three months ended June 30, 2007 and 2006, as we incurred a net loss in each of those fiscal periods. Due to the uncertainty of the realizability of our deferred tax assets, including loss carryforwards, a full valuation allowance has been recorded as of June 30, 2007 and 2006 against these assets.

*Net Loss*

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For the reasons stated above, there was a net loss of \$6.9 million, or \$0.46 per basic and diluted share, for the three months ended June 30, 2007 compared to a net loss of \$6.7 million, or \$0.57 per basic and diluted share for the three months ended June 30, 2006.

### **Results of Operations for the Six-Month Period Ended June 30, 2007 as Compared to the Six-Month Period Ended June 30, 2006**

#### *Revenues*

Total revenues for each of the six-month periods ended June 30, 2007 and 2006 were \$1.7 million. Total revenues remained stable for the six months ended June 30, 2007 as compared to the six months ended June 30, 2006 principally due to an increase in the recognition of deferred license fee revenue from a license and marketing

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agreement covering *Combidex*, offset by decreased product sales and royalty revenue. Three companies were responsible for approximately 89% of our revenue during the six months ended June 30, 2007. Bayer represented approximately 43%, Guerbet represented approximately 24%, and Cytogen represented approximately 22% of our revenue during the six months ended June 30, 2007. Two companies were responsible for approximately 82% of our revenue during the six months ended June 30, 2006. Bayer represented approximately 43% and Guerbet represented approximately 39% of our revenue during the six months ended June 30, 2006.

Our revenues for the six months ended June 30, 2007 and 2006 consisted of the following (in thousands):

	Six-Month Periods Ended June 30,		\$ Change	% Change	
	2007	2006			
License fees	\$ 726	\$ 467	\$ 259	55	%
Royalties	141	211	(70)	)	-33
Product sales	791	980	(189)	)	-19
Total revenues	\$ 1,658	\$ 1,658	\$ 0	0	%

### *License Fee Revenue*

License fee revenue for the six months ended June 30, 2007 and 2006 consisted of license fee revenue related to a license and marketing agreement signed with Cytogen in fiscal 2000 and license fee revenue associated with a license and marketing agreement with Bayer signed in fiscal 1995.

During the six months ended June 30, 2007 our revenue associated with the Cytogen agreement increased as compared with the six months ended June 30, 2006. On February 15, 2007, as part of the settlement of a lawsuit with Cytogen, the license and marketing agreement with Cytogen was terminated. Therefore, the remainder of the deferred revenue associated with this agreement, \$0.4 million, was recognized during the six months ended June 30, 2007 compared to \$0.1 million recognized in the six months ended June 30, 2006.

Total license fee revenue for the six months ended June 30, 2007 and 2006 was recognized as follows (in thousands):

	Six-Month Periods Ended June 30,		\$ Change	% Change	
	2007	2006			
License fee revenue recognized in connection with the Cytogen agreement	\$ 357	\$ 98	\$ 259	>100	%
License fee revenue recognized in connection with the Bayer agreement	369	369	0	0	%
Total	\$ 726	\$ 467	\$ 259	56	%

### *Product Sale Revenue*

Product sale revenue for the six months ended June 30, 2007 and 2006 consisted of the following (in thousands):

	Six-Month Periods Ended June 30,		\$ Change	% Change	
	2007	2006			
<i>Feridex I.V.</i>	\$ 344	\$ 598	\$ (254)	)	-43
<i>GastroMARK</i>	312	382	(70)	)	-18
<i>Combidex</i>	135	0	135	N/A	
Total	\$ 791	\$ 980	\$ (189)	)	-19

The decrease in product sale revenue in the six months ended June 30, 2007 as compared to the six months ended June 30, 2006 was primarily the result of a decrease in sales of *Feridex I.V.* and *GastroMARK* to our marketing partners, partially offset by an increase in sales of bulk *Combidex* to one of our foreign marketing partners for research and development purposes. Product sales may fluctuate from period to period. Fluctuations in our product sales are largely attributable to unpredictable annual product demand by end users and the batch size in which our products are manufactured and shipped, which creates uneven purchasing patterns by our marketing



partners. We expect revenue from product sales will continue to fluctuate from period to period as a result of these factors.

#### *Costs and Expenses*

##### *Cost of Product Sales*

We incurred costs of \$0.3 million associated with product sales during the six months ended June 30, 2007 compared to costs of \$0.1 million associated with product sales during the six months ended June 30, 2006. This constituted approximately 33% and 14% of product sales during the six months ended June 30, 2007 and 2006, respectively. The increase in cost of product sales is due primarily to the sale of bulk *Combindex* at cost to one of our foreign marketing partners for research and development purposes.

##### *Research and Development Expenses*

Research and development expenses for the six months ended June 30, 2007 and 2006 consisted of the following (in thousands):

	Six-Month Periods Ended June 30,				
	2007	2006	\$ Change	% Change	
<b>External Research and Development Expenses</b>					
Ferumoxytol as an Iron Replacement Therapeutic	\$ 4,915	\$ 6,792	\$ (1,877)	) -28	%
Ferumoxytol as an Imaging Agent		72	(72)	) -100	%
<i>Combindex</i>	310	91	219	) >100	%
Other external costs	193	302	(109)	) -36	%
<b>Total</b>	<b>\$ 5,418</b>	<b>\$ 7,257</b>	<b>\$ (1,839)</b>	<b>) -25</b>	<b>%</b>
<b>Internal Research and Development Expenses</b>	<b>5,838</b>	<b>3,065</b>	<b>2,773</b>	<b>90</b>	<b>%</b>
<b>Total Research and Development Expenses</b>	<b>\$ 11,256</b>	<b>\$ 10,322</b>	<b>\$ 934</b>	<b>9</b>	<b>%</b>

Total research and development expenses incurred in the six months ended June 30, 2007 amounted to \$11.3 million, an increase of \$0.9 million from the six months ended June 30, 2006. This increase was due to a \$2.8 million increase in internal costs partially offset by a decrease of \$1.8 million in external costs.

The \$1.8 million decrease in external costs for the six months ended June 30, 2007 as compared to the six months ended June 30, 2006 was primarily due to a decrease in expenditures associated with the development program for ferumoxytol as an IV iron replacement therapeutic as we completed our Phase III clinical trials.

The \$2.8 million increase in internal costs for the six months ended June 30, 2007 as compared to the six months ended June 30, 2006 was primarily due to higher compensation-related costs as a result of hiring additional research and development personnel and the implementation of a company-wide bonus plan. There were no company-wide bonus plans in place during the six months ended June 30, 2006. For the six-month period ended June 30, 2007, the amount of stock-based compensation expense included in research and development was \$0.8 million, an increase of \$0.4 million as compared to the same period in 2006. The increase in stock-based compensation expense was largely attributable to increased stock option grants.

##### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses for the six months ended June 30, 2007 and 2006 consisted of the following (in thousands):

	Six-Month Periods Ended June 30,		\$ Change	% Change	
	2007	2006			
Compensation, payroll taxes and benefits	\$ 5,158	\$ 2,730	\$ 2,428	89	%
Professional and consulting fees and other expenses	2,716	1,107	1,609	>100	%
Total	\$ 7,874	\$ 3,837	\$ 4,037	>100	%

The \$4.0 million increase in selling, general and administrative expenses for the six months ended June 30, 2007 as compared to the six months ended June 30, 2006 was primarily due to costs associated with the establishment of our commercial operations function, including the professional staff and consultants hired to assist in preparation for the potential commercialization of ferumoxytol as an IV iron replacement therapeutic, and the implementation of a company-wide bonus plan. There were no company-wide bonus plans in place during the six months ended June 30, 2006. For the six-month period ended June 30, 2007, the amount of stock-based compensation expense included in selling, general and administrative expenses was \$3.0 million, an increase of \$1.4 million as compared to the same period in 2006. The increase in stock-based compensation expense during the second quarter of calendar 2007 was largely attributable to increased option grants as well as a modification which occurred in connection with the resignation of our former Executive Chairman of the Board.

#### *Other Income (Loss)*

Other income (loss) for the six months ended June 30, 2007 and 2006 consisted of the following (in thousands):

	Six-Month Periods Ended June 30,		\$ Change	% Change	
	2007	2006			
Interest income	\$ 4,592	\$ 839	\$ 3,753	>100	%
Litigation settlement	(4,000 )		(4,000 )	N/A	
Total Other Income (Loss)	\$ 592	\$ 839	\$ (247 )	-29	%

The increase in other income (loss) in the six months ended June 30, 2007, as compared to the six months ended June 30, 2006, was primarily attributable to increased interest income associated with a higher average total dollar amount of invested funds partially offset by a \$4.0 million settlement with our former licensee Cytogen in the six months ended June 30, 2007 as compared to the six months ended June 30, 2006. The increase in funds available for investment was the result of our December 2006 and May 2007 financings.

#### *Income Taxes*

We had no annualized income tax provision for the six months ended June 30, 2007 and 2006, as we incurred a net loss in each of those periods. Due to the uncertainty of the realizability of our deferred tax assets, including loss carryforwards, a full valuation allowance has been recorded as of June 30, 2007 and 2006 against these assets.

#### *Net Loss*

For the reasons stated above, there was a net loss of \$17.1 million, or \$1.17 per basic and diluted share, for the six months ended June 30, 2007 compared to a net loss of \$11.8 million, or \$1.07 per basic and diluted share for the six months ended June 30, 2006.

#### **Liquidity and Capital Resources**

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We have financed our operations primarily from the sale of our equity securities, proceeds from our marketing and distribution partners and cash generated from our investing activities. Our long-term capital requirements will depend on many factors, including, but not limited to, the following:

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- the progress of, and our ability to successfully complete development of ferumoxytol as an IV iron replacement therapeutic in a timely manner and within our projected budget;
- our ability to successfully obtain regulatory approval for ferumoxytol as an IV iron replacement therapeutic;
- our ability to satisfy the conditions specified by the FDA for approval of *Combidex*;
- our need to hire additional staff and lease additional office space as part of our commercialization efforts for our product candidates, including our efforts to build an internal sales and marketing function;
- the costs associated with preparing for commercial-scale manufacturing of our product candidates, including the costs associated with qualifying a second manufacturing facility;
- costs associated with our potential development of additional indications for ferumoxytol;
- costs associated with our pursuit of approval for ferumoxytol as an IV iron replacement therapeutic outside the U.S.;
- the magnitude of product sales and royalties;
- our ability to establish additional development and marketing arrangements or to enter into alternative strategic relationships;
- the costs involved in filing, prosecuting and enforcing patent claims; and
- our ability to raise additional capital on terms and within a timeframe acceptable to us, if necessary.

As of June 30, 2007, our investments consisted of corporate debt and preferred securities, U.S. treasury and government agency securities, commercial paper, and auction rate securities. Cash and cash equivalents (which consist of cash on hand, money market funds and U.S. Treasury Bills having an original maturity of less than three months) and investments consisted of the following (in thousands):

	June 30, 2007	December 31, 2006	\$ Change	% Change	
Cash and cash equivalents	\$ 9,750	\$ 114,460	\$ (104,710 )	-91	%
Short-term investments	276,049	41,599	234,450	>100	%
Long-term investments	8,760		8,760	N/A	
Total cash, cash equivalents and investments	\$ 294,559	\$ 156,059	\$ 138,500	89	%

The significant increase in cash, cash equivalents and investments as of June 30, 2007 compared to December 31, 2006 is primarily the result of the receipt of net proceeds of \$154.5 million from our May 2007 public offering of common stock. As of June 30, 2007, we believe that our cash, cash equivalents, and investments, combined with cash we currently expect to receive from earnings on our investments, will be sufficient to satisfy our future cash flow needs for at least the next twelve months, including projected operating expenses and research and development costs related to our development and commercialization programs for ferumoxytol as an IV iron replacement therapeutic.

Net cash used in operating activities was \$17.9 million in the six months ended June 30, 2007 compared to \$6.2 million in the six months ended June 30, 2006, an increase of \$11.7 million. This increase was principally due to a \$4.0 million settlement payment to Cytogen, an increase in compensation-related expenses associated with the hiring of additional employees for research and development and commercial operating activities, and payments for activities in preparation for the potential commercialization of ferumoxytol as an IV iron replacement therapeutic.

We anticipate cash used in operating activities will increase in future periods as we continue to advance our ongoing development and commercialization programs for ferumoxytol as an IV iron replacement therapeutic, including our preparation of our NDA submission for ferumoxytol, our development of new indications for ferumoxytol in the United States, and/or our planning and initiation of clinical trials

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outside the United States, our continued expansion of our commercial organization in support of ferumoxytol, our efforts to qualify second source suppliers and manufacturers of ferumoxytol, and finalization of our strategy for responding to the FDA's March 2005 approvable letter with respect to *Combidex*.

In addition to our internal research and development costs, we currently estimate that the future cost of the external efforts necessary to complete development prior to the submission of our NDA for ferumoxytol as an IV iron replacement therapeutic for the treatment of anemia in CKD patients in the U.S. will be in the range of

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approximately \$5.0 to \$7.0 million through the end of 2007. Our external costs could increase if we experience inadequate performance or errors by third party service providers, if we need to increase the scope and/or budget of the services provided by third parties, if there are deficiencies in the design or oversight by us of these studies, or if we need to conduct additional clinical trials or we otherwise experience a delay in the submission of our NDA for ferumoxytol as an IV iron replacement therapeutic.

Cash used in investing activities was \$243.2 million in the six months ended June 30, 2007 compared to \$16.8 million in the six months ended June 30, 2006, an increase of \$226.4 million. The increase was primarily due to the purchase of investments in connection with proceeds received from our December 2006 and May 2007 financings.

Cash provided by financing activities was \$156.4 million in the six months ended June 30, 2007 compared to \$34.8 million in the six months ended June 30, 2006, an increase of \$121.6 million. In May 2007, we sold 2,500,000 shares of our common stock in an underwritten public offering. Net proceeds to us from the financing were approximately \$154.5 million after deducting external transaction costs directly associated with the common stock offering. The shares were issued pursuant to a shelf registration statement on Form S-3 which became effective upon filing.

#### *Facility Lease and Related Letter of Credit*

On February 28, 2006, we entered into a lease agreement with CambridgePark 125 Realty Corporation, for certain real property located at 125 CambridgePark Drive, Cambridge, Massachusetts. The lease has a three year term, with an additional partial month at the beginning of the term and provides for one option to extend the lease for a two year period. Under the terms of the lease, we were required to pay the landlord approximately \$15,600 per calendar month for the first year of the term (plus the partial month at the beginning of the term), approximately \$16,300 per calendar month for the next year of the term and approximately \$17,000 per calendar month for the last year of the term. In addition to rent, we are also required to pay a proportionate share of the landlord's annual operating costs and electricity. The rent for any extension term will be determined at the time of the exercise of the option under terms set out in the lease.

On November 29, 2006, we entered into an amendment to our lease with CambridgePark 125 Realty Corporation, for the purpose of securing the rental of an additional 8,154 square feet of executive office space at 125 CambridgePark Drive on a coterminous basis with our existing lease. Under the terms of the lease amendment, we were required to pay the landlord approximately \$18,300 per calendar month for the first year of the amended lease for the additional space, approximately \$19,000 per calendar month for the second year of the amended lease for the additional space, and approximately \$19,700 per calendar month for the remaining term of the amended lease for the additional space. All of the other terms and conditions of the original lease apply to the additional rented space. In addition to rent, we are also required to pay a proportionate share of the landlord's annual operating costs and electricity. The rent for any extension term will be determined at the time of the exercise of the option under terms set out in the lease. In addition, in fulfillment of a security deposit requirement for both the original space and the additional space, we issued a \$33,949 irrevocable letter of credit to the landlord. This amount is classified on the balance sheet as a long-term asset and is restricted in its use.

#### **Off-Balance Sheet Arrangements**

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As of June 30, 2007, we did not have any off-balance sheet arrangements as defined by SEC rules and regulations.

### **Critical Accounting Policies**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect the reported amount of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reported period. In making these estimates and assumptions, management employs critical accounting policies. Our critical accounting

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policy for equity-based compensation, as described below, has been updated since our Annual Report on Form 10-K for the fiscal year ended September 30, 2006.

*Equity-Based Compensation.* On October 1, 2005, we adopted Statement of Financial Accounting Standards, or SFAS, No. 123R Share-Based Payment, or SFAS 123R, and its related implementation guidance as promulgated by both the Financial Accounting Standards Board, or the FASB, and the SEC Staff Accounting Bulletin 107, or SAB 107, associated with the accounting for the share-based compensation arrangements of our employees and certain directors, including our Employee Stock Purchase Plan. These pronouncements require that equity-based compensation cost be measured at the grant date (based upon an estimate of the fair value of the compensation granted) and recorded to expense over the requisite service period, which generally is the vesting period. Because stock-based compensation expense recognized in the Statements of Operations for the three and six month periods ended June 30, 2007 and 2006 is based on awards ultimately expected to vest, we must make certain judgments about whether employees will complete the requisite service period. We have reduced the compensation expense being recognized for estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. In addition, for awards that contain performance conditions, compensation cost will only be recognized if the performance condition is considered probable of being achieved. Management must make judgments and estimates about the probability that the performance condition will be achieved based on a number of factors, both internally and externally. If factors change and we employ different assumptions in the application of SFAS 123R in future periods, the compensation expense that we record under SFAS 123R may differ significantly from what we have recorded in the current period.

We estimate the fair value of equity-based compensation involving stock options based on the Black-Scholes option pricing model. This model requires the input of several factors such as the expected option term, expected volatility of our stock price over the expected option term, expected risk-free interest rate over the expected option term, and expected dividend yield over the expected option term and is subject to various assumptions. Risk free interest rates utilized are based upon published U.S. Treasury yield curves at the date of the grant for the expected option term. For stock options issued prior to the three-month period ended June 30, 2007, we relied exclusively on the historical volatility of our own common stock price over the prior period equivalent to our expected option term. During the three-month period ended June 30, 2007, we augmented our method of estimating our expected stock price volatility by basing it upon a blend of the historical volatility of our own common stock price with the historical volatility of other similar companies to better reflect expected future volatility. For stock options issued prior to the three-month period ended June 30, 2007, we used the simplified method as promulgated by SAB 107 for estimating the expected option term. During the three-month period ended June 30, 2007, we began using the calculated historical term of stock options in computing the expected option term. We believe this valuation methodology is appropriate for estimating the fair value of stock options we grant to employees and directors which are subject to SFAS 123R requirements. These amounts are estimates and thus may not be reflective of actual future results or amounts ultimately realized by recipients of these grants. These amounts, and the amounts applicable to future quarters, are also subject to future quarterly adjustments based upon a variety of factors, which include, but are not limited to, the issuance of new options. The fair value of restricted stock units granted to employees and directors is determined at the grant date and is computed using the fair value method, which is based upon the estimated fair market value per share on the date of the grant. With any accounting policy that applies judgments and estimates, actual results could significantly differ from those estimates and our financial results could be materially and adversely impacted.

**Impact of Recently Issued and Proposed Accounting Pronouncements**

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In September 2006, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 157, *Fair Value Measurements*, or SFAS 157. This statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, SFAS 157 does not require any new fair value measurements. However, for some entities, the application of this statement will change current practice. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Accordingly, we are in the process of evaluating the impact of SFAS 157, however, we do not expect it to have a significant impact on our condensed financial statements.

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115*, or SFAS 159. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value, thereby providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. The amendment to SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, applies to all entities with available-for-sale and trading securities. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Accordingly, we are in the process of evaluating the impact of SFAS 159.

In June 2007, the Emerging Issues Task Force, or EITF, of the FASB reached a consensus on Issue 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, which addresses the diversity which exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under this EITF, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-03 is effective for fiscal years beginning after December 15, 2007 and interim periods within those years. Accordingly, we are in the process of evaluating the impact of EITF 07-03, but we do not expect it to have a significant impact on our condensed financial statements.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

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As of June 30, 2007, we invested a portion of our surplus cash in fixed income investments in U.S. treasury and U.S. government agency securities, auction rate securities and commercial paper from U.S. corporations. These investments are subject to interest rate risk and will fall in value if market interest rates increase. However, even if market interest rates for comparable investments were to hypothetically increase immediately and uniformly by approximately 10% from levels at June 30, 2007, then this would have resulted in a hypothetical decline in the fair value of our investments of approximately \$0.2 million.

### **Item 4. Controls and Procedures.**



**Managements Evaluation of our Disclosure Controls and Procedures**

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Our principal executive officer and our principal financial and accounting officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Securities Exchange Act of 1934, as amended, or the Exchange Act, Rule 13a-15(e), or Rule 15d-15(e), with the participation of our management, has concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures are effective and are designed to ensure that information we are required to disclose in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. It should be noted that any system of controls is designed to provide reasonable, but not absolute, assurances that the system will achieve its stated goals under all reasonably foreseeable circumstances.

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Our principal executive officer and principal financial and accounting officer have concluded that our disclosure controls and procedures are effective at a level that provides such reasonable assurances.

**Changes in Internal Control Over Financial Reporting**

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There were no changes in our internal control over financial reporting that occurred during the three months ended June 30, 2007 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings.**

On January 25, 2006, Cytogen filed a lawsuit against us in Massachusetts Superior Court in connection with a license and marketing agreement entered into in August 2000 between us and Cytogen. We filed an answer to the complaint asserting numerous counterclaims. On February 15, 2007, we settled the lawsuit with Cytogen. As a result, on February 15, 2007, each party dropped all claims against the other, and all agreements between the parties were terminated. Under the terms of the settlement, we paid Cytogen \$4.0 million in cash and released to Cytogen 50,000 shares of Cytogen common stock held in escrow under the terms of the original license and marketing agreement.

**Item 1A. Risk Factors.**

*The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial conditions and results of operations could be materially and adversely affected.*

***Our ability to successfully complete the development of, and obtain regulatory approval to market and sell, ferumoxytol as an IV iron replacement therapeutic is uncertain because the results of our clinical trials may not demonstrate that ferumoxytol is safe and efficacious at a standard to obtain approval by the necessary regulatory authorities.***

Before obtaining regulatory approvals for the commercial sale of ferumoxytol, we must demonstrate through extensive pre-clinical testing and human clinical trials that ferumoxytol is safe and efficacious. We have completed and publicly announced the results of all four of our planned pivotal Phase III studies of ferumoxytol as an IV iron replacement therapeutic. However, ferumoxytol may be found to be unsafe by the FDA, to have harmful side effects in humans, to be ineffective or may otherwise fail to meet regulatory standards or receive necessary regulatory approvals. If the FDA determines that ferumoxytol has failed in any of the Phase III clinical trials or our Phase III clinical trials do not demonstrate sufficient safety and efficacy of ferumoxytol as an IV iron replacement therapeutic, we will not be able to obtain regulatory approval for, and market, ferumoxytol as an IV iron replacement therapeutic, thereby dramatically reducing our potential future revenues and severely adversely impacting the future prospects for our business. For example, there are certain serious adverse reactions and side effects that are often associated with iron replacement therapeutics such as ferumoxytol. For IV iron replacement products that are currently being marketed, these serious adverse reactions have been seen more frequently when large doses of iron are delivered rapidly. In our clinical trials we administered a relatively large dose of ferumoxytol more rapidly than the currently marketed products. If our studies show a sufficient number of cases of such reactions or side effects in patients which are deemed related to ferumoxytol, then ferumoxytol may be considered unsafe by the FDA and/or the physicians who select which iron replacement product patients will receive. In addition, our clinical trials are conducted in patients in the most advanced stages of kidney disease. During the course of the trials, these patients can and do die or suffer adverse medical effects for reasons that may or may not be related to ferumoxytol, but which could nevertheless adversely affect clinical trial results for ferumoxytol as an IV iron replacement therapeutic and could adversely affect our ability to obtain approval by the FDA. Any such adverse results from our Phase III clinical trials would likely have a severe adverse impact on our stock price.

Our results from pre-clinical testing, early clinical trials, and completed Phase III clinical trials of ferumoxytol as an IV iron replacement therapeutic may not be predictive of results obtained in subsequent human clinical trials with respect to the safety or efficacy of ferumoxytol. For example, a number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage or post-approval clinical trials even after achieving promising results in early-stage, or even Phase III, development. In addition, new information may arise from our continuing analysis of the disclosed Phase III data that may be less favorable than currently anticipated. Clinical data is often susceptible to varying interpretations and many companies that have

believed their products performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products. We cannot be sure that the data obtained from our Phase III clinical trials for ferumoxytol as an IV iron replacement therapeutic will support the indication we are seeking or demonstrate sufficient safety and efficacy to obtain regulatory approvals.

***We may not be able to obtain the necessary regulatory approvals in order to market and sell our products, and the approval process is lengthy and unpredictable.***

Prior to marketing, every product candidate must undergo an extensive regulatory approval process in the United States and in every other country in which a drug sponsor intends to test and market its product candidates and products. This regulatory process includes testing and clinical trials of product candidates to demonstrate safety and efficacy and can take many years and require the expenditure of substantial resources. In addition, changes in FDA or foreign regulatory approval policies or requirements may occur or new regulations may be promulgated which may result in a delay or failure to receive FDA or foreign regulatory approval. Delays and related costs in obtaining regulatory approvals could delay our product commercialization and revenue and consume our resources, both financial and managerial.

Clinical testing of pharmaceutical products is itself subject to approvals by various governmental regulatory authorities. For example, we conducted our Phase III clinical trials in accordance with specific protocols, which are filed with the FDA. The FDA could determine that there were flaws in the design of the protocols or conduct of the trials during the course of the studies which could require us to conduct additional Phase III trials or invalidate the data from completed trials. For example, in discussions with us, the FDA recommended that we also test ferumoxytol at doses lower than 510 mg. We chose to continue our studies of ferumoxytol using only a 510 mg dose. If the FDA determines that the data we submit with our NDA for ferumoxytol does not support the safety of a 510 mg dose, it could require us to conduct additional studies and/or studies at lower doses as a condition for approval, in which case we could incur significant additional costs and experience significant delays in our efforts to obtain regulatory approval for ferumoxytol.

In addition, the FDA guidelines generally suggest that a sponsor like us conduct two adequate and well-controlled studies to demonstrate the safety and efficacy of a product candidate such as ferumoxytol in support of FDA approval. FDA interpretation of the statutory requirements also states that a single study may be sufficient to support approval if the FDA determines that based on relevant science and other confirmatory evidence from pertinent, adequate and well-controlled studies, there is strong evidence to establish the safety and efficacy of the drug candidate to support a single adequate and well-controlled study demonstrating safety and efficacy. We have chosen to conduct only a single study for ferumoxytol as an IV iron replacement therapeutic in the hemodialysis dependent CKD patient population. If the FDA determines that the results of our single study in hemodialysis dependent CKD patients, together with other confirmatory evidence we provide, is not sufficiently strong to demonstrate ferumoxytol's safety and efficacy in hemodialysis dependent CKD patients, then ferumoxytol may not be approved by the FDA for our proposed indication or may be approved for a more limited indication. Any such deficiency in the design or oversight of our Phase III clinical studies by us would delay or prevent us from obtaining regulatory approval for ferumoxytol and would significantly increase the costs of our clinical trials and negatively affect our future prospects and stock price.

If, upon completion of our current Phase III clinical trial program, we need to perform additional studies, we could incur significant additional costs and experience significant delays in our efforts to obtain regulatory approval for ferumoxytol as an IV iron replacement therapeutic. In addition, regulatory approvals may entail limitations on the indicated uses of our ferumoxytol products and impose labeling requirements which may also adversely impact our ability to market such products. Any such requirements or limitations could also result in delays in, or the prevention of, our ability to make regulatory submissions and delays in, or the prevention of, the commercialization of our products. Any such delays would significantly impair or delay our ability to generate future revenues from product sales of ferumoxytol as an IV iron replacement therapeutic and adversely impact the future prospects for our business. Any such delays could also have a severe adverse impact on our stock price.

***We may not complete our development program, file the NDA for ferumoxytol and obtain regulatory approval for ferumoxytol as an IV iron replacement therapeutic in a timely or cost-effective manner.***

Our ability to complete our development program for ferumoxytol as an IV iron replacement therapeutic and file the NDA for ferumoxytol in a timely and cost-effective manner is subject to a number of uncertainties, many of which are out of our control. For example, we rely on third-parties for a variety of activities in our IV iron replacement therapy development program, including collection and analysis of data, drafting study reports and assisting in regulatory submissions. We are relying on a number of third party consultants to help us write and prepare the NDA submission for ferumoxytol. If we cannot engage a sufficient number of such third-parties or if they should fail to perform or perform inadequately, we may not complete our development program for ferumoxytol, file the NDA or obtain regulatory approval for ferumoxytol as an IV iron replacement therapeutic on our intended schedule or within our estimated budget. Any such delays or inadequate performance would also significantly impair or delay our ability to generate future revenues from sales of ferumoxytol as an IV iron replacement therapeutic and adversely impact the future prospects for our business and our stock price.

In addition to our internal research and development costs, we estimated that as of June 30, 2007, the future cost of the external efforts necessary to complete development prior to the submission of our NDA for ferumoxytol as an IV iron replacement therapeutic for the treatment of anemia in CKD patients in the U.S. would be in the range of approximately \$5 to \$7 million through the end of 2007. Our total estimated external costs necessary to complete development of ferumoxytol as an IV iron replacement therapeutic could increase as a result of a number of factors. Examples of such factors include significant delays due to inadequate performance or errors by third-party service providers, deficiencies in our design or oversight of our studies, or the need to conduct additional clinical trials.

***We have limited marketing and sales experience.***

We have very limited experience in marketing and selling products and rely on our corporate partners to market and sell *Feridex I.V.* and *GastroMARK*.

In order to achieve commercial success for ferumoxytol as an IV iron replacement therapeutic, we will have to either develop our own internal marketing and sales function, including a direct sales force, enter into a collaborative arrangement with a third party or parties to market and sell ferumoxytol, or otherwise contract for these services with a third party. If we market and sell ferumoxytol ourselves, which we currently intend to do, we may not be able to successfully recruit and retain the qualified marketing and sales personnel that would be necessary to market and sell ferumoxytol. In addition, in order to establish our own marketing and sales force, we will have to expend substantial amounts of additional capital to support the costs associated with such an effort. If we choose not to market and sell ferumoxytol ourselves, we may not be able to enter into marketing and sales agreements or otherwise contract with others for such services on acceptable terms, if at all.

If we are unsuccessful in developing our own sales and marketing function or if we are unsuccessful in entering into a collaborative relationship or otherwise contracting with a third party for such services, then our product marketing efforts and potential product launch of ferumoxytol as an IV iron replacement therapeutic would be delayed and the commercialization of ferumoxytol would be severely impaired. Furthermore, whether we market and sell ferumoxytol ourselves or through marketing and sales arrangements, we, or our corporate partners, may not be successful in marketing and selling our products. Any delay or failure in our commercial product launch of ferumoxytol as an IV iron replacement therapeutic would have a material adverse impact on our ability to generate additional revenues, our ability to achieve profitability, and on the future prospects for our business.

***We are dependent on a limited number of products and product candidates.***

We have two products, *Feridex I.V.* and *GastroMARK*, currently approved for marketing and sale in the United States and in certain foreign jurisdictions. The only other products currently in our development pipeline, ferumoxytol as an IV iron replacement therapeutic and *Combidex*, are not yet approved for marketing or sale in the United States or in any other country. Sales of *Feridex I.V.* and *GastroMARK* by our marketing partners have been at relatively low levels in recent years, and we expect sales of *Feridex I.V.* and *GastroMARK* will remain at current low levels overall. We may not be able to obtain regulatory approval for ferumoxytol as an IV iron replacement therapeutic or *Combidex* in the United States or in any other country. Even if approved, ferumoxytol as an IV iron replacement therapeutic and *Combidex* may fail to achieve market acceptance. In this event, we do not currently

have an alternative source of revenue or profits, other than *Feridex I.V.* and *GastroMARK*. Any failure by us to obtain approval of ferumoxytol as an IV iron replacement therapeutic or *Combidex* would have a material adverse impact on our ability to generate additional revenues, our ability to achieve profitability, and on the future prospects for our business.

In addition, although we have dedicated significant resources to our research and development efforts in the past, we may not develop new applications for our existing technology or expand the indications for our current products or product candidates for development into future product candidates. We are not currently conducting or sponsoring research to expand our development pipeline. Any failure by us to develop and commercialize additional products and product candidates will place greater pressure on the performance of our existing products and product candidates and will materially adversely affect our ability to increase revenues, our ability to achieve profitability, and the future prospects of our business.

***Our inability to obtain raw materials and our reliance on sole source suppliers could adversely impact our business.***

We currently purchase the raw materials used to manufacture our products from third-party suppliers. However, only in certain limited cases do we have any long-term supply contracts with these third parties. Certain raw materials used in our products are procured from a single source with no qualified alternative supplier. If any of these third-party suppliers should cease to produce the raw materials used in our products, we would be unable to manufacture our products until we were able to qualify an alternative source. For example, during fiscal 2005 one of our suppliers notified us of its decision to discontinue manufacturing a key raw material in our manufacturing process for our products. At that time, we purchased all remaining inventory from the supplier and have since identified an alternative supplier and are continuing our efforts to find a second supplier of this raw material. The qualification of an alternative source may require repeated testing of the new materials and generate greater expenses to us if materials that we test do not perform in an acceptable manner. In addition, we sometimes obtain raw materials from one vendor only, even where multiple sources are available, to maintain quality control and enhance working relationships with suppliers, which could make us susceptible to price inflation by the sole supplier, thereby increasing our production costs. As a result of the high quality standards imposed on our raw materials, we may not be able to obtain raw materials of the quality required to manufacture our products from an alternative source on commercially reasonable terms, or in a timely manner, if at all. Any delay in or failure to obtain sufficient quantities of raw materials would prevent us from manufacturing our products, both for commercial sale and for use by us in clinical trials. In addition, even if we are able to obtain raw materials from an alternative source, if these raw materials are not available in a timely manner or on commercially reasonable terms, we would be unable to manufacture our products, both for commercial sale and for use in our clinical trials, on a timely and cost-effective basis. Any such difficulty in obtaining raw materials would severely hinder our ability to manufacture our products and would have a material adverse impact on our ability to generate additional revenues and our ability to achieve profitability, and on the future prospects for our business.

***Our success is dependent on third-party reimbursement.***

In both the United States and foreign markets, our ability to commercialize our products will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. We expect that our products will be purchased by hospitals, clinics, dialysis centers, doctors and other users that bill various third-party payors, such as Medicare, Medicaid and other government insurance programs, and private payors including indemnity insurers and managed care organizations such as health maintenance organizations. Most of these third-party payors provide coverage for IV iron replacement therapeutics and for MRI for some indications but may not include a separate payment for the use of an MRI contrast agent. Third-party private payors often mirror Medicare coverage policy and payment limitations in setting their own reimbursement payment and coverage policies. Reimbursement rates vary depending on the procedure performed, the third-party payor, the type of insurance plan and other factors.

In the United States, there have been, and we expect there will continue to be, a number of federal and state proposals to reform the health care system. Significant uncertainty exists as to the reimbursement status of



newly-approved healthcare products and products which have competitors for their approved indications. If Medicare or third-party payors do not approve our therapeutic products, MRI products and/or related MRI procedures for reimbursement, or do not approve them for adequate levels of reimbursement, the adoption of our products may be limited. Sales may suffer as some physicians or their patients will opt for a competing product that is approved for sufficient reimbursement, or some patients may forgo the treatment or MRI procedure instead of paying out-of-pocket for costs associated with the treatment or procedure and contrast agent, and our ability to generate revenue may be impaired. Even if third-party payors make reimbursement available, these payors' reimbursement policies may be insufficient, which may negatively impact us and our corporate partners' ability to sell our products on a profitable basis.

Health care reform is an area of continuing national and international attention and a priority of many government officials. Future changes could impose limitations on the prices that can be charged in the United States and elsewhere for our products or the amount of reimbursement available for our products from government agencies or third-party private payors. The increasing use of managed care organizations, health maintenance organizations and the growing trend in capitated coverage as well as continued legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our products which could harm our ability to profit from product sales. In addition, recent and possible future legislation and regulations affecting the pricing of pharmaceuticals may change reimbursement in ways adverse to us that may affect the marketing of our current or future products. While we cannot predict the likelihood or timing of adoption of any of these legislative or regulatory proposals, if the government or a private third-party payor adopts these proposals, our ability to price our products at desired levels would be adversely affected.

***We may be unable to address the issues raised by the FDA in the March 2005 approvable letter with respect to Combidex, and we may not be able to obtain FDA approval for Combidex.***

Although we have received an approvable letter from the FDA with respect to *Combidex*, approval of *Combidex* remains very uncertain and subject to the satisfaction of certain conditions imposed by the FDA and final resolution of labeling. We are working to determine whether additional data from a Phase III study sponsored by Guerbet in Europe in patients with pelvic cancers, including prostate, bladder, cervical and uterine cancer, together with other additional analyses and information we intend to provide to the FDA will address the concerns raised in the March 2005 approvable letter. Based on our preliminary review of the data from the Guerbet trial, it remains uncertain whether the data from that trial will be sufficient to address the concerns raised by the FDA. Until our evaluation and analysis of the additional data is complete and we meet with the FDA to discuss our intended response to the March 2005 approvable letter, we cannot predict with certainty the timing or likelihood of our ability to satisfy the conditions specified by the FDA for approval of *Combidex*. We may be unable to address the conditions specified in the March 2005 approvable letter to the satisfaction of the FDA, or we may be unable to satisfy these conditions in a timely manner and/or without the expenditure of significant additional resources, both financial and managerial. If we are unable to successfully address the concerns of the FDA in a timely manner, the NDA for *Combidex* may not be approved, or, if approved, may be approved for a limited or much narrower indication. Any failure to successfully market and sell *Combidex* or any delay in these efforts would significantly impair or delay our ability to generate future revenues from product sales of *Combidex*, reduce the amount of cash generated from operations available to fund research and development or other activities and adversely impact the future prospects for our business.

***We may not be successful in competing with other companies or our technology may become obsolete.***

The pharmaceutical and biopharmaceutical industries are subject to intense competition and rapid technological change. We believe that our ability to compete successfully will depend on a number of factors including our ability to develop safe and efficacious products, our timely receipt of regulatory approvals, our ability to manufacture products at commercially acceptable costs, secure adequate reimbursement and the implementation of effective marketing campaigns by us or our marketing and distribution partners. We may not be able to successfully develop safe and efficacious products, obtain timely regulatory approvals, manufacture products at commercially acceptable costs, secure adequate reimbursement, market our products alone or with our partners, gain satisfactory market acceptance or otherwise successfully compete in the future.

We have many competitors currently developing and/or marketing IV iron replacement therapy products or MRI contrast agents, many of whom have substantially greater capital and other resources than we do and represent significant competition for us. For example, in May 2007, The Galenica Group, a Swiss company, or Galenica, announced that Luitpold Pharmaceuticals, Inc., a subsidiary of Daiichi Sankyo, Inc. of Japan, and the U.S. licensing partner of Vifor (International), a Galenica subsidiary, submitted an NDA to the FDA for Ferinject® (under the name Injectafer®). According to Galenica, Injectafer® is an IV iron replacement product for which approval is being sought in the treatment of iron deficiency anemia in heavy uterine bleeding, post partum, inflammatory bowel disease and hemodialysis patients. If the FDA approves Injectafer® during the current review period, commercial launch of the product may occur later this year. Our competitors may succeed in developing technologies and products that are safer, more effective or less costly than any that we may develop, and may be more successful than we are in developing, manufacturing and marketing products. In addition, our collaborators are not restricted from developing and marketing certain competing products and, as a result of certain cross-license agreements with our competitors (including one of our collaborators), our competitors will be able to utilize elements of our technology in the development of certain competing contrast agents. We may not be able to compete successfully with these companies. Further technological and product developments may make other iron replacement therapy products more competitive than IV iron products or other imaging modalities more compelling than MRI, and adversely impact sales of our iron replacement therapy and imaging products.

Additionally, although we believe ferumoxytol will offer advantages over existing products in the IV iron replacement therapy market, competing IV iron replacement therapy products may receive greater acceptance. The IV iron replacement market is highly sensitive to several factors including, but not limited to, the ability to obtain appropriate reimbursement, price competitiveness, and product characteristics such as dosing regimens. In particular, the IV iron replacement market is extremely sensitive to the perceived relative safety profiles of the various IV iron replacement therapeutics, and it will be critical for us to be able to demonstrate that ferumoxytol's safety profile is as good or better than that of other IV iron replacement products in order to be competitive in the marketplace. In addition, market acceptance of MRI as an appropriate technique for imaging the lymphatic system and the use of our products as part of such imaging is critical to the success of *Combidex*, if approved. Although we believe that our contrast agents offer advantages over competing MRI, CT or x-ray contrast agents, competing contrast agents might receive greater acceptance. Additionally, to the extent that other diagnostic techniques may be perceived as providing greater value than MRI, any corresponding decrease in the use of MRI could have an adverse effect on the demand for our contrast agent products.

*Our operating results will likely fluctuate so you should not rely on the results of any single quarter to predict how we will perform over time.*

Our future operating results will likely vary from quarter to quarter depending on a number of factors including:

- the timing and magnitude of external research and development expenses, in particular, those related to our development program for ferumoxytol as an IV iron replacement therapeutic;
- the timing and likelihood of FDA approval of ferumoxytol, including the magnitude of potential revenues associated with sales of ferumoxytol, if approved;
- the timing and magnitude of costs associated with the potential commercial launch of ferumoxytol, including manufacturing costs and costs associated with hiring additional sales and marketing personnel;
- the timing and likelihood of FDA approval of *Combidex*, including the magnitude of potential costs we may incur to satisfy the conditions specified by the FDA for approval of *Combidex* and the magnitude of potential revenues associated with sales of *Combidex*, if approved;
- the variable nature of our product sales to our marketing partners and the batch size in which our products are manufactured;

- uneven demand for our products by end users which affects the royalties we receive from our marketing partners;
- the magnitude of future non-cash accounting charges we expect to record to expense in a given period as a result of our adoption of Statement of Financial Accounting Standards No. 123R; and
- the extent of and changes in reimbursement for our approved products from government health administration authorities, private health insurers and other third-party payors.

As a result of these and other factors, our quarterly operating results could fluctuate, and this fluctuation could cause the market price of our common stock to decline. Results from one quarter should not be used as an indication of future performance.

***We need to maintain, and possibly increase, our manufacturing capabilities in order to commercialize our products.***

We manufacture bulk *Feridex I.V.* and *GastroMARK*, as well as *Feridex I.V.* finished product, for sale by our marketing partners, *Combidex* bulk product for use in non-Phase III clinical trials and ferumoxytol for use in human clinical trials, in our Cambridge, MA manufacturing facility. Pending FDA approval, we intend to manufacture ferumoxytol finished product and *Combidex* formulated drug product in bulk at our manufacturing facility as well. This facility is subject to current Good Manufacturing Practices, or cGMP, regulations enforced by the FDA. We may not be able to continue to operate at commercial scale in compliance with cGMP regulations. Failure to operate in compliance with cGMP regulations and other applicable manufacturing requirements of various regulatory agencies could delay our development efforts and impede product sales due to the unavailability of our products and product candidates. In addition, we are dependent on contract manufacturers for the final production of *Combidex* and do not currently have any long-term contracts in place with any third-party manufacturers to conduct this work. In the event that we are unable to arrange final manufacturing for *Combidex*, if approved, we will not be able to develop and commercialize this product as planned. Additionally, we may not be able to enter into agreements for the manufacture of future products with manufacturers whose facilities and procedures comply with cGMP regulations and other regulatory requirements. Furthermore, such manufacturers may not be able to deliver required quantities of product that conform to specifications in a timely manner.

We currently have only one manufacturing facility at which we produce limited quantities of ferumoxytol. Although we have tested scale-up for production of ferumoxytol, when we manufacture ferumoxytol in larger volumes for commercial sale, we could experience higher than anticipated material, labor and overhead costs per unit. Additionally, manufacturing and quality control problems may arise as we increase our level of production. We may not be able to increase our manufacturing capacity in a timely and cost-effective manner, and we may experience delays in manufacturing ferumoxytol. Furthermore, if we fail to attract and retain key members of our manufacturing or quality control departments, we may be unable to manufacture our products and product candidates in a timely manner, which could delay our product sales and development efforts.

If we are unable to consistently manufacture our products on a timely basis because of these or other factors, we will not be able to meet anticipated demand. As a result, we may lose sales and fail to generate increased revenue.

***Our success depends on our ability to attract and retain key employees.***

Because of the specialized nature of our business, we are highly reliant on our executive officers, senior scientists, regulatory and clinical professionals, and manufacturing and quality control personnel, including our Chief Executive Officer and President, Brian J.G. Pereira, MD, and our Vice President of Scientific Operations, Jerome Lewis. If we are unable to attract and retain qualified scientific, technical, clinical, regulatory and sales and marketing personnel for the development activities conducted or sponsored by us, including our development program for ferumoxytol as an IV iron replacement therapeutic, or we fail to hire qualified people or lose the services of our key personnel, our product development efforts could be delayed or curtailed. For example, in order

to achieve commercial success for ferumoxytol as an IV iron replacement therapeutic, we will have to either develop our own internal marketing and sales function, including a direct sales force, enter into a collaborative arrangement with a third party or parties to market and sell ferumoxytol, or otherwise contract for these services with a third party. We may not be able to successfully recruit and retain the qualified marketing and sales personnel that would be necessary to market and sell ferumoxytol. In addition, if we fail to attract and retain key members of our manufacturing or quality control departments, our ability to manufacture our products, or to manufacture our products in a timely and cost-effective manner, could be hindered and our product sales and development efforts delayed. Furthermore, our expected expansion into areas and activities requiring additional expertise, such as late-stage development and marketing and sales, will require the addition of new management personnel and the development of additional expertise by existing management personnel. There is intense competition for qualified personnel in the areas of our activities, and we may not be able to continue to attract and retain the qualified personnel necessary for the development of our business. The failure to attract and retain such personnel or to develop such expertise could impose significant limits on our business operations and hinder our ability to successfully and efficiently complete our development projects.

***We have a limited number of customers and are dependent on our collaborative relationships.***

Our strategy for the development, commercialization and marketing of our product candidates in the past has been to enter into strategic relationships with various corporate partners, licensees and other collaborators. We rely on a limited number of marketing and distribution partners to market and sell our approved products, *Feridex I.V.* and *GastroMARK*, both in the United States and in foreign countries, and we depend on these strategic partners for a significant portion of our revenue. Three companies, Bayer, Guerbet, and Cytogen, accounted for 43%, 24% and 22%, respectively, of our revenues in the six-month period ended June 30, 2007. On February 15, 2007, as part of the settlement of a lawsuit with Cytogen, the license and marketing agreement with Cytogen was terminated, therefore Cytogen is no longer our partner and we will not be receiving any additional revenue from them. A decrease in revenue from any of our significant marketing or distribution partners would impair our overall revenues. In some cases, we have granted exclusive rights to these partners. If these partners are not successful in marketing our products, or if these partners fail to meet minimum sales requirements or projections, our ability to generate revenue would be substantially harmed. For example, to date, we have not generated significant revenues on royalties from the sale of our approved products by our marketing partners. In addition, we might incur further costs in an attempt to enforce our contractual rights, renegotiate agreements, find new partners or market our own products. In some cases, we are dependent upon some of our collaborators to manufacture and market our products. We may not be able to derive any revenues from these arrangements. If any of our collaborators breaches its agreement with us or otherwise fails to perform, such event could impair our revenue and impose additional costs on us. In addition, many of our corporate partners have considerable discretion in electing whether to pursue the development of any additional products and may pursue technologies or products either on their own or in collaboration with competitors. Given these and other risks, our current and future collaborative efforts may not be successful. Failure of these efforts would materially adversely impact our ability to generate revenue from product sales, thereby decreasing the amount of cash from operations available to support our development efforts for our existing product candidates in development.

***We cannot be certain that our products will be accepted in the marketplace.***

For a variety of reasons, many of which are beyond our control, our products may not achieve market acceptance or become commercially successful. If our products do not receive market acceptance for any reason, it may limit sales of our products and reduce our revenues. The degree of market acceptance of any of our products will depend on a number of factors, including:

- the establishment and demonstration in the medical community of the clinical efficacy and safety of our products;
- our products' potential advantage over existing treatments or diagnostic methods; and
- reimbursement policies of government and third-party payors, including insurance companies.

For example, even if we obtain regulatory approval to sell our products, physicians and health care payors could conclude that our products are not safe or effective and decide not to use them to treat patients. Our

competitors may also develop new technologies or products which are more effective or less costly, or that are perceived as more effective or cost-effective than our products. Physicians, patients, third-party payors or the medical community in general may fail to accept or choose not to use any of the products that we develop.

To date, we have not generated significant revenues on royalties from the sale of our approved products by our marketing partners, and these products have not achieved broad market acceptance. *Feridex I.V.* and *GastroMARK*, approved in 1996 and 1997, respectively, represented an alternative technology platform for physicians to adopt in MRI. *Feridex I.V.* sales have decreased from their peak based on changes in MRI technology and competition in the market, and we expect product sales of *Feridex I.V.* to remain at current low levels overall. *Combidex*, if approved, will represent a shift in the diagnostic process that physicians could use to stage and monitor cancer patients that may not be adopted by physicians. In addition, ferumoxytol, if approved as an IV iron replacement therapeutic, will represent an alternative to existing products or procedures that might not be adopted by the medical community, especially if it is perceived to not be as safe as other available products which are equally effective. If our approved products or future products are not adopted by physicians, revenues will be delayed or fail to materialize, and our ability to achieve profitability will be significantly adversely effected.

***We may need additional capital to achieve our business objectives.***

We have expended and will continue to expend substantial funds to complete the research, development, clinical trials, applications for regulatory approvals, market conditioning and other activities necessary to achieve final commercialization of our product candidates, ferumoxytol as an IV iron replacement therapeutic and *Combidex*. In particular, we anticipate that the high levels of expenditures related to our development activities will continue due to the conduct of our development program for ferumoxytol as an IV iron replacement therapeutic, our preparation of the NDA for ferumoxytol, our development of a sales and marketing function, our pursuit of additional indications for ferumoxytol, and our efforts to obtain approval for ferumoxytol outside the U.S., and that our cash-burn rate will continue to increase in the near- and long-term. Our long-term capital requirements will also depend on additional factors, including, but not limited to,

- the progress of, and our ability to successfully complete development of ferumoxytol as an IV iron replacement therapeutic in a timely manner and within our projected budget;
- our ability to successfully obtain regulatory approval for ferumoxytol as an IV iron replacement therapeutic;
- our ability to satisfy the conditions specified by the FDA for approval of *Combidex*;
- our need to hire additional staff and lease additional office space as part of our commercialization efforts for our product candidates, including our efforts to build an internal sales and marketing function;
- the costs associated with preparing for commercial-scale manufacturing of our product candidates, including the costs associated with qualifying a second manufacturing facility;
- costs associated with our potential development of additional indications for ferumoxytol;
- costs associated with our pursuit of approval for ferumoxytol as an IV iron replacement therapeutic outside the U.S.;
- the magnitude of product sales and royalties;
- our ability to establish additional development and marketing arrangements or to enter into alternative strategic relationships;
- the costs involved in filing, prosecuting and enforcing patent claims; and
- our ability to raise additional capital on terms and within a timeframe acceptable to us, if necessary.



We estimate that our existing cash resources, combined with cash we currently expect to receive from earnings on our investments, excluding new financings, will be sufficient to finance our operations for at least the next twelve months. Thereafter, we may require additional funds or need to establish alternative strategic arrangements to continue our research and development activities, including our ferumoxytol and *Combidex* development programs, to conduct future clinical trials for ferumoxytol in new indications and in countries outside the U.S., and to market and sell our products. We may seek needed funding through arrangements with collaborative partners or through public or private equity or debt financings. We may not be able to obtain financing or to secure alternative strategic arrangements on acceptable terms or within an acceptable timeframe, if at all. Any additional equity financings or alternative strategic arrangements would likely be dilutive to our stockholders. In addition, the terms of any debt financing could greatly restrict our ability to raise additional capital and may provide rights and preferences to the investors in any such financing which are not available to current stockholders. Our inability to raise additional capital on terms and within a timeframe acceptable to us when needed could force us to dramatically reduce our expenses and delay, scale back or eliminate certain of our activities and operations, including our research and development activities, any of which could have a material adverse effect on our business, financial condition and results of operations.

***Our success depends on our ability to maintain the proprietary nature of our technology.***

We rely on a combination of patents, trademarks, copyrights and trade secrets in the conduct of our business. The patent positions of pharmaceutical and biopharmaceutical firms are generally uncertain and involve complex legal and factual questions. We may not be successful or timely in obtaining any patents for which we submit applications. The breadth of the claims obtained in our patents may not provide significant protection for our technology. The degree of protection afforded by patents for licensed technologies or for future discoveries may not be adequate to protect our proprietary technology. The patents issued to us may not provide us with any competitive advantage. In addition, there is a risk that others will independently develop or duplicate similar technology or products or circumvent the patents issued to us.

Moreover, patents issued to us may be contested or invalidated. Future patent interference proceedings involving either our patents or patents of our licensors may harm our ability to commercialize our products. Claims of infringement or violation of the proprietary rights of others may be asserted against us. If we are required to defend against such claims or to protect our own proprietary rights against others, it could result in substantial costs to us and distraction of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling our products, limit our development of our product candidates or harm our competitive position and result in additional significant costs. In addition, any successful claim of infringement asserted against us could subject us to monetary damages or injunction preventing us or our marketing partners from making or selling products. We also may be required to obtain licenses to use the relevant technology. Such licenses may not be available on commercially reasonable terms, if at all.

We currently hold approximately 19 U.S. patents and approximately 29 foreign patents, which expire between the years 2007 and 2020, some of which are subject to extension under FDA regulations. Because certain patents that cover our products will begin to expire in the coming years, the protection provided by these patents will also begin to expire. Our inability to commercialize our products prior to the expiration of our patents could have a material adverse effect on our business, financial condition and prospects. In the future, we may be required to obtain additional licenses to patents or other proprietary rights of others in order to commercialize our products or continue with our development efforts. Such licenses may not be available on acceptable terms, if at all. The failure to obtain such licenses could result in delays in marketing our products or our inability to proceed with the development, manufacture or sale of our products or product candidates requiring such licenses. In addition, the termination of any of our existing licensing arrangements could impair our revenues and impose additional costs which could limit our ability to sell our products commercially.

The laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States. In countries where we do not have or have not applied for patents on our products, we will be unable to prevent others from developing or selling similar products. In addition, in jurisdictions outside the United States where we have patent rights, we may be unable to prevent unlicensed parties from selling or importing

products or technologies derived elsewhere using our proprietary superparamagnetic iron oxide nanoparticle technology.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants. These agreements, however, may be breached. We may not have adequate remedies for any such breaches, and our trade secrets might otherwise become known or be independently discovered by our competitors. In addition, we cannot be certain that others will not independently develop substantially equivalent or superseding proprietary technology, or that an equivalent product will not be marketed in competition with our products, thereby substantially reducing the value of our proprietary rights.

***We are exposed to potential liability claims and we may not be able to maintain or obtain sufficient insurance coverage.***

We maintain product liability insurance coverage for claims arising from the use of our products and product candidates in clinical trials and commercial use. However, coverage is becoming increasingly expensive and costs may continue to increase significantly, and we may not be able to maintain insurance at a reasonable cost. Furthermore, our insurance may not provide sufficient coverage amounts to protect us against liability that could deplete our capital resources. We also may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future. Our insurance coverage and our resources may not be sufficient to satisfy any liability or cover costs resulting from product liability claims. A product liability claim or series of claims brought against us could reduce or eliminate our resources, whether or not the plaintiffs in such claims ultimately prevail. In addition, pursuant to our certificate of incorporation, by-laws and contractual agreements with our directors, and in order to attract competent candidates, we are obligated to indemnify our officers and directors against certain claims arising from their service to us. We maintain directors and officers liability insurance to cover such potential claims against our officers and directors. However, this insurance may not be adequate for certain claims and deductibles apply. As a result of our indemnification obligations and in instances where insurance coverage is not available or insufficient, any liability claim or series of claims brought against our officers or directors could deplete or exhaust our resources, regardless of the ultimate disposition of such claims.

***We are subject to environmental laws and potential exposure to environmental liabilities.***

Because we use certain hazardous materials in the production of our products, we are subject to various federal, state and local environmental laws and regulations that govern our operations, including the handling and disposal of non-hazardous and hazardous wastes, and emissions and discharges into the environment. Failure to comply with these laws and regulations could result in costs for corrective action, penalties or the imposition of other liabilities. We also are subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment. Under certain of these laws and regulations, a current or previous owner or operator of property may be liable for the costs of remediating the release or spill of hazardous substances or petroleum products on or from its property, without regard to whether the owner or operator knew of, or caused, the contamination, and such owner or operator may incur liability to third parties impacted by such contamination. The presence of, or failure to remediate properly the release or spill of, these substances could adversely affect the value of, and our ability to transfer or encumber, our real property.

***We may be unable to comply with continuing regulatory requirements even after our products have been approved for marketing.***

Even if we obtain regulatory approval for our product candidates, a marketed product and its manufacturer are subject to continuing regulatory review. Noncompliance with the regulatory requirements of the approval process at any stage may result in adverse consequences, including the FDA's withdrawal of an approved product from the market or, under certain circumstances, the imposition of criminal penalties. We may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered. Any such adverse



consequence could limit or preclude our ability to sell our products commercially which would hinder our ability to generate revenue through royalties or direct sales of our products.

**Item 5. Other Information.**

On July 24, 2007, we changed our corporate name from Advanced Magnetics, Inc. to AMAG Pharmaceuticals, Inc. This change was approved by our Board on May 14, 2007. Our stock continues to trade on the NASDAQ Global Market under the symbol AMAG .

On July 31, 2007, we entered into amended and restated employment agreements with each of our executive officers including Brian J.G. Pereira, President and Chief Executive Officer, David A. Arkowitz, Chief Financial Officer and Chief Business Officer, Joseph L. Farmer, General Counsel and Vice President of Legal Affairs, Louis Brenner, Senior Vice President, and Timothy G. Healey, Senior Vice President of Commercial Operations. In addition, in connection with his appointment as an executive officer of the Company, we entered into an amended and restated employment agreement and indemnification agreement with Jerome Lewis, our Vice President of Scientific Operations. The indemnification agreement is identical in all material respects to our previously-filed form of indemnification agreement dated as of August 4, 2004.

On August 6, 2007, Dr. Lee F. Allen, M.D., Ph.D. joined us as our new Chief Medical Officer and Senior Vice President of Clinical Development. In connection with his appointment, we entered into an employment agreement and an indemnification agreement with Dr. Allen. The indemnification agreement is identical in all material respects to our previously-filed form indemnification agreement dated as of August 4, 2004. Dr. Allen's employment agreement provides for the following, among other things: (i) an initial base salary of \$300,000 per year, (ii) an opportunity for an annual bonus of up to 40% of his base annual salary upon the achievement of certain performance goals (commencing with the fiscal year ending December 31, 2008), (iii) a \$50,000 signing bonus payable within two weeks of his first day of employment, and (iv) an additional \$50,000 bonus payable within two weeks following the sixth-month anniversary of his first day of employment with us (provided that Dr. Allen remains employed by us on such date). Dr. Allen was also granted restricted stock units granting him the right to receive 5,000 shares of our common stock at no cost as well as options to purchase 50,000 shares of our common stock at an exercise price of \$52.17, which was equal to the fair market value of a share of our common stock on the date of grant. The options and restricted stock units will vest in equal annual installments over four years from the grant date.

In addition, Dr. Allen's employment agreement includes certain severance and change-of-control benefits as set forth below.

Severance Due After Termination of Employment

In the event that we terminate Dr. Allen's employment, other than for death, disability or cause (as such term is defined in his employment agreement), or Dr. Allen resigns for good reason (as such term is defined in his employment agreement), and (i) Dr. Allen has complied with all his obligations under all agreements with us, and (ii) Dr. Allen signs a general release of claims in a form acceptable to us, then we have agreed to pay severance to Dr. Allen in an amount equal to 12 months of base salary, paid in equal installments over the severance period in accordance with our usual payroll schedule. This paragraph does not apply during the one year period following a change of control (as such term is defined in his employment agreement).

Payments and Benefits upon a Change of Control

Upon the closing of a transaction that constitutes a change of control of the Company, 50% of the unvested outstanding options and/or restricted stock units then held by Dr. Allen will become vested. In addition, in the event that within one year from the date a change of control occurs, we or our successor terminates the employment of Dr. Allen other than for death, disability or cause, or Dr. Allen resigns for good reason, and Dr. Allen (i) has complied with all his obligations under all agreements with us, and (ii) signs a general release of claims in a form acceptable to us, then we have agreed to provide Dr. Allen with the following benefits post-termination:

- 12 months of base salary, paid in equal installments over the severance period in accordance with our usual payroll schedule;
- one time the average bonus paid to Dr. Allen during the prior three years; provided that in no event will a year prior to the year ended December 31, 2007 be used in the calculation;
- continuation of health and dental benefits until the earlier of (a) 24 months post termination and (b) health and dental coverage being provided to Dr. Allen under another employer's health and dental plan; and
- the acceleration of vesting of any unvested outstanding stock options and restricted stock units that were granted before such change of control.

The form of Dr. Allen's employment agreement is filed as Exhibit 10.1 to this report.

On May 14, 2007, our Board approved a change in our fiscal year end from September 30 to December 31. In connection with our changed fiscal year, we have rescheduled our next annual meeting of stockholders, which will now be held on May 6, 2008. Accordingly, the deadline for our stockholders to submit proposals to be included in our fiscal year 2007 proxy statement has been extended from August 23, 2007 until December 3, 2007. Proposals must satisfy the procedures set forth in Rule 14a-8 under the Securities Exchange Act of 1934, or the Exchange Act, to be included in our proxy statement. In order to curtail controversy as to the date on which a proposal was received by us, we suggest that stockholders submit proposals by registered mail, return receipt requested, attention: General Counsel and Vice President of Legal Affairs.

We have also extended the deadline for our stockholders to provide us with matters that they otherwise desire to introduce at our next annual meeting of stockholders, other than those that will be included in our proxy materials, from November 6, 2007 until February 16, 2008. If our stockholders wish to present such a proposal, but fail to notify us by the close of business on February 16, 2008, such stockholders will not be entitled to present the proposal at the meeting. Under the rules of the Securities and Exchange Commission, or SEC, the persons chosen by us to serve as proxies will be permitted to exercise their discretionary voting authority to direct the voting of proxies on any matter submitted for a vote at the next annual meeting of stockholders if notice concerning proposal of such matter is not received on or prior to February 16, 2008. In order to curtail any controversy as to the date on which a proposal was received by us, we suggest that stockholders submit proposals by registered mail, return receipt requested, attention: General Counsel and Vice President of Legal Affairs.

**Item 6. Exhibits.**

- (a) List of Exhibits

Edgar Filing: AMAG PHARMACEUTICALS INC. - Form 10-Q

Exhibit  
Number

Description

10.1+	Employment Agreement dated August 6, 2007 between AMAG Pharmaceuticals, Inc. and Lee F. Allen
31.1+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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+ Exhibits marked with a plus sign ( + ) are filed herewith.

++ Exhibits marked with a double plus sign ( ++ ) are furnished herewith.

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**SIGNATURES**

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Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMAG PHARMACEUTICALS, INC.

By: */s/ Brian J.G. Pereira*  
Brian J.G. Pereira,  
*Chief Executive Officer,*  
*President and Director*

Date: August 8, 2007

AMAG PHARMACEUTICALS, INC.

By: */s/ David A. Arkowitz*  
David A. Arkowitz,  
*Chief Financial Officer and*  
*Chief Business Officer*

Date: August 8, 2007

**EXHIBIT INDEX**

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+ Exhibits marked with a plus sign ( + ) are filed herewith.

++ Exhibits marked with a double plus sign ( ++ ) are furnished herewith.

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