AMAG PHARMACEUTICALS INC.
Form 10-Q
November 05, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2008

OR

o **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	**04-2742593**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)

100 Hayden Avenue **Lexington, Massachusetts** (Address of Principal Executive Offices)	**02421** (Zip Code)

125 CambridgePark Drive **Cambridge, Massachusetts** (Former 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 the definitions of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x Accelerated filer o Non-accelerated filer o Smaller reporting company o

(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 October 31, 2008 there were 17,001,951 shares of the registrant s Common Stock, par value $.01 per share, outstanding.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

AMAG PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

AS OF SEPTEMBER 30, 2008 AND DECEMBER 31, 2007

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

(Unaudited)

	September 30, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 63,333	$ 28,210
Short-term investments	117,387	258,597
Accounts receivable	306	223
Inventories	312	384
Prepaid and other current assets	5,368	2,800
Total current assets	186,706	290,214
Property, plant and equipment:		
Land	360	360
Building and improvements	9,887	5,106
Laboratory equipment	6,228	5,959
Furniture and fixtures	3,277	1,569
Construction in process	386	
Total property, plant and equipment	20,138	12,994
Less - accumulated depreciation	(9,425)	(8,452)
Net property, plant and equipment	10,713	4,542
Long-term investments	60,386	
Restricted cash	521	95
Total assets	$ 258,326	$ 294,851
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 5,185	$ 1,733
Accrued expenses	11,481	5,547
Deferred revenue and rent expense	738	738
Total current liabilities	17,404	8,018
Long-term liabilities:		
Deferred revenue and rent expense	1,716	879
Total liabilities	19,120	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 September 30, 2008 and 25,000,000 shares authorized at December 31, 2007; 17,001,451 and 16,945,662 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	170	169
Additional paid-in capital	412,954	402,346
Accumulated other comprehensive (loss) income	(7,345)	127
Accumulated deficit	(166,573)	(116,688)
Total stockholders equity	239,206	285,954
Total liabilities and stockholders equity	$ 258,326	$ 294,851

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 NINE MONTHS ENDED

SEPTEMBER 30, 2008 AND 2007

(IN THOUSANDS, EXCEPT PER SHARE DATA)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues:				
License fees	$ 184	$ 184	$ 553	$ 911
Royalties	52	59	177	200
Product sales	24	260	628	1,050
Total revenues	260	503	1,358	2,161
Costs and expenses:				
Cost of product sales	3	39	78	297
Research and development expenses	10,269	5,776	22,153	17,032
Selling, general and administrative expenses	14,543	5,841	35,539	13,714
Total costs and expenses	24,815	11,656	57,770	31,043
Other income (expense):				
Interest and dividend income, net	2,021	4,121	7,486	8,712
Losses on investments, net	(1,321)		(1,237)	
Litigation settlement (Note L)				(4,000)
Total other income	700	4,121	6,249	4,712
Net loss before income taxes	(23,855)	(7,032)	(50,163)	(24,170)
Income tax benefit	278		278	
Net loss	$ (23,577)	$ (7,032)	$ (49,885)	$ (24,170)
Net loss per share:				
Basic and diluted	$ (1.39)	$ (0.42)	$ (2.94)	$ (1.57)
Weighted average shares outstanding used to compute net loss per share:				
Basic and diluted	17,001	16,838	16,989	15,393

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 NINE MONTHS ENDED

SEPTEMBER 30, 2008 AND 2007

(IN THOUSANDS)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net loss	$ (23,577)	$ (7,032)	$ (49,885)	$ (24,170)
Other comprehensive loss:				
Unrealized (losses) gains on securities:				
Holding (losses) gains arising during period	(4,453)	54	(8,709)	(9)
Reclassification adjustment for losses and gains, net included in net loss	1,321		1,237	
Net unrealized (losses) gains	(3,132)	54	(7,472)	(9)
Comprehensive loss	$ (26,709)	$ (6,978)	$ (57,357)	$ (24,179)

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 NINE MONTHS ENDED

SEPTEMBER 30, 2008 AND 2007

(IN THOUSANDS)

(Unaudited)

	Nine Months Ended September 30,	
	2008	2007
Net loss	$ (49,885)	$ (24,170)
Cash flows from operating activities:		
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	973	578
Non-cash expense associated with stock options and restricted stock units	9,763	5,758
Amortization of premium/discount on purchased securities	274	(817)
Losses on investments	1,328	
Changes in operating assets and liabilities:		
Accounts receivable	(83)	166
Inventories	72	(2)
Prepaid and other current assets	(2,568)	(569)
Accounts payable and accrued expenses	8,518	(1,609)
Deferred revenue and rent expense	837	(872)
Total adjustments	19,114	2,633
Net cash used in operating activities	(30,771)	(21,537)
Cash flows from investing activities:		
Proceeds from sales or maturities of available-for-sale investments	191,718	217,638
Proceeds from maturities of held-to-maturity investments		126,749
Purchase of available-for-sale investments	(119,968)	(453,889)
Purchase of held-to-maturity investments		(110,787)
Restricted cash	(426)	(61)
Capital expenditures	(6,276)	(823)
Net cash provided by (used in) investing activities	65,048	(221,173)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	684	2,732
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	846	157,322
Net increase (decrease) in cash and cash equivalents	35,123	(85,388)
Cash and cash equivalents at beginning of the period	28,210	114,460
Cash and cash equivalents at end of the period	$ 63,333	$ 29,072
Supplemental data:		
Non-cash activities:		
Non-cash stock option exercises	$	$ 683
Accrued furnishing and build-out costs	$ 868	$

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

SEPTEMBER 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 technology for the development and commercialization of a therapeutic iron compound 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 our lead product candidate, ferumoxytol. Ferumoxytol 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, or PAD. In December 2007, we submitted our New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for marketing approval of ferumoxytol for the treatment of iron deficiency anemia in chronic kidney disease, or CKD, patients. In October 2008, we received a Complete Response letter from the FDA with respect to our NDA for ferumoxytol requesting certain additional information prior to the approval of ferumoxytol for marketing and sale in the U.S. *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

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

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investments, accrued expenses, income taxes and equity-based compensation expense. Actual results could differ from those estimates.

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 September 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 September 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 generally 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 our ARS as long-term investments. During the three months ended September 30, 2008, various regulatory agencies began investigating the sales and marketing activities of the banks and broker-dealers that have sold ARS to investors. One of the banks from which we purchased our ARS has announced preliminary settlement offers under which they will repurchase the ARS at par value at a future date. We will continue to account for our ARS in the same manner as set forth above until any such settlements are finalized. 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.

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

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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.

- 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 September 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 September 30, 2008 (in thousands):

			Fair Value Measurements at September 30, 2008 Using		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 58,046	$ 58,046	$	$
Corporate debt securities	64,445		64,445	
U.S. treasury and government agency securities	52,942		52,942	
Auction rate securities	60,386			60,386
	$ 235,819	$ 58,046	$ 117,387	$ 60,386

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 September 30, 2008, all of our ARS were municipal bonds with an auction reset feature. Greater than 90% were AAA-rated by at least one of the major securities rating agencies, most of which were collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program. We had traditionally recorded these investments at cost, which approximated fair market value due to their variable interest rates. These investments typically reset through an auction process every 7 or 28 days which 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 as opposed to valuing

them at par value. 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 ability or 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 call features may be

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exercised by the issuer. Based upon this methodology, we have recorded an unrealized loss related to our ARS of approximately $6.1 million to accumulated other comprehensive (loss) income as of September 30, 2008. We believe that the temporary impairment related to our ARS of approximately $6.1 million is primarily attributable to the limited liquidity of these investments, coupled with the recent turmoil in the credit and capital markets. As of September 30, 2008, all of our ARS continue to pay interest according to their stated terms. 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 September 30, 2008:

		Unobservable Inputs (Level 3) Auction Rate Securities
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		(6,139)
Purchases (settlements), net		(14,200)
Balance at September 30, 2008	$	60,386
The amount of total gains (losses) for the period included in earnings attributable to the change in unrealized gains (losses) relating to assets still held at September 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 consolidated statement of operations and a new cost basis in the security will be established.

Gains and losses are determined on the specific identification method and accordingly, during the three months ended September 30, 2008, we recorded an impairment charge of $1.3 million to our consolidated statements of operations related to certain corporate debt securities held by us. This impairment charge was required after we conducted an analysis of other-than-temporary impairment factors for our securities including the severity of declines and current financial market conditions as noted above, which caused us to determine that the $1.3 million impairment was other-than-temporary. There were no unrealized losses in our investments which were deemed to be other-than-temporary at December 31, 2007.

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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 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. We estimate the fair value of our restricted stock units whose vesting is contingent upon market conditions using the Monte-Carlo simulation model. These models require 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 are subject to various assumptions. The fair value of awards whose fair values are calculated using the Black-Scholes option pricing model are generally being amortized based on the proportionate amount of the requisite service period that has been rendered to date for each respective performance period. The fair value of awards with market conditions are being amortized based upon the estimated derived service period. We believe our valuation methodologies are appropriate for estimating the fair value of equity awards we grant to employees and directors which are subject to SFAS 123R requirements. Our equity award 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 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.

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Reclassifications

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

C. Investments

At September 30, 2008 and December 31, 2007, our short- and long-term investments totaled $177.8 million and $258.6 million, respectively, and consisted solely of securities classified as available-for-sale.

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

	September 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	$ 49,545	$ 21	$ (1,235)	$ 48,331
Due in one to three years	16,338	21	(245)	16,114
U.S. treasury and government agency securities				
Due in one year or less	17,161	59		17,220
Due in one to three years	35,549	189	(16)	35,722
Total short-term investments	$ 118,593	$ 290	$ (1,496)	$ 117,387
Long-term investments:				
Auction rate securities				
Due in one year or less				
Due after five years	66,525		(6,139)	60,386
Total long-term investments	$ 66,525	$	$ (6,139)	$ 60,386
Total short and long-term investments	$ 185,118	$ 290	$ (7,635)	$ 177,773

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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 September 30, 2008, we held $60.4 million in market value of ARS, which reflects a temporary impairment of $6.1 million from our cost basis of these securities of $66.5 million. Greater than 90% of these ARS were rated AAA by at least one of the major securities rating agents, most of which were collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program. We had traditionally recorded these investments at cost, which approximated fair market value due to their variable interest rates. These investments typically reset through an auction process every 7 or 28 days which 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 as opposed to valuing them at par value. 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 ability or 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 call features may be exercised by the issuer. Based upon this methodology, we have recorded an unrealized loss related to our ARS of approximately $6.1 million to accumulated other comprehensive (loss) income as of September 30, 2008.

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Due to our belief that the market for ARS may take in excess of twelve months to fully recover, we have classified our ARS as long-term investments in our condensed consolidated balance sheet at September 30, 2008.

We believe that the temporary impairment related to our ARS of approximately $6.1 million is primarily attributable to the limited liquidity of these investments, coupled with the recent turmoil in the credit and capital markets, 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. During the three months ended September 30, 2008, various regulatory agencies began investigating the sales and marketing activities of the banks and broker-dealers that have sold ARS to investors. One of the banks from which we purchased our ARS has announced preliminary settlement offers under which they will repurchase the ARS at par at a future date. We will continue to account for our ARS in the same manner as set forth above until any such settlements are finalized.

Gains and losses are determined on the specific identification method and accordingly, during the three months ended September 30, 2008, we recorded an impairment charge of $1.3 million to our consolidated statements of operations related to certain corporate debt securities held by us. This impairment charge was required after we conducted an analysis of other-than-temporary impairment factors for our securities including the severity of declines and current financial market conditions as noted above, which caused us to determine that the $1.3 million impairment was other-than-temporary. 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 September 30, 2008 and December 31, 2007 (in thousands):

	September 30, 2008					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	$ 56,131	$ (1,480)	$	$	$ 56,131	$ (1,480)
U.S. treasury and government agency securities	11,023	(16)			11,023	(16)
Commercial paper						
Auction rate securities	60,386	(6,139)			60,386	(6,139)
	$ 127,540	$ (7,635)	$	$	$ 127,540	$ (7,635)

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	December 31, 2007					
	Less than 12 Months		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 September 30, 2008 and December 31, 2007 were primarily caused by the recent uncertainty in the capital markets and changes in interest rates. Since the decline in market value is primarily attributable to 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 September 30, 2008.

D. Inventories

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

	September 30, 2008	December 31, 2007
Raw materials	$ 231	$ 259
Work in process	45	96
Finished goods	36	29
Total inventories	$ 312	$ 384

Prior to regulatory approval of our product candidates, we incur expenses for the manufacture of drug product that could potentially be available to support the commercial launch of these product candidates. Until the necessary initial regulatory approval has been received, we charge all such amounts to research and development expenses.

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.

During the three months ended September 30, 2008, we recognized approximately $0.3 million of tax benefit associated with U.S. research and development tax credits against which we had previously provided a full valuation allowance, but which became refundable as a result of legislation passed in July 2008. There were no significant income tax provisions or benefits for the three and nine months ended September 30, 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.

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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), the total of which was 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):

	As of September 30,	
	2008	2007
Options to purchase shares of common stock	2,016	1,287
Shares of common stock issuable upon the vesting of restricted stock units	226	36
Total	2,242	1,323

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net loss	$ (23,577)	$ (7,032)	$ (49,885)	$ (24,170)
Weighted average common shares outstanding	17,001	16,838	16,989	15,393
Loss per share:				
Basic and diluted	$ (1.39)	$ (0.42)	$ (2.94)	$ (1.57)

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 an automatic 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 September 30, 2008 we have granted options and restricted stock units covering 1,002,546 shares of common stock of which 13,930 stock options and no restricted stock units have expired or terminated, and of which no options have been exercised and no shares of common stock were issued pursuant to restricted stock units that became fully vested. The number of options and restricted stock units outstanding under this plan as of

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September 30, 2008 was 789,116 and 199,500, respectively. The remaining number of shares available for future grants as of September 30, 2008 was 1,051,109, 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 NDA for ferumoxytol is approved by the FDA on or prior to December 31, 2008. For awards that contain performance conditions, compensation cost is recognized if the performance conditions are considered probable of being achieved as of the date of the financial statement.

In August 2008, we granted 50,000 restricted stock units to our Chief Executive Officer. The closing price of our common stock on the date of grant was $41.57 per share. These restricted stock units 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 on 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.

As of September 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 expired or terminated, and of which 690,520 stock options have been exercised and 16,750 shares of common stock were issued pursuant to restricted stock units that became fully vested. The remaining number of shares underlying outstanding options and restricted stock units pursuant to our 2000 Plan as of September 30, 2008 was 1,226,505 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Research and development	$ 1,049	$ 484	$ 2,641	$ 1,283
Selling, general and administrative	2,826	1,488	7,122	4,476
Total equity-based compensation expense	$ 3,875	$ 1,972	$ 9,763	$ 5,759

Equity-based compensation expense for the nine months ended September 30, 2008 and 2007 included approximately $2.6 million and $1.7 million, respectively, in equity-based compensation expense associated with grants subject to market or performance conditions.

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At September 30, 2008, the amount of unrecorded equity-based compensation expense attributable to future periods was approximately $36.4 million, of which $28.2 million was associated with stock options and $8.2 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, generally on a straight line basis over a weighted average amortization periods of approximately 3.0 and 3.4 years, respectively. 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 equity-based 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 three and nine months ended September 30, 2008 and 2007. No other company accounted for more than 10% of our total revenues for the three and nine months ended September 30, 2008 and 2007.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Bayer Healthcare Pharmaceuticals	75%	39%	44%	42%
Covidien, Ltd.	16%	25%	16%	13%
Guerbet S.A.	0%	31%	35%	26%
Cytogen Corporation	0%	0%	0%	17%

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 38% and 28% of our total revenues for the nine months ended September 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 Staff Position, or 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. In October 2008, the FASB issued FSP No. 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active, or FSP 157-3. FSP 157-3

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clarifies the application of SFAS 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP 157-3 was effective upon issuance, including prior periods for which financial statements have not been issued. 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 significant impact on our 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 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 elected not 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 significant impact on our 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, or SFAS 161. 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 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 do not expect it to have a significant impact on our consolidated financial statements.

In June 2008, the FASB issued 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

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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 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 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

New 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. We recognize rent expense on this facility on a straight-line basis over the initial term of the lease. In addition, the lease provides for approximately $2.2 million of tenant improvement reimbursements from the landlord. These reimbursements will be recorded as a deferred rent liability in our consolidated balance sheet and are amortized on a straight-line basis as a reduction to rent expense over the term of the lease. We have recorded all tenant improvements as leasehold improvements and are amortizing these improvements over the shorter of the estimated useful life of the improvement or the remaining life of the initial lease term. Amortization of leasehold improvements is included in depreciation expense.

The lease requires us to pay rent as follows:

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

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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,* our investigational functional molecular imaging agent, 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 September 30, 2008.

M. Subsequent Event

In December 2007, we submitted our NDA to the FDA for marketing approval of ferumoxytol for the treatment of iron deficiency anemia in CKD patients. In October 2008, we received a Complete Response letter from the FDA with respect to our NDA for ferumoxytol requesting certain additional information prior to the approval of ferumoxytol for marketing and sale in the U.S.

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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 potential approval of ferumoxytol in the U.S. and outside of the U.S., statements regarding our belief that we will not need to conduct any additional clinical trials prior to approval of ferumoxytol, our plan to launch ferumoxytol in the first quarter of 2009, the progress of our intended development and commercialization of ferumoxytol, the potential clinical trials for ferumoxytol we may initiate in indications other than chronic kidney disease, future revenues (including expected future revenues under our agreements with Bayer), 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 securities, including our auction rate securities, is temporary and that we will ultimately be able to liquidate our 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. 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 technology for the development and commercialization of a therapeutic iron compound 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 one product candidate, ferumoxytol. Ferumoxytol 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 PAD.

In December 2007, we submitted our NDA to the FDA for marketing approval of ferumoxytol for the treatment of iron deficiency anemia in CKD patients. In October 2008, we received a Complete Response letter from the FDA with respect to our NDA for ferumoxytol requesting certain additional information prior to the approval of ferumoxytol for marketing and sale in the U.S. Three issues were raised in the FDA s Complete Response letter, including a request for certain clinical information,

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observations made during a Good Clinical Practices inspection at one of our Phase III clinical sites, and observations noted during the pre-approval inspection of our manufacturing facility. We are working with the FDA to address the Complete Response letter and believe that we will not need to conduct any additional clinical trials prior to approval. We continue to seek approval of ferumoxytol for the treatment of iron deficiency anemia in patients with CKD, whether or not on dialysis, and we are continuing our preparations for our planned U.S. commercial launch of ferumoxytol during the first quarter of 2009.

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. In August 2008, we announced that the FDA granted Fast Track designation to ferumoxytol for its development as a diagnostic agent for vascular-enhanced MRI to improve the assessment of PAD in patients with known or suspected CKD. In the third quarter of 2008, we began screening patients for a Phase II study of ferumoxytol for vascular-enhanced MRI for the detection of clinically significant arterial stenosis or occlusion in subjects with intermittent claudication, or leg pain with walking. In addition, we have begun incurring costs with respect to our planned Phase III studies for ferumoxytol as a therapeutic agent for the treatment of iron deficiency anemia in women with abnormal uterine bleeding, or AUB. Although we have begun to incur costs in our PAD and AUB trials, the timelines for initiation of our AUB and other therapeutic development programs for ferumoxytol are subject to the completion of protocol discussions with the FDA.

If approved, we intend to sell and market ferumoxytol in the U.S. through our own commercial organization and we are currently in the process of building an internal sales and marketing function, including a direct sales force, in preparation for the planned U.S. commercial launch of ferumoxytol as an IV iron replacement therapeutic agent in CKD patients in the first quarter of 2009.

We continue to evaluate our strategy for seeking approval for ferumoxytol as an IV iron replacement therapeutic agent in countries outside of 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 of 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.

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 September 30, 2008 as Compared to the Three Months Ended September 30, 2007

Revenues

Total revenues were $0.3 million and $0.5 million for the three months ended September 30, 2008 and 2007, respectively, representing a decrease of approximately 48%. The decrease in revenues was primarily the result of a decrease in product sales of *GastroMARK*.

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

	Three Months Ended September 30, 2008	2007	$ Change	% Change
Revenues:				
License fees	$ 184	$ 184	$	0%
Royalties	52	59	(7)	-12%
Product sales	24	260	(236)	-91%
Total	$ 260	$ 503	$ (243)	-48%

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

	Three Months Ended September 30, 2008	2007
Bayer	75%	39%
Covidien, Ltd.	16%	25%
Guerbet S.A.	0%	31%

License Fee Revenues

Our license fee revenues for each of the three months ended September 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 straight-line basis over the 15 year term of the Bayer Agreements due to the existence of an established contract period. In October 2008, Bayer notified us of its election to convert its exclusive license to a nonexclusive license, effective as of December 2, 2008, which we do not expect will have a substantial impact on our revenues under the Bayer Agreements. The Bayer Agreements expire in 2010 but can be terminated earlier upon the occurrence of certain specified events.

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Product Sale Revenues

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

	Three Months Ended September 30,			
	2008	2007	$ Change	% Change
Feridex I.V.	$ 24	$ 25	$ (1)	-4%
GastroMARK		235	(235)	-100%
Total	$ 24	$ 260	$ (236)	-91%

The decrease in product sale revenues for the three months ended September 30, 2008 as compared to the three months ended September 30, 2007 was the result of a decrease in product sales of *GastroMARK*. 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 September 30, 2008 and 2007 of approximately $3,000 and $39,000, respectively. This constituted approximately 13% and 15% of product sales during the three months ended September 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. 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 September 30, 2008 and 2007 consisted of the following (in thousands):

	Three Months Ended September 30, 2008	2007	$ Change	% Change
External Research and Development Expenses:				
Ferumoxytol as an IV iron replacement therapeutic agent in CKD patients	$ 662	$ 2,184	$ (1,522)	-70%
Ferumoxytol as an IV iron replacement therapeutic agent in AUB patients	1,362		1,362	N/A
Ferumoxytol as an imaging agent in PAD patients	619		619	N/A
Ferumoxytol manufacturing and materials	1,302		1,302	N/A
Other external costs	133	511	(378)	-74%
Total	4,078	2,695	1,383	51%
Internal Research and Development Expenses:				
Compensation, payroll taxes, benefits and other expenses	5,142	2,597	2,545	98%
Equity-based compensation expense	1,049	484	565	>100%
Total	6,191	3,081	3,110	>100%
Total Research and Development Expenses	$ 10,269	$ 5,776	$ 4,493	78%

Total research and development expenses incurred in the three months ended September 30, 2008 amounted to $10.3 million, an increase of $4.5 million, or 78%, from the three months ended September 30, 2007. The $4.5 million increase was primarily attributable to costs associated with increased headcount, increased production materials and supply costs, costs associated with the commencement of spending on our clinical trials for PAD and AUB and increased equity-based compensation expense, partially offset by a decrease in expenditures related to our December 2007 NDA submission for ferumoxytol which were not present during the three months ended September 30, 2008.

Our external research and development expenses increased by $1.4 million, or 51%, for the three months ended September 30, 2008 as compared to the three months ended September 30, 2007. The increase in our external expenses was due primarily to costs associated with our preparation for initiation of clinical trials for ferumoxytol in PAD and AUB during the three months ended September 30, 2008, which were not present during the three months ended September 30, 2007 and an increase in costs associated with our preparation for commercial scale manufacturing of ferumoxytol, partially offset by expenditures associated with the preparation of our December 2007 NDA submission for ferumoxytol during the three months ended September 30, 2007, which were not present during the three months ended September 30, 2008.

Our internal research and development expenses increased by $3.1 million, or greater than 100%, for the three months ended September 30, 2008 as compared to the three months ended September 30, 2007. The increase in internal costs was due primarily to higher compensation and benefits costs as a result of hiring additional research and development personnel as we continued to expand our development infrastructure and scale up our manufacturing capabilities for the planned commercialization of ferumoxytol. At September 30, 2008, we had 85 employees in research and development as compared to 44 employees at September 30, 2007, an increase of 93%. The $0.6 million increase in equity-based compensation expense was primarily attributable to increased equity awards to both new and existing employees.

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We expect research and development expenses to increase during the remainder of 2008 as we advance our PAD, AUB and other clinical development programs, continue commercial manufacturing 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.

During 2008, we began incurring costs related to our PAD and AUB clinical development programs. However, 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 our additional indications for ferumoxytol, we are unable to estimate with any certainty the costs we will incur in the development of such other indications. 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 this Quarterly Report on Form 10-Q beginning on page 39. While we are currently focused on the potential U.S. commercial launch of ferumoxytol as an IV iron replacement therapeutic agent in CKD patients, we anticipate that we will make determinations as to which, if any additional indications to pursue and how much funding to direct to each additional 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 September 30, 2008 and 2007 consisted of the following (in thousands):

	Three Months Ended September 30,			
	2008	2007	$ Change	% Change
Compensation, payroll taxes and benefits	$ 4,621	$ 1,116	$ 3,505	>100%
Professional and consulting fees and other expenses	7,096	3,237	3,859	>100%
Equity-based compensation expense	2,826	1,488	1,338	90%
Total	$ 14,543	$ 5,841	$ 8,702	>100%

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The $8.7 million increase in selling, general and administrative expenses for the three months ended September 30, 2008 as compared to the three months ended September 30, 2007 was due primarily to increased costs associated with the on-going expansion of our commercial operations function, including compensation and benefits costs related to increased headcount in our commercial operations function, consulting costs related to preparing for the potential U.S. commercial launch of ferumoxytol, equity-based compensation expense, which includes increased expense associated with market and performance condition based equity awards, and the expansion of our general and administrative infrastructure. At September 30, 2008, we had 132 employees in our selling, general and administrative departments as compared to 26 employees at September 30, 2007, a greater than four-fold increase. The $1.3 million increase in equity-based compensation expense was primarily attributable to increased equity awards associated with new and existing employees and included a $0.4 million incremental expense related to market and performance condition based equity awards in the three months ended September 30, 2008 as compared to the three months ended September 30, 2007.

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 U.S. 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 in the U.S.

Other Income (Expense)

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

	Three Months Ended September 30,			
	2008	2007	$ Change	% Change
Interest and dividend income, net	$ 2,021	$ 4,121	$ (2,100)	-51%
Loss on investments, net	(1,321)		(1,321)	N/A
Total	$ 700	$ 4,121	$ (3,421)	-83%

The $3.4 million decrease in other income (expense) for the three months ended September 30, 2008 as compared to the three months ended September 30, 2007 was primarily attributable to a $2.1 million decrease in interest and dividend income as the result of a lower average total dollar amount of invested funds and lower interest rates in the three months ended September 30, 2008 as compared to the three months ended September 30, 2007 and the recognition of $1.3 million of losses associated with securities whose decline in value we deemed to be an other-than-temporary impairment as of September 30, 2008. No such losses were recognized in the three months ended September 30, 2007.

Income Tax Benefit

During the three months ended September 30, 2008, we recognized approximately $0.3 million of tax benefit associated with U.S. research and development tax credits against which we had previously provided a full valuation allowance, but which became refundable as a result of legislation passed in July 2008.

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Net Loss

For the reasons stated above, we incurred a net loss of $23.6 million, or $1.39 per basic and diluted share, for the three months ended September 30, 2008 compared to a net loss of $7.0 million, or $0.42 per basic and diluted share, for the three months ended September 30, 2007.

Results of Operations for the Nine Months Ended September 30, 2008 as Compared to the Nine Months Ended September 30, 2007

Revenues

Total revenues were $1.4 million and $2.2 million for the nine months ended September 30, 2008 and 2007, respectively, representing a decrease of approximately 37%. The decrease in revenues was due primarily to a decrease in product sales as well as the recognition in February 2007 of $0.4 million of deferred license fee revenues as a result of the termination of our *Combidex* License and Marketing Agreement with Cytogen.

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

	Nine Months Ended September 30, 2008	2007	$ Change	% Change
Revenues:				
License fees	$ 553	$ 911	$ (358)	-39%
Royalties	177	200	(23)	-12%
Product sales	628	1,050	(422)	-40%
Total	$ 1,358	$ 2,161	$ (803)	-37%

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

	Nine Months Ended September 30, 2008	2007
Bayer Healthcare Pharmaceuticals	44%	42%
Guerbet S.A.	35%	26%
Covidien, Ltd.	16%	13%
Cytogen Corporation	0%	17%

License Fee Revenues

Our license fee revenues for the nine months ended September 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 nine months ended September 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.

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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. In October 2008, Bayer notified us of its election to convert its exclusive license to a nonexclusive license, effective as of December 2, 2008, which we do not expect will have a substantial impact on our revenues under the Bayer Agreements. 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 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 License and Marketing 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 License and Marketing 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 License and Marketing 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.

Total license fee revenues for the nine months ended September 30, 2008 and 2007 consisted of the following (in thousands):

	Nine Months Ended September 30,			
	2008	2007	$ Change	% Change
License fee revenues recognized in connection with the Cytogen Agreement	$	$ 358	$ (358)	-100%
License fee revenues recognized in connection with the Bayer Agreements	553	553		0%
Total	$ 553	$ 911	$ (358)	-39%

Product Sale Revenues

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

	Nine Months Ended September 30, 2008	2007	$ Change	% Change
Feridex I.V.	$ 291	$ 368	$ (77)	-21%
GastroMARK	317	547	(230)	-42%
Combidex	20	135	(115)	-85%
Total	$ 628	$ 1,050	$ (422)	-40%

The decrease in product sale revenues for the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007 was the result of a decrease in sales of *GastroMARK* and *Feridex I.V.* to our marketing partners and a decrease in the sale of bulk *Combidex* to one of our foreign marketing partners for research and development purposes. Product sales may fluctuate from period to period.

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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 nine months ended September 30, 2008 and 2007 of approximately $0.1 million and $0.3 million, respectively. This constituted approximately 12% and 28% of product sales during the nine months ended September 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 nine months ended September 30, 2007 as compared to the nine months ended September 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.

Research and Development Expenses

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

	Nine Months Ended September 30, 2008	2007	$ Change	% Change
External Research and Development Expenses:				
Ferumoxytol as an IV iron replacement therapeutic agent in CKD patients	$ 938	$ 7,099	$ (6,161)	-87%
Ferumoxytol as an IV iron replacement therapeutic agent in AUB patients	1,863		1,863	N/A
Ferumoxytol as an imaging agent in PAD patients	1,199		1,199	N/A
Ferumoxytol manufacturing and materials	3,028		3,028	N/A
Other external costs	591	1,482	(891)	-60%
Total	7,619	8,581	(962)	-11%
Internal Research and Development Expenses:				
Compensation, payroll taxes, benefits and other expenses	11,893	7,168	4,725	66%
Equity-based compensation expense	2,641	1,283	1,358	>100%
Total	14,534	8,451	6,083	72%
Total Research and Development Expenses	$ 22,153	$ 17,032	$ 5,121	30%

Total research and development expenses of $22.2 million for the nine months ended September 30, 2008 increased by $5.1 million or 30%, as compared to total research and development expenses of $17.0 million for the nine months ended September 30, 2007. Our external research and development expenses decreased by $1.0 million, or 11%, primarily as the result of a decrease in expenditures associated with the development program and regulatory submission for ferumoxytol as an IV iron replacement therapeutic agent in CKD patients as we completed our Phase III clinical trials and prepared for the submission of our NDA in 2007, partially offset by costs associated with the commencement of spending on our clinical trials

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for ferumoxytol in PAD and AUB and an increase in costs associated with our preparation for commercial scale manufacturing of ferumoxytol. The decrease in external costs was offset by a $6.1 million, or 72%, increase in our internal costs primarily due to higher compensation and benefits costs as a result of hiring additional research and development personnel as we continued to expand our development infrastructure and scale up our manufacturing capabilities for the planned commercialization of ferumoxytol. At September 30, 2008, we had 85 employees in research and development as compared to 44 employees at September 30, 2007, an increase of 93%. The $1.4 million increase in equity-based compensation expense was primarily attributable to increased equity awards to both new and existing employees.

Selling, General and Administrative Expenses

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

	Nine Months Ended September 30, 2008	2007	$ Change	% Change
Compensation, payroll taxes and benefits	$ 10,258	$ 3,125	$ 7,133	>100%
Professional and consulting fees and other expenses	18,159	6,113	12,046	>100%
Equity-based compensation expense	7,122	4,476	2,646	59%
Total	$ 35,539	$ 13,714	$ 21,825	>100%

The $21.8 million, or 159%, increase in selling, general and administrative expenses for the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007 was due primarily to increased costs associated with the on-going expansion of our commercial operations function, including higher compensation and benefits costs related to increased headcount in our commercial operations function, equity-based compensation expense, which includes increased expense associated with market and performance condition based equity awards, as well as consulting costs related to preparing for the potential U.S. commercial launch of ferumoxytol and the expansion of our general and administrative infrastructure. At September 30, 2008, we had 132 employees in our selling, general and administrative departments as compared to 26 employees at September 30, 2007, a greater than four-fold increase. The $2.6 million increase in equity-based compensation expense was primarily attributable to increased equity awards associated with new and existing employees and included a $0.9 million incremental expense related to market and performance condition based equity awards in the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007.

Other Income (Expense)

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

	Nine Months Ended September 30, 2008	2007	$ Change	% Change
Interest income	$ 7,486	$ 8,712	$ (1,226)	-14%
Loss on investments, net	$ (1,237)		(1,237)	N/A
Litigation settlement		(4,000)	4,000	-100%
Total	$ 6,249	$ 4,712	$ 1,537	33%

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The $1.5 million, or 33%, increase in other income (expense) for the nine months ended September 30, 2008, as compared to the nine months ended September 30, 2007 was primarily attributable to a $4.0 million settlement payment made to Cytogen in the nine months ended September 30, 2007 which was not present in the nine months ended September 30, 2008, partially offset by a $1.2 million decrease in interest and dividend income as the result of a lower average amount of invested funds and lower interest rates in the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007 and the recognition of $1.3 million of losses associated with securities whose decline in value we deemed to be an other-than-temporary impairment as of September 30, 2008. No such losses were recognized in the nine months ended September 30, 2007.

Income Tax Benefit

During the nine months ended September 30, 2008, we recognized approximately $0.3 million of tax benefit associated with U.S. research and development tax credits against which we had previously provided a full valuation allowance, but which became refundable as a result of legislation passed in July 2008.

Net Loss

For the reasons stated above, we incurred a net loss of $49.9 million, or $2.94 per basic and diluted share, for the nine months ended September 30, 2008 compared to a net loss of $24.2 million, or $1.57 per basic and diluted share, for the nine months ended September 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;
- Our ability to generate revenues from product sales of ferumoxytol, if approved;
- Costs associated with our preparations for the potential U.S. commercial launch of ferumoxytol, including costs associated with building and maintaining our commercial infrastructure and executing our promotional and marketing strategy for ferumoxytol, if approved;
- Costs associated with commercial-scale manufacturing of ferumoxytol, including costs associated with building commercial inventory and qualifying additional manufacturing capacity and second source suppliers;
- Costs associated with our development of additional indications for ferumoxytol;
- Costs associated with the pursuit of potential business development activities;

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- Costs associated with our pursuit of approval for ferumoxytol as an IV iron replacement therapeutic agent outside of the U.S.;
- Our ability to liquidate our ARS investments in a timely manner and without significant loss;
- The impact of the current deterioration in the credit and capital markets upon the investments in our portfolio;
- 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.

As of September 30, 2008, our investments consisted of corporate debt securities, U.S. treasury and government agency securities, and 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.

At September 30, 2008, we held $60.4 million in market value of ARS, which reflects a temporary impairment of $6.1 million from our cost basis of these securities of $66.5 million. Greater than 90% of these ARS were rated AAA by at least one of the major securities rating agents, most of which were collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program. We had traditionally recorded these investments at cost, which approximated fair market value due to their variable interest rates. These investments typically reset through an auction process every 7 or 28 days which 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 as opposed to valuing them at par value. 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 ability or 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 call features may be exercised by the issuer. Based upon this methodology, we have recorded an unrealized loss related to our ARS of approximately $6.1 million to accumulated other comprehensive (loss) income as of September 30, 2008. During the three months ended September 30, 2008, various regulatory agencies began investigating the sales and marketing activities of the banks and broker-dealers that have sold ARS to investors. One of the banks from which we purchased our ARS has announced preliminary settlement offers under which they will repurchase the ARS at par value at a future date. We will continue to account for our ARS in the same manner as set forth above until any such settlements are finalized.

Due to our belief that the market for ARS may take in excess of twelve months to fully recover, we have classified our ARS as long-term investments in our condensed consolidated balance sheet at September 30, 2008.

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We believe that the temporary impairment related to our ARS of approximately $6.1 million is primarily attributable to the limited liquidity of these investments, coupled with the recent turmoil in the credit and capital markets, 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.

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 September 30, 2008 and December 31, 2007 consisted of the following (in thousands):

	September 30, 2008	December 31, 2007	$ Change	% Change
Cash and cash equivalents	$ 63,333	$ 28,210	$ 35,123	>100%
Short-term investments	117,387	258,597	(141,210)	-55%
Long-term investments	60,386		60,386	N/A
Total cash, cash equivalents and investments	$ 241,106	$ 286,807	$ (45,701)	-16%

The decrease in cash and cash equivalents and investments as of September 30, 2008 as compared to December 31, 2007 is primarily the result of cash used in operations, costs incurred for our new corporate headquarters, and the net impact of unrealized and realized losses of our investments, partially offset by interest income.

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

Recent distress in the global financial markets has had an adverse impact on financial market activities world-wide, resulting in, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. We have evaluated the effect of the recent distress in the financial markets on the value of our investments and as a result, during the three months ended September 30, 2008 we recorded an impairment charge of $1.3 million related to certain corporate debt securities held by us. This impairment charge was required after we conducted an analysis of other-than-temporary impairment factors for our

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securities, including the severity of declines and current financial market conditions, as noted above. There can be no assurance that changing circumstances will not continue to affect our future financial position, results of operations or liquidity.

Cash flows from operating activities

During the nine months ended September 30, 2008, our use of cash in operations of $30.8 million was attributable principally to our net loss of approximately $49.9 million, partially offset by the impact of $6.8 million of changes in certain assets and liabilities, approximately $11.0 million in stock compensation and other non-cash expenses and $1.3 million net losses on securities. Our net loss includes compensation-related expenses associated with the hiring of additional employees for research and development and commercial operating activities, payments for activities in preparation for the potential commercialization of ferumoxytol as an IV iron replacement therapeutic agent, and costs associated with clinical trials in indications other than CKD.

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 planned 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.

Cash flows from investing activities

Cash provided by investing activities was $65.0 million during the nine months ended September 30, 2008 and was primarily attributable to proceeds from maturities of our investments, partially offset by $6.3 million of cash used for capital expenditures primarily related to the occupancy, furnishing and build-out of our new corporate headquarters which we began to occupy in September 2008.

Cash flows from financing activities

Cash provided by financing activities was $0.8 million during the nine months ended September 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, including leases of certain automobiles and certain laboratory and office equipment under operating leases that expire through 2011.

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 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:

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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 in our balance sheet as a long-term asset and is restricted in its use.

Off-Balance Sheet Arrangements

As of September 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. These investments typically reset through an auction process every 7 or 28 days which 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 opposed to valuing them at par value, 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

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and any associated guarantees, the ability or 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 call 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. During the three months ended September 30, 2008, various regulatory agencies began investigating the sales and marketing activities of the banks and broker-dealers that have sold ARS to investors. One of the banks from which we purchased our ARS has announced preliminary settlement offers under which they will repurchase the ARS at par value at a future date. We will continue to account for our ARS in the same manner as set forth above until any such settlements are finalized. Holding all other factors constant, if we were to increase the discount rate utilized in our valuation analysis by 50 basis points, or 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 September 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 $1.3 million as of September 30, 2008. We also consider credit ratings with respect to our investments provided by investment ratings agencies. As of September 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 and a downgrade in rating would adversely affect the value of our investments.

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 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. In October 2008, the FASB issued FSP No. 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active, or FSP 157-3. FSP 157-3 clarifies the application of SFAS 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP 157-3 was effective upon issuance, including prior periods for which financial statements have not been issued. 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 significant impact on our 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 consolidated financial statements.

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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 elected not 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 significant impact on our 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, or SFAS 161. 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 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 do not expect it to have a significant impact on our consolidated financial statements.

In June 2008, the FASB issued 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 consolidated financial statements.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As of September 30, 2008, our short- and long-term investments totaled $177.8 million and were invested in corporate debt securities, U.S. treasury and government agency securities, and 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 September 30, 2008, this would have resulted in a hypothetical decline in fair value of our investments, excluding ARS which are described below, of approximately $0.5 million.

At September 30, 2008, we held $60.4 million in market value of ARS, which reflects a temporary impairment of $6.1 million from our cost basis of these securities of $66.5 million. Greater than 90% of these ARS were rated AAA by at least one of the major securities rating agents, most of which were collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program. We had traditionally recorded these investments in ARS at cost, which approximated fair market value due to their variable interest rates. These investments typically reset through an auction process every 7 or 28 days which 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 as opposed to valuing them at par value. 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 ability or 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 call features may be exercised by the issuer. Based upon this methodology, we have recorded an unrealized loss related to our ARS of approximately $6.1 million to accumulated other comprehensive (loss) income as of September 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. During the three months ended September 30, 2008, various regulatory agencies began investigating the sales and marketing activities of the banks and broker-dealers that have sold ARS to investors. One of the banks from which we purchased our ARS has announced preliminary settlement offers under which they will repurchase the ARS at par value at a future date. We will continue to account for our ARS in the same manner as set forth above until any such settlements are finalized. Holding all other factors constant, if we were to increase the discount rate utilized in our valuation analysis by 50 basis points, or 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 September 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 $1.3 million as of September 30, 2008.

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Item 4. Controls and Procedures.

Managements Evaluation of our Disclosure Controls and Procedures

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

There were no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2008 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1A. Risk Factors.

The following is a summary description of some of the material risks and uncertainties that may affect our business, including our future financial and operational results. In addition to the other information in this Quarterly Report on Form 10-Q, the following statements should be carefully considered in evaluating us.

We are solely dependent on the success of ferumoxytol.

We are currently investing most of our efforts and financial resources in the development and commercialization of ferumoxytol. Our ability to generate future revenues is solely dependent on our ability to obtain marketing approval for and successfully commercialize ferumoxytol as an IV iron replacement therapeutic agent in the U.S. If we are unable to generate revenues from ferumoxytol, our ability to create long-term shareholder value and our business prospects will be very limited unless we are able to successfully acquire, develop and commercialize other products.

Although we have dedicated significant resources to development efforts in the past, we may not be successful in developing new applications for our existing technology or in expanding the potential indications for ferumoxytol. Although we have commenced additional clinical trials for ferumoxytol in indications other than CKD in an effort to expand the potential indications for ferumoxytol, we are not currently conducting or sponsoring research to expand our product development pipeline beyond

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ferumoxytol. Any failure by us to acquire, develop and commercialize additional products and product candidates or additional indications for ferumoxytol will materially adversely affect our ability to achieve profitability and the future prospects of our business.

We have two products, *Feridex I.V.* and *GastroMARK*, currently approved for marketing and sale in the U.S. and in certain foreign jurisdictions. However, sales of *Feridex I.V.* and *GastroMARK* by our marketing partners have been at relatively low levels, and we expect sales of *Feridex I.V.* and *GastroMARK* will not substantially increase from their current levels overall.

We may experience significant delays in our efforts to obtain approval for ferumoxytol or we may never receive regulatory approval for the marketing and commercial sale of ferumoxytol in the U.S.

The FDA imposes substantial requirements on the development, production and commercial introduction of all drug products. Before obtaining regulatory approval for the commercial marketing and sale of ferumoxytol, we must demonstrate through extensive pre-clinical testing and human clinical trials that ferumoxytol is safe and efficacious. In December 2007, we submitted our NDA to the FDA for marketing approval of ferumoxytol for the treatment of iron deficiency anemia in CKD patients. In October 2008, we received a Complete Response letter from the FDA with respect to our NDA for ferumoxytol requesting certain additional information prior to the approval of ferumoxytol for marketing and sale in the U.S. If we are unable to adequately address the issues raised in this letter, we may experience significant delays in our efforts to obtain approval for ferumoxytol or ferumoxytol may not receive approval at all.

The FDA has substantial discretion in the approval process and may decide that the data in our NDA, including any information we provide in our reply to the Complete Response letter is insufficient for approval. Clinical and other data is often susceptible to varying interpretations, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products. The FDA may review our data and determine that ferumoxytol is not efficacious and/or does not have an acceptable safety profile. The FDA could also determine that our pre-clinical studies, our clinical trials and/or our manufacturing processes were not properly designed, were not conducted in accordance with federal laws and regulations, or were otherwise not properly managed. For example, the FDA guidelines generally suggest that sponsors conduct two adequate and well-controlled studies to demonstrate the safety and efficacy of a product candidate such as ferumoxytol in support of FDA approval. FDA interpretation of the statutory requirements also states that a single study may be sufficient to support approval if the FDA determines that based on relevant science and other confirmatory evidence from pertinent, adequate and well-controlled studies, there is strong evidence to establish the safety and efficacy of the drug candidate to support using a single adequate and well-controlled study to demonstrate safety and efficacy and support approval. We have chosen to conduct only a single Phase III study for ferumoxytol as an IV iron replacement therapeutic in the hemodialysis dependent CKD patient population along with two additional Phase III studies of ferumoxytol in nondialysis dependent CKD patients and one additional safety study in patients with all stages of CKD. If the FDA determines that the results of our single study in hemodialysis dependent CKD patients, together with other confirmatory evidence we provide, is not sufficiently strong to demonstrate ferumoxytol s safety and efficacy in hemodialysis dependent CKD patients, then ferumoxytol may not be approved by the FDA for our proposed indication, may be approved for a more limited indication, or the FDA may require us to conduct additional studies before approving ferumoxytol for use in hemodialysis dependent CKD patients. In addition, in discussions with us, the FDA recommended that we test ferumoxytol at doses lower than 510 milligrams. We chose to conduct our studies of ferumoxytol using primarily a 510 milligram dose. If the FDA determines that the

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data we submitted with our NDA does not support the safety of a 510 milligram dose, it could decide not to approve ferumoxytol at this dosing regimen or require additional studies prior to approval.

In addition, under the FDA s current good clinical practices, or cGCP, regulations, we are responsible for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA may conduct inspections of clinical investigator sites which were involved in our clinical development programs to ensure their compliance with cGCP regulations. If the FDA determines that we, our contract research organizations or our study sites fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may disqualify certain data generated from those sites or require us to perform additional clinical trials before approving our marketing applications. The FDA recently completed inspections at certain of our ferumoxytol Phase III clinical investigator sites. At the completion of the inspection of one of our Phase III sites, the FDA noted certain observations regarding the site s compliance with cGCP. If the FDA determines that we or any of our clinical sites did not comply with cGCP and/or that the data and results from our Phase III studies are not credible and accurate, the FDA could disqualify some or all of our clinical data which could adversely impact our ability to obtain approval for ferumoxtyol.

Any such deficiency in the design, implementation or oversight of our clinical development program identified by the FDA could cause us to incur significant additional costs, experience significant delays in our efforts to obtain regulatory approval for ferumoxytol, or even prevent us from obtaining regulatory approval for ferumoxytol. The requirement to conduct additional trials or any other delay in obtaining regulatory approval would delay the commercialization of ferumoxytol and associated revenues, and would consume extensive amounts of our resources, both financial and managerial. This would, in turn, materially adversely impact our cash position, our ability to increase revenues, our ability to achieve profitability, and the future prospects of our business.

Ferumoxytol s approved indication may be more restrictive than proposed in our application to the FDA, which would adversely impact our ability to generate revenues from sales of ferumoxytol.

Any regulatory approvals granted by the FDA may entail limitations on the approved indications for ferumoxytol. As part of our NDA, we have requested approval to market ferumoxytol as an IV iron replacement therapy for iron deficiency anemia in all CKD patients, whether or not on dialysis. The FDA could determine that the data from our clinical trials is adequate to show safety and efficacy in only a portion of the CKD population, in which case the FDA might approve ferumoxytol only for marketing in a subset of the CKD population. Even if approved, the FDA may impose labeling requirements that adversely impact our ability to successfully market ferumoxytol. For example, if the FDA has safety concerns with respect to ferumoxytol, ferumoxytol s label could include a black box warning indicating significant concerns of adverse events. Any such labeling requirements or limitations could significantly impair our ability to generate future revenues from product sales of ferumoxytol as an IV iron replacement therapeutic agent and adversely impact our ability to achieve profitability and the future prospects for our business.

We may not be able to operate our manufacturing facility in compliance with current good manufacturing practices and other FDA regulations, and failure by us to operate our manufacturing facility in compliance with current good manufacturing practices and other FDA regulations could result in a substantial delay in the approval of ferumoxytol or a suspension of our ability to manufacture ferumoxytol.

Our Cambridge, Massachusetts manufacturing facility is subject to current good manufacturing practices, or cGMP, regulations enforced by the FDA. The FDA conducts periodic inspections as well as pre-approval and post-approval inspections of our manufacturing facility to determine

whether we are in compliance with cGMP and other FDA regulations. Based on these inspections the FDA may issue notices that would require us to modify our manufacturing operations. Failure to operate in compliance with cGMP regulations and other applicable manufacturing requirements of various regulatory agencies could result in fines, unanticipated compliance expenditures, recall, total or partial suspension of production, suspension of the FDA s review of our ferumoxytol NDA or future supplemental NDAs, enforcement actions, injunctions or criminal prosecution and could impair our ability to generate product sales or delay our development efforts. In September 2008, the FDA completed an on-site inspection of our Cambridge, Massachusetts manufacturing facility. At the completion of the inspection the FDA noted certain observations made during that inspection with respect to our compliance with cGMP regulations. We will need to address the observations noted by the FDA in a satisfactory manner in order to obtain approval to market and sell ferumoxytol. If we do not provide a response that adequately addresses the FDA s observations, the FDA may take regulatory action that could result in a substantial delay in the approval of ferumoxytol or a suspension of our ability to manufacture ferumoxytol, either of which would have a severe adverse impact on our profitability and the future prospects of our business.

The commercial success of ferumoxytol will depend upon the degree of its market acceptance among physicians, patients, healthcare payors, and the two major operators of dialysis clinics in the U.S.

The success of our business is highly dependent on the commercial success of ferumoxytol in the U.S. For a variety of reasons, many of which are beyond our control, ferumoxytol may not achieve market acceptance among physicians, patients, or healthcare payors or providers, including dialysis clinics. If

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ferumoxytol does not achieve an adequate level of market acceptance for any reason, our potential profitability and our future business prospects would be severely adversely impacted. Ferumoxytol will represent an alternative to existing products and might not be adopted by the medical community if perceived to be no safer or more effective than currently available products. The degree of market acceptance of ferumoxytol will depend on a number of factors, including:

- Our ability to demonstrate to the medical community, particularly nephrologists, hematologists, dialysis clinics and others who may purchase or prescribe ferumoxytol, the clinical efficacy and safety of ferumoxytol as an alternative to current treatments for iron deficiency anemia;

- The ferumoxytol labeling and product insert required by the FDA;

- The adequacy of third-party insurance coverage and reimbursement for ferumoxytol from payors, including government payors, such as Medicare and Medicaid, and private payors, particularly in light of the expected bundling of costs of providing care to dialysis patients;

- The timing of market entry of ferumoxytol relative to competitive treatments;

- The relative price of ferumoxytol as compared to alternative iron replacement therapeutic agents;

- Convenience and ease of administration of ferumoxytol as compared to alternative iron therapeutic agents;

- The actual or perceived safety profile of ferumoxytol relative to alternative iron therapeutic agents;

- The availability of generic iron preparations; and

- The effectiveness of our sales, marketing and distribution organizations.

Currently IV iron therapeutic products are not widely used by physicians who treat pre-dialysis CKD patients in the physician s office setting due to safety concerns and the inconvenience and often impracticability of administering currently approved IV iron therapeutic products in that setting. A key component of our commercialization strategy is to create a market for IV iron replacement therapeutics, specifically ferumoxytol, in the pre-dialysis CKD market. Therefore, if approved, it will be critical for us to successfully market and sell ferumoxytol to physicians who treat pre-dialysis CKD patients in the physician s office setting. It is often difficult to change physicians existing treatment paradigms even when supportive clinical data is available. If we are not successful in marketing and selling ferumoxytol, if and when approved, to physicians who treat pre-dialysis CKD patients in the physician s office setting, our ability to generate revenues, achieve and maintain profitability, and long-term business prospects would be adversely affected.

The dialysis market is the largest and most established market for IV iron replacement therapies, with two companies serving a significant majority of all dialysis patients on Medicare. Fresenius Medical Care Ag & Co., or Fresenius, and DaVita, Inc., or DaVita, treat more than 60% of the U.S. dialysis population. If we are unable to successfully market and sell ferumoxytol to physicians who treat dialysis

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dependent CKD patients in clinics controlled by either or both of Fresenius and DaVita, our ability to realize and grow revenues from sales of ferumoxytol will be severely limited, which would have a material adverse impact on our potential profitability, and our future business prospects. In addition, in September 2008, Fresenius finalized an exclusive sublicense agreement with Luitpold Pharmaceuticals, Inc., or Luitpold, a wholly owned subsidiary of Daiichi Sankyo Company, Ltd., or Daiichi, to manufacture, sell and distribute Venofer®, an existing IV iron replacement therapeutic, to independent outpatient dialysis clinics in the U.S. Luitpold retains the right to sell Venofer® in the U.S. to any other customer. Fresenius has significant experience selling and distributing dialysis equipment and supplies to outpatient dialysis clinics and, as a result of this agreement, it may be more difficult for us to penetrate the dialysis market, in particular at Fresenius clinics.

Our ability to generate future revenues from ferumoxytol will depend heavily on our ability to obtain and maintain satisfactory insurance coverage, reimbursement and pricing for ferumoxytol.

Our ability to successfully commercialize ferumoxytol will depend on the adequacy of insurance coverage and reimbursement for ferumoxytol from third-party payors, including governmental payors, such as Medicare and Medicaid, and private payors. Payors generally have discretion whether and how to cover new pharmaceutical products, and there is no guarantee that we will be able to convince payors to cover ferumoxytol. We expect that ferumoxytol will be purchased by hospitals, clinics, dialysis centers, physicians and other users, each of which generally relies on third-party payors to reimburse them or their patients for pharmaceutical products administered in the hospital, clinic, dialysis center and physician-office settings. Public and private insurance coverage and reimbursement plans are therefore central to new product acceptance, with customers unlikely to use ferumoxytol if they do not receive adequate reimbursement. If we fail to demonstrate clear clinical and/or comparative value of ferumoxytol as compared to existing therapeutics, we may not receive adequate reimbursement. This could result in lower sales of ferumoxytol, which would have a material adverse effect on us and the results of our operations.

In the U.S., there have been, and we expect there will continue to be, a number of federal and state proposals to reform the healthcare system in ways that could impact our ability to sell ferumoxytol profitably. As a result of these reimbursement and legislative proposals, and the trend toward managed health care in the U.S., third-party payors, including government and private payors, are increasingly attempting to contain health care costs by limiting the coverage and the level of reimbursement of new drugs. These cost-containment methods may include, but are not limited to, using formularies, which are lists of approved or preferred drugs, requiring prior authorization, utilizing variable co-payments, limiting reimbursement where less-costly alternatives are available, or refusing to provide coverage of approved products for medical indications other than those for which the FDA has granted marketing approval.

With respect to ferumoxytol, Medicare currently reimburses for physician-administered drugs in the dialysis center, physician clinic, and hospital outpatient settings at a rate of 106% of the drug s average selling price, or ASP. If the Centers for Medicare & Medicaid Services, or CMS, or its local contractor, believes that ferumoxytol s ASP is too high, it may attempt to initiate one or more of the cost-containment methods discussed above at either the national or local level. It is highly uncertain whether the ASP reimbursement methodology will continue to apply if and when ferumoxytol is approved by the FDA, and any changes in reimbursement policies may have a negative impact on the level of reimbursement available for ferumoxytol. On July 15, 2008, Congress enacted The Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, which created a bundled payment system for the treatment of End Stage Renal Disease, or ESRD, to take effect on January 1, 2011. MIPPA requires CMS to begin a process of moving from a system in which it pays separately for physician-administered drugs for dialysis patients to a

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system in which all costs of providing care to dialysis patients are bundled together into a single capitated payment beginning on January 1, 2011 and to complete the phase-in by January 1, 2014. This bundled approach to reimbursement may lower utilization of physician-administered drugs in the ESRD market. In addition, the bundled approach to reimbursement in the dialysis setting may lower the amount of reimbursement available for ferumoxytol and consequently put downward pressure on the price we can charge for ferumoxytol. Therefore, we may be limited in our ability to successfully market and sell ferumoxytol. While MIPPA applies only to Medicare, private payors and state Medicaid plans frequently adopt Medicare principles in setting their own reimbursement methodologies. Any change in the Medicare reimbursement rate would therefore likely result in changes to payment rates from non-Medicare payors as well, further limiting our ability to successfully market and sell ferumoxytol.

To the extent we sell our products internationally, market acceptance may also depend, in part, upon the availability of reimbursement within existing healthcare payment systems. Generally, in Europe and other countries outside of the U.S., the government sponsored healthcare system is the primary payer of healthcare costs of patients and therefore enjoys significant market power. Some foreign countries also set prices for pharmaceutical products as part of the regulatory process, and we cannot guarantee that the prices set by such governments will be sufficient to generate substantial revenues in those countries.

We have limited marketing and sales experience and any failure on our part to effectively execute our ferumoxytol commercial plans would have a severe adverse impact on our business.

We have never marketed or sold a drug product as we have relied on our corporate partners to market and sell our current approved products, *Feridex I.V.* and *GastroMARK*. In preparation for the potential U.S. commercial launch of ferumoxytol as an IV iron replacement therapeutic agent for CKD patients, we have been building an internal sales and marketing function, including a direct sales force, in the U.S. Developing an internal marketing team and sales force is expensive and time-consuming. We may not be able to successfully recruit and retain the qualified marketing and sales personnel that will be necessary to effectively market and sell ferumoxytol. In addition, we continue to build our commercial infrastructure, hire our sales force, and expend substantial amounts of capital to prepare for the U.S. commercial launch of ferumoxytol before we know whether the FDA has approved the marketing and sale of ferumoxytol. If ferumoxytol is not approved by the FDA or is not approved in a timely manner, we will not have the ability to redeploy the sales force, and we will have no way to recoup the capital expended in building the sales force and commercial organization.

Competition for experienced and skilled marketing and sales personnel is intense and we cannot guarantee that we will be able to attract and retain a sufficient number of qualified individuals to successfully promote ferumoxytol. If we are unsuccessful in developing an effective sales and marketing function then our marketing efforts and our potential product launch of ferumoxytol as an IV iron replacement therapeutic agent would be delayed, and the commercialization of ferumoxytol would be severely impaired. Furthermore, we may not be successful in marketing and selling ferumoxytol. Factors that may adversely impact our ability to effectively market and sell ferumoxytol include:

- Our inability to recruit, train and retain adequate numbers of qualified sales and marketing personnel;

- The inability of our sales personnel to obtain access to and persuade adequate numbers of physicians to prescribe or use ferumoxytol;

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- A lack of complementary products that can be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with larger product lines; and

- Unforeseen costs and expenses associated with creating a sales and marketing organization.

Any delay or failure in our commercial product launch of ferumoxytol as an IV iron replacement therapeutic agent would have a material adverse impact on our ability to generate revenues, our ability to achieve profitability, and the future prospects for our business.

Competition in the pharmaceutical and biopharmaceutical industries is intense. If our competitors are able to develop and market products that are more effective, safer, more convenient or have more favorable pricing, insurance coverage and reimbursement than ferumoxytol, our commercial opportunity for ferumoxytol will be adversely impacted.

The pharmaceutical and biopharmaceutical industries are subject to intense competition and rapid technological change. Most of our competitors have significantly greater financial resources and expertise in product development, manufacturing, conducting clinical trials, obtaining regulatory approvals, and marketing and selling approved products than we do. Our ferumoxytol commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are or are perceived to be more effective, have fewer side effects, are easier to administer, or have more favorable pricing and reimbursement than ferumoxytol. In addition, any significant delays in the development, FDA approval or U.S. commercial launch of ferumoxytol could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize ferumoxytol.

There are currently two types of treatment options for treating iron deficiency anemia in CKD patients: oral iron supplements and IV iron. We anticipate that, if approved, ferumoxytol will primarily compete with existing IV iron replacement therapies, including Venofer®, which is marketed by American Regent and Fresenius, Ferrlecit®, which is marketed by Watson Pharmaceuticals, Inc., and certain oral iron products. These competing iron replacement therapy products may receive greater market acceptance, especially since these products are already on the market and are currently widely used by physicians. We may not be able to convince physicians to switch from using the currently approved IV iron therapeutic products to ferumoxytol. The iron replacement market is highly sensitive to several factors including, but not limited to, the ability to obtain appropriate reimbursement, price competitiveness, and product characteristics such as convenience of administration and dosing regimens. In particular, the IV iron replacement market is extremely sensitive to the perceived relative safety profiles of the various IV iron replacement therapeutics, and it will be critical for us to be able to demonstrate that ferumoxytol s safety profile is acceptable in order to be competitive in the marketplace. To date, we have not conducted any head-to-head clinical studies comparing the relative safety profiles of ferumoxytol to other IV iron replacement products.

In addition to the currently marketed products, there are several iron replacement therapy products in various stages of clinical development in the U.S. and abroad, including VIT-45, also known as Ferinject® or Injectafer®, and SFP, a form of iron given as part of the hemodialysis procedure. In addition to competition from currently approved products and products known by us to be currently under development, the market opportunity for ferumoxytol would be negatively affected if generic IV iron replacement therapy products were to be approved and achieve commercial success. Companies that manufacture generic products typically invest far less resources in research and development than the manufacturer of a branded product and can therefore price their products significantly lower than those

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already on the market. It remains unclear whether a generic product will enter this market. If any of these product candidates are approved for marketing and sale by the FDA before ferumoxytol is approved, our efforts to market and sell ferumoxytol, if approved, and our ability to generate additional revenues and achieve profitability would be adversely affected.

Further technological and product developments may also make new iron replacement therapy products more competitive than IV iron products, adversely impacting our ability to successfully commercialize ferumoxytol.

We need to maintain, and possibly increase our manufacturing capabilities or establish and qualify second source manufacturing facilities in order to successfully commercialize ferumoxytol.

We currently manufacture bulk *Feridex I.V.* and *GastroMARK,* as well as *Feridex I.V.* finished product, and ferumoxytol for use in human clinical trials, in our Cambridge, Massachusetts manufacturing facility. We also intend to use this facility to manufacture ferumoxytol for commercial sale if and when it is approved by the FDA. Although we have begun the work to establish and qualify second source manufacturing facilities for ferumoxytol, we currently have only one manufacturing facility at which we produce limited quantities of ferumoxytol. We have been manufacturing large scale commercial lots of ferumoxytol for the last several months, but as we continue to manufacture ferumoxytol in larger volumes for commercial sale, we could experience higher than anticipated material, labor and overhead costs per unit. Additionally, manufacturing and quality control problems may arise as we increase our level of production. We may not be able to continue to increase our manufacturing capacity in a timely and cost-effective manner to meet demand for ferumoxytol if and when it is approved by the FDA, and we may experience delays in manufacturing ferumoxytol, which could result in a shortage in the supply of

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ferumoxytol. Furthermore, we will need to continue to recruit, train and retain additional qualified manufacturing and quality control personnel as we prepare for production of ferumoxytol on a commercial scale. If we fail to continue to attract, train and retain key members of our manufacturing or quality control departments, we may be unable to manufacture sufficient quantities of ferumoxytol in a timely manner, which could delay or impair our product sales and development efforts.

In determining the required quantities of our products and the manufacturing schedule, we will also need to make significant judgments and estimates based on inventory levels, current market trends, anticipated sales, and other factors. Because of the inherent nature of estimates there could be significant differences between our estimates and the actual amount of product need. Any difference between our estimates and the actual amount of product need could result in unmet demand or excess inventory, each of which would adversely impact our financial results and business prospects.

Although we are working to establish and qualify second source manufacturing facilities for ferumoxytol, we may not be able to enter into agreements with manufacturers whose facilities and procedures comply with cGMP regulations and other regulatory requirements. Furthermore, use of a second-source manufacturing facility may increase the risk of certain problems, including cost overruns, process reproducibility, stability issues, or an inability to deliver required quantities of product that conform to specifications in a timely manner.

If we are unable to consistently manufacture our products on a timely basis because of these or other factors, we will not be able to meet anticipated demand for ferumoxytol. As a result, we may lose sales and fail to generate increased revenues, which would have a severe adverse impact on our potential profitability and future business prospects.

Our inability to obtain raw materials and our reliance on sole source suppliers could adversely impact our ability to manufacture sufficient quantities of ferumoxytol, which would have a severe adverse impact on our business.

We currently purchase certain raw materials used to manufacture ferumoxytol from third-party suppliers. We do not have any long-term supply contracts with these third-parties. Some of these raw materials are procured from a single source with no qualified alternative supplier. We are in the process of identifying additional third-party suppliers for these raw materials. Third-party suppliers may cease to produce the raw materials used in ferumoxytol or otherwise fail to supply these raw materials to us or fail to supply these raw materials to us in sufficient quantities for any reason, including the following:

- Unexpected demand for or shortage of the raw materials;
- Labor disputes or shortages;
- Manufacturing difficulties;

- Regulatory requirements or action;

- Adverse financial developments at or affecting the supplier; or

- Import or export problems.

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If any of our third-party suppliers ceases to supply our raw materials for any of the above reasons, we would be unable to manufacture ferumoxytol or be unable to manufacture ferumoxytol in sufficient quantities until we are able to qualify an alternative source.

The qualification of an alternative source may require repeated testing of the new materials and generate greater expenses to us if materials that we test do not perform in an acceptable manner. In addition, we sometimes obtain raw materials from one vendor only, even where multiple sources are available, to maintain quality control and enhance working relationships with suppliers, which could make us susceptible to price inflation by the sole supplier, thereby increasing our production costs. As a result of the high quality standards imposed on our raw materials, we may not be able to obtain raw materials of the quality required to manufacture our products, including ferumoxytol, from an alternative source on commercially reasonable terms, or in a timely manner, if at all.

Any delay in or failure to obtain sufficient quantities of raw materials would prevent us from manufacturing ferumoxytol, both for commercial sale and for use by us in clinical trials. In addition, even if we are able to obtain raw materials from an alternative source, if these raw materials are not available in a timely manner or on commercially reasonable terms, we would be unable to manufacture ferumoxytol, both for commercial sale and for use in our clinical trials, on a timely and cost-effective basis. Any such difficulty in obtaining raw materials would severely hinder our ability to manufacture ferumoxytol and would have a material adverse impact on our ability to generate additional revenues and our ability to achieve profitability.

Ferumoxytol, if approved, will remain subject to ongoing regulatory review, and if we fail to comply with such continuing regulations we could be subject to penalties up to and including the suspension of the manufacturing, marketing and sale of ferumoxytol.

If approved, ferumoxytol will remain subject to FDA regulatory requirements and review pertaining to its manufacture, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. If we fail to comply with such regulatory requirements, we could be subject to sanctions, including but not limited to warning letters, civil or criminal penalties, injunctions, suspension or withdrawal of regulatory approvals, temporary or permanent closing of our manufacturing facilities, requirements to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, and other issues involving ferumoxytol, restrictions on our continued manufacturing, marketing or sale of ferumoxytol, recalls or a refusal by the FDA to consider or approve applications for additional indications.

Significant safety or drug interaction problems could arise for ferumoxytol even after FDA approval, resulting in recalls, restrictions in ferumoxytol s label, or withdrawal of ferumoxytol from the market.

Discovery of previously unknown problems with an approved product may result in recalls, restrictions on the product s permissible uses, or withdrawal of the product from the market. The data submitted to the FDA as part of our NDA was obtained in controlled clinical trials of limited duration. If approved, new safety or drug interaction issues may arise as ferumoxytol is used over longer periods of time by a wider group of patients taking numerous other medicines and with additional underlying health problems. These new safety or drug interaction issues may require us to provide additional warnings on our labels or narrow our approved indications, each of which could reduce the market acceptance of ferumoxytol. In addition, if significant safety or drug interaction issues arise, FDA approval for ferumoxytol could be withdrawn and the FDA could require the recall of all existing ferumoxytol in the marketplace. The

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FDA also has the authority to require the recall of our products if there is contamination or other problems with manufacturing, transport or storage of the product. A government-mandated recall, or a voluntary recall, could divert managerial and financial resources, could be difficult and costly to correct, could result in the suspension of sales of ferumoxytol, and would have a severe adverse impact on our potential profitability and the future prospects of our business.

We may also be required to conduct certain post-approval clinical studies to assess known or suspected significant risks associated with ferumoxytol. The Food and Drug Administration Amendments Act of 2007, or the FDAAA, expanded the FDA s authority. Under the FDAAA, the FDA may: (i) require manufacturers to conduct post-approval clinical studies to assess known risks or signals of serious risks, or to identify unexpected serious risks; (ii) mandate labeling changes to a product based on new safety information; or (iii) require sponsors to implement risk evaluation and mitigation strategies, or REMS, where necessary to assure safe use of the drug. If we are required to conduct post-approval clinical studies or implement REMS, or if the FDA changes the label for ferumoxytol to include additional discussion of potential safety issues, such requirements or restrictions would have a material adverse impact on our ability to generate revenues from sales of ferumoxytol, or require us to expend significant additional funds on clinical studies.

Our stock price has been and may continue to be volatile, and your investment in our stock could decline in value or fluctuate significantly.

The market price of our common stock has been, and may continue to be, volatile and your investment in our stock could decline in value or fluctuate significantly. Our stock price has ranged between $23.66 and $66.94 in the fifty-two week period through October 31, 2008. The stock market has from time to time experienced extreme price and volume fluctuations, particularly in the biotechnology and pharmaceuticals sectors, which have often been unrelated to the operating performance of particular companies. Various factors and events, many of which are beyond our control, may have a significant impact on the market price of our common stock. Factors which may affect the market price of our common stock, among others, include:

- Public announcements of regulatory actions with respect to ferumoxytol or products or product candidates of our competitors;

- The availability of reimbursement coverage for ferumoxytol and changes in the reimbursement policies of governmental or private payors;

- Actual or anticipated fluctuations in our operating results;

- Changes in financial estimates or recommendations by securities analysts;

- Sales of large blocks of our common stock;

- Loss of any of our key scientific or management personnel;

- General market conditions;

- The results of clinical trials for ferumoxytol or potentially competitive products or product candidates;

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- The acquisition or development of technologies, product candidates or products by us or our competitors;

- Developments in patents or other proprietary rights by us or our competitors;

- Public concern regarding the safety of ferumoxytol or products or product candidates of our competitors;

- The initiation of litigation to enforce or defend any of our assets;

- Changes in legislative initiatives by Congress or reimbursement policies by government or private payors; and

- Significant collaboration, acquisition, joint venture or similar agreements by us or our competitors.

For example, any announcement of any positive or negative developments with respect to our efforts to obtain FDA approval to market and sell ferumoxytol, or our competitors efforts to obtain FDA approval for competitive product candidates, would likely have a dramatic impact on our stock price. Thus, as a result of events both within and beyond our control, our stock price could fluctuate significantly or lose value rapidly.

Our ability to generate and grow revenues from the sale of ferumoxytol will be limited if we do not obtain approval or if we experience significant delays in our efforts to obtain approval to market ferumoxytol for additional indications in the U.S. or if we do not obtain approval to market ferumoxytol in countries outside of the U.S.

The NDA we submitted to the FDA in December 2007 requests approval to market and sell ferumoxytol in the U.S. as an IV iron replacement therapeutic agent for the treatment of iron deficiency anemia in CKD patients, whether or not on dialysis. We are conducting and plan to conduct additional clinical trials and seek regulatory approval to market ferumoxytol in indications other than CKD. Before we can obtain approval to market ferumoxytol for these additional indications, we will need to successfully conduct clinical trials showing that ferumoxytol is safe and effective for these new uses and in these new patient populations and then apply for and obtain appropriate regulatory approvals. Conducting clinical trials is a complex, time-consuming and expensive process that requires adherence to a wide range of regulatory requirements. There is no guarantee that we will be successful in completing any clinical trials for additional indications in a timely manner or that, if completed, the results of such clinical trials will demonstrate ferumoxytol to be safe and effective in such uses and/or patient populations.

Our ability to complete our clinical trials in a timely manner depends on a number of factors including:

- Protocol design;
- Timing of regulatory and institutional review board approval;
- Availability of clinical study material; and
- The rate of patient enrollment.

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Any delay incurred in our clinical trials for additional indications could result in increased development costs and delays in regulatory approvals and could have an adverse effect on our development strategy.

To the extent we wish to manufacture, market or sell ferumoxytol in foreign countries, we will need to comply with foreign regulatory requirements, which vary widely from country to country and may in some cases be more rigorous than requirements in the U.S. Foreign regulatory agents may require additional studies or studies designed with different clinical endpoints and/or comparators than those which we have already completed. The time required for approval may also be longer or shorter than in the U.S. Any failure by us to obtain approval for additional ferumoxytol indications in the U.S. or any failure to obtain approval outside the U.S. may limit the commercial success of ferumoxytol and our ability to grow our revenues.

We rely on third parties in the conduct of our clinical trials, and if they fail to fulfill their obligations, our development plans may be adversely affected.

We rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our clinical trials. We have and we plan to contract with certain third-parties to provide certain services, including site selection, enrollment, monitoring and data management services. Although we depend heavily on these parties, we do not control them and therefore we cannot be assured that these third-parties will adequately perform all of their contractual obligations to us. If our third-party service providers cannot adequately fulfill their obligations to us on a timely and satisfactory basis or if the quality and accuracy of our clinical trial data is compromised due to failure to adhere to our protocols or regulatory requirements or if such third-parties otherwise fail to meet deadlines, our development plans may be delayed or terminated.

The investment of our cash and our investments is subject to risks which may cause losses or adversely affect the liquidity of these investments.

At September 30, 2008, we had $63.3 million in cash and cash equivalents, $117.4 classified as short-term investments, and $60.4 million classified as long-term investments. We have historically invested our funds in institutional money market funds, corporate debt securities, commercial paper, U.S. Treasury and government agency securities, municipal debt securities, and ARS in accordance with the criteria set out in our investment policy. These investments are subject to general credit, liquidity, market and interest rate risks, which may be exacerbated by the U.S. sub-prime mortgage defaults and the ensuing fallout which have affected various sectors of the financial markets and caused credit and liquidity issues. We may realize losses in the fair value of these investments or a complete loss of these investments which would have an adverse effect on our results of operations, liquidity and financial condition.

At September 30, 2008, we held $60.4 million in market value of ARS, which reflects a temporary impairment of $6.1 million from our cost basis of these securities of $66.5 million. Greater than 90% of these ARS were rated AAA by at least one of the major securities rating agents, most of which were collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program. We had traditionally recorded these investments at cost, which approximated fair market value due to their variable interest rates. These investments typically reset through an auction process every 7 or 28 days which 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

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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 as opposed to valuing them at par value.

Since February 2008, the continued uncertainty in the credit markets has caused additional auctions with respect to our ARS to fail and prevented us from liquidating certain of our holdings of ARS because the amount of these securities submitted for sale has exceeded the amount of purchase orders for these securities. There is a risk that auctions related to other securities that we own will continue to fail indefinitely and that there could be a decline in value of these securities or any other securities which may ultimately be deemed to be other-than-temporary. In the future, should we experience additional auction failures and/or determine that these declines in value of ARS are other than temporary, we would recognize a loss in our consolidated statement of operations, which could be material. In addition, any future failed auctions may adversely impact the liquidity of our investments. 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 these securities 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.

The condition of the credit markets remains dynamic. As a result, we may experience a reduction in value or loss of liquidity with respect to our investments. For example, in three months ended September 30, 2008 we recorded an impairment charge of $1.3 million related to certain corporate debt securities held by us. This impairment charge was required after we conducted an analysis of other-than-temporary impairment factors for our securities including the severity of declines and current financial market conditions, which caused us to determine that the $1.3 million impairment was other-than-temporary. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. These market risks associated with our investment portfolio may have an adverse effect on our results of operations, cash position, liquidity and overall financial condition.

The current credit and financial market conditions may exacerbate certain risks affecting our business.

In recent months the U.S. and global economy have taken a dramatic downturn as the result of the deterioration in the credit markets and related financial crisis as well as a variety of other factors including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. The U.S. and certain foreign governments have recently taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If the actions taken by the U.S. government are not successful, the continued economic decline may continue to negatively affect the liquidity of our investments, including our ARS, cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all, or cause our investments to substantially decline in value. Any of these effects could have a material adverse effect on our liquidity, cash position and the potential future prospects of our business. In addition, we rely and intend to rely on third-parties, including our clinical research organizations, third-party manufacturers and second source suppliers, and certain other important vendors and consultants. As the result of the current volatile and unpredictable global economic situation, there may be a disruption or delay in the performance of our third-party contractors and suppliers. If such third-parties are unable to satisfy their contractual commitments to us, our business could be severely adversely affected.

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Our corporate compliance program cannot ensure that we are in compliance with all applicable laws and regulations, and our failure to comply with such laws and regulations could harm our business.

Our general operations, and the research, development, manufacture, sale and marketing of our products and product candidates, including ferumoxytol, are subject to extensive federal and state regulation, including but not limited to FDA regulations, the federal false claims act, and the federal anti-kickback statute. While we are in the process of developing and implementing a corporate compliance program based on what we believe are current best practices in the pharmaceuticals industry, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potential federal and state regulations and/or laws. If we or our representatives fail to comply with any of these laws or regulations, a range of fines, penalties and/or other sanctions could be imposed on us, including, but not limited to, the termination of our clinical trials, the failure to approve ferumoxytol, restrictions on how we market and sell ferumoxytol, restrictions on our manufacturing processes, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation, or other sanctions. If any such actions are instituted against us, and we are not successful in defending ourselves, such actions could have a significant adverse impact on our business.

Legislative or regulatory changes may adversely impact our business.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. New laws, regulations or judicial decisions, or new interpretations of existing laws and regulations, may require us to modify our development programs, revise the way we manufacture, market and sell ferumoxytol, require additional clinical trials or post-approval safety studies, or limit coverage or reimbursement for ferumoxytol. Any such new laws, regulations, decisions or interpretations may therefore have a significant adverse impact on our ability to successfully develop and commercialize ferumoxytol, and could have a material adverse impact on our ability to generate and grow our revenues and achieve profitability.

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

Our future operating results will likely vary from quarter to quarter depending on a number of factors, some of which we cannot control, including:

- The timing and likelihood of obtaining regulatory approval in the U.S. for ferumoxytol as an IV iron replacement therapeutic agent in the U.S.;

- The timing and magnitude of revenues from product sales of ferumoxytol, if approved;

- The timing and magnitude of costs associated with our preparations for the potential U.S. commercial launch of ferumoxytol, including costs associated with building and maintaining our commercial infrastructure and executing

our promotional and marketing strategy for ferumoxytol, if approved;

- The timing and magnitude of costs associated with commercial-scale manufacturing of ferumoxytol, including costs associated with building commercial inventory and qualifying additional manufacturing capacity and second source suppliers;

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- The timing and magnitude of costs associated with our development of additional indications for ferumoxytol;

- Changes in laws and regulations concerning reimbursement for ferumoxytol, if approved, from government health administration authorities, private health insurers and other third-party payors; and

- Implementation of new or revised accounting or tax rules or policies.

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

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

Because of the specialized nature of our business, our success depends to a significant extent on the continued service of our Chief Executive Officer and President, Brian J.G. Pereira, MD, our other executive officers and on our ability to continue to attract, retain and motivate qualified personnel. If we are unable to retain these personnel, or we lose the services of our key personnel for any reason, our ferumoxytol development and commercialization efforts could be severely adversely impacted. We have entered into employment agreements with the majority of our senior executives but such agreements do not guarantee that these executives will remain employed by us for any significant period of time, or at all. The loss of services of one or several of our key employees could have a material adverse affect on us and our development and commercialization efforts for ferumoxytol.

Furthermore, our expansion into areas and activities requiring additional expertise, such as late-stage development and marketing and sales, has required the addition of new management personnel and the development of additional expertise by existing management personnel. There is intense competition for qualified personnel in the areas of our activities, and we may not be able to continue to attract and retain the qualified personnel necessary for the development of our business. The failure to attract and retain such personnel or to develop such expertise could impose significant limits on our business operations and hinder our ability to successfully and efficiently complete our development projects.

If we do not effectively manage our growth, our ability to commercialize ferumoxytol, pursue opportunities and expand our business could be adversely affected.

We have experienced and continue to experience significant growth that has placed and may continue to place a substantial strain on our employees, management, facilities and resources. In anticipation of the potential approval and U.S. commercial launch of ferumoxytol, we continue to rapidly expand our regulatory, medical affairs, marketing, sales, manufacturing and compliance capabilities. As our operations expand, we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. In addition, we will need to continue to improve our operational and financial systems, train and manage our expanding workforce, and maintain close

coordination among our various departments. We may not be able to accomplish these tasks, and our failure to accomplish any one of them could prevent us from successfully commercializing ferumoxytol, pursuing new business opportunities, or expanding our business, any one of which could adversely impact our future business prospects.

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We may enter into collaborations, in-licensing arrangements, or acquisition agreements that could disrupt our business, decrease our profitability, result in dilution to stockholders or cause us to incur debt or significant additional expense.

As part of our business strategy, we intend to pursue collaboration, in-licensing opportunities, acquisitions of products or businesses, and/or strategic alliances that we believe would be complementary to our existing business. We have limited experience with respect to these business development activities. Any such strategic transactions by us could result in large and immediate write-offs or the incurrence of debt and contingent liabilities, any of which would adversely impact our operating results. Management of a license arrangement, collaboration, or other strategic arrangement and/or integration of an acquired asset or company may also disrupt our ongoing business, require management resources that otherwise would be available for ongoing development of our existing business and our planned U.S. commercial launch of ferumoxytol. We may not identify or complete any such transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated financial benefits of any such transaction. In addition, to finance any such strategic transactions, we may choose to issue shares of our common stock as consideration, which would result in dilution to our stockholders. Alternatively, it may be necessary for us to raise additional funds through public or private financings, and such additional funds may not be available on terms that are favorable to us. In addition, proposing, negotiating and implementing collaborations, in-licensing arrangements or acquisition agreements may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us in these arrangements and we may not be able to enter into such arrangements on acceptable terms or at all.

We may need additional capital to achieve our business objectives.

We have expended and will continue to expend substantial funds to complete development, clinical trials, commercial launch preparations, and other activities necessary to successfully commercialize ferumoxytol. As a result, we anticipate that our expenses will increase and that our cash-burn rate will continue to increase in the near- and long-term. Our long-term capital requirements will depend on many factors, including, but not limited to:

- Our ability to successfully obtain regulatory approval in the U.S. for ferumoxytol as an IV iron replacement therapeutic agent in a timely manner;

- The timing and magnitude of revenues from product sales of ferumoxytol, if approved;

- Costs associated with our preparations for the potential U.S. commercial launch of ferumoxytol, including costs associated with building and maintaining our commercial infrastructure and executing our promotional and marketing strategy for ferumoxytol, if approved;

- Costs associated with commercial-scale manufacturing of ferumoxytol, including costs associated with building commercial inventory and qualifying additional manufacturing capacity and second source suppliers;

- Costs associated with our development of additional indications for ferumoxytol;

- Costs associated with the pursuit of potential business development activities;

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- Costs associated with our pursuit of approval for ferumoxytol as an IV iron replacement therapeutic agent outside of the U.S.;

- 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.

We estimate that our existing cash resources, combined with cash we currently expect to receive from earnings on our investments, will be sufficient to finance our operations for at least the next twelve months. Thereafter, we may require additional funds or need to establish alternative strategic arrangements to continue our ferumoxytol commercialization efforts and development activities. We may seek needed funding through arrangements with collaborative partners or through public or private equity or debt financings. We may not be able to obtain financing or to secure alternative strategic arrangements on acceptable terms or within an acceptable timeframe, if at all.

Any additional equity financings or alternative strategic arrangements would be dilutive to our stockholders. In addition, the terms of any debt financing could greatly restrict our ability to raise additional capital and may provide rights and preferences to the investors in any such financing which are not available to current stockholders. Our inability to raise additional capital on terms and within a timeframe acceptable to us when needed could force us to dramatically reduce our expenses and delay, scale back or eliminate certain of our activities and operations, including our development activities, any of which would have a material adverse effect on our business, financial condition and future business prospects.

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

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

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

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We currently hold approximately 17 U.S. patents and approximately 25 foreign patents, which expire between the years 2008 and 2020, some of which may be subject to extension under FDA regulations. Because certain patents that cover our products will begin to expire in the coming years, the protection provided by these patents will also begin to expire. Our inability to commercialize our products prior to the expiration of our patents could have a material adverse effect on our business, financial condition and prospects as the expiration of such patents could permit generic drug manufacturers to manufacture, market and sell lower cost drugs that compete with our products and product candidates. In the future, we may be required to obtain additional licenses to patents or other proprietary rights of others in order to commercialize our products or continue with our development efforts. Such licenses may not be available on acceptable terms, if at all. The failure to obtain such licenses could result in delays in marketing our products or our inability to proceed with the development, manufacture or sale of our products or product candidates requiring such licenses.

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

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

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

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

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

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

If securities analysts downgrade our stock or cease coverage of us, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. Currently, eleven financial analysts publish reports about us and our business. We do not control these or any other analysts. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. If any of the analysts who cover us downgrade our stock or issue commentary or observations that are perceived by the market to be adverse to us or our stock, our stock price would likely decline rapidly. If these analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

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 September 30, 2008.

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Item 6. Exhibits.

(a) List of Exhibits

Exhibit Number		Description
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.

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

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SIGNATURES

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: November 5, 2008

AMAG PHARMACEUTICALS, INC.

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

Date: November 5, 2008

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EXHIBIT INDEX

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

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