

AMAG PHARMACEUTICALS INC.

Form 10-Q

August 07, 2008

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**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, 2008

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**  
**Cambridge, Massachusetts**  
(Address of Principal Executive Offices)

**02140**  
(Zip Code)

**(617) 498-3300**

(Registrant's Telephone Number, Including Area Code)

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

As of August 1, 2008 there were 17,001,451 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.**

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## AMAG PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

AS OF JUNE 30, 2008 AND DECEMBER 31, 2007

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

(Unaudited)

	June 30, 2008	December 31, 2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 56,060	\$ 28,210
Short-term investments	146,160	258,597
Accounts receivable	1,182	223
Inventories	303	384
Prepaid expenses and interest receivable	3,110	2,800
Total current assets	206,815	290,214
Property, plant and equipment:		
Land	360	360
Building and improvements	5,233	5,106
Laboratory equipment	6,214	5,959
Furniture and fixtures	1,629	1,569
Construction in process	1,351	
Total property, plant and equipment	14,787	12,994
Less - accumulated depreciation	(8,997)	(8,452)
Net property, plant and equipment	5,790	4,542
Long-term investments	62,106	
Restricted cash	521	95
Total assets	\$ 275,232	\$ 294,851
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,769	\$ 1,733
Accrued expenses	7,090	5,547
Deferred revenue and rent expense	821	738
Total current liabilities	11,680	8,018
Long-term liabilities:		
Deferred revenue and rent expense	1,524	879
Total liabilities	13,204	8,897
Commitments and contingencies (Note L)		
Stockholders equity:		
Preferred stock, par value \$0.01 per share, 2,000,000 shares authorized; none issued		
Common stock, par value \$0.01 per share, 58,750,000 shares authorized at June 30, 2008 and 25,000,000 shares authorized at December 31, 2007; 17,000,451 and 16,945,662 shares issued and outstanding at June 30, 2008 and December 31, 2007, respectively	170	169
Additional paid-in capital	409,067	402,346
Accumulated other comprehensive (loss) income	(4,213)	127
Accumulated deficit	(142,996)	(116,688)
Total stockholders equity	262,028	285,954

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Total liabilities and stockholders' equity	\$	275,232	\$	294,851
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The accompanying notes are an integral part of the condensed consolidated financial statements.

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## AMAG PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

## FOR THE THREE AND SIX MONTHS ENDED

JUNE 30, 2008 AND 2007

(IN THOUSANDS, EXCEPT PER SHARE DATA)

**(Unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
<b>Revenues:</b>				
License fees	\$ 185	\$ 184	\$ 369	\$ 726
Royalties	89	64	125	141
Product sales	212	497	604	791
Total revenues	486	745	1,098	1,658
<b>Costs and expenses:</b>				
Cost of product sales	31	101	75	258
Research and development expenses	7,061	5,115	11,884	11,256
Selling, general and administrative expenses	12,611	5,083	20,996	7,874
Total costs and expenses	19,703	10,299	32,955	19,388
<b>Other income (expense):</b>				
Interest and dividend income, net	2,210	2,619	5,549	4,592
Litigation settlement (Note L)				(4,000)
Total other income (expense)	2,210	2,619	5,549	592
Net loss	\$ (17,007)	\$ (6,935)	\$ (26,308)	\$ (17,138)
<b>Net loss per share:</b>				
Basic and diluted	\$ (1.00)	\$ (0.46)	\$ (1.55)	\$ (1.17)
<b>Weighted average shares outstanding used to compute net loss per share:</b>				
Basic and diluted	16,994	15,150	16,982	14,658

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

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**AMAG PHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**FOR THE THREE AND SIX MONTHS ENDED**

**JUNE 30, 2008 AND 2007**

**(IN THOUSANDS)**

**(Unaudited)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Net loss	\$ (17,007)	\$ (6,935)	\$ (26,308)	\$ (17,138)
Other comprehensive loss:				
Unrealized losses on securities	(1,770)	(63)	(4,340)	(63)
Comprehensive loss	\$ (18,777)	\$ (6,998)	\$ (30,648)	\$ (17,201)

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

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## AMAG PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

## FOR THE SIX MONTHS ENDED

JUNE 30, 2008 AND 2007

(IN THOUSANDS)

(Unaudited)

	Six Months Ended June 30,	
	2008	2007
Net loss	\$ (26,308)	\$ (17,138)
Cash flows from operating activities:		
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	545	369
Non-cash expense associated with stock options and restricted stock units	5,888	3,787
Amortization of premium/discount on purchased securities	87	(600)
Gain on sale of securities	(84)	
Changes in operating assets and liabilities:		
Accounts receivable	(959)	(70)
Inventories	81	12
Prepaid expenses and interest receivable	(310)	(759)
Accounts payable and accrued expenses	3,069	(2,837)
Deferred revenue and rent expense	728	(687)
Total adjustments	9,045	(785)
Net cash used in operating activities	(17,263)	(17,923)
Cash flows from investing activities:		
Proceeds from maturities of available-for-sale investments	160,650	74,308
Proceeds from maturities of held-to-maturity investments		124,034
Purchase of available-for-sale investments	(114,662)	(330,229)
Purchase of held-to-maturity investments		(110,787)
Restricted cash	(426)	
Capital expenditures	(1,283)	(545)
Net cash provided by (used in) investing activities	44,279	(243,219)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	672	1,842
Proceeds from the issuance of common stock under ESPP	162	111
Proceeds from the issuance of common stock, net of underwriting discount and other expenses		154,479
Net cash provided by financing activities	834	156,432
Net increase (decrease) in cash and cash equivalents	27,850	(104,710)
Cash and cash equivalents at beginning of the period	28,210	114,460
Cash and cash equivalents at end of the period	\$ 56,060	\$ 9,750
Supplemental data:		
Non-cash financing activities:		
Non-cash stock option exercises	\$	\$ 516
Accrued construction in process	\$ 510	\$

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

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**AMAG PHARMACEUTICALS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2008**

**(Unaudited)**

**A. Description of Business**

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a biopharmaceutical company that utilizes our 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 agent for the treatment of iron deficiency anemia and as a diagnostic agent for vascular-enhanced magnetic resonance imaging, or MRI, to assess peripheral arterial disease. *Combidex* is our investigational functional molecular imaging agent consisting of iron oxide nanoparticles for use in conjunction with MRI to aid in the differentiation of cancerous from normal lymph nodes. *Feridex I.V.*, our liver contrast agent, is approved and marketed in the U.S., Europe and other countries. *GastroMARK*, our oral contrast agent used for delineating the bowel in MRI, is approved and marketed in the U.S., Europe and other countries. Throughout this Quarterly Report on Form 10-Q, AMAG Pharmaceuticals, Inc. and our consolidated subsidiary are collectively referred to as the Company, we, us, or our.

**B. Basis of Presentation and Significant Accounting Policies**

*Basis of Presentation*

These condensed consolidated 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. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America.

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 year ended December 31, 2007. 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 December 31, 2007.

*Use of Estimates and Assumptions*

**B. Basis of Presentation and Significant Accounting Policies**

The preparation of condensed consolidated 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 the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reported period. The most significant estimates and assumptions are used in, among other things, assessing investments and long-lived assets for potential impairment and determining values of investments, accrued expenses, income taxes and equity-based compensation expense. Actual results could differ from those estimates.

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*Principles of Consolidation*

The accompanying condensed consolidated financial statements include the accounts of AMAG Pharmaceuticals, Inc. and its wholly-owned subsidiary, AMAG Securities Corporation. All significant intercompany account balances and transactions between the companies have been eliminated.

*Cash and Cash Equivalents*

Cash and 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. At June 30, 2008 and December 31, 2007, substantially all of our cash and cash equivalents were held in either commercial banks or money market accounts.

*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 Statement of Financial Accounting Standards, or 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 at the time of purchase. As of June 30, 2008 and December 31, 2007, all of our investments were classified as available-for-sale securities.

Available-for-sale securities are those securities which we view as available for use in current operations, if needed. We classify 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. However, due to our belief that the market for auction rate securities, or ARS, may take in excess of twelve months to fully recover, we have classified those ARS for which we have not received notice of the issuer's intent to redeem as long-term investments. 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) income, until such gains and losses are realized or until an unrealized loss is considered other-than-temporary.

*Fair Value of Financial Instruments*

As of January 1, 2008, we partially adopted the provisions of SFAS No. 157, Fair Value Measurements, or SFAS 157, for financial assets and liabilities recognized at fair value on a recurring basis. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. The provisions of SFAS 157 related to other nonfinancial assets and liabilities will be effective for us on January 1, 2009, and will be applied prospectively.

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Fair value is defined under SFAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy to measure fair value which is based on three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.

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- Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of June 30, 2008, we held certain assets that are required to be measured at fair value on a recurring basis, including our cash equivalents and short- and long-term investments. In accordance with SFAS 157, the following table represents the fair value hierarchy for our financial assets measured at fair value on a recurring basis as of June 30, 2008 (in thousands):

	Total	Fair Value Measurements at June 30, 2008 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	\$ 49,449	\$ 49,449		
Corporate debt securities	75,069		75,069	
U.S. treasury and government agency securities	58,770		58,770	
Commercial paper	9,964		9,964	
Auction rate securities	64,463			64,463
	\$ 257,715	\$ 49,449	\$ 143,803	\$ 64,463

With the exception of our ARS, which are valued using Level 3 inputs as discussed below, the fair value of our investments is generally determined from quoted market prices based upon either quoted prices from active markets or other significant observable market transactions at fair value.

At June 30, 2008, all of our ARS were municipal bonds with an auction reset feature, of which greater than 90% were AAA-rated by at least one of the major securities rating agencies. Most of these ARS were collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program, with the majority of remaining securities being backed by monoline bond insurance companies. We have traditionally recorded these investments at cost, which approximated fair market value due to their variable interest rates, which typically reset through an auction process every 7 or 28 days. This auction mechanism generally allowed existing investors to roll over their holdings and continue to own their securities or liquidate their holdings by selling their securities at par value. In mid-February 2008, our ARS began to experience failed auctions, and have continued to experience failed auctions. As a result of the lack of market activity, we changed our valuation methodology for these securities to a discounted cash flow analysis. Accordingly, these securities changed from Level 2 to Level 3 within SFAS 157's hierarchy since our initial adoption of SFAS 157 at January 1, 2008. Our valuation analyses consider, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, the inability to sell the investment in an active market, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when callability features may be exercised by the issuer. Based upon this methodology, we have recorded an unrealized loss related to our ARS of approximately \$4.4 million to accumulated other comprehensive (loss) income as of June 30, 2008. We believe that the temporary impairment related to our ARS of approximately \$4.4 million is primarily attributable to the limited liquidity of these investments. As of June 30, 2008, all of our ARS continue to pay interest according to their stated terms.



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Any future fluctuation in fair value related to these instruments that we deem to be temporary, including any recoveries of previous write-downs, would be recorded to accumulated other comprehensive (loss) income. If we determine that any future unrealized loss is other-than-temporary, we will record a charge to earnings as appropriate.

The following table presents our ARS measured at fair value on a recurring basis using significant unobservable inputs (Level 3) as defined in SFAS 157 as of June 30, 2008:

<b>Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Auction Rate Securities</b>	
Balance at December 31, 2007	\$
Transfers to Level 3	80,725
Total gains (losses) (realized or unrealized):	
Included in earnings	
Included in other comprehensive (loss) income	(4,437)
Purchases and settlements (net)	(11,825)
Balance at June 30, 2008	\$ 64,463
The amount of total gains or (losses) for the period included in earnings attributable to the change in unrealized gains or (losses) relating to assets still held at June 30, 2008	
	\$

Investments are considered to be impaired when a decline in fair value below cost basis is determined to be other-than-temporary. We periodically evaluate whether a decline in fair value below cost basis is other-than-temporary and consider available evidence regarding our investments. In the event that the cost basis of a security significantly 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 issuer, including industry and sector performance, operational and financing cash flow factors, overall market conditions and trends, and our intent and ability to hold the investment to recovery, which may be maturity. We also consider credit ratings with respect to our investments provided by investments ratings agencies. All of our investments, including our ARS, are classified as available-for-sale securities and are reflected at fair value. If a decline in fair value is determined to be other-than-temporary, we will record a write-down in our condensed consolidated statement of operations and a new cost basis in the security will be established.

There were no unrealized losses in our investments which were deemed to be other-than-temporary at June 30, 2008 and December 31, 2007. Realized gains and losses are determined on the specific identification method and are included in interest income in our condensed consolidated statements of operations. Interest income is accrued as earned.

*Equity-Based Compensation*

We account for our equity-based compensation arrangements with our employees and non-employee directors, including options granted under our 2006 Employee Stock Purchase Plan, under 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. Under these pronouncements, equity-based compensation cost is required to 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

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equity-based compensation expense is based on awards ultimately expected to vest, we must make certain judgments about whether employees and directors will complete the requisite service period. Accordingly, 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 are 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 internal and external. 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, the expected risk-free interest rate over the expected option term, the expected volatility of our stock price over the expected option term, and the expected dividend yield over the expected option term and is subject to various assumptions. We believe our 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. Our stock option valuations 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, changes in estimated forfeiture rates and the issuance of new options and other stock awards. The fair value of restricted stock units granted to employees and directors is determined based upon the quoted closing market price per share on the date of grant. As with any accounting policy that applies judgments and estimates, actual results could significantly differ from those estimates and as a result, our financial results could be materially and adversely impacted.

*Comprehensive Loss*

SFAS No. 130, Reporting Comprehensive Income, requires us to display comprehensive loss and its components as part of our condensed consolidated financial statements. Comprehensive loss consists of net loss and other comprehensive (loss) income. Other comprehensive (loss) income includes changes in equity that are excluded from net loss, which for all periods presented relates to unrealized holding gains and losses on available-for-sale investments.

*Reclassifications*

Certain amounts from the prior fiscal quarter have been reclassified to conform to the current quarter's presentation.

**C. Investments**

At June 30, 2008 and December 31, 2007, our short- and long-term investments totaled \$208.3 million and \$258.6 million, respectively, and consisted solely of securities classified as available-for-sale.



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The following is a summary of our available-for-sale securities at June 30, 2008 and December 31, 2007 (in thousands):

	June 30, 2008			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	\$ 42,535	\$ 46	\$ (115)	\$ 42,466
Due in one to three years	32,581	143	(121)	32,603
U.S. treasury and government agency securities				
Due in one year or less	27,341	85	(22)	27,404
Due in one to three years	31,153	227	(14)	31,366
Commercial paper and certificates of deposit				
Due in one year or less	9,969		(5)	9,964
Due in one to three years				
Auction rate securities				
Due in one year or less				
Due after five years	2,375		(18)	2,357
Total short-term investments	\$ 145,954	\$ 501	\$ (295)	\$ 146,160
Long-term investments:				
Auction rate securities				
Due in one year or less				
Due after five years	66,525		(4,419)	62,106
Total long-term investments	\$ 66,525	\$	\$ (4,419)	\$ 62,106
Total short and long-term investments	\$ 212,479	\$ 501	\$ (4,714)	\$ 208,266

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	December 31, 2007			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	\$ 33,894	\$ 10	\$ (62)	\$ 33,842
Due in one to three years	48,673	139	(74)	48,738
U.S. treasury and government agency securities				
Due in one year or less	15,841	7	(1)	15,847
Due in one to three years	25,944	108		26,052
Commercial paper				
Due in one year or less	26,745	9	(1)	26,753
Due in one to three years				
Municipal debt securities				
Due in one year or less	1,998		(8)	1,990
Due in one to three years				
Auction rate securities				
Due in one year or less				
Due after five years	105,375			105,375
Total short-term investments	\$ 258,470	\$ 273	\$ (146)	\$ 258,597
Total long-term investments	\$	\$	\$	\$
Total short and long-term investments	\$ 258,470	\$ 273	\$ (146)	\$ 258,597

At June 30, 2008, we held \$64.5 million (par value of \$68.9 million) of ARS, of which greater than 90% were rated AAA by at least one of the major securities rating agents, most of which were collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program, with the majority of remaining securities being backed by monoline bond insurance companies. We have traditionally recorded these investments at cost, which approximated fair market value due to their variable interest rates, which typically reset through an auction process every 7 or 28 days. This auction mechanism generally allowed existing investors to roll over their holdings and continue to own their securities or liquidate their holdings by selling their securities at par value. In mid-February 2008, our ARS began to experience failed auctions, and have continued to experience failed auctions. As a result of the lack of market activity, we changed our valuation methodology for these securities to a discounted cash flow analysis. Our valuation analyses consider, among other items, assumptions that market participants would use in their estimates of fair value such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, the inability to sell the investment in an active market, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when callability features may be exercised by the issuer. Based upon this methodology, we have recorded an unrealized loss related to our ARS of approximately \$4.4 million to accumulated other comprehensive (loss) income as of June 30, 2008.

Due to our belief that the market for ARS may take in excess of twelve months to fully recover, we have classified those ARS for which we have not received notices of the issuer's intent to redeem as noncurrent and have included securities totaling approximately \$62.1 million in long-term investments on

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our condensed consolidated balance sheet at June 30, 2008. The remainder of our ARS, totaling approximately \$2.4 million, are securities for which we have received notices of the issuer's intent to redeem and accordingly, we have classified those securities as short-term investments on our condensed consolidated balance sheet at June 30, 2008.

We believe that the temporary impairment related to our ARS of approximately \$4.4 million is primarily attributable to the limited liquidity of these investments, and we have no reason to believe that any of the underlying issuers of our ARS are presently at risk of default. Any future fluctuation in fair value related to these instruments that we deem to be temporary, including any recoveries of previous write-downs, would be recorded to accumulated other comprehensive (loss) income. If we determine that any future unrealized loss is other-than-temporary, we will record a charge to earnings as appropriate. In the event that we need to access our investments in these securities, we will not be able to do so until a future auction is successful, the issuer calls the security pursuant to a mandatory tender or redemption prior to maturity, a buyer is found outside the auction process, or the securities mature. For all of our ARS, the underlying maturity date is in excess of one year and can be as far as 40 years in the future. We believe we will ultimately be able to liquidate our investments without significant loss primarily due to the collateral securing most of the ARS. However, it could take until final maturity of the ARS to realize our investments' par value.

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 at June 30, 2008 and December 31, 2007 (in thousands):

	Less than 12 Months		June 30, 2008 12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	\$ 36,434	\$ (236)	\$	\$	\$ 36,434	\$ (236)
U.S. treasury and government agency securities	12,798	(36)			12,798	(36)
Commercial paper	9,964	(5)			9,964	(5)
Auction rate securities	64,463	(4,437)			64,463	(4,437)
	\$ 123,659	\$ (4,714)	\$	\$	\$ 123,659	\$ (4,714)

	Less than 12 Months		December 31, 2007 12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	\$ 45,427	\$ (136)	\$	\$	\$ 45,427	\$ (136)
U.S. treasury and government agency securities	2,491	(1)			2,491	(1)
Commercial paper	9,056	(1)			9,056	(1)
Municipal debt securities	1,990	(8)			1,990	(8)
	\$ 58,964	\$ (146)	\$	\$	\$ 58,964	\$ (146)

With the exception of the ARS as discussed above, the unrealized losses on our investments at June 30, 2008 and December 31, 2007 were primarily caused by the recent uncertainty in the capital markets coupled with interest rate increases. Since the decline in market value is primarily attributable to



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changes in these factors, 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, 2008.

**D. Inventories**

The major classes of inventories were as follows at June 30, 2008 and December 31, 2007 (in thousands):

	<b>June 30, 2008</b>		<b>December 31, 2007</b>	
Raw materials	\$	231	\$	259
Work in process		59		96
Finished goods		13		29
Total inventories	\$	303	\$	384

**E. Income Taxes**

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized.

There were no significant income tax provisions or benefits for the three and six months ended June 30, 2008 and 2007. 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.

**F. Net Loss per Share**

We compute basic net loss per share by dividing net loss by the weighted average number of common shares outstanding during the relevant period. The following table sets forth the potential common shares issuable upon the exercise of outstanding options and restricted stock units (prior to consideration of the treasury stock method) excluded from our computation of diluted net loss per share because such options and restricted stock units were anti-dilutive due to a net loss in the relevant periods (in thousands):

	<b>As of June 30,</b>	
	<b>2008</b>	<b>2007</b>
Options to purchase shares of common stock	1,832	1,162
Shares of common stock issuable upon the vesting of restricted stock units	32	29
Total	1,864	1,191



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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Net loss	\$ (17,007)	\$ (6,935)	\$ (26,308)	\$ (17,138)
Weighted average common shares outstanding	16,994	15,150	16,982	14,658
Loss per share:				
Basic and diluted	\$ (1.00)	\$ (0.46)	\$ (1.55)	\$ (1.17)

### G. Common Stock Transactions

At our Annual Meeting of Stockholders held on May 6, 2008, a proposal to amend our Certificate of Incorporation, as amended, to increase the number of shares of our common stock authorized thereunder from 25,000,000 to 58,750,000, was approved by a vote of our stockholders.

**In May 2007, we sold an aggregate of 2.5 million 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 to us 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.**

**H. Equity-Based Compensation**

We maintain several equity-based compensation plans, including our 2007 Equity Incentive Plan, or 2007 Plan, our Amended and Restated 2000 Stock Plan, or 2000 Plan, and our 2006 Employee Stock Purchase Plan.

Under our 2007 Plan, which was approved by our stockholders in November 2007, as of June 30, 2008 we have granted options and restricted stock units covering 621,046 shares of common stock of which 11,180 stock options and no restricted stock units have expired or terminated, and of which no options or restricted stock units have been exercised. The number of options and restricted stock units outstanding under this plan as of June 30, 2008 was 609,866. The remaining number of shares available for future grants as of June 30, 2008 was 1,429,859, not including shares subject to outstanding awards under the 2000 Plan, which will be added to the total number of shares available for issuance under the 2007 Plan to the extent that such awards expire or terminate for any reason prior to exercise. All outstanding options granted under our 2007 Plan have an exercise price equal to the closing price of our common stock on the grant date and a ten-year term.

In February 2008, we granted 100,000 performance-based stock options to our Chief Executive Officer at an exercise price of \$47.08. These options will vest in equal annual installments over a three-year period but will only begin vesting upon the achievement of a performance target with respect to our commercial sale of ferumoxytol by the end of the first quarter of 2009. We have also previously granted 110,000 performance-based stock options to certain of our executive officers with a weighted average exercise price of \$63.00. These performance options will vest if, and only if, our New Drug Application, or NDA, for ferumoxytol is approved by the U.S. Food and Drug Administration, or FDA, on or prior to December 31, 2008. For awards that contain performance conditions, compensation cost is only recognized if the performance conditions are considered probable of being achieved.

As of June 30, 2008, we granted options and restricted stock units covering 2,182,700 shares of common stock under our 2000 Plan of which 221,675 stock options and 750 restricted stock units have

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expired or terminated, and of which stock options and restricted stock units covering 689,520 and 16,750 shares of common stock, respectively, have been exercised. The remaining number of shares underlying outstanding options and restricted stock units pursuant to our 2000 Plan as of June 30, 2008 was 1,227,505 and 26,500, respectively. All outstanding options granted under our 2000 Plan have an exercise price equal to the closing price of our common stock on the grant date and a ten-year term. In November 2007, the 2000 Plan was succeeded by our 2007 Plan and, accordingly, no further grants may be made under this plan. Any shares that remained available for issuance under the 2000 Plan as of the date of adoption of the 2007 Plan are included in the number of shares that may be issued under the 2007 Plan. Any shares subject to outstanding awards granted under the 2000 Plan that expire or terminate for any reason prior to exercise will be added to the total number of shares available for issuance under the 2007 Plan.

Equity-based compensation expense as reflected in our condensed consolidated statements of operations was approximately as follows (in thousands):

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Research and development	\$ 883	\$ 392	\$ 1,592	\$ 799
Selling, general and administrative	2,311	1,861	4,296	2,988
Total equity-based compensation expense	\$ 3,194	\$ 2,253	\$ 5,888	\$ 3,787

Equity-based compensation expense for the six months ended June 30, 2008 and 2007 included approximately \$1.5 million and \$1.0 million, respectively, in equity-based compensation expense associated with performance grants.

At June 30, 2008, the amount of unrecorded equity-based compensation expense for stock options attributable to future periods was approximately \$29.8 million, of which \$28.8 million was associated with stock options and \$1.0 million was associated with restricted stock units. Such amounts will be amortized, in varying amounts, primarily to research and development or selling, general and administrative expense, on a straight line basis over a weighted average amortization period of approximately 3.1 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 and other stock awards.

**I. Concentration of Credit Risk**

Our operations are located solely within the U.S. We are focused principally on developing and manufacturing IV iron replacement therapeutic agents and contrast agents for use in MRI. We perform ongoing credit evaluations of our customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our revenues for the six months ended June 30, 2008 and 2007. No other company accounted for more than 10% of our total revenues for the six months ended June 30, 2008 and 2007.

	<b>Six Months Ended June 30,</b>	
	<b>2008</b>	<b>2007</b>
Guerbet S.A.	43%	24%
Bayer Healthcare Pharmaceuticals	37%	43%
Covidien, Ltd.	16%	0%
Cytogen Corporation	0%	22%



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All of the revenue attributable to Cytogen Corporation, or Cytogen, and a large portion of the revenue attributable to Bayer Healthcare Pharmaceuticals, or Bayer, in both periods was the result of previously deferred revenue related to up-front license fees that were either amortized into revenue on a straight-line basis or amortized over the period of the estimated performance obligation.

Revenues from customers outside of the U.S., principally in Europe, amounted to 45% and 26% of our total revenues for the six months ended June 30, 2008 and 2007, respectively.

**J. Recently Issued Accounting Pronouncements**

In September 2006, the FASB issued 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 but rather eliminates inconsistencies in guidance found in various prior accounting policies. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. In February 2008, the FASB issued FASB FSP 157-2, which delays the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. These nonfinancial items include assets and liabilities such as reporting units measured at fair value in a goodwill impairment test and nonfinancial assets acquired and liabilities assumed in a business combination. Effective January 1, 2008, we partially adopted SFAS 157 for financial assets and liabilities recognized at fair value on a recurring basis. The partial adoption of SFAS 157 for financial assets and liabilities did not have a material impact on our condensed consolidated financial statements. The provisions of SFAS 157 related to other nonfinancial assets and liabilities will be effective for us on January 1, 2009, and will be applied prospectively. We are currently evaluating the impact that these additional SFAS 157 provisions will have on our condensed consolidated financial statements.

Effective January 1, 2008, we adopted 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. We did not elect to adopt the fair value option under this statement.

Effective January 1, 2008, we adopted EITF 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities, or EITF 07-3. EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. The adoption of EITF 07-03 did not have a material impact on our condensed consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133. SFAS 161 is intended to improve financial standards for derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. Entities are required to provide enhanced disclosures about: (a) how and why an entity uses derivative instruments; (b) how derivative instruments and related hedged items are accounted for under SFAS 133 and its related interpretations; and (c) how derivative instruments and related hedged items affect



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an entity's financial position, financial performance, and cash flows. SFAS 161 is effective for financial statements issued for fiscal years beginning after November 15, 2008, with early adoption encouraged. We are in the process of evaluating the impact of SFAS 161, but we do not expect it to have a significant impact on our condensed consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), Business Combinations, or SFAS 141R. SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141R is effective for financial statements issued for years beginning after December 15, 2008. We are in the process of evaluating the impact of SFAS 141R, but we do not expect it to have a significant impact on our condensed consolidated financial statements.

In June 2008, the FASB issued FASB Staff Position, or FSP, EITF No. 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities. The FSP addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting and therefore need to be included in the earnings allocation in calculating earnings per share under the two-class method described in SFAS No. 128, Earnings per Share. The FSP requires companies to treat unvested share-based payment awards that have non-forfeitable rights to dividend or dividend equivalents as a separate class of securities in calculating earnings per share. The FSP is effective for fiscal years beginning after December 15, 2008 and earlier application is not permitted. We are in the process of evaluating the impact of FSP EITF No. 03-6-1, but we do not expect it to have a significant impact on our condensed consolidated financial statements.

**K. Collaborations**

On May 25, 2008, we entered into a Collaboration and Exclusive License Agreement, or License Agreement, and a Supply Agreement with 3SBio Inc., or 3SBio, with respect to the development and commercialization of ferumoxytol as an IV iron replacement therapeutic agent in China. The License Agreement grants 3SBio an exclusive license for an initial term of thirteen years to develop and commercialize ferumoxytol as a therapeutic agent in China for an initial indication in the treatment of iron deficiency anemia in patients with chronic kidney disease, or CKD, and an option to expand into additional therapeutic indications. In consideration for the grant of the license, we received an upfront payment of \$1 million, the recognition of which has been deferred, and we are eligible to receive certain other specified milestone payments upon regulatory approval of ferumoxytol in China for CKD and other indications. We are also entitled to receive tiered, double-digit royalties, of up to 25% based on sales of ferumoxytol by 3SBio in China. We retain all manufacturing rights for ferumoxytol. In addition, pursuant to the Supply Agreement, 3SBio has agreed to purchase from us, and we have agreed to supply to 3SBio, ferumoxytol at a predetermined supply price for clinical and commercial use in connection with 3SBio's development and commercialization obligations described above for so long as the License Agreement is in effect.

**L. Commitments and Contingencies**

*Facility Lease*

On May 27, 2008, we entered into a lease agreement for certain real property located at 100 Hayden Avenue, Lexington, Massachusetts to be utilized as our principal executive offices. The term of the lease began on May 22, 2008 and will continue until August 31, 2016 with two

successive five year extension terms at our option. The lease requires us to pay rent as follows:

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Period	Minimum Lease Payments
Year Ended December 31, 2008	\$
Year Ended December 31, 2009	\$ 1,686,575
Year Ended December 31, 2010	\$ 1,891,164
Year Ended December 31, 2011	\$ 1,947,088
Year Ended December 31, 2012	\$ 2,003,012
Thereafter	\$ 7,892,742
Total	\$ 15,420,581

During any extension term, the base rent will be an amount agreed upon by us and the landlord. In addition to base rent, we are also required to pay a proportionate share of the landlord's annual operating costs. On May 20, 2008, in connection with our new lease, we delivered to the landlord a security deposit of approximately \$0.5 million in the form of an irrevocable letter of credit. The cash securing this letter of credit is classified on our balance sheet as a long-term asset and is restricted in its use.

*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. With the termination of our agreements with Cytogen, we re-acquired the U.S. marketing rights to *Combidex* as well as the U.S. marketing rights to ferumoxytol for oncology imaging applications. 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. We recorded the \$4.0 million payment as a non-operating expense during the first quarter of 2007.

We may periodically become subject to legal proceedings and claims arising in connection with on-going business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which we are focused. We are not aware of any material claims against us at June 30, 2008.

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

*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 year ended December 31, 2007.*

*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, expect, intend, and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Examples of forward looking statements contained in this report include statements regarding the following: the progress of our intended development and commercialization of ferumoxytol and Combidex, the potential clinical trials of ferumoxytol we may initiate in indications other than chronic kidney disease, the potential approval and launch of ferumoxytol and our other product candidates in the U.S. and outside the U.S., future revenues, expected research and development expenses and sales, general and administrative expenses, our expectations regarding our short- and long-term liquidity and capital requirements and our ability to finance our operations, our belief that the impairment in the value of our auction rate securities is temporary and that we will ultimately be able to liquidate our auction rate security investments without significant loss, and information with respect to any other plans and strategies for our business. 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 SEC filings, including but not limited to our Annual Report on Form 10-K for the year ended December 31, 2007. 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 our 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**

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a biopharmaceutical company that utilizes our 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 *Combidx*.

Ferumoxytol, our key product candidate, is being developed for use as an IV iron replacement therapeutic agent for the treatment of iron deficiency anemia and as a diagnostic agent for vascular-enhanced MRI to assess peripheral arterial disease. In December 2007, we submitted an NDA to the FDA seeking marketing approval for ferumoxytol as an IV iron replacement therapeutic agent in CKD patients, including both dialysis dependent and non-dialysis dependent patients. Our NDA was accepted for standard review by the FDA, and we expect a decision from the FDA in late October 2008. Our NDA is supported by data from three open-label, multi-center, randomized Phase III efficacy and safety clinical



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studies and a fourth Phase III safety study. The three efficacy and safety studies demonstrated a statistically significant achievement of all primary and secondary endpoints. In total, over 1,700 patients and healthy volunteers were treated with ferumoxytol in eleven clinical studies. We have released data on all four of our planned Phase III clinical trials of ferumoxytol as an IV iron replacement therapeutic agent in patients with CKD.

*Iron deficiency anemia is widely prevalent in many different patient populations and disease states. In addition to its use in the treatment of iron deficiency anemia, ferumoxytol may also be useful as a vascular enhancing agent in MRI. As a result, we believe the product characteristics of ferumoxytol could support clinical development in additional indications and intend to initiate Phase II and/or Phase III studies in patient populations other than CKD patients in the second half of 2008.*

*We are currently in the process of building an internal sales and marketing function, including a direct sales force, in preparation for the expected commercial launch of ferumoxytol as an IV iron replacement therapeutic agent in CKD patients in the U.S. in the first quarter of 2009.*

On May 25, 2008, we entered into a License Agreement and a Supply Agreement with 3SBio with respect to the development and commercialization of ferumoxytol as an IV iron replacement therapeutic agent in China. The License Agreement grants 3SBio an exclusive license for an initial term of thirteen years to develop and commercialize ferumoxytol in China for an initial indication in the treatment of iron deficiency anemia in patients with CKD and an option to expand into additional therapeutic indications. We will form a joint steering committee, with equal representation from both parties, to oversee and guide the development and commercialization of ferumoxytol in China. 3SBio has agreed to use diligent efforts to develop and commercialize ferumoxytol in China in accordance with certain objectives and timelines agreed to by the parties. In consideration for the grant of the license, we received an upfront payment of \$1 million, the recognition of which has been deferred, and we are eligible to receive certain other specified milestone payments upon regulatory approval of ferumoxytol in China for CKD and other indications. We are also entitled to receive tiered, double-digit royalties, of up to 25%, based on sales of ferumoxytol by 3SBio. We retain all manufacturing rights for ferumoxytol. 3SBio has also agreed that, with our prior written consent, 3SBio will not develop or market in China any iron based therapeutic product or any generic version of ferumoxytol during the term of the License Agreement and for a defined term thereafter. In addition, pursuant to the Supply Agreement, 3SBio has agreed to purchase from us, and we have agreed to supply to 3SBio, ferumoxytol at a predetermined supply price for clinical and commercial use in connection with 3SBio's development and commercialization obligations described above for so long as the License Agreement is in effect.

*We continue to evaluate our strategy for seeking approval for ferumoxytol as an IV iron replacement therapeutic agent in countries outside the U.S. The commercial opportunity for ferumoxytol as an IV iron replacement therapeutic agent varies from country to country, and in determining which additional markets outside the U.S. we intend to enter, we are assessing factors such as potential pricing and reimbursement, patient access to dialysis and the role of iron in medical treatment protocols in each country. We are also currently evaluating possible strategic alliances and partnerships to assist us in entering attractive foreign markets.*

Combidex is our investigational functional molecular imaging agent consisting of iron oxide nanoparticles for use in conjunction with 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,

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subject to certain conditions, including the provision of additional data to demonstrate its safety and efficacy. We do not currently have plans to sponsor additional clinical studies of Combix.

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

**Results of Operations for the Three Months Ended June 30, 2008 as Compared to the Three Months Ended June 30, 2007***Revenues*

Total revenues were \$0.5 million and \$0.7 million for the three months ended June 30, 2008 and 2007, respectively, representing a decrease of approximately 35%. The decrease in revenues was primarily the result of a decrease in product sales of *Feridex I.V.*, partially offset by an increase in royalty revenues.

Our revenues for the three months ended June 30, 2008 and 2007 consisted of the following (in thousands):

	Three Months Ended June 30,			
	2008	2007	\$ Change	% Change
Revenues:				
License fees	\$ 185	\$ 184	\$ 1	1%
Royalties	89	64	25	39%
Product sales	212	497	(285)	-57%
Total	\$ 486	\$ 745	\$ (259)	-35%

The following table sets forth customers who represented 10% or more of our revenues for the three months ended June 30, 2008 and 2007. No other company accounted for more than 10% of our total revenues in either period.

	Three Months Ended June 30,	
	2008	2007
Bayer	46%	70%
Covidien, Ltd.	29%	0%
Guerbet S.A.	16%	22%

*License Fee Revenues*

All of our license fee revenues for each of the three months ended June 30, 2008 and 2007 consisted of \$0.2 million of deferred license fee revenues that are being amortized in connection with a License and Marketing Agreement with Bayer.

In February 1995, we entered into a License and Marketing Agreement and a Supply Agreement, or the Bayer Agreements, with Bayer, granting Bayer a product license and exclusive marketing rights to *Feridex I.V.* in the U.S. and Canada. In 1996, the parties agreed to remove Canada from the territories subject to the Bayer Agreements. Bayer paid us non-refundable license fees and other fees in connection with the Bayer Agreements. We account for the revenues associated with the Bayer Agreements on a

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straight-line basis over the 15 year term of the Bayer Agreements due to the existence of an established contract period. The Bayer Agreements expire in 2010 but can be terminated earlier upon the occurrence of certain specified events.

*Product Sale Revenues*

Product sale revenues for the three months ended June 30, 2008 and 2007 consisted of the following (in thousands):

	Three Months Ended June 30,					
	2008	2007		\$ Change		% Change
<i>Feridex I.V.</i>	\$ 32	\$ 343	\$	(311)		-91%
<i>GastroMARK</i>	160	154		6		4%
<i>Combindex</i>	20			20		N/A
Total	\$ 212	\$ 497	\$	(285)		-57%

The decrease in product sale revenues for the three months ended June 30, 2008 as compared to the three months ended June 30, 2007 was primarily the result of a decrease in product sales of *Feridex I.V.* Product sales may fluctuate from period to period. Fluctuations in our product sales are primarily attributable to unpredictable annual product demand by end users and the batch sizes in which our products are manufactured and shipped, which create uneven purchasing patterns by our marketing partners. We expect that revenues from our current products will not substantially change from their current levels.

*Costs and Expenses**Cost of Product Sales*

We incurred costs associated with product sales during the three months ended June 30, 2008 and 2007 of approximately \$31,000 and \$101,000, respectively. This constituted approximately 15% and 20% of product sales during the three months ended June 30, 2008 and 2007, respectively. The cost of product sales and therefore our gross margin is 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*

Research and development expenses include external expenses, such as costs of clinical trials, contract research and development expenses, commercial manufacturing preparation and related materials costs, consulting and professional fees and expenses, and internal expenses, such as compensation of employees engaged in research and development activities, the manufacture of products needed to support research and development efforts, related costs of facilities, and other general costs related to research and development. Manufacturing costs are expensed as incurred until a product has received the necessary initial regulatory approval or approval is otherwise considered assured. To the extent that

external costs are not attributable to a specific major project or activity, they are included in other external costs.

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Research and development expenses for the three months ended June 30, 2008 and 2007 consisted of the following (in thousands):

	Three Months Ended June 30,			
	2008	2007	\$ Change	% Change
<b>External Research and Development Expenses:</b>				
Ferumoxytol as an IV iron replacement therapeutic agent	\$ 580	\$ 1,917	\$ (1,337)	-70%
Ferumoxytol as an imaging agent	576		576	N/A
Ferumoxytol manufacturing and materials	1,128		1,128	N/A
<i>Combidex</i> and other external costs	253	214	39	18%
<b>Total</b>	<b>2,537</b>	<b>2,131</b>	<b>406</b>	<b>19%</b>
<b>Internal Research and Development Expenses:</b>				
Compensation, payroll taxes, benefits and other expenses	3,641	2,592	1,049	40%
Equity-based compensation expense	883	392	491	>100%
<b>Total</b>	<b>4,524</b>	<b>2,984</b>	<b>1,540</b>	<b>52%</b>
<b>Total Research and Development Expenses</b>	<b>\$ 7,061</b>	<b>\$ 5,115</b>	<b>\$ 1,946</b>	<b>38%</b>

Total research and development expenses incurred in the three months ended June 30, 2008 amounted to \$7.1 million, an increase of \$1.9 million, or 38%, from the three months ended June 30, 2007. The \$1.9 million increase is primarily attributable to costs associated with an increased headcount, increased production materials and supply costs and increased equity-based compensation expense, partially offset by lower costs due to the completion in 2007 of our Phase III clinical trials for ferumoxytol as an IV iron replacement therapeutic agent in CKD patients. No such trials were ongoing during the three months ended June 30, 2008.

Our external research and development expenses increased by \$0.4 million, or 19%, for the three months ended June 30, 2008 as compared to the three months ended June 30, 2007. The \$0.4 million increase in our external expenses was due primarily to an increase in costs associated with our preparation for commercial scale manufacturing of ferumoxytol and start-up costs associated with potential clinical trials of ferumoxytol in indications other than CKD, partially offset by a decrease in expenditures associated with the development program for ferumoxytol as an IV iron replacement therapeutic agent in CKD patients as we completed our Phase III clinical trials.

Our internal research and development expenses increased by \$1.5 million, or 52%, for the three months ended June 30, 2008 as compared to the three months ended June 30, 2007. The \$1.5 million increase in internal costs was due primarily to higher compensation and benefit costs as a result of hiring additional research and development personnel as we began to expand our development infrastructure and scale-up our manufacturing capabilities for the expected commercialization of ferumoxytol. At June 30, 2008, we had 70 employees in research and development as compared to 43 employees at June 30, 2007, an increase of 63%. The \$0.5 million increase in equity-based compensation expense was primarily attributable to increased stock option grants to both new and existing employees.

We expect research and development expenses to increase during the remainder of 2008 as we initiate new clinical trials to develop additional indications for ferumoxytol as both a therapeutic and an imaging agent, seek approval for ferumoxytol in non-U.S. geographies, continue commercial manufacturing



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preparations, build commercial inventory, and continue other research and development related functions and activities in support of ferumoxytol.

We do not track our internal costs by project since our research and development personnel work on a number of projects concurrently and much of our fixed costs benefit multiple projects or our operations in general. We track our external costs on a major project by major project basis, in most cases through the NDA submission to the FDA. In December 2007, we submitted an NDA for ferumoxytol as an IV iron replacement therapeutic agent in CKD patients and therefore do not intend to track additional external costs related to that project. However, during 2008, we intend to initiate additional Phase II and/or Phase III studies in patient populations other than CKD patients. As of June 30, 2008, we have not incurred significant costs related to these projects.

At this time, due to the numerous risks and uncertainties inherent in the clinical development and regulatory approval process, including significant and changing government regulation, and given the current stage of our development of new indications for ferumoxytol, we are unable to estimate with any certainty the costs we will incur in the development of new indications for ferumoxytol for potential commercialization. The estimated costs to completion for the various stages of clinical development can vary significantly depending on the nature of the product candidate, the number of patients enrolled in each trial, the speed at which patients are enrolled, the disease indications being tested and many other factors. For a discussion of the risks and uncertainties associated with the timing and cost of completing development of a product candidate, see Item 1A Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2007. While we are currently focused on the potential commercial launch of ferumoxytol as an IV iron replacement therapeutic agent in CKD patients, we anticipate that we will make determinations as to which new indications to pursue and how much funding to direct to each new indication on an ongoing basis in response to the scientific and clinical progress associated with each indication, as well as an ongoing assessment as to each indication's commercial potential. We cannot forecast with any degree of certainty which indications may be subject to future collaborative or licensing arrangements, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. Similarly, we are currently unable to provide meaningful estimates of the timing of completion of each of our development projects for additional indications for ferumoxytol as an estimation of completion dates would be highly speculative and subject to a number of risks and uncertainties.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses for the three months ended June 30, 2008 and 2007 consisted of the following (in thousands):

	Three Months Ended June 30,				
	2008	2007	\$ Change	% Change	
Compensation, payroll taxes and benefits	\$ 3,083	\$ 1,365	\$ 1,718	>100%	
Professional and consulting fees and other expenses	7,217	1,857	5,360	>100%	
Equity-based compensation expense	2,311	1,861	450	24%	
Total	\$ 12,611	\$ 5,083	\$ 7,528	>100%	

The increase of \$7.5 million in selling, general and administrative expenses for the three months ended June 30, 2008 as compared to the three months ended June 30, 2007 was due primarily to increased



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costs associated with the on-going expansion of our commercial operations function, including consulting costs related to preparing for the potential commercial launch of ferumoxytol; higher compensation and benefit costs related to increased headcount in our commercial operations function; equity-based compensation expense, which includes increased expense associated with performance-based stock option grants; and the expansion of our general administrative infrastructure. At June 30, 2008 we had 62 employees in our selling, general and administrative departments as compared to 18 employees at June 30, 2007, an increase of 244%. The \$0.5 million increase in equity-based compensation expense was primarily attributable to increased stock option grants associated with new and existing employees.

We expect selling, general and administrative expenses to significantly increase during the remainder of 2008 as we continue our efforts to augment our infrastructure and prepare for the potential commercial launch of ferumoxytol. We continue to incur significant expense related to the hiring of our own sales force, developing our marketing infrastructure, executing related marketing and promotional programs and hiring consultants in preparation for the potential commercialization of ferumoxytol as an IV iron replacement therapeutic agent in patients with CKD.

*Other Income (Expense)*

Other income (expense) consisted of \$2.2 million and \$2.6 million of interest income for the three months ended June 30, 2008 and 2007, respectively. The \$0.4 million decrease in other income (expense) was primarily attributable to decreased interest income associated with lower interest rates in the three months ended June 30, 2008 as compared to the three months ended June 30, 2007.

*Net Loss*

For the reasons stated above, we incurred a net loss of \$17.0 million, or \$1.00 per basic and diluted share, for the three months ended June 30, 2008 compared to a net loss of \$6.9 million, or \$0.46 per basic and diluted share, for the three months ended June 30, 2007.

**Results of Operations for the Six Months Ended June 30, 2008 as Compared to the Six Months Ended June 30, 2007**

*Revenues*

Total revenues were \$1.1 million and \$1.7 million for the six months ended June 30, 2008 and 2007, respectively, representing a decrease of approximately 34%. The decrease in revenues was due primarily to the recognition in February 2007 of \$0.4 million of deferred license fee revenues as the result of the termination of our *Combidex* License and Marketing Agreement with Cytogen as well as a decrease in product sales.



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Our revenues for the six months ended June 30, 2008 and 2007 consisted of the following (in thousands):

	Six Months Ended June 30,		\$ Change	% Change
	2008	2007		
Revenues:				
License fees	\$ 369	\$ 726	\$ (357)	-49%
Royalties	125	141	(16)	-12%
Product sales	604	791	(187)	-24%
Total	\$ 1,098	\$ 1,658	\$ (560)	-34%

The following table sets forth customers who represented 10% or more of our revenues for the six months ended June 30, 2008 and 2007. No other company accounted for more than 10% of our total revenues in either period.

	Six Months Ended June 30,	
	2008	2007
Guerbet S.A.	43%	24%
Bayer Healthcare Pharmaceuticals	37%	43%
Covidien, Ltd.	16%	0%
Cytogen Corporation	0%	22%

*License Fee Revenues*

Our license fee revenues for the six months ended June 30, 2008 and 2007 consisted of deferred license fee revenues that are being amortized in connection with the Bayer Agreements. In addition, our license fee revenues for the six months ended June 30, 2007 also included deferred license fee revenues that were being amortized in connection with a License and Marketing Agreement with Cytogen which terminated in February 2007.

In February 1995, we entered into the Bayer Agreements, granting Bayer a product license and exclusive marketing rights to *Feridex I.V.* in the U.S. and Canada. In 1996, the parties agreed to remove Canada from the territories subject to the Bayer Agreements. Bayer paid us non-refundable license fees and other fees in connection with the Bayer Agreements. We account for the revenues associated with the Bayer Agreements on a straight-line basis over the 15 year term of the Bayer Agreements due to the existence of an established contract period. The Bayer Agreements expire in 2010 but can be terminated earlier upon the occurrence of certain specified events.

In August 2000, we entered into a License and Marketing Agreement with Cytogen, or the Cytogen Agreement, in which, among other things, we granted Cytogen exclusive U.S. marketing rights to *Combidex*. At the time of signing that agreement, we received shares of common stock of Cytogen with a market value of approximately \$13.5 million as a non-refundable licensing fee. This fee was recognized as revenue over the development period of the products subject to the Cytogen Agreement based upon costs incurred and expected remaining expenditures related to the agreement. The entire amount of the license fee was recorded as deferred revenues upon signing the Cytogen Agreement. In February 2007, as part of the settlement of a lawsuit with Cytogen, we paid Cytogen \$4.0 million in cash. In addition, the Cytogen Agreement was terminated and the remainder of the deferred revenues associated with this agreement, \$0.4 million, was recognized in February 2007 as there were no

additional performance obligations under the License Agreement due to its termination.

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Total license fee revenues for the six months ended June 30, 2008 and 2007 were recognized as follows (in thousands):

	Six Months Ended June 30,		\$ Change	% Change
	2008	2007		
License fee revenues recognized in connection with the Cytogen Agreement	\$	\$ 357	\$ (357)	-100%
License fee revenues recognized in connection with the Bayer Agreement		369		0%
Total	\$	\$ 369	\$ (357)	-49%

*Product Sale Revenues*

Product sale revenues for the six months ended June 30, 2008 and 2007 consisted of the following (in thousands):

	Six Months Ended June 30,		\$ Change	% Change
	2008	2007		
<i>Feridex I.V.</i>	\$	\$ 267	\$ (77)	-22%
<i>GastroMARK</i>		317	5	2%
<i>Combidex</i>		20	(115)	-85%
Total	\$	\$ 604	\$ (187)	-24%

The decrease in product sale revenues for the six months ended June 30, 2008 as compared to the six months ended June 30, 2007 was the result of a decrease in the sale of bulk *Combidex* to one of our foreign marketing partners for research and development purposes and a decrease in sales of *Feridex I.V.* to our marketing partners. Product sales may fluctuate from period to period. Fluctuations in our product sales are primarily attributable to unpredictable annual product demand by end users and the batch sizes in which our products are manufactured and shipped, which create uneven purchasing patterns by our marketing partners. We expect that revenues from our current products will not substantially change from their current levels.

*Costs and Expenses**Cost of Product Sales*

We incurred costs associated with product sales during the six months ended June 30, 2008 and 2007 of approximately \$0.1 million and \$0.3 million, respectively. This constituted approximately 12% and 33% of product sales during the six months ended June 30, 2008 and 2007, respectively. The decrease in cost of product sales as a percentage of product sale revenues was due primarily to a decrease in the sale of bulk *Combidex* at cost to one of our foreign marketing partners for research and development purposes during the six months ended June 30, 2007 compared to the six months ended June 30, 2008. The cost of product sales and therefore our gross margin is dependent on the mix of customers, prices we charge for our products, product mix, changes in unit volume and production efficiencies.



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*Research and Development Expenses*



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Research and development expenses for the six months ended June 30, 2008 and 2007 consisted of the following (in thousands):

	Six Months Ended June 30,		\$ Change	% Change
	2008	2007		
<b>External Research and Development Expenses:</b>				
Ferumoxytol as an IV iron replacement therapeutic agent	\$ 781	\$ 4,915	\$ (4,134)	-84%
Ferumoxytol as an imaging agent	576		576	N/A
Ferumoxytol manufacturing and materials	1,704		1,704	N/A
<i>Combidex</i> and other external costs	426	503	(77)	-15%
<b>Total</b>	<b>3,487</b>	<b>5,418</b>	<b>(1,931)</b>	<b>-36%</b>
<b>Internal Research and Development Expenses:</b>				
Compensation, payroll taxes, benefits and other expenses	6,805	5,039	1,766	35%
Equity-based compensation expense	1,592	799	793	99%
<b>Total</b>	<b>8,397</b>	<b>5,838</b>	<b>2,559</b>	<b>44%</b>
<b>Total Research and Development Expenses</b>	<b>\$ 11,884</b>	<b>\$ 11,256</b>	<b>\$ 628</b>	<b>6%</b>

Total research and development expenses of \$11.9 million for the six months ended June 30, 2008 remained relatively stable as compared to total research and development expenses of \$11.3 million for the six months ended June 30, 2007. Our external research and development expenses decreased by \$1.9 million, or 36%, primarily as the result of a decrease in expenditures associated with the development program for ferumoxytol as an IV iron replacement therapeutic agent in CKD patients as we completed our Phase III clinical trials in 2007, partially offset by an increase in costs associated with our preparation for commercial scale manufacturing of ferumoxytol and start-up costs associated with potential clinical trials of ferumoxytol in indications other than CKD. The decrease in external costs was offset by a \$2.6 million, or 44%, increase in our internal costs primarily due to higher compensation and benefit costs as a result of hiring additional research and development personnel as we continue to expand our development infrastructure and scale-up our manufacturing capabilities for the expected commercialization of ferumoxytol. At June 30, 2008, we had 70 employees in research and development as compared to 43 employees at June 30, 2007, an increase of 63%. The \$0.8 million increase in equity-based compensation expense was primarily attributable to increased stock option grants to both new and existing employees.

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*Selling, General and Administrative Expenses*



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Selling, general and administrative expenses for the six months ended June 30, 2008 and 2007 consisted of the following (in thousands):

	Six Months Ended June 30,		\$ Change	% Change
	2008	2007		
Compensation, payroll taxes and benefits	\$ 5,632	\$ 2,010	\$ 3,622	>100%
Professional and consulting fees and other expenses	11,068	2,876	8,192	>100%
Equity-based compensation expense	4,296	2,988	1,308	44%
Total	\$ 20,996	\$ 7,874	\$ 13,122	>100%

The increase in selling, general and administrative expenses for the six months ended June 30, 2008 as compared to the six months ended June 30, 2007 was due primarily to increased costs associated with the on-going expansion of our commercial operations function, including consulting costs related to preparing for the potential commercial launch of ferumoxytol, higher compensation and benefit costs related to increased headcount in our commercial operations function, equity-based compensation expense, which includes increased expense associated with performance-based stock option grants, and the expansion of our general administrative infrastructure. At June 30, 2008, we had 62 employees in our selling, general and administrative departments as compared to 18 employees at June 30, 2007, an increase of 244%. The \$1.3 million increase in equity-based compensation expense was primarily attributable to increased stock option grants associated with new and existing employees and also included a \$0.5 million incremental expense related to performance-based stock option grants in the six months ended June 30, 2008 as compared to the six months ended June 30, 2007.

*Other Income (Expense)*



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Other income (expense) for the six months ended June 30, 2008 and 2007 consisted of the following (in thousands):

	Six Months Ended June 30,		\$ Change	% Change
	2008	2007		
Interest income	\$ 5,549	\$ 4,592	\$ 957	21%
Litigation settlement		(4,000)	4,000	-100%
<b>Total</b>	<b>\$ 5,549</b>	<b>\$ 592</b>	<b>\$ 4,957</b>	<b>&gt;100%</b>

The \$5.0 million increase in other income (expense) for the six months ended June 30, 2008, as compared to the six months ended June 30, 2007 was primarily attributable to increased interest income associated with a higher average amount of invested funds in the six months ended June 30, 2008 as compared to the six months ended June 30, 2007 as the result of our May 2007 financing, which resulted in net proceeds to us of approximately \$154.5 million. In addition, we paid a \$4.0 million settlement to Cytogen in the six months ended June 30, 2007 which was not present in the six months ended June 30, 2008.

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*Net Loss*



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For the reasons stated above, we incurred a net loss of \$26.3 million, or \$1.55 per basic and diluted share, for the six months ended June 30, 2008 compared to a net loss of \$17.1 million, or \$1.17 per basic and diluted share, for the six months ended June 30, 2007.

### **Liquidity and Capital Resources**



*General*

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

- Our ability to successfully obtain regulatory approval in the U.S. for ferumoxytol as an IV iron replacement therapeutic agent in a timely manner;
  
- Costs associated with our preparations for the commercial launch of ferumoxytol, including costs associated with our hiring of additional staff and our leasing and build-out of our additional office space;
  
- Costs associated with preparing for commercial-scale manufacturing of ferumoxytol, including costs associated with building commercial inventory and qualifying additional manufacturing capacity and second source suppliers;
  
- Our ability to generate revenues from product sales of ferumoxytol;
  
- Costs associated with our development of additional indications for ferumoxytol;
  
- Costs associated with the pursuit of potential business development activities;
  
- Costs associated with our pursuit of approval for ferumoxytol as an IV iron replacement therapeutic agent outside the U.S.;
  
- Our ability to liquidate our ARS investments in a timely manner or without significant loss;
  
- Our ability to establish additional development and marketing arrangements or to enter into alternative strategic relationships, if necessary; and
  
- Our ability to raise additional capital on terms and within a timeframe acceptable to us, if necessary.

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As of June 30, 2008, our investments consisted of corporate debt securities, U.S. treasury and government agency securities, commercial paper, and municipal ARS. We place our cash investments in instruments that meet high credit quality standards, as specified in our investment policy. Our investment policy also limits the amount of our credit exposure to any one issue or issuer and seeks to manage these assets to achieve our goals of preserving principal, maintaining adequate liquidity at all times, and maximizing returns.

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At June 30, 2008, we held \$64.5 million (par value of \$68.9 million) of ARS, of which greater than 90% were rated AAA by at least one of the major securities rating agents, most of which were collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program, with the majority of remaining securities being backed by monoline bond insurance companies. We have traditionally recorded these investments at cost, which approximated fair market value due to their variable interest rates, which typically reset through an auction process every 7 or 28 days. This auction mechanism generally allowed existing investors to roll over their holdings and continue to own their securities or liquidate their holdings by selling their securities at par value. In mid-February 2008, our ARS began to experience failed auctions, and have continued to experience failed auctions. As a result of the lack of market activity, we changed our valuation methodology for these securities to a discounted cash flow analysis. Our valuation analyses consider, among other items, assumptions that market participants would use in their estimates of fair value such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, the inability to sell the investment in an active market, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when callability features may be exercised by the issuer. Based upon this methodology, we have recorded an unrealized loss related to our ARS of approximately \$4.4 million to accumulated other comprehensive (loss) income as of June 30, 2008.

Due to our belief that the market for ARS may take in excess of twelve months to fully recover, we have classified those ARS for which we have not received notices of the issuer's intent to redeem as noncurrent and have included securities totaling approximately \$62.1 million in long-term investments on our condensed consolidated balance sheet at June 30, 2008. The remainder of our ARS, totaling approximately \$2.4 million, are securities for which we have received notices of the issuer's intent to redeem and, accordingly, we have classified those securities as short-term investments on our condensed consolidated balance sheet at June 30, 2008.

We believe that the temporary impairment related to our ARS of approximately \$4.4 million is primarily attributable to the limited liquidity of these investments, and we have no reason to believe that any of the underlying issuers of our ARS are presently at risk of default. Any future fluctuation in fair value related to these instruments that we deem to be temporary, including any recoveries of previous write-downs, would be recorded to accumulated other comprehensive (loss) income. If we determine that any future unrealized loss is other-than-temporary, we will record a charge to earnings as appropriate. In the event that we need to access our investments in these securities, we will not be able to do so until a future auction is successful, the issuer calls the security pursuant to a mandatory tender or redemption prior to maturity, a buyer is found outside the auction process, or the securities mature. For all of our ARS the underlying maturity date is in excess of one year and can be as far as 40 years in the future. We believe we will ultimately be able to liquidate our investments without significant loss primarily due to the collateral securing most of the ARS. However, it could take until final maturity of the ARS to realize our investments' par value.

Based on our ability to access our cash and other short-term investments, our expected operating cash flows, and our other sources of cash, we do not anticipate that the current lack of liquidity with respect to our ARS will materially affect our ability to operate our business in the ordinary course, however, we are uncertain when the current liquidity issues relating to ARS will improve, if at all.

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Cash and cash equivalents (which consist principally of cash held in commercial bank accounts, money market funds and U.S. Treasury Bills having an original maturity of less than three months) and investments at June 30, 2008 and December 31, 2007 consisted of the following (in thousands):

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	June 30, 2008		December 31, 2007		\$	Change	% Change
Cash and cash equivalents	\$	56,060	\$	28,210	\$	27,850	99%
Short-term investments		146,160		258,597		(112,437)	-43%
Long-term investments		62,106				62,106	N/A
Total cash, cash equivalents and investments	\$	264,326	\$	286,807	\$	(22,481)	-8%

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The decrease in cash and cash equivalents and investments as of June 30, 2008 as compared to December 31, 2007 is primarily the result of cash used in operations and the net impact of unrealized losses of short- and long-term investments, partially offset by interest income.

As of June 30, 2008, we believe that our cash, cash equivalents, and investments, combined with cash we currently expect to receive from earnings on our investments and from our business development activities, will be sufficient to satisfy our future cash flow needs for at least the next twelve months, including projected operating expenses related to our development and commercialization programs for ferumoxytol.

### *Cash flows from operating activities*

During the six months ended June 30, 2008, our use of cash in operations of \$17.3 million was attributable principally to our net loss of approximately \$26.3 million partially offset by the impact of changes in certain assets and liabilities of \$2.6 million, and approximately \$6.4 million in non-cash expense associated with employee stock options and restricted stock units and depreciation. Our net loss includes 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 agent.

We anticipate cash used in operating activities will increase over current levels during the remainder of 2008 as we continue to advance our ongoing commercialization efforts for ferumoxytol as an IV iron replacement therapeutic agent and incur additional costs associated with our development of new indications for ferumoxytol in the U.S., including our continued expansion of our commercial, clinical, medical, regulatory and manufacturing organizations in support of our anticipated ferumoxytol launch, and our efforts to build commercial inventory and qualify second source suppliers and manufacturers for ferumoxytol. The actual amount of these expenditures will depend on numerous factors, including the timing of expenses and the timing and progress of the regulatory approval of ferumoxytol and our development, sales and marketing efforts. During the remainder of 2008 we also expect to incur substantial expenditures related to the occupancy, furnishing and build-out of our new corporate headquarters, a portion of which will be reimbursed to us by the landlord.

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*Cash flows from investing activities*

Cash provided by investing activities was \$44.7 million during the six months ended June 30, 2008 and was primarily attributable to proceeds from maturities of our investments, partially offset by \$1.3 million of cash used for capital expenditures primarily related to the construction in process at our new facility.

*Cash flows from financing activities*

Cash provided by financing activities was \$0.8 million during the six months ended June 30, 2008 and was primarily attributable to the proceeds from the exercise of stock options.

*Operating and Facility Lease Obligations*

We have entered into several agreements to lease certain office and laboratory equipment under operating leases that expire through 2009.

We are a party to a lease agreement with W2007 CPD Realty, L.L.C. (successor to CambridgePark 125 Realty Corporation) for certain real property comprised of approximately 25,000 square feet of executive office space located at 125 CambridgePark Drive, Cambridge, Massachusetts. The lease has a three year term which expires on February 28, 2009. Under the terms of the lease, we are required to pay the landlord \$66,800 per month for the remainder of the lease term. In addition to rent, we are also required to pay a proportionate share of the landlord's annual operating costs and electricity. In fulfillment of a security deposit requirement for the leased space described above we have issued a \$60,687 irrevocable letter of credit to the landlord. The cash securing this letter of credit is classified on our balance sheet as a long-term asset and is restricted in its use.

On May 27, 2008, we entered into a lease agreement with Mortimer B. Zuckerman and Edward H. Linde, Trustees of 92 Hayden Avenue Trust under Declaration of Trust dated August 18, 1983 for certain real property located at 100 Hayden Avenue, Lexington, Massachusetts to be utilized as our principal executive offices. The term of the lease began on May 22, 2008 and will continue until August 31, 2016 with two successive five year extension terms at our option. The aggregate size of rentable floor area for the offices is 55,924 square feet, and the rent for the initial term will commence in February 2009. The lease requires us to pay rent as follows:

<b>Period</b>	<b>Minimum Lease Payments</b>	
Year Ended December 31, 2008	\$	
Year Ended December 31, 2009	\$	1,686,575
Year Ended December 31, 2010	\$	1,891,164
Year Ended December 31, 2011	\$	1,947,088

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Year Ended December 31, 2012	\$	2,003,012
Thereafter	\$	7,892,742
Total	\$	15,420,581

During any extension term, the base rent will be an amount agreed upon by us and the landlord. In addition to base rent, we are also required to pay a proportionate share of the landlord's annual operating costs. On May 20, 2008, in connection with our new lease, we delivered to the landlord a security deposit of approximately \$0.5 million in the form of an irrevocable letter of credit. The cash securing this letter of credit is classified on our balance sheet as a long-term asset and is restricted in its use.

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**Off-Balance Sheet Arrangements**



As of June 30, 2008, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

### **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 policies and estimates are discussed in our Annual Report on Form 10-K for the year ended December 31, 2007 and we have updated our critical accounting policy with respect to the valuation of investments as follows:

*Valuation of investments.* The fair value of our investments and/or marketable securities is generally determined from quoted market prices based upon market transactions. We also have investments in ARS which consist entirely of municipal debt securities and which we have historically recorded at cost, which approximated fair market value due to their variable interest rates, which typically reset through an auction process every 7 or 28 days. This auction mechanism generally allowed existing investors to roll over their holdings and continue to own their securities or liquidate their holdings by selling their securities at par value. In mid-February 2008, several of our municipal ARS experienced failed auctions, and have continued to experience failed auctions. As a result, we no longer had evidence that the par value of these investments approximated their fair value and were required to seek other alternatives to determine the fair value of these securities which are not based on observable market transactions. As a result, we began estimating the fair values of these securities utilizing a discounted cash flow analysis as of March 31, 2008. Our valuation analyses consider, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, the inability to sell the investment in an active market, the timing of expected future cash flows, and the expectation of the next time the security is expected to have a successful auction or when callability features may be exercised by the issuer. We believe there are several significant assumptions that are utilized in our valuation analysis, the two most critical of which are the discount rate and the average expected term. Holding all other factors constant, if we were to increase the discount rate utilized in our valuation analysis by 50 basis points, one-half of a percentage point, this change would have the effect of reducing the fair value of our ARS by approximately \$1.1 million as of June 30, 2008. Similarly, holding all other factors constant, if we were to increase the average expected term utilized in our fair value calculation by one year, this change would have the effect of reducing the fair value of our ARS by approximately \$0.9 million as of June 30, 2008. We also consider credit ratings with respect to our investments provided by investment ratings agencies. As of June 30, 2008, all of our investments conformed to the requirements of our investment policy, which requires that all of our investments meet high credit quality standards as defined by credit ratings of the major investment ratings agencies. These ratings are subject to change.

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**Impact of Recently Issued Accounting Pronouncements**

In September 2006, the FASB issued 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 but rather eliminates inconsistencies in guidance found in various prior accounting policies. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. In February 2008, the FASB issued FASB FSP 157-2, which delays the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. These nonfinancial items include assets and liabilities such as reporting units measured at fair value in a goodwill impairment test and nonfinancial assets acquired and liabilities assumed in a business combination. Effective January 1, 2008, we partially adopted SFAS 157 for financial assets and liabilities recognized at fair value on a recurring basis. The partial adoption of SFAS 157 for financial assets and liabilities did not have a material impact on our condensed consolidated financial statements. The provisions of SFAS 157 related to other nonfinancial assets and liabilities will be effective for us on January 1, 2009, and will be applied prospectively. We are currently evaluating the impact that these additional SFAS 157 provisions will have on our condensed consolidated financial statements.

Effective January 1, 2008, we adopted 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. We did not elect to adopt the fair value option under this statement.

Effective January 1, 2008, we adopted EITF 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities, or EITF 07-3. EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. The adoption of EITF 07-03 did not have a material impact on our condensed consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133. SFAS 161 is intended to improve financial standards for derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. Entities are required to provide enhanced disclosures about: (a) how and why an entity uses derivative instruments; (b) how derivative instruments and related hedged items are accounted for under SFAS 133 and its related interpretations; and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS 161 is effective for financial statements issued for fiscal years beginning after November 15, 2008, with early adoption encouraged. We are in the process of evaluating the impact of SFAS 161, but we do not expect it to have a significant impact on our condensed consolidated financial statements.

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In December 2007, the FASB issued SFAS No. 141 (revised 2007), Business Combinations, or SFAS 141R. SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141R is effective for financial statements issued for years beginning after December 15, 2008. Accordingly, we are in the process of evaluating the impact of SFAS 141R.

In June 2008, the FASB issued FASB Staff Position, or FSP, EITF No. 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities. The FSP addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting and therefore need to be included in the earnings allocation in calculating earnings per share under the two-class method described in SFAS No. 128, Earnings per Share. The FSP requires companies to treat unvested share-based payment awards that have non-forfeitable rights to dividend or dividend equivalents as a separate class of securities in calculating earnings per share. The FSP is effective for fiscal years beginning after December 15, 2008 and earlier application is not permitted. We are in the process of evaluating the impact of FSP EITF No. 03-6-1, but we do not expect it to have a significant impact on our condensed consolidated financial statements.

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



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As of June 30, 2008, our short- and long-term investments totaled \$208.3 million and were invested in corporate debt securities, U.S. treasury and government agency securities, commercial paper, and municipal ARS. 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 increase immediately and uniformly by 50 basis points, or one-half of a percentage point, from levels at June 30, 2008, this would have resulted in a hypothetical decline in fair value of our investments, excluding ARS which are described below, of approximately \$0.6 million.

At June 30, 2008, we held \$64.5 million (par value of \$68.9 million) of ARS, of which greater than 90% were rated AAA by at least one of the major securities rating agents, most of which were collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program, with the majority of remaining securities being backed by monoline bond insurance companies. We have traditionally recorded these investments in ARS at cost, which approximated fair market value due to their variable interest rates, which typically reset through an auction process every 7 or 28 days. This auction mechanism generally allowed existing investors to roll over their holdings and continue to own their securities or liquidate their holdings by selling their securities at par value. In mid-February 2008, our ARS began to experience failed auctions, and have continued to experience failed auctions. As a result of the lack of market activity, we changed our valuation methodology for these securities to a discounted cash flow analysis. Our valuation analyses consider, among other items, assumptions that market participants would use in their estimates of fair value such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, the inability to sell the investment in an active market, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when callability features may be exercised by the issuer. Based upon this methodology, we have recorded an unrealized loss related to our ARS of approximately \$4.4 million to accumulated other comprehensive (loss) income as of June 30, 2008. We believe there are several significant assumptions that are utilized in our valuation analysis, the two most critical of which are the discount rate and the average expected term. Holding all other factors constant, if

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we were to increase the discount rate utilized in our valuation analysis by 50 basis points (one-half of a percentage point), this change would have the effect of reducing the fair value of our ARS by approximately \$1.1 million as of June 30, 2008. Similarly, holding all other factors constant, if we were to increase the average expected term utilized in our fair value calculation by one year, this change would have the effect of reducing the fair value of our ARS by approximately \$0.9 million as of June 30, 2008.

**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 officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in the 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 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. Our principal executive officer and principal financial 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, 2008 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **PART II OTHER INFORMATION**

#### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

There were no purchases by us, or any affiliated purchaser of ours, of our equity securities that are registered pursuant to Section 12 of the Exchange Act during the three months ended June 30, 2008.

#### **Item 4. Submission of Matters to a Vote of Security Holders.**

On May 6, 2008, we held our Annual Meeting of Stockholders.

Votes for represented affirmative votes and do not include abstentions or broker non-votes. In cases where a signed proxy was submitted without designation, the shares represented by the proxy were voted FOR the proposal in the manner described in the Proxy Statement delivered to the holders of shares of our common stock on the record date (March 11, 2008). On the record date established for the meeting, 16,983,362 shares of our common stock were issued and outstanding.

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The following matters were submitted to a vote of our stockholders:

1. Election of the following persons as directors to serve until the next Annual Meeting and until their successors have been elected and qualified. Voting results were as follows:

	For	Against	Withheld	Abstain
Joseph V. Bonventre	14,138,915		35,936	
Michael D. Loberg	13,525,095		649,756	
Michael Narachi	13,694,453		480,398	
Brian J.G. Pereira, MD	14,138,865		35,986	
Davey S. Scoon	14,138,815		36,036	
Mark Skaletsky	13,610,159		564,692	
Ron Zwanziger	13,081,847		1,093,004	

2. An amendment to our Certificate of Incorporation, as amended, increasing the number of shares of our common stock authorized thereunder from 25,000,000 to 58,750,000. Voting results were as follows:

For	Against	Abstain	Broker Non Votes
12,351,542	1,809,115	14,192	0

3. Ratification of the appointment of PricewaterhouseCoopers LLP as the Company's independent auditor for the year ending December 31, 2008. Voting results were as follows:

For	Against	Abstain	Broker Non Votes
14,157,969	10,990	5,892	0

**Item 5. Other Information.**

On August 5, 2008, our Board of Directors granted 50,000 restricted stock units to our President and Chief Executive Officer, Brian J.G. Pereira, M.D., and 30,000 restricted stock units to our Executive Vice President, Chief Financial Officer and Chief Business Officer, David A. Arkowitz. The closing price of our common stock on the date of grant was \$41.57 per share. The grant to Dr. Pereira will commence vesting upon achievement of a specific stock price target as follows: fifty percent will vest upon the first anniversary of such stock price target achievement and the remaining fifty percent will vest upon the second anniversary of such stock price target achievement; provided that if the price target is not achieved on or prior to August 5, 2012, then such grant shall automatically terminate. The grant to Mr. Arkowitz will vest as follows: fifty percent on the second anniversary of the grant date, twenty five percent on the third anniversary of the grant date and the remaining twenty five percent on the fourth anniversary of the grant date.



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**Item 6. Exhibits.**

- (a) **List of Exhibits**



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**Exhibit  
Number**

**Description**

- 3.1, 4.1 + Composite Copy of Certificate of Incorporation of AMAG Pharmaceuticals, Inc., as amended.
- 10.1 + Collaboration and Exclusive License Agreement between AMAG Pharmaceuticals, Inc. and 3SBio Inc. dated May 25, 2008 (portions of this exhibit have been omitted and filed separately with the Commission pursuant to a request for confidential treatment.)
- 10.2 + Supply Agreement between AMAG Pharmaceuticals, Inc. and 3SBio Inc. dated May 25, 2008 (portions of this exhibit have been omitted and filed separately with the Commission pursuant to a request for confidential treatment.)
- 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 and*  
*President*

Date: August 7, 2008

AMAG PHARMACEUTICALS, INC.

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

Date: August 7, 2008

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