AMAG PHARMACEUTICALS INC.
Form 10-Q
August 05, 2009
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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 June 30, 2009

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 Number 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)

(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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). **Yes** o **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 (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of August 3, 2009 there were 17,120,251 shares of the registrant s Common Stock, par value $.01 per share, outstanding.

Table of Contents

AMAG PHARMACEUTICALS, INC.

FORM 10-Q

Table of Contents

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

AMAG PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

AS OF JUNE 30, 2009 AND DECEMBER 31, 2008

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

(Unaudited)

	June 30, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 70,226	$ 64,182
Short-term investments	54,985	94,914
Settlement rights	458	
Accounts receivable		408
Inventories	62	96
Prepaid and other current assets	3,066	4,710
Total current assets	128,797	164,310
Property, plant and equipment, net	11,192	11,223
Settlement rights		1,566
Long-term investments	50,097	54,335
Restricted cash	460	521
Total assets	$ 190,546	$ 231,955
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,400	$ 2,305
Accrued expenses	11,261	11,571
Deferred revenue		516
Total current liabilities	13,661	14,392
Long-term liabilities:		
Deferred revenue and rent expense	4,201	4,149
Total liabilities	17,862	18,541
Commitments and contingencies (Note K)		
Stockholders equity:		
Preferred stock, par value $.01 per share, 2,000,000 shares authorized; none issued		
Common stock, par value $.01 per share, 58,750,000 shares authorized; 17,056,714 and 17,018,159 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively	171	170
Additional paid-in capital	419,966	411,538
Accumulated other comprehensive loss	(6,241)	(9,959)
Accumulated deficit	(241,212)	(188,335)
Total stockholders equity	172,684	213,414

Total liabilities and stockholders equity	$ 190,546	$ 231,955

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

Table of Contents

AMAG PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE THREE AND SIX MONTHS ENDED

JUNE 30, 2009 AND 2008

(IN THOUSANDS, EXCEPT PER SHARE DATA)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Revenues:				
License fees	$	$ 185	$ 516	$ 369
Royalties	55	89	102	125
Product sales		212	393	604
Total revenues	55	486	1,011	1,098
Costs and expenses:				
Cost of product sales		31	61	75
Research and development expenses	10,114	7,061	21,186	11,884
Selling, general and administrative expenses	17,268	12,611	35,018	20,996
Total costs and expenses	27,382	19,703	56,265	32,955
Other income (expense):				
Interest and dividend income, net	783	2,198	2,039	5,465
Gains on investments, net	275	12	1,267	84
Fair value adjustment of settlement rights	(185)		(1,108)	
Total other income (expense)	873	2,210	2,198	5,549
Net loss before income taxes	(26,454)	(17,007)	(53,056)	(26,308)
Income tax benefit			179	
Net loss	$ (26,454)	$ (17,007)	$ (52,877)	$ (26,308)
Net loss per share:				
Basic and diluted	$ (1.55)	$ (1.00)	$ (3.10)	$ (1.55)
Weighted average shares outstanding used to compute net loss per share:				
Basic and diluted	17,038	16,994	17,030	16,982

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

Table of Contents

AMAG PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

FOR THE THREE AND SIX MONTHS ENDED

JUNE 30, 2009 AND 2008

(IN THOUSANDS)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Net loss	$ (26,454)	$ (17,007)	$ (52,877)	$ (26,308)
Other comprehensive income (loss):				
Unrealized gains (losses) on securities:				
Holding gains (losses) arising during period	1,512	(1,782)	3,713	(4,424)
Reclassification adjustment for losses and gains, net, included in net loss	1	12	5	84
Net unrealized gains (losses)	1,513	(1,770)	3,718	(4,340)
Total comprehensive loss	$ (24,941)	$ (18,777)	$ (49,159)	$ (30,648)

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

Table of Contents

AMAG PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE SIX MONTHS ENDED

JUNE 30, 2009 AND 2008

(IN THOUSANDS)

(Unaudited)

	Six Months Ended June 30,	
	2009	2008
Net loss	$ (52,877)	$ (26,308)
Cash flows from operating activities:		
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	883	545
Non-cash equity-based compensation expense	7,625	5,888
Amortization of premium/discount on purchased securities	357	87
Fair value adjustment on settlement rights	1,108	
Gains on investments, net	(1,267)	(84)
Changes in operating assets and liabilities:		
Accounts receivable	408	(959)
Inventories	34	81
Prepaid and other current assets	1,644	(310)
Accounts payable and accrued expenses	(215)	3,069
Deferred revenue and rent expense	(464)	728
Total adjustments	10,113	9,045
Net cash used in operating activities	(42,764)	(17,263)
Cash flows from investing activities:		
Proceeds from sales or maturities of available-for-sale investments	49,105	160,650
Purchase of available-for-sale investments	(310)	(114,662)
Capital expenditures	(852)	(1,283)
Restricted cash	61	(426)
Net cash provided by investing activities	48,004	44,279
Cash flows from financing activities:		
Proceeds from the exercise of stock options	225	672
Proceeds from the issuance of common stock under ESPP	579	162
Net cash provided by financing activities	804	834
Net increase in cash and cash equivalents	6,044	27,850
Cash and cash equivalents at beginning of the period	64,182	28,210
Cash and cash equivalents at end of the period	$ 70,226	$ 56,060
Supplemental data:		
Non-cash investing and financing activities:		
Accrued construction in process	$	$ 510

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

Table of Contents

AMAG PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2009

(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 currently manufacture and sell two products, Feraheme (ferumoxytol) Injection and GastroMARK®.

On June 30, 2009, *Feraheme* was approved for marketing in the U.S. by the U.S. Food and Drug Administration for use as an intravenous, or IV, iron replacement therapy for the treatment of iron deficiency anemia in adult patients with chronic kidney disease. We will market and sell *Feraheme* through our own commercial organization, consisting of approximately 150 seasoned professionals, including an 80-person specialized sales force, an experienced account management and reimbursement team, and a contract nurse team. We began shipping *Feraheme* to our authorized wholesalers and specialty distributors on July 13, 2009.

GastroMARK, our oral contrast agent used for delineating the bowel in magnetic resonance imaging is approved and marketed in the U.S., Europe, and other countries through our marketing partners.

Feridex I.V.®, our liver contrast agent, had been marketed and sold in the U.S., Europe and other countries for a number of years through our marketing partners. In November 2008, we decided to cease manufacturing *Feridex I.V.* Accordingly, we have terminated all of our agreements with our marketing partners for *Feridex I.V.* throughout the world and do not intend to continue commercializing *Feridex I.V.*

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 Summary of 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, 2008. 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 Annual Report on Form 10-K for the year ended December 31, 2008.

Table of Contents

In addition, in connection with the preparation of our condensed consolidated financial statements and in accordance with the recently issued Statement of Financial Accounting Standards, or SFAS, No. 165 Subsequent Events, we have evaluated subsequent events occurring after the balance sheet date of June 30, 2009 through August 5, 2009, the date we issued these financial statements. No matters arose subsequent to the balance sheet date requiring disclosure in the financial statements.

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 disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reported period. The most significant estimates and assumptions are used in, but are not limited to, assessing investments for potential impairment and determining values of investments, accrued expenses, income taxes and equity-based compensation expense. Actual results could differ materially from those estimates.

Principles of Consolidation

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

Cash and Cash Equivalents

Cash and cash equivalents consist principally of cash held in commercial bank accounts, money market funds and U.S. Treasury securities having an original maturity of less than three months. At June 30, 2009 and December 31, 2008, 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 SFAS No. 115 Accounting for Certain Investments in Debt and Equity Securities, or SFAS 115. The determination of the appropriate classification by us is based on a variety of factors, including management s intent at the time of purchase. As of June 30, 2009 and December 31, 2008, all of our investments were classified as either available-for-sale or trading 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. Available-for-sale investments are stated at fair value with their unrealized gains and losses included as a separate component of stockholders equity entitled Accumulated other comprehensive loss, until such gains and losses are realized or until an unrealized loss is considered other-than-temporary.

Trading securities are securities bought and held principally for the purpose of selling them at a later date and are carried at fair value with unrealized gains and losses reported in other income (expense) in

Table of Contents

our condensed consolidated statements of operations. In November 2008, we elected to participate in a rights offering, or the Settlement Rights, by UBS AG, or UBS, one of our securities brokers, which provides us with rights to sell to UBS $9.3 million in par value of our ARS portfolio, at par value, at any time during a two-year sale period beginning June 30, 2010. With the opportunity provided by the Settlement Rights, we have designated these ARS as trading securities as we are likely to sell these investments to UBS.

Effective April 1 2009, we adopted Financial Accounting Standards Board, or FASB, Staff Position, or FSP, Nos. 115-2 and FSP 124-2, Recognition and Presentation of Other-Than-Temporary Impairments, or FSP 115-2 and FSP 124-2. FSP 115-2 and FSP 124-2 collectively establish a new method of recognizing and reporting other-than-temporary impairments of debt securities and provide additional disclosure requirements related to debt and equity securities. Prior to our adoption of FSP 115-2 and FSP 124-2, our assessment of the impairment of our investments included an evaluation of whether a decline in fair value below amortized cost basis was other-than-temporary considering various factors such as the duration of the period that, and extent to which, the fair value was 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, underlying collateral, credit ratings with respect to our investments provided by investments ratings agencies, as well as whether we had the intent and ability to hold an investment for a sufficient period of time to recover its value. Under FSP 115-2 and FSP 124-2, for debt securities with a decline in fair value below amortized cost basis, an other-than-temporary impairment exists if (i) we have the intent to sell the security or (ii) it is more likely than not that we will be required to sell the security prior to recovery of its amortized cost basis. If either of these conditions is met, we recognize the difference between the amortized cost of the security and its fair value at the impairment measurement date in our condensed consolidated statement of operations. If neither of these conditions is met, we must perform additional analyses, including evaluation of the security, issuer and environmental factors noted above, to evaluate whether the unrealized loss is associated with the creditworthiness of the security or is associated with other factors, such as interest rates or market factors. If we determine from this analysis that we do not expect to receive cash flows sufficient to recover the entire amortized cost of the security, a credit loss exists, and the impairment is considered other-than-temporary and recognized in our condensed consolidated statement of operations. There were no impairments previously recognized on securities we owned at March 31, 2009 which would not have been recognized under FSP 115-2 and FSP 124-2 and therefore there was no cumulative effect adjustment to accumulated deficit and other comprehensive loss as a result of adopting FSP 115-2 and FSP 124-2.

Fair Value of Financial Instruments

Fair value is defined under SFAS No. 157, Fair Value Measurements, or SFAS 157, as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs.

Effective April 1, 2009, we adopted FSP No. 157-4, Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly, or FSP 157-4. FSP 157-4 provides additional guidance in accordance with SFAS 157 when the volume and level of activity for the asset or liability have significantly decreased. In addition, FSP 157-4 provides guidance on identifying circumstances that indicate when a transaction is not considered orderly. The adoption of FSP 157-4 did not have a significant impact on our condensed consolidated financial statements.

Table of Contents

SFAS 157 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 June 30, 2009, we held certain assets that are required to be measured at fair value on a recurring basis, including our cash equivalents, short- and long-term investments and our Settlement Rights. In accordance with SFAS 157, the following tables represent the fair value hierarchy for our assets measured at fair value on a recurring basis as of June 30, 2009 and December 31, 2008 (in thousands):

		Fair Value Measurements at June 30, 2009 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	$ 68,773	$ 68,773	$	$
Corporate debt securities	24,986		24,986	
U.S. treasury and government agency securities	21,148		21,148	
Auction rate securities	58,948			58,948
Settlement rights	458			458
	$ 174,313	$ 68,773	$ 46,134	$ 59,406

		Fair Value Measurements at December 31, 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	$ 60,403	$ 60,403	$	$
Corporate debt securities	54,320		54,320	
U.S. treasury and government agency securities	37,094		37,094	
Commercial paper	3,500		3,500	
Auction rate securities	54,335			54,335
Settlement rights	1,566			1,566
	$ 211,218	$ 60,403	$ 94,914	$ 55,901

With the exception of our ARS and Settlement Rights, which are valued using Level 3 inputs, as discussed below, the fair value of our non-money market fund investments is primarily determined from independent pricing services which use Level 2 inputs for the determination of fair value. Independent pricing services normally derive security prices from recently reported trades for identical or similar securities in active markets, making adjustments based upon other significant observable market transactions at fair value. At each reporting period, we perform quantitative and qualitative analyses on prices received from third parties to determine whether prices are reasonable estimates of fair value.

Table of Contents

As a result of the adoption of FSP 157-4, we consider the impact of a significant decrease in volume and level of activity for an asset or liability when compared with what is considered normal activity. In order to determine whether the volume and level of activity for an asset or liability has significantly decreased, we assess current activity with normal market activity for the asset or liability. For corporate positions, we utilize the Trade Reporting and Compliance Engine , or TRACE, through which published trade activity is made available, to assess trading activity levels. For other positions, we rely on many factors such as trading levels and activity as reported by market participants and current market conditions. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if there has been a significant decrease in the volume and level of activity for an asset, or group of similar assets.

Similarly, in order to identify transactions that are not orderly, we take into consideration the activity in the market as stated above, which can influence the determination and occurrence of an orderly transaction. Also, we inquire as to whether there may have been restrictions on the marketing of the security to a single or limited number of participants. Where possible, we assess the financial condition of the seller to determine whether observed transactions may have been forced. If the trading price for a security held by us is significantly out of line when compared to the trading prices of similar recent transactions, we consider whether this disparity is an indicator of a disorderly trade. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if the evidence suggests that a transaction or group of similar transactions is not orderly. Based upon these procedures, we determined that market activity for our assets appeared normal and that transactions did not appear disorderly as of June 30, 2009.

In November 2008, we elected the SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities - Including an Amendment of FASB Statement No. 115, or SFAS 159, fair value option with respect to the Settlement Rights. We are required to assess the fair value of both the Settlement Rights and our ARS subject to Settlement Rights and record changes each period until the Settlement Rights are exercised and our ARS subject to Settlement Rights are redeemed. Although the Settlement Rights represent the right to sell the securities back to UBS at par, we are required to periodically assess the ability of UBS to meet that obligation in assessing the fair value of the Settlement Rights.

The following table presents assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) as defined in SFAS 157 as of June 30, 2009 (in thousands):

		Six Months Ended June 30, 2009
Balance at beginning of period	$	55,901
Transfers to Level 3		
Total gains (losses) (realized or unrealized):		
Included in earnings		93
Included in other comprehensive income (loss)		3,612
Purchases (settlements), net		(200)
Balance at end of period	$	59,406
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 end of period	$	

Table of Contents

Gains and losses (realized and unrealized) included in earnings in each of the periods in the table above are reported in other income (expense) in our condensed consolidated statement of operations.

Comprehensive Loss

SFAS No. 130, Reporting Comprehensive Income, requires us to display comprehensive loss and its components as part of our condensed consolidated financial statements. Comprehensive loss consists of net loss and other comprehensive income (loss). Other comprehensive income (loss) 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.

C. Investments

In April 2009, we adopted FSP No. 107-1 and Accounting Principles Board, or APB, No. 28-1, Interim Disclosures About Fair Value of Financial Investments, or FSP 107-1 and APB 28-1, respectively. FSP 107-1 and APB 28-1 amend SFAS No. 107, Disclosures about Fair Values of Financial Instruments, to require disclosures about fair value of financial instruments in interim financial statements as well as in annual financial statements. FSP 107-1 and APB 28-1 also amend APB Opinion No. 28, Interim Financial Reporting, to require those disclosures in all interim financial statements.

At June 30, 2009 and December 31, 2008, our short- and long-term investments totaled $105.1 million and $149.2 million, respectively, and consisted of securities classified as available-for-sale and trading in accordance with SFAS 115.

The following is a summary of our available-for-sale and trading securities at June 30, 2009 and December 31, 2008 (in thousands):

Table of Contents

	June 30, 2009			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	$ 21,944	$ 167	$	$ 22,111
Due in one to three years	2,802	74	(1)	2,875
U.S. treasury and government agency securities				
Due in one year or less	12,131	150		12,281
Due in one to three years	8,595	272		8,867
Auction rate securities - trading				
Due in one year or less				
Due after five years	8,851			8,851
Total short-term investments	$ 54,323	$ 663	$ (1)	$ 54,985
Long-term investments:				
Auction rate securities - available for sale				
Due in one year or less	$	$	$	$
Due after five years	57,000		(6,903)	50,097
Total long-term investments	$ 57,000	$	$ (6,903)	$ 50,097
Total short and long-term investments	$ 111,323	$ 663	$ (6,904)	$ 105,082

Table of Contents

	December 31, 2008			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	$ 42,845	$ 106	$ (263)	$ 42,688
Due in one to three years	11,647	58	(73)	$ 11,632
U.S. treasury and government agency securities				
Due in one year or less	18,184	235		18,419
Due in one to three years	18,183	492		18,675
Commercial paper				
Due in one year or less	3,499	1		3,500
Due in one to three years				
Total short-term investments	$ 94,358	$ 892	$ (336)	$ 94,914
Long-term investments:				
Auction rate securities - available for sale				
Due in one year or less	$	$	$	$
Due after five years	57,200		(10,515)	46,685
Auction rate securities - trading				
Due in one year or less				
Due after five years	7,650			7,650
Total long-term investments	$ 64,850	$	$ (10,515)	$ 54,335
Total short and long-term investments	$ 159,208	$ 892	$ (10,851)	$ 149,249

Auction Rate Securities and UBS Settlement Rights

At June 30, 2009, we held a total of $58.9 million in fair market value of ARS, reflecting an impairment of approximately $7.4 million compared to the par value of these securities of $66.3 million. Of the $7.4 million impairment, approximately $6.9 million is considered a temporary impairment and is reported as an unrealized loss at June 30, 2009. The remaining $0.5 million represents an impairment associated with our UBS ARS, the recording of which is described below. Of our total ARS, $50.1 million in fair market value are not subject to Settlement Rights and are classified as available-for-sale. The remaining $8.8 million are subject to Settlement Rights and are classified as trading securities. At June 30, 2009, all of our ARS were municipal bonds with an auction reset feature. The substantial majority of our ARS portfolio was rated AAA as of June 30, 2009 by at least one of the major securities rating agencies and greater than 90% of our ARS 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. Prior to February 2008, these ARS typically reset through an auction process every 7 or 28 days, which generally allowed existing investors to either roll over their holdings and continue to own their securities or liquidate their holdings by selling their securities at par value. In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions. As a result of the lack of observable ARS market activity, we changed our valuation methodology for these securities

Table of Contents

to a discounted cash flow analysis as opposed to valuing them at par value. Our valuation analysis considers, 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, credit ratings of the security by the major securities rating agencies, 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 estimated the fair value of our ARS subject to Settlement Rights to be $8.8 million at June 30, 2009 and, accordingly, we recorded realized gains of approximately $0.2 million and $1.2 million, respectively, during the three and six months ended June 30, 2009. In addition, based upon this methodology, we have estimated the fair value of our remaining ARS not subject to Settlement Rights to be $50.1 million at June 30, 2009, and have recorded a $6.9 million unrealized loss to accumulated other comprehensive loss as of June 30, 2009. As discussed in greater detail below, for all available-for-sale debt securities with unrealized losses, management performs an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security s decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded in our condensed consolidated statement of operations as an impairment loss. Regardless of our intent to sell a security, we perform additional analyses on all securities with unrealized losses to evaluate whether there could be a credit loss associated with the security. We have not recognized any credit losses related to our securities during the three months ended June 30, 2009. We believe that the temporary impairment related to our ARS not subject to Settlement Rights is primarily attributable to the limited liquidity of these investments, coupled with the recent turmoil in the credit and capital markets. As of June 30, 2009, all of our ARS continue to pay interest according to their stated terms.

In November 2008, we elected to participate in a rights offering by UBS which provides us with the right to sell to UBS $9.3 million in par value of our ARS portfolio, at par value, at any time during a two-year sale period beginning June 30, 2010. By electing to participate in the rights offering, we granted UBS the right, exercisable at any time prior to June 30, 2010 or during the two-year sale period, to purchase or cause the sale of our ARS at par value, or the Call Right. UBS has stated that it will only exercise the Call Right for the purpose of restructurings, dispositions or other solutions that will provide its clients with par value for their ARS. UBS has agreed to pay its clients the par value of their ARS within one day of settlement of any Call Right transaction. Notwithstanding the Call Right, we are permitted to sell the ARS to parties other than UBS, which would extinguish the Settlement Rights attached to such ARS.

In accordance with SFAS 159, we have recorded an asset equal to the estimated fair value of the Settlement Rights of approximately $0.5 million in our condensed consolidated balance sheet at June 30, 2009. This represents a decrease to the estimated fair value of our Settlement Rights of approximately $0.2 million and $1.1 million from the estimated fair value at March 31, 2009 and December 31, 2008, respectively, which we have recorded in other income (expense) in our condensed consolidated statement of operations. We estimate the fair value of these Settlement Rights utilizing a discounted cash flow analysis. Certain key assumptions used in this valuation are the estimated value of these rights at the future date of settlement, the expected term until that date of settlement, and the risk that UBS will not be able to perform under the agreement. With the opportunity provided by the Settlement Rights, we have designated the UBS ARS with a par value of $9.3 million and an estimated fair value of $8.8 million as of June 30, 2009, as trading securities as we are likely to sell these investments to UBS. Accordingly, as of June 30, 2009, we have recognized gains of approximately $0.2 million and $1.2 million to other income (expense) in our condensed consolidated statement of operations during the three and six months ended June 30, 2009, respectively. We are required to assess the fair value of both the Settlement Rights and our ARS subject to Settlement Rights and record changes each period until the Settlement Rights are

Table of Contents

exercised or our ARS subject to Settlement Rights are redeemed. Although the Settlement Rights represent the right to sell the securities back to UBS at par, we are required to periodically assess the ability of UBS to meet its obligation in assessing the fair value of the Settlement Rights.

Due to our belief that the market for ARS may take in excess of twelve months to fully recover, we have classified our portfolio of ARS not subject to Settlement Rights as long-term investments in our condensed consolidated balance sheet at both June 30, 2009 and December 31, 2008. As discussed in greater detail below, we believe that the temporary impairment related to our ARS not subject to Settlement Rights 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 our ARS not subject to Settlement Rights that we deem to be temporary, including any recoveries of previous write-downs, would be recorded to accumulated other comprehensive loss. If we determine that any future unrealized loss is other-than-temporary, we will record a charge to our condensed consolidated statement of operations. 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 the majority have final maturity dates of 30 to 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 our ARS. However, it could take until final maturity of the ARS to realize our investments par value. In addition, as part of our determination of the fair value of our investments, we consider credit ratings provided by independent investment rating agencies as of the valuation date. These ratings are subject to change, and we may be required to adjust our future valuation of these ARS, which may adversely affect the value of our investments.

Impairments and Unrealized Gains and Losses on Investments

The following is a summary of the gross unrealized losses and fair value of our investments with unrealized losses that are deemed to be temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position at June 30, 2009 and December 31, 2008 (in thousands):

	June 30, 2009					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	$ 302	$ (1)	$	$	$ 302	$ (1)
Auction rate securities			50,097	(6,903)	50,097	(6,903)
	$ 302	$ (1)	$ 50,097	$ (6,903)	$ 50,399	$ (6,904)

Table of Contents

	December 31, 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	$ 33,996	$ (295)	$ 963	$ (41)	$ 34,959	$ (336)
Auction rate securities	46,685	(10,515)			46,685	(10,515)
	$ 80,681	$ (10,810)	$ 963	$ (41)	$ 81,644	$ (10,851)

As noted above, for available-for-sale debt securities with unrealized losses, we perform an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security s decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded in our condensed consolidated statement of operations as an impairment loss. Regardless of our intent to sell a security, we perform additional analyses on all securities with unrealized losses to evaluate whether there could be a credit loss associated with the security.

Our assessment of whether unrealized losses are other-than-temporary requires significant judgment. Factors we consider in making this judgment include, but are not limited to: (i) the extent to which market value is less than the cost basis; (ii) the length of time that the market value has been less than cost; (iii) whether the unrealized loss is event-driven, credit-driven or a result of changes in market interest rates or risk premium; (iv) the investment s rating and whether the investment is investment-grade and/or has been downgraded since its purchase; (v) whether the issuer is current on all payments in accordance with the contractual terms of the investment and is expected to meet all of its obligations under the terms of the investment; (vi) our intent not to sell an impaired investment before its recovery occurs; (vii) whether it is more likely than not that we will be required to sell the investment before recovery occurs; (viii) any underlying collateral and the extent to which the recoverability of the carrying value of our investment may be affected by changes in such collateral; (ix) unfavorable changes in expected cash flows and (x) other subjective factors. Based upon our evaluation, including the discussion of ARS above, we do not consider the unrealized losses on our available-for-sale investments at June 30, 2009 and December 31, 2008 to be other-than-temporarily impaired. Accordingly, no impairment losses were recognized in our condensed consolidated statement of operations related to available-for-sale securities during the three or six months ended June 30, 2009.

Future events may occur, or additional information may become available, which may cause us to identify credit losses where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security and which may necessitate future realized losses on securities in our portfolio. Significant losses in the estimated fair values of our investments could have a material adverse effect on our earnings in future periods.

Realized Gains and Losses

Gains and losses are determined on the specific identification method and, accordingly, during the three and six months ended June 30, 2009 we recorded realized gains of $0.3 million and $1.3 million, respectively, to our condensed consolidated statement of operations principally related to our estimated valuation of ARS subject to Settlement Rights. In addition, during the three and six months ended June 30, 2009, we recorded realized losses related to the fair value adjustment of our Settlement Rights of $0.2 and $1.1 million, respectively, to our condensed consolidated statement of operations.

Table of Contents

D. Inventories

Our major classes of inventories were as follows at June 30, 2009 and December 31, 2008, respectively (in thousands):

	June 30, 2009	December 31, 2008
Raw materials	$ 9	$ 9
Work in process	44	57
Finished goods	9	30
Total inventories	$ 62	$ 96

Prior to the June 30, 2009 regulatory approval of *Feraheme*, costs associated with manufacturing process development and the manufacture of drug product were recorded as research and development expenses. Subsequent to approval, costs associated with the manufacture of *Feraheme* to be sold in the U.S. will be capitalized. We review inventories for obsolescence and alternative or future use by reviewing manufacturing plans, future demand, and market conditions. Should we determine that any inventory items have become obsolete, we will record such amounts to cost of product sales.

E. Property, Plant and Equipment

Property, plant and equipment consisted of the following at June 30, 2009 and December 31, 2008, respectively (in thousands):

	June 30, 2009	December 31, 2008
Land	$ 360	$ 360
Buildings and improvements	10,093	9,986
Laboratory equipment	6,243	5,994
Furniture and fixtures	3,648	3,474
Construction in process	595	298
	20,939	20,112
Less- accumulated depreciation	(9,747)	(8,889)
Property, plant and equipment, net	$ 11,192	$ 11,223

F. 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 future enacted 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.

For the six months ended June 30, 2009, we recognized a current federal income tax benefit of $0.2 million 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 February 2009. There were no other income tax provisions or benefits for the three and six months ended June 30, 2009 and 2008 given our continued net operating loss position. Due to the uncertainty surrounding realization of

Table of Contents

favorable tax attributes in future tax returns, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets.

G. 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 June 30,	
	2009	**2008**
Options to purchase shares of common stock	2,704	1,832
Shares of common stock issuable upon the vesting of restricted stock units	225	32
Total	2,929	1,864

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	**2008**	**2009**	**2008**
Net loss	$ (26,454)	$ (17,007)	$ (52,877)	$ (26,308)
Weighted average common shares outstanding	17,038	16,994	17,030	16,982
Net loss per share:				
Basic and diluted	$ (1.55)	$ (1.00)	$ (3.10)	$ (1.55)

H. Equity-Based Compensation

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

On May 5, 2009, our stockholders approved a proposal to amend and restate our 2007 Plan to, among other things, increase the number of shares of our common stock available for issuance thereunder by 600,000 shares. The amendment also replaced a limitation that no more than 600,000 shares in the aggregate could be issued under the 2007 Plan with respect to restricted stock units, restricted stock, stock and similar equity interests in our company with a fungible share reserve whereby the number of shares available for issuance under the 2007 Plan will now be reduced by one share of our common stock issued pursuant to an option or stock appreciation right and by 1.5 shares for each share of our common stock issued pursuant to a restricted stock unit award or other similar equity-based award.

As of June 30, 2009, we have granted options and restricted stock units covering 2,025,831 shares of common stock under our 2007 Plan, of which 178,392 stock options and 6,000 restricted stock units have expired or terminated, and of which 450 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 June 30, 2009 was 1,637,489 and 203,500, respectively. The remaining number of shares available for future grants as of June 30, 2009 was 934,361, not including shares

Table of Contents

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.

As of June 30, 2009, we have granted options and restricted stock units covering 2,182,700 shares of common stock under the 2000 Plan, of which 362,750 stock options and 750 restricted stock units have expired or terminated, and of which stock options and restricted stock units covering 709,645 and 21,750 shares of common stock, respectively, have been exercised. The remaining number of shares underlying outstanding options and restricted stock units pursuant to the 2000 Plan as of June 30, 2009 was 1,066,305 and 21,500, respectively. All outstanding options granted under the 2000 Plan have an exercise price equal to the closing price of our common stock on the grant date. 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 as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Research and development	$ 1,241	$ 883	$ 2,336	$ 1,592
Selling, general and administrative	2,882	2,311	5,289	4,296
Total equity-based compensation expense	$ 4,123	$ 3,194	$ 7,625	$ 5,888

Equity-based compensation expense for the six months ended June 30, 2009 and 2008 included approximately $0.4 million and $1.5 million, respectively, in equity-based compensation expense associated with grants subject to market or performance conditions.

I. Concentration of Credit Risk

Our operations are located solely within the U.S. We are focused principally on developing and manufacturing an IV iron replacement therapeutic agent and novel imaging agents. We perform ongoing credit evaluations of our customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our revenues for the six months ended June 30, 2009 and 2008. No other company accounted for more than 10% of our total revenues for the six months ended June 30, 2009 and 2008.

	Six Months Ended June 30,	
	2009	2008
Bayer Healthcare Pharmaceuticals	52%	37%
Guerbet S.A.	31%	43%
Covidien, Ltd.	17%	16%

20

Table of Contents

A large portion of the revenue attributable to Bayer Healthcare Pharmaceuticals in both periods was the result of previously deferred revenue related to up-front license fees.

Revenues from customers outside of the U.S., principally in Europe, amounted to 31% and 45% of our total revenues for the six months ended June 30, 2009 and 2008, respectively.

J. Recently Issued Accounting Standards and Pronouncements

In June 2009, the FASB issued SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162, or SFAS 168. The FASB Accounting Standards Codification, or the Codification, will be the single source of authoritative nongovernmental U.S. Generally Accepted Accounting Principles, or GAAP. Rules and interpretive releases of the SEC under the authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. SFAS 168 is effective for interim and annual periods ending after September 15, 2009. On the effective date, the Codification will supersede all then-existing non-SEC accounting and reporting standards. All other non-grandfathered non-SEC accounting literature not included in the Codification will become non-authoritative. We do not expect the adoption of the Codification to have a significant impact on our condensed consolidated financial statements.

In June 2009, the FASB issued SFAS No. 167, Amendments to FASB Interpretation No. 46(R), or SFAS 167. SFAS 167 is a revision to FASB Interpretation No. 46 (Revised December 2003), Consolidation of Variable Interest Entities. SFAS 167 changes how a reporting entity determines when an entity that is insufficiently capitalized or is not controlled through voting (or similar rights) should be consolidated. The determination of whether a reporting entity is required to consolidate another entity is based on, among other things, the other entity s purpose and design and the reporting entity s ability to direct the activities of the other entity that most significantly impact the other entity s economic performance. SFAS 167 will require a reporting entity to provide additional disclosures about its involvement with variable interest entities and any significant changes in risk exposure due to that involvement. A reporting entity will be required to disclose how its involvement with a variable interest entity affects the reporting entity s financial statements. SFAS 167 will be effective for fiscal years beginning after November 15, 2009. Early application is not permitted. We do not expect the adoption of SFAS 167 to have a significant impact on our condensed consolidated financial statements.

In June 2009, the FASB issued SFAS No. 166 Accounting for Transfers of Financial Assets, or SFAS 166. SFAS 166 is a revision to FASB Statement No. 140, Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities, and will require more information about transfers of financial assets, including securitization transactions, where entities have continuing exposure to the risks related to transferred financial assets. It eliminates the concept of a qualifying special-purpose entity, changes the requirements for de-recognizing financial assets, and requires additional disclosures. SFAS 166 enhances information reported to users of financial statements by providing greater transparency about transfers of financial assets and an entity s continuing involvement in transferred financial assets. SFAS 166 is effective for fiscal years beginning after November 15, 2009. We do not expect the adoption of SFAS 166 to have a significant impact on our condensed consolidated financial statements.

K. Commitments and Contingencies

We may periodically become subject to legal proceedings and claims arising in connection with on-going business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which we are focused. We are not aware of any material claims against us at June 30, 2009.

Table of Contents

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, 2008.

Except for the historical information contained herein, the matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q, words such as may, will, expect, intend, and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Examples of forward-looking statements contained in this report include statements regarding the following: the progress of our intended development and commercialization of Feraheme *(ferumoxytol) Injection, the design and timing of potential clinical trials for Feraheme we may initiate in indications other than chronic kidney disease such as a broad Phase III clinical development program to treat iron deficiency anemia in a wide range of patient populations and disease states, the potential approval of Feraheme outside of the U.S., future revenues, including expected future Feraheme revenues and revenues under our agreements with Bayer Healthcare Pharmaceuticals and 3SBio Inc., expected research and development expenses and selling, general and administrative expenses, our expectations regarding our dividend and interest income, 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 not subject to settlement right agreements, is temporary and that we will ultimately be able to liquidate our investments without significant loss, our intention to sell our auction rate securities subject to settlement right agreements to UBS AG, 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 the 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 Securities and Exchange Commission to publicly update or revise any such statements to reflect any change in company expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.*

Overview

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 currently manufacture and sell two approved products, Feraheme (ferumoxytol) Injection and GastroMARK®.

On June 30, 2009, *Feraheme* was approved for marketing in the U.S. by the U.S. Food and Drug Administration, or the FDA, for use as an intravenous, or IV, iron replacement therapy for the treatment of iron deficiency anemia, or IDA, in adult patients with chronic kidney disease, or CKD. We will market and sell *Feraheme* through our own commercial organization, consisting of approximately 150 seasoned

Table of Contents

professionals, including an 80-person specialized sales force, an experienced account management and reimbursement team, and a contract nurse team. We began shipping *Feraheme* to our authorized wholesalers and specialty distributors on July 13, 2009. The wholesale acquisition cost of *Feraheme* is $396.78 per 510 milligram vial.

We continue to evaluate our strategy for seeking approval for *Feraheme* as an IV iron replacement therapeutic agent in countries outside of the U.S. The commercial opportunity for *Feraheme* 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, the role of iron in medical treatment protocols and the regulatory requirements of each country. We are also currently evaluating possible strategic alliances and partnerships to assist us in entering attractive foreign markets. For example, in 2008 we entered into a license agreement and a supply agreement with 3SBio Inc., or 3SBio, with respect to the development and commercialization of *Feraheme* as an IV iron replacement therapeutic agent in China.

We also plan to advance our *Feraheme* clinical development program by conducting additional clinical trials to assess *Feraheme* for the treatment of IDA in a broad range of patients, which may include women with abnormal uterine bleeding, or AUB, and patients with cancer and gastrointestinal diseases. We are currently in discussions with the FDA to determine the design of a Phase III clinical development program for *Feraheme* to treat IDA in these broader patient populations and disease states.

In addition to its use for the treatment of IDA, *Feraheme* may also be useful as a vascular enhancing agent in magnetic resonance imaging, or MRI. In August 2008, the FDA granted Fast Track designation to *Feraheme* with respect to its development as a diagnostic agent for vascular-enhanced MRI for the assessment of peripheral arterial disease, or PAD, in patients with CKD. We are currently conducting a 108 patient Phase II study of *Feraheme* in vascular-enhanced MRI for the detection of clinically significant arterial stenosis or occlusion in subjects with intermittent claudication, or leg pain when walking.

GastroMARK, our oral contrast agent used for delineating the bowel in MRI, is approved and marketed in the U.S., Europe, and other countries through our marketing partners. Sales of GastroMARK by our marketing partners have been at their current levels for the last several years, and we do not expect sales of GastroMARK to change materially.

Feridex I.V. ®, our liver contrast agent, had been marketed and sold in the U.S., Europe and other countries for a number of years through our marketing partners. In November 2008, we decided to cease manufacturing *Feridex I.V.* Accordingly, we have terminated all of our agreements with our marketing partners for *Feridex I.V.* throughout the world and do not intend to continue commercializing *Feridex I.V.*

Table of Contents

Results of Operations for the Three Months Ended June 30, 2009 as Compared to the Three Months Ended June 30, 2008

Revenues

Total revenues were $55,000 and $0.5 million for the three months ended June 30, 2009 and 2008, respectively, representing a decrease of approximately 89%. The decrease in revenues was primarily the result of a decrease in license fee revenues and product sales, as discussed below.

Our revenues for the three months ended June 30, 2009 and 2008 consisted of the following (in thousands):

	Three Months Ended June 30,			
	2009	2008	$ Change	% Change
Revenues:				
License fees	$	$ 185	$ (185)	-100%
Royalties	55	89	(34)	-38%
Product sales		212	(212)	-100%
Total	$ 55	$ 486	$ (431)	-89%

The following table sets forth customers who represented 10% or more of our revenues for the three months ended June 30, 2009 and 2008. No other company accounted for more than 10% of our total revenues in either period.

	Three Months Ended June 30,	
	2009	2008
Covidien, Ltd.	74%	29%
Bayer Healthcare Pharmaceuticals	26%	46%
Guerbet S.A.	0%	16%

License Fee Revenues

There were no license fee revenues and $0.2 million of license fee revenues for the three months ended June 30, 2009 and 2008, respectively. The license fee revenues for the three months ended June 30, 2008 consisted solely of deferred revenues that were being amortized in connection with our agreements with Bayer Healthcare Pharmaceuticals, or Bayer, which were terminated in November 2008.

In 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 connection with our decision to cease manufacturing *Feridex I.V.*, the Bayer Agreements were terminated in November 2008 by mutual agreement. Prior to the termination of the Bayer Agreements, we accounted for the revenues associated with the Bayer Agreements on a straight line basis over their 15 year contract term. Pursuant to the

termination agreement, Bayer could continue to sell any remaining *Feridex I.V.* inventory in its possession through April 1, 2009, and other than royalties owed by Bayer to us on such sales, no further obligation exists by either party. As a result of the termination of these agreements, we do not expect any additional license fee revenues from Bayer.

Table of Contents

In May 2008, we entered into a Collaboration and Exclusive License Agreement with 3SBio with respect to the development and commercialization of *Feraheme* as an IV iron replacement therapeutic agent in China. In consideration of the grant of the license, we received an up-front payment of $1.0 million, the recognition of which has been deferred and is being recognized under the proportional performance methodology as we supply *Feraheme* to 3SBio over the thirteen-year initial term of the agreement. We do not expect license revenues under our agreement with 3SBio to be significant in 2009.

Product Sale Revenues

Product sale revenues for the three months ended June 30, 2009 and 2008 consisted of the following (in thousands):

	Three Months Ended June 30,			
	2009	**2008**	**$ Change**	**% Change**
GastroMARK	$	$ 160	$ (160)	-100%
Feridex I.V.		32	(32)	-100%
Other		20	(20)	-100%
Total	$	$ 212	$ (212)	-100%

There were no product sale revenues for the three months ended June 30, 2009 and $0.2 million of product sale revenues for the three months ended June 30, 2008, primarily reflecting a decrease in sales of *GastroMARK*. For certain of our products, product sales may fluctuate from period to period as a result of 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. As a result of FDA approval of *Feraheme* on June 30, 2009, we expect our product sales revenues to increase for the remainder of 2009 and to be principally comprised of *Feraheme* sales.

Costs and Expenses

Cost of Product Sales

We incurred no costs associated with product sales during the three months ended June 30, 2009 and approximately $31,000 of costs associated with product sales, or 15% of product sales, during the three months ended June 30, 2008. The cost of our product sales, and therefore our gross margins, is dependent on the mix of customers, prices we charge for our products, product mix, changes in unit volume and production efficiencies, none of which had a material impact during the three months ended June 30, 2009 or 2008. Our cost of product sales is expected to increase for the remainder of 2009 as a result of FDA approval of *Feraheme* on June 30, 2009.

Research and Development Expenses

Research and development expenses include external expenses, such as commercial manufacturing preparation and related materials costs, costs of clinical trials, contract research and development expenses, consulting and professional fees and expenses, and internal expenses, such as compensation of employees engaged in research and development activities, the manufacture of product needed to support research and development efforts, related costs of facilities, and other general costs related to research and development. To the extent that external costs are not attributable to a specific major project or activity, they are included

Table of Contents

in other external costs. Prior to the June 30, 2009 regulatory approval of *Feraheme*, costs associated with manufacturing process development and the manufacture of drug product were recorded as research and development expenses. Subsequent to approval, costs associated with the manufacture of *Feraheme* to be sold in the U.S. will be capitalized.

Research and development expenses for the three months ended June 30, 2009 and 2008 consisted of the following (in thousands):

	Three Months Ended June 30, 2009	2008	$ Change	% Change
External Research and Development Expenses				
Feraheme as an IV iron replacement therapeutic agent	$ 1,704	$ 598	$ 1,106	>100%
Feraheme as an imaging agent in PAD patients	499	571	(72)	-13%
Feraheme manufacturing and materials	859	1,128	(269)	-24%
Other external costs	126	300	(174)	-58%
Total	$ 3,188	$ 2,597	$ 591	23%
Internal Research and Development Expenses				
Compensation, payroll taxes, benefits and other expenses	5,685	3,581	2,104	59%
Equity-based compensation expense	1,241	883	358	41%
Total	$ 6,926	$ 4,464	$ 2,462	55%
Total Research and Development Expenses	$ 10,114	$ 7,061	$ 3,053	43%

Total research and development expenses incurred in the three months ended June 30, 2009 amounted to $10.1 million, an increase of $3.1 million, or 43%, from the three months ended June 30, 2008. The $3.1 million increase was primarily attributable to costs associated with increased headcount, activities necessary to address the manufacturing observations noted during the 2008 FDA inspection of our Cambridge, Massachusetts manufacturing facility, preparation for commercial scale manufacturing of *Feraheme*, and costs associated with our clinical development programs in indications other than CKD.

Our external research and development expenses increased by $0.6 million, or 23%, for the three months ended June 30, 2009 as compared to the three months ended June 30, 2008. The $0.6 million increase in our external expenses was due primarily to costs associated with our efforts to address the manufacturing observations noted by the FDA during the 2008 inspection of our Cambridge, Massachusetts manufacturing facility, costs associated with second source manufacturing and other activities related to preparation for commercial scale manufacturing partially offset by a slight decrease in costs incurred with respect to production materials and supplies and our clinical development programs.

Our internal research and development expenses increased by $2.5 million, or 55%, for the three months ended June 30, 2009 as compared to the three months ended June 30, 2008. The $2.5 million increase in internal costs was due primarily to higher compensation and benefit costs as a result of additional research and development personnel hired as we expanded our development infrastructure and scaled up our manufacturing capabilities for the U.S. commercialization of *Feraheme*. At June 30, 2009, we had 100 employees in research and development as compared to 70 employees at June 30, 2008, an increase of 43%.

Table of Contents

The $0.4 million increase in equity-based compensation expense was primarily attributable to increased equity awards to both new and existing employees.

We expect research and development expenses to decrease for the remainder of 2009 primarily as a result of FDA approval of *Feraheme* on June 30, 2009 and our capitalization of certain *Feraheme* materials and manufacturing related costs which will be partially offset by costs associated with the advancement and initiation of new clinical development programs and other research and development related functions and activities in support of *Feraheme.*

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 New Drug Application, or NDA, submission to the FDA with respect to such project.

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 additional indications for *Feraheme*, 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 also vary significantly depending on the nature of the product candidate, the design of the clinical study, 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. While we are currently focused on the U.S. commercial launch of *Feraheme* 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 our continuing discussions with the FDA regarding our proposed protocols and study designs, 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 *Feraheme* as an estimation of completion dates would be highly speculative and subject to a number of risks and uncertainties.

Table of Contents

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended June 30, 2009 and 2008 consisted of the following (in thousands):

	Three Months Ended June 30,			
	2009	2008	$ Change	% Change
Compensation, payroll taxes and benefits	$ 8,074	$ 3,083	$ 4,991	>100%
Professional and consulting fees and other expenses	6,312	7,217	(905)	-13%
Equity-based compensation expense	2,882	2,311	571	25%
Total	$ 17,268	$ 12,611	$ 4,657	37%

The $4.7 million, or 37%, increase in selling, general and administrative expenses for the three months ended June 30, 2009 as compared to the three months ended June 30, 2008 was due primarily to increased costs associated with the expansion of our commercial operations function and our general administrative infrastructure, including compensation and benefits costs related to increased headcount. Professional and consulting fees and other expenses decreased as the result of a decrease in marketing and other consulting costs due to the delay in the U.S. commercial launch of *Feraheme,* partially offset by increased costs related to field force activities. At June 30, 2009, we had 174 employees in our selling, general and administrative departments as compared to 62 employees at June 30, 2008, an increase of 181%. The $0.6 million increase in equity-based compensation expense in the three months ended June 30, 2009 as compared to the three months ended June 30, 2008 was primarily attributable to increased equity awards to both new and existing employees.

With the recent FDA approval of *Feraheme,* we expect selling, general and administrative expenses to continue to increase during the remainder of 2009 as the result of costs associated with executing our post-approval *Feraheme* marketing and promotional programs, building and maintaining our administrative infrastructure to support the commercialization of *Feraheme*, and the continued use of consultants during the U.S. launch of *Feraheme*.

Other Income (Expense)

Other income (expense) for the three months ended June 30, 2009 and 2008 consisted of the following (in thousands):

	Three Months Ended June 30,			
	2009	2008	$ Change	% Change
Interest and dividend income, net	$ 783	$ 2,198	$ (1,415)	-64%
Gains on investments, net	275	12	263	>100%
Fair value adjustment of settlement rights	(185)		(185)	N/A
Total	$ 873	$ 2,210	$ (1,337)	-60%

The $1.3 million, or 60%, decrease in other income (expense) for the three months ended June 30, 2009, as compared to the three months ended June 30, 2008 was primarily attributable to a $1.4 million decrease in interest and dividend income as the result of a lower average amount of invested funds and

28

Table of Contents

lower interest rates in the three months ended June 30, 2009 as compared to the three months ended June 30, 2008.

In November 2008, we elected to participate in a rights offering, or the Settlement Rights, by UBS AG, or UBS, one of our securities brokers, which provides us with the right to sell to UBS $9.3 million in par value of our auction rate securities, or ARS, portfolio, at par value, at any time during a two-year sale period beginning June 30, 2010. As a result of the lack of either quoted market prices or other observable market data, we estimate the value of our ARS and Settlement Rights using discounted cash flow analyses using Level 3 inputs as defined by Statement of Financial Accounting Standards, or SFAS, No. 157 Fair Value Measurements, or SFAS 157. We have elected the SFAS 159 The Fair Value Option for Financial Assets and Financial Liabilities - Including an Amendment of FASB Statement No. 115, or SFAS 159, fair value option with respect to the Settlement Rights, and as of June 30, 2009, we have recorded an asset equal to our estimated fair value of the Settlement Rights of approximately $0.5 million in our condensed consolidated balance sheet. This represents a decrease of approximately $0.2 million to the estimated fair value of our Settlement Rights from the estimated fair value at March 31, 2009, which we have recorded in other income (expense) in our condensed consolidated statement of operations. In addition, with the opportunity provided by the Settlement Rights, we have designated the ARS subject to the Settlement Rights with a par value of $9.3 million and an estimated fair value of $8.8 million as of June 30, 2009 as trading securities. Accordingly, as of June 30, 2009, we have adjusted our estimated value of these trading securities by approximately $0.2 million from the estimated value at March 31, 2009, which we have recorded as a gain on investments in other income (expense) in our condensed consolidated statement of operations.

We expect interest and dividend income to continue to decrease in 2009 as a result of declining interest rates due to the current economic climate coupled with declining cash and investments balances as a result of expected expenditures related to the commercial, clinical, and manufacturing activities noted above. We are required to assess the fair value of both the Settlement Rights and our ARS subject to Settlement Rights and record changes each period until the Settlement Rights are exercised or our ARS subject to Settlement Rights are redeemed. Although the Settlement Rights represent the right to sell the securities back to UBS at par, we are required to periodically assess the ability of UBS to meet that obligation in assessing the fair value of the Settlement Rights.

Net Loss

For the reasons stated above, we incurred a net loss of $26.5 million, or $1.55 per basic and diluted share, for the three months ended June 30, 2009 compared to a net loss of $17.0 million, or $1.00 per basic and diluted share, for the three months ended June 30, 2008.

Table of Contents

Results of Operations for the Six Months Ended June 30, 2009 as Compared to the Six Months Ended June 30, 2008

Revenues

Total revenues were $1.0 million and $1.1 million for the six months ended June 30, 2009 and 2008, respectively, representing a decrease of approximately 8%. The decrease in revenues was due primarily to a decrease in product sales, partially offset by an increase in license fee revenues.

Our revenues for the six months ended June 30, 2009 and 2008 consisted of the following (in thousands):

	Six Months Ended June 30,			
	2009	2008	$ Change	% Change
Revenues:				
License fees	$ 516	$ 369	$ 147	40%
Royalties	102	125	(23)	-18%
Product sales	393	604	(211)	-35%
Total	$ 1,011	$ 1,098	$ (87)	-8%

The following table sets forth customers who represented 10% or more of our revenues for the six months ended June 30, 2009 and 2008. No other company accounted for more than 10% of our total revenues in either period.

	Six Months Ended June 30,	
	2009	2008
Bayer Healthcare Pharmaceuticals	52%	37%
Guerbet S.A.	31%	43%
Covidien, Ltd.	17%	16%

License Fee Revenues

Our license fee revenues of $0.5 million and $0.4 million for the six months ended June 30, 2009 and 2008, respectively, consisted solely of deferred license fee revenues that were being amortized in connection with our agreements with Bayer, which were terminated in November 2008.

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 connection with our decision to cease manufacturing Feridex I.V., the Bayer Agreements were terminated in November 2008 by mutual agreement. Prior to the termination of the Bayer Agreements, we accounted for the revenues associated with the Bayer Agreements on a straight line basis over their 15 year contract term. Pursuant to the termination agreement, Bayer could continue to sell

any remaining Feridex I.V. inventory in its possession through April 1, 2009, and other than royalties owed by Bayer to us on such sales, no further obligation exists by either party. As a result of the termination of these agreements, during the six months ended June 30, 2009 we recognized the remaining $0.5 million of deferred revenues under the Bayer Agreements, and we do not expect any additional license fee revenues from Bayer during the remainder of 2009.

Table of Contents

Product Sale Revenues

Product sale revenues for the six months ended June 30, 2009 and 2008 consisted of the following (in thousands):

	Six Months Ended June 30,			
	2009	**2008**	**$ Change**	**% Change**
GastroMARK	$ 393	$ 317	$ 76	24%
Feridex I.V.		267	(267)	-100%
Other		20	(20)	-100%
Total	$ 393	$ 604	$ (211)	-35%

The $0.2 million decrease in total product sale revenues for the six months ended June 30, 2009 as compared to the six months ended June 30, 2008 was primarily the result of a decrease in sales of *Feridex I.V.* due to our November 2008 decision to cease the manufacture and commercialization of *Feridex I.V.,* partially offset by an increase in sales of *GastroMARK* to our marketing partners. Product sales may fluctuate from period to period. Fluctuations in certain of 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.

Costs and Expenses

Cost of Product Sales

We incurred $61,000 and $75,000 of costs associated with product sales during the six months ended June 30, 2009 and 2008, respectively. This constituted approximately 16% and 12% of product sales during the six months ended June 30, 2009 and 2008, respectively. The cost of our 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, none of which had a material impact during the six months ended June 30, 2009 or 2008.

Table of Contents

Research and Development Expenses

Research and development expenses for the six months ended June 30, 2009 and 2008 consisted of the following (in thousands):

	Six Months Ended June 30, 2009	2008	$ Change	% Change
External Research and Development Expenses				
Feraheme as an IV iron replacement therapeutic agent in CKD patients	$ 3,350	$ 317	$ 3,033	>100%
Feraheme as an IV iron replacement therapeutic agent in AUB patients	1,131	461	670	>100%
Feraheme as an imaging agent in PAD patients	822	571	251	44%
Feraheme manufacturing and materials	1,991	1,704	287	17%
Other external costs	324	527	(203)	-39%
Total	$ 7,618	$ 3,580	$ 4,038	>100%
Internal Research and Development Expenses				
Compensation, payroll taxes, benefits and other expenses	11,232	6,712	4,520	67%
Equity-based compensation expense	2,336	1,592	744	47%
Total	$ 13,568	$ 8,304	$ 5,264	63%
Total Research and Development Expenses	$ 21,186	$ 11,884	$ 9,302	78%

Total research and development expenses of $21.2 million for the six months ended June 30, 2009 increased by $9.3 million as compared to total research and development expenses of $11.9 million for the six months ended June 30, 2008. Our external research and development expenses increased by $4.0 million, or by more than 100%, primarily due to costs associated with our efforts to address the manufacturing observations noted by the FDA during the 2008 inspection of our Cambridge, Massachusetts manufacturing facility, costs incurred with respect to production materials and supplies, costs associated with second source manufacturing and other activities related to preparation for commercial scale manufacturing and spending on our clinical development programs for *Feraheme* for the treatment of patients with AUB and PAD. Our internal costs increased by $5.3 million, or 63%, due primarily to higher compensation and benefit costs as a result of additional research and development personnel hired as we expanded our development infrastructure and scaled-up our manufacturing capabilities in preparation for the U.S. commercial launch of *Feraheme*. At June 30, 2009, we had 100 employees in research and development as compared to 70 employees at June 30, 2008, an increase of 43%. The $0.7 million increase in equity-based compensation expense was primarily attributable to increased stock option grants to both new and existing employees.

During 2008, we began incurring costs related to our intended *Feraheme* clinical development program in patients with AUB. However, following discussions with the FDA regarding the proposed design of our Phase III oncology program, during the first quarter of 2009 we decided to pursue a broad Phase III clinical development program for the treatment of IDA in a wide range of patient populations and disease states rather than pursue individual indications, such as AUB or oncology. As a result, we did not begin enrollment in our previously planned Phase III studies of *Feraheme* in women with IDA and AUB and did not advance our plans for a separate Phase III clinical development program for *Feraheme* in patients with IDA and cancer. Subsequent to the first quarter of 2009, we did not incur any costs associated with the AUB clinical development program and do not expect to incur any significant additional future costs associated with the AUB clinical development program but expect that we will

Table of Contents

begin to incur costs in future quarters associated with our broader IDA clinical program. The study designs and timelines for the initiation of a broader Phase III clinical development program for *Feraheme* for the treatment of IDA are currently in progress and subject to the completion of discussions with the FDA and final protocol review.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the six months ended June 30, 2009 and 2008 consisted of the following (in thousands):

	Six Months Ended June 30,			
	2009	2008	$ Change	% Change
Compensation, payroll taxes and benefits	$ 16,494	$ 5,632	$ 10,862	>100%
Professional and consulting fees and other expenses	13,235	11,068	2,167	20%
Equity-based compensation expense	5,289	4,296	993	23%
Total	$ 35,018	$ 20,996	$ 14,022	67%

The $14.0 million increase in selling, general and administrative expenses for the six months ended June 30, 2009 as compared to the six months ended June 30, 2008 was due primarily to increased costs associated with the expansion of our commercial operations function, including compensation and benefits costs related to increased headcount, consulting costs related to preparation for the U.S. commercial launch of *Feraheme*, and the expansion of our general administrative infrastructure. At June 30, 2009, we had 174 employees in our selling, general and administrative departments as compared to 62 employees at June 30, 2008, an increase of 181%. The $1.0 million increase in equity-based compensation expense was primarily attributable to increased stock option grants associated with new and existing employees.

Other Income (Expense)

Other income (expense) for the six months ended June 30, 2009 and 2008 consisted of the following (in thousands):

	Six Months Ended June 30,			
	2009	2008	$ Change	% Change
Interest and dividend income, net	$ 2,039	$ 5,465	$ (3,426)	-63%
Gains on investments, net	1,267	84	1,183	>100%
Fair value adjustment of settlement rights	(1,108)		(1,108)	N/A
Total	$ 2,198	$ 5,549	$ (3,351)	-60%

The $3.4 million decrease in other income (expense) for the six months ended June 30, 2009, as compared to the six months ended June 30, 2008 was primarily attributable to a $3.4 million decrease in interest and dividend income as the result of a lower average amount of invested funds and lower interest rates in the six months ended June 30, 2009 as compared to the six months ended June 30, 2008.

In November 2008, we elected to participate in a rights offering by UBS which provides us with the right to sell to UBS $9.3 million in par value of our ARS portfolio, at par value, at any time during a two-

Table of Contents

year sale period beginning June 30, 2010. As a result of the lack of either quoted market prices or other observable market data, we estimate the value of our ARS and Settlement Rights using discounted cash flow analyses using Level 3 inputs as defined by SFAS 157. We have elected the SFAS 159 fair value option with respect to the Settlement Rights, and as of June 30, 2009, we have recorded an asset equal to our estimated fair value of the Settlement Rights of approximately $0.5 million in our condensed consolidated balance sheet. This represents a decrease of approximately $1.1 million to the estimated fair value of our Settlement Rights from the estimated fair value at December 31, 2008, which we have recorded in other income (expense) in our condensed consolidated statement of operations. In addition, with the opportunity provided by the Settlement Rights, we have designated the ARS subject to the Settlement Rights with a par value of $9.3 million and an estimated fair value of $8.8 million as of June 30, 2009 as trading securities. Accordingly, as of June 30, 2009, we have adjusted our estimated value of these trading securities by approximately $1.2 million from the estimated value at December 31, 2008, which we have recorded as a gain on investments in other income (expense) in our condensed consolidated statement of operations.

Net Loss

For the reasons stated above, we incurred a net loss of $52.9 million, or $3.10 per basic and diluted share, for the six months ended June 30, 2009 compared to a net loss of $26.3 million, or $1.55 per basic and diluted share, for the six months ended June 30, 2008.

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 commercialize *Feraheme* in the U.S. as an IV iron replacement therapeutic agent;

- The timing and magnitude of revenues from sales of *Feraheme*;

- Costs associated with the U.S. commercial launch of *Feraheme,* including costs associated with maintaining our commercial infrastructure and executing our promotional and marketing strategy for *Feraheme*;

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

- Our ability to liquidate our investments in ARS 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;

Table of Contents

- Costs associated with our development of additional indications for *Feraheme*;

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

- Costs associated with our pursuit of approval for *Feraheme* 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.

As of June 30, 2009, 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 June 30, 2009, we held a total of $58.9 million in fair market value of ARS, reflecting an impairment of approximately $7.4 million compared to the par value of these securities of $66.3 million. Of the $7.4 million impairment, approximately $6.9 million is considered a temporary impairment and is reported as an unrealized loss at June 30, 2009. The remaining $0.5 million represents an impairment associated with our UBS ARS, which are described below, and has been recognized in our condensed consolidated statement of operations, reducing our UBS ARS from a par value of $9.3 million to a new cost basis of $8.8 million. The substantial majority of our ARS portfolio was rated AAA as of June 30, 2009 by at least one of the major securities rating agencies, and greater than 90% of our ARS were collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program.

In November 2008, we elected to participate in a rights offering by UBS which provides us with the right to sell to UBS $9.3 million in par value of our ARS portfolio, at par value, at any time during a two-year sale period beginning June 30, 2010. By electing to participate in the rights offering, we granted UBS the right, exercisable at any time prior to June 30, 2010 or during the two-year sale period, to purchase or cause the sale of our ARS at par value, or the Call Right. UBS has stated that it will only exercise the Call Right for the purpose of restructurings, dispositions or other solutions that will provide its clients with par value for their ARS. UBS has agreed to pay its clients the par value of their ARS within one day of settlement of any Call Right transaction. Notwithstanding the Call Right, we are permitted to sell the ARS to parties other than UBS, which would extinguish the Settlement Rights attached to such ARS. Although the Settlement Rights represent the right to sell the securities back to UBS at par, we are required to periodically assess the ability of UBS to meet that obligation in assessing the fair value of the Settlement Rights.

We believe that the $6.9 million temporary impairment related to our ARS not subject to Settlement Rights 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. If we determine that any future unrealized loss is

Table of Contents

other-than-temporary, we will record a charge to our condensed consolidated statement of operations. 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 the majority have final maturity dates of 30 to 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 our ARS. However, it could take until final maturity of our ARS to realize the investments par value.

Based on our ability to access our cash, cash equivalents, and short-term investments, coupled with the cash we currently expect to receive from sales of *Feraheme*, 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 over at least the next twelve months, however, we are uncertain when the current liquidity issues relating to ARS will improve, if at all.

Our cash and cash equivalents, which consisted principally of cash held in commercial bank accounts and money market funds, and investments at June 30, 2009 and December 31, 2008 consisted of the following (in thousands):

	June 30, 2009	December 31, 2008	$ Change	% Change
Cash and cash equivalents	$ 70,226	$ 64,182	$ 6,044	9%
Short-term investments	54,985	94,914	(39,929)	-42%
Long-term investments	50,097	54,335	(4,238)	-8%
Total cash, cash equivalents and investments	$ 175,308	$ 213,431	$ (38,123)	-18%

The $38.1 million decrease in cash and cash equivalents and investments as of June 30, 2009 as compared to December 31, 2008 is primarily the result of cash used in operations, partially offset by the net impact of unrealized and realized gains and losses on our investments and by interest income.

As of June 30, 2009, we believe that our cash, cash equivalents, and short-term investments, combined with cash we currently expect to receive from sales of *Feraheme* and earnings on our investments, will be sufficient to satisfy our future cash flow needs for at least the next twelve months.

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. 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 six months ended June 30, 2009, our use of $42.8 million of cash in operations was due principally to our net loss of approximately $52.9 million, partially offset by approximately $8.7 million in equity-based compensation and other non-cash expenses. Our net loss is the

result of revenues of approximately $1.0 million offset by compensation and other expenses associated with additional employees hired for research and development and commercial operating activities, payments for pre-commercialization activities in anticipation of the U.S. commercial launch of *Feraheme* as an IV iron

Table of Contents

replacement therapeutic agent, and general and administrative costs associated with clinical trials in indications other than CKD.

We anticipate cash used in operating activities will increase for the remainder of 2009 over current levels as we incur costs related to our U.S. commercial launch of *Feraheme*, incur additional costs associated with our clinical trials and development of new indications for *Feraheme* in the U.S., continue our expansion of our commercial, clinical, medical, regulatory, development, finance and manufacturing organizations in support of our *Feraheme* launch, and continue our efforts to build commercial inventory and qualify second source suppliers and manufacturers for *Feraheme*. The actual amount of these expenditures will depend on numerous factors, including the timing of revenues and expenses associated with the commercialization and sales of *Feraheme* and the timing and progress of our development efforts for *Feraheme* in indications other than CKD.

Cash flows from investing activities

Cash provided by investing activities was $48.0 million during the six months ended June 30, 2009 and was primarily attributable to net proceeds from sales and maturities of our investments.

Cash flows from financing activities

Cash provided by financing activities was $0.8 million during the six months ended June 30, 2009 and was attributable to the proceeds from the issuance of common stock under our Employee Stock Purchase Plan as well as proceeds from the exercise of stock options.

Contractual Obligations

There have been no material changes to our contractual obligations since December 31, 2008.

Off-Balance Sheet Arrangements

As of June 30, 2009, 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 revenues and expenses during the reported period. The most significant estimates and assumptions are used in, but are not limited to, assessing investments for potential impairment and determining values of investments, accrued expenses, income taxes and equity-based compensation expense. Actual results could differ materially from those estimates. 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, 2008, and, although our critical accounting policies have not changed, given our adoption of FSP 115-2 and FSP 124-2 on April 1, 2009, for debt securities with a decline in fair value below amortized cost basis, we evaluate whether an other-than-temporary impairment exists if (i) we have the intent to sell the security or (ii) it is more likely than not that we will be required to sell the security

Table of Contents

prior to recovery of its amortized cost basis. If either of these conditions is met, we recognize the difference between the amortized cost of the security and its fair value at the impairment measurement date in our consolidated statement of operations. If neither of these conditions is met, we must perform additional analyses to evaluate whether there could be a credit loss associated with the security. Factors we consider include, but are not limited to: (i) the extent to which market value is less than the cost basis; (ii) the length of time that the market value has been less than cost; (iii) whether the unrealized loss is event-driven, credit-driven or a result of changes in market interest rates or risk premium; (iv) the investment s rating and whether the investment is investment-grade and/or has been downgraded since its purchase; (v) whether the issuer is current on all payments in accordance with the contractual terms of the investment and is expected to meet all of its obligations under the terms of the investment; (vi) any underlying collateral and the extent to which the recoverability of the carrying value of our investment may be affected by changes in such collateral; (vii) unfavorable changes in expected cash flows and (viii) other subjective factors. If we determine from this analysis that we do not expect to receive cash flows sufficient to recover the entire amortized cost of the security, a credit loss exists, and the impairment is considered other-than-temporary and recognized in our condensed consolidated statement of operations. Our assessment of whether unrealized losses are other-than-temporary requires significant judgment.

Impact of Recently Issued Accounting Standards and Pronouncements

In June 2009, the Financial Accounting Standards Board, or FASB, issued SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162, or SFAS 168. The FASB Accounting Standards Codification, or the Codification, will be the single source of authoritative nongovernmental U.S. Generally Accepted Accounting Principles, or GAAP. Rules and interpretive releases of the Securities and Exchange Commission, or SEC, under the authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. SFAS 168 is effective for interim and annual periods ending after September 15, 2009. On the effective date, the Codification will supersede all then-existing non-SEC accounting and reporting standards. All other non-grandfathered non-SEC accounting literature not included in the Codification will become non-authoritative. We do not expect the adoption of the Codification to have a significant impact on our condensed consolidated financial statements.

In June 2009, the FASB issued SFAS No. 167, Amendments to FASB Interpretation No. 46(R), or SFAS 167. SFAS 167 is a revision to FASB Interpretation No. 46 (Revised December 2003), Consolidation of Variable Interest Entities. SFAS 167 changes how a reporting entity determines when an entity that is insufficiently capitalized or is not controlled through voting (or similar rights) should be consolidated. The determination of whether a reporting entity is required to consolidate another entity is based on, among other things, the other entity s purpose and design and the reporting entity s ability to direct the activities of the other entity that most significantly impact the other entity s economic performance. SFAS 167 will require a reporting entity to provide additional disclosures about its involvement with variable interest entities and any significant changes in risk exposure due to that involvement. A reporting entity will be required to disclose how its involvement with a variable interest entity affects the reporting entity s financial statements. SFAS 167 will be effective for fiscal years beginning after November 15, 2009. Early application is not permitted. We do not expect the adoption of SFAS 167 to have a significant impact on our condensed consolidated financial statements.

In June 2009, the FASB issued SFAS No. 166 Accounting for Transfers of Financial Assets, or SFAS 166. SFAS 166 is a revision to FASB Statement No. 140, Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities, and will require more information about transfers of

Table of Contents

financial assets, including securitization transactions, where entities have continuing exposure to the risks related to transferred financial assets. It eliminates the concept of a qualifying special-purpose entity, changes the requirements for de-recognizing financial assets, and requires additional disclosures. SFAS 166 enhances information reported to users of financial statements by providing greater transparency about transfers of financial assets and an entity s continuing involvement in transferred financial assets. SFAS 166 is effective for fiscal years beginning after November 15, 2009. We do not expect the adoption of SFAS 166 to have a significant impact on our condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As of June 30, 2009, our short- and long-term investments totaled $105.1 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 June 30, 2009, this would have resulted in a hypothetical decline in fair value of our investments, excluding ARS, which are described below, of approximately $0.1 million.

At June 30, 2009, we held a total of $58.9 million in fair market value of ARS, reflecting an impairment of approximately $7.4 million compared to the par value of these securities of $66.3 million. In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions. As a result of the lack of observable ARS 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 analysis considers, 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, credit ratings of the security by the major securities rating agencies, 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 a $6.9 million unrealized loss related to our ARS, other than those subject to Settlement Rights, to accumulated other comprehensive loss as of June 30, 2009. In November 2008, we elected to participate in a rights offering by UBS which provides us with rights to sell to UBS $9.3 million in par value of our ARS portfolio, at par value, at any time during a two-year sale period beginning June 30, 2010.

We believe there are several significant assumptions that are utilized in our valuation analysis, the two most critical of which are the discount rate and the average expected term. Holding all other factors constant, if we were to increase the discount rate utilized in our valuation analysis by 50 basis points, or one-half of a percentage point, this change would have the effect of reducing the fair value of our ARS by approximately $1.3 million as of June 30, 2009. 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 $1.4 million as of June 30, 2009.

Item 4. Controls and Procedures.

Managements Evaluation of our Disclosure Controls and Procedures

Our principal executive officer and 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

Table of Contents

Exchange Act, Rule 13a-15(e) or Rule 15d-15(e), with the participation of our management, have each concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective and were 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 Securities and Exchange Commission 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 each concluded that our disclosure controls and procedures as of the end of the period covered by this report 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 six months ended June 30, 2009 that materially affected, or that 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 Feraheme.

Our ability to generate future revenues is solely dependent on our successful commercialization and development of *Feraheme.* We currently sell only one other product, *GastroMARK*, in the U.S. and in certain foreign jurisdictions. However, sales of *GastroMARK* have been at their current levels for the last several years, and we do not expect sales of *GastroMARK* to materially increase. Accordingly, if we are unable to generate sufficient revenues from sales of *Feraheme*, we may never be profitable, our financial condition will be materially adversely affected, and our business prospects will be limited.

We intend to dedicate significant resources to our *Feraheme* development efforts; however, we may not be successful in developing new applications for *Feraheme* or expanding the potential indications for *Feraheme*. Although we have commenced and are pursuing additional clinical trials for *Feraheme* in indications other than CKD, we are not currently conducting or sponsoring research to expand our product development pipeline beyond *Feraheme* and therefore our revenues and operations will not be diversified as some of our competitors which have multiple products or product candidates. Any failure by us to acquire, develop and commercialize additional products and product candidates or additional indications for *Feraheme* could limit long-term shareholder value and would adversely affect the future prospects of our

business.

Table of Contents

We may not be able to operate our manufacturing facility in compliance with current good manufacturing practices, or cGMP, and other FDA regulations, which could result in a suspension of our ability to manufacture Feraheme, the loss of our Feraheme inventory, our inability to manufacture sufficient quantities of Feraheme to meet demand, or other unanticipated compliance costs.

Our Cambridge, Massachusetts manufacturing facility is subject to cGMP regulations enforced by the FDA through periodic inspections to confirm such compliance. We must continually expend time, money and effort in production, record-keeping and quality assurance and control to ensure that our manufacturing facility meets the FDA s regulatory requirements. Failure to maintain ongoing compliance with cGMP regulations and other applicable manufacturing requirements of various regulatory agencies could result in the FDA s issuance of warning letters, fines, the withdrawal or recall of *Feraheme* from the marketplace, total or partial suspension of *Feraheme* production, the loss of our *Feraheme* inventory, suspension of the FDA s review of any future supplemental NDAs, enforcement actions, injunctions or criminal prosecution. If the FDA inspects our manufacturing facility and determines that we are not in compliance with cGMP regulations or we otherwise determine that we are not in compliance with cGMP regulations, we could experience an inability to manufacture sufficient quantities of *Feraheme* to meet demand or could incur unanticipated compliance expenditures, either of which would have an adverse impact on our potential profitability and the future prospects of our business.

We currently manufacture Feraheme at one manufacturing facility without a qualified second source manufacturer, and if we experience any difficulties, disruptions or delays in the manufacturing process, we may not be able to produce sufficient quantities of Feraheme to meet commercial demand or continue our Feraheme development efforts.

We currently manufacture *Feraheme* for commercial use and for use in human clinical trials in our Cambridge, Massachusetts manufacturing facility. Although we are working to establish and qualify second source manufacturing facilities for *Feraheme*, we currently have only one facility at which we produce *Feraheme*. Our ability to manufacture *Feraheme* in sufficient quantities to meet commercial demand and our clinical development needs at acceptable costs is dependent on the uninterrupted and efficient operation of our manufacturing facility. If there are any difficulties, disruptions or delays in the *Feraheme* manufacturing process, including quality control problems, we may experience manufacturing failures which could result in product defects or shipment delays, recall or withdrawal of products previously shipped for commercial or clinical purposes, inventory write-offs or the inability to meet commercial demand for *Feraheme* in a timely and cost-effective manner. In addition, as we manufacture *Feraheme* for commercial sale, we could experience higher than anticipated material, labor and overhead costs per unit which would impair our profitability. Furthermore, if we fail to continue to attract and retain key members of our manufacturing or quality control departments, we may be unable to manufacture sufficient quantities of *Feraheme* in a timely manner, which could delay or impair our product sales and development efforts.

If we cannot produce sufficient quantities of Feraheme at our manufacturing facility, we will need to rely on third party manufacturers, which may expose us to a number of risks.

If we are unable to produce sufficient quantities of *Feraheme* to meet demand or we experience any manufacturing difficulties at our Cambridge, Massachusetts manufacturing facility, we will be required to enter into arrangements with third-party manufacturers. We are currently working to establish and qualify second source manufacturing facilities for *Feraheme*, however we may not be able to enter into agreements with manufacturers whose facilities and procedures comply with cGMP regulations and other regulatory requirements on terms that are favorable to us, if at all. Even if we were to reach agreement, the transition of the manufacturing process to a third party could take a significant amount of time. Any prolonged interruption in our manufacturing operations could result in cancellations of orders or loss of product in the

Table of Contents

manufacturing process. Furthermore, use of second-source manufacturing facilities may increase the risk of certain problems, including cost overruns, process reproducibility, stability issues, the inability to deliver required quantities of product that conform to specifications in a timely manner, or the inability to manufacture *Feraheme* in accordance with cGMP. 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 commercial demand and our clinical development needs for *Feraheme*. As a result, we may lose sales and fail to generate increased revenues and our clinical development programs may be delayed, which could have an 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 Feraheme, which would have a severe adverse impact on our business.

We currently purchase certain raw materials used to manufacture *Feraheme* 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 *Feraheme* or otherwise fail to supply these raw materials to us or fail to supply these raw materials to us in sufficient quantities for a number of reasons, including but not limited to the following:

- Unexpected demand for or shortage of 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.

If any of our third-party suppliers cease to supply our raw materials for any reason, we will be unable to manufacture *Feraheme* or unable to manufacture *Feraheme* in sufficient quantities until we are able to qualify an alternative source, which would adversely affect our ability to satisfy commercial demand and our clinical development needs for *Feraheme*.

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 *Feraheme* from an alternative source on commercially reasonable terms, or in a timely manner, if at all.

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 *Feraheme*, 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 *Feraheme*

Table of Contents

and would have a material adverse impact on our ability to generate additional revenues and to achieve profitability.

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

The pharmaceutical and biopharmaceutical industries are subject to intense competition and rapid technological change. We have competitors both in the U.S. and internationally, and many have greater financial and other resources, such as more experienced sales, marketing and manufacturing organizations than we do. In addition, many of our competitors have name recognition, established positions in the market and have long-standing relationships with customers and distributors. Our *Feraheme* commercial opportunity will be reduced or eliminated if our competitors develop, commercialize or acquire or license technologies and drug products that are or are perceived to be safer, more effective, and/or easier to administer, or have more favorable pricing, insurance coverage, coding and reimbursement than *Feraheme*.

There are currently two options for treating IDA in CKD patients: oral iron supplements and IV iron. *Feraheme* will primarily compete with existing IV iron replacement therapies, including Venofer®, which is marketed in the U.S. by Fresenius Medical Care North America, or Fresenius, and American Regent Laboratories, Inc., a subsidiary of Luitpold Pharmaceuticals, Inc., or Luitpold, Ferrlecit®, which is marketed by Watson Pharmaceuticals, Inc., and certain oral iron products. *Feraheme* may not receive the same level of market acceptance as these competing iron replacement therapy products, especially since these products have been on the market longer and are currently widely used by physicians. We may not be able to convince physicians to switch from using the existing marketed IV iron therapeutic products to *Feraheme*. The iron replacement therapy market is highly sensitive to several factors including, but not limited to, the perceived safety profile of the available products, the ability to obtain appropriate insurance coverage, coding and reimbursement, price competitiveness, and product characteristics such as convenience of administration and dosing regimens. To date, we have not conducted any head-to-head clinical studies comparing *Feraheme* to other IV iron replacement products.

In addition to the foregoing currently marketed products, there are several iron replacement therapy products in various stages of clinical and commercial development in the U.S. and abroad, including VIT-45, also known as Ferinject® in Europe or Injectafer® in the U.S. and Canada, and soluble ferric pyrophosphate a form of iron given as part of the hemodialysis procedure.

In addition to competition from existing marketed products and products known by us to be currently under development, the market opportunity for *Feraheme* could be negatively affected if generic IV iron replacement therapy products were to be approved and achieve commercial success. For example, on July 29, 2009, Watson Pharmaceuticals, Inc. announced that it entered into a license agreement with GeneraMedix, Inc. for the exclusive U.S. marketing rights to a generic version of Ferrlecit®, which is indicated for the treatment of iron deficiency anemia in hemodialysis patients receiving supplemental erythropoiesis stimulating agent therapy. GeneraMedix, Inc. has filed an Abbreviated New Drug Application with the FDA, which is under expedited review. 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 already on the market.

Table of Contents

It remains unclear if and when a generic product will enter this market. If any of these product candidates are approved for marketing and sale by the FDA our efforts to market and sell *Feraheme* and our ability to generate additional revenues and achieve profitability could 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 *Feraheme*.

Feraheme may not be widely adopted by physicians, patients, healthcare payors, and the two major operators of dialysis clinics in the U.S.

The commercial success of *Feraheme* depends upon its level of market adoption by physicians, patients, or healthcare payors or providers, including dialysis clinics. If *Feraheme* does not achieve an adequate level of market adoption for any reason, our potential profitability and our future business prospects would be severely adversely impacted. *Feraheme* represents an alternative to existing products and might not be adopted by the medical community if perceived to be no safer, no more effective, or no more convenient than currently available products. The degree of market acceptance of *Feraheme* will depend on a number of factors, including but not limited to:

- Our ability to demonstrate to the medical community, particularly nephrologists, hematologists, dialysis clinics and others who may purchase or prescribe *Feraheme*, the clinical efficacy and safety of *Feraheme* as an alternative to current treatments for IDA in both dialysis and non-dialysis CKD patients;

- The adequacy of third-party coding, insurance coverage and reimbursement for *Feraheme* 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 development of unanticipated adverse reactions to *Feraheme* after commercial launch resulting in safety concerns among prescribers;

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

- The actual or perceived convenience and ease of administration of *Feraheme* as compared to alternative iron replacement therapeutic agents; and

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

We plan to market and sell *Feraheme* for use by CKD patients who are on dialysis. 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 in the U.S. Fresenius, and DaVita, Inc., or DaVita, together treat more than 60% of the U.S. dialysis population. If we are unable to successfully market and sell *Feraheme* to physicians who treat dialysis dependent CKD patients in clinics controlled by either or both of Fresenius and DaVita, our ability to realize and grow revenues from sales of *Feraheme* could be limited, which would have a material adverse impact on our potential profitability, and our future business prospects. In September 2008, Fresenius finalized an exclusive sublicense agreement with Luitpold, the U.S. licensing partner of Vifor Pharma, a subsidiary of Galenica Ltd., or Galenica, to manufacture, sell and distribute Venofer®, an existing IV iron replacement therapeutic, to independent outpatient dialysis clinics in the U.S.

Table of Contents

Luitpold retains the right to sell Venofer® in the U.S. to any other customer. In addition, in 2008, Galenica, Vifor Pharma and Fresenius entered into a strategic joint-venture, which became effective on January 1, 2009, to market and distribute the IV iron products Venofer® and Ferinject® in the dialysis market in Europe, the Middle East, Africa and Latin America. Fresenius has significant experience selling and distributing dialysis equipment and supplies to outpatient dialysis clinics and, as a result of these agreements, it may be difficult for us to penetrate the dialysis market, in particular at Fresenius clinics.

Another key component of our commercialization strategy is to develop a market for *Feraheme* in the non-dialysis CKD market. Therefore, it is critical for us to successfully market and sell *Feraheme* to physicians who treat non-dialysis CKD patients in the physician s office setting. Currently IV iron therapeutic products are not widely used by physicians who treat non-dialysis CKD patients in the physician s office setting due to safety concerns and the inconvenience and often impracticability of administering the existing marketed IV iron therapeutic products in that 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 *Feraheme* to physicians who treat non-dialysis CKD patients in the physician s office setting, our ability to generate revenues and achieve and maintain profitability, and our long-term business prospects could be adversely affected.

Our ability to generate future revenues from Feraheme depends heavily on our ability to obtain and maintain satisfactory reimbursement for Feraheme.

The commercial success of *Feraheme* substantially depends on the availability and extent of reimbursement for *Feraheme* 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 *Feraheme*. *Feraheme* is 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 *Feraheme* if they do not receive adequate reimbursement. If we fail to demonstrate the clear clinical and/or comparative value of *Feraheme* as compared to existing therapeutics, *Feraheme* may not be reimbursed or may be reimbursed at an inadequate level, which could result in lower sales of *Feraheme.*

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 *Feraheme* 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 or step therapy, which is a program to encourage using lower cost alternative treatments, basing payment amounts on the least costly alternative treatment, or refusing to provide coverage of approved products for medical indications other than those for which the FDA has granted marketing approval. As a result, significant uncertainty exists as to whether and how much third party payors will reimburse end users for their use of newly approved drugs. Cost control initiatives could adversely affect the commercial opportunity or decrease the price of *Feraheme* and may impede the ability of potential *Feraheme* users to obtain reimbursement, any of which could have a material adverse effect on our profitability and future business prospects.

Table of Contents

Medicare currently reimburses for physician-administered drugs in the dialysis center and physician clinic 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, believe that *Feraheme* 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 unlikely that the current ASP reimbursement methodology will continue to apply in the dialysis setting beyond 2010, and any future changes in reimbursement policies may have a negative impact on the level of reimbursement available for *Feraheme*. In July 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 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 *Feraheme* and consequently put downward pressure on the price we can charge for *Feraheme*. Therefore, we may be limited in our ability to successfully market and sell *Feraheme* in the dialysis setting. 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 *Feraheme*.

In addition, when seeking reimbursement for *Feraheme* from Medicare, Medicaid and certain third-party payors, providers are required to include on their claim form a drug code, which is intended to help the payor identify the product used. Certain unique drug codes for new products are issued to manufacturers at the discretion of CMS only once per year and generally go into effect the following January. As a result, we may not obtain a unique billing code for *Feraheme* until January 2011. Until a new product obtains a unique drug code, it can only be billed by using a miscellaneous drug code. However, inclusion of this miscellaneous drug code will subject each claim to manual review and could delay or prevent reimbursement. Therefore, users of *Feraheme* may be reluctant to use *Feraheme* without a unique billing code in place. There is no guarantee that we will be successful in obtaining a unique billing code for *Feraheme*. Any delay in or failure to obtain a unique code could complicate provider reimbursement and have a material negative impact on *Feraheme* utilization and sales.

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 experience independently commercializing a pharmaceutical product, and any failure on our part to effectively execute our Feraheme commercial plans would have a severe adverse impact on our business.

We have never independently marketed or sold a drug product as we have relied on our corporate partners to market and sell our other approved products, *Feridex I.V.* and *GastroMARK*. We have established an internal sales and marketing infrastructure to market and sell *Feraheme*, and if we are

Table of Contents

unsuccessful in maintaining an effective sales and marketing function or experience a high level of turnover, then the commercialization of *Feraheme* could be severely impaired.

Any failure by us to successfully execute our commercialization plans for *Feraheme* could have a material adverse impact on our ability to generate revenues, our ability to achieve profitability, and the future prospects for our business.

We have no experience independently distributing a pharmaceutical product, and our Feraheme commercialization plans could suffer if we fail to effectively manage and maintain our supply chain and distribution network.

We do not have significant experience in managing and maintaining a supply chain and distribution network, and we are placing substantial reliance on third-parties to perform product supply chain services for us. Such services include packaging, warehousing, inventory management, storage and distribution of *Feraheme*. We have contracted with Integrated Commercialization Services, Inc., or ICS, to be our exclusive third party logistics provider to perform a variety of functions related to the sale and distribution of *Feraheme*, including services related to warehousing and inventory management, distribution, contract administration and chargeback processing, government price reporting calculations, accounts receivable management and customer service call center management. As a result, most of our inventory is stored at a single warehouse maintained by ICS. In addition, we have contracted with Catalent Pharma Solutions, LLC, or Catalent, to provide certain labeling and packaging services for final *Feraheme* drug product. If ICS or Catalent are unable to provide uninterrupted supply chain services or labeling and packaging services, respectively, we may incur substantial losses of sales to wholesalers or other purchasers of *Feraheme*.

In addition, the packaging, storage and distribution of *Feraheme* requires significant coordination among our manufacturing, sales, marketing and finance organizations and multiple third parties including our third party logistics provider, packaging and labeling provider, distributors, and wholesalers. In most cases, we do not currently have back-up suppliers or service providers to perform these tasks. If any of these third-parties experience significant difficulties in their respective processes, fail to maintain compliance with applicable legal or regulatory requirements, fail to meet expected deadlines or otherwise do not carry out their contractual duties to us, or encounter physical or natural damages at their facilities, our ability to deliver *Feraheme* to meet commercial demand would be significantly impaired. The loss of any of our third party providers, together with a delay or inability to secure an alternate distribution source for end users could cause the distribution of *Feraheme* to be delayed or interrupted, which would have an adverse effect on our business, financial condition and results of operation.

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 but not limited to:

- The timing and magnitude of revenues from sales of *Feraheme*;

- The timing and magnitude of costs associated with the commercialization of *Feraheme* in the U.S., including costs associated with maintaining our commercial infrastructure and executing our promotional and marketing strategy for *Feraheme*;

Table of Contents

- The timing and magnitude of costs associated with commercial-scale manufacturing of *Feraheme*, including costs associated with building and maintaining commercial inventory and qualifying additional manufacturing capacities and second source suppliers;

- Changes in buying patterns of our wholesalers or distributors;

- Actual or anticipated difficulties, disruptions or delays associated with our manufacturing facility, packager, or supply chain and distribution network;

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

- The timing and magnitude of costs associated with potential business development activities;

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

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

If the estimates we make, or the assumptions on which we rely, in preparing our consolidated financial statements prove inaccurate, our actual results may vary from those reflected in our projections and accruals.

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us, and related disclosure of contingent assets and liabilities. On an ongoing basis, our management evaluates our critical and other significant estimates and judgments, including among others, those related to investments, stock-based compensation, accrued expenses and income taxes. We base our estimates on market data, our observance of trends in

our industry, and on various other assumptions that we believe to be reasonable under the circumstances. If actual results differ from these estimates, there could be a material adverse effect on our financial results and the performance of our stock.

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 $18.33 and $58.23 in the fifty-two week period through August 3, 2009. The stock market has from time to time experienced extreme price and volume fluctuations, particularly in the biotechnology and pharmaceuticals

Table of Contents

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 include, among others:

- Our ability to successfully commercialize *Feraheme* in the U.S.;
- Actual or anticipated fluctuations in our operating results;
- Changes in or our failure to meet financial estimates published by securities analysts;
- The availability of reimbursement coverage for *Feraheme* and changes in the reimbursement policies of governmental or private payors;
- Public announcements of regulatory actions with respect to *Feraheme* or products or product candidates of our competitors;
- Safety concerns related to *Feraheme* or products or product candidates of our competitors;
- General market conditions;
- Sales of large blocks of our common stock;
- The results of clinical trials for *Feraheme* in indications other than CKD or products or product candidates of our competitors;
- 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;

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

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

Thus, as a result of events both within and beyond our control, our stock price could fluctuate significantly or lose value rapidly.

If securities analysts downgrade our stock, cease coverage of us, or if our operating results do not meet analysts forecasts and expectations, our stock price 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 and our business. Currently, [ten] 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. In addition, our future operating results are subject to substantial uncertainty, and if we fail to meet or exceed analysts forecasts and expectations, our stock price could decline significantly. 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.

Table of Contents

We have a history of net losses, and we may not be able to generate sufficient revenues to achieve and maintain profitability in the future.

We have a history of significant operating losses, and we may not be profitable in the future or if we attain profitability, it may not be sustainable. In the past, we have financed our operations primarily from the sale of our equity securities, cash generated by our investing activities, and payments from our marketing and distribution partners. As of June 30, 2009, we have an accumulated deficit of approximately $241.2 million. Our losses are primarily the result of costs incurred in research and development, including costs associated with our *Feraheme* and other development programs, costs associated with establishing our sales and marketing infrastructure, and selling, general and administrative costs. We expect to continue to incur significant expenses to manufacture, market and sell *Feraheme* as an iron replacement therapeutic in CKD patients in the U.S. and further develop *Feraheme* in indications other than CKD. As a result, we will need to generate sufficient revenues in future periods to achieve and maintain profitability. We anticipate that the vast majority of any revenue we generate in the near future will be from sales of *Feraheme* as an iron replacement therapeutic agent for CKD patients in the U.S. We have never independently marketed or sold any products, and we may not be successful in marketing or selling *Feraheme*. If we are not successful in marketing and selling *Feraheme*, if revenues grow more slowly than we anticipate or if our operating expenses exceed our expectations, our business, results of operations and financial condition could be materially adversely affected. In addition, if we are unable to achieve, maintain or increase profitability on a quarterly or annual basis, the market price of our common stock may decline.

We may need additional capital to achieve our business objectives.

We have expended and will continue to expend substantial funds to successfully commercialize and develop *Feraheme*. 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:

- The timing and magnitude of revenues from sales of *Feraheme*;

- Costs associated with the U.S. commercialization of *Feraheme*, including costs associated with maintaining our commercial infrastructure and distribution network and executing our promotional and marketing strategy for *Feraheme*;

- Costs associated with commercial-scale manufacturing of *Feraheme*, including costs associated with building and maintaining commercial inventory and qualifying additional manufacturing capacities and second source suppliers;

- Costs associated with our development of additional indications for *Feraheme*;

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

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

- Our ability to liquidate our investments in a timely manner and without significant loss;

Table of Contents

- 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.

We estimate that our existing cash resources, combined with cash we currently expect to receive from sales of *Feraheme* and 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 *Feraheme* 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.

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

At June 30, 2009, we had $70.2 million in cash and cash equivalents, $55.0 million in short-term investments, $50.1 million in long-term investments, and $0.5 million in Settlement Rights. These investments are subject to general credit, liquidity, market and interest rate risks, which have been and may continue to be exacerbated by the U.S. sub-prime mortgage defaults and the ensuing fallout. The current disruptions in the credit and financial markets have negatively affected many industries, including those in which we invest, and we may realize losses in the fair value of certain of our investments or a complete loss of these investments, which would have an adverse effect on our results of operations, liquidity and financial condition.

At June 30, 2009, we held a total of $58.9 million in fair market value of ARS, reflecting an impairment of approximately $7.4 million compared to the par value of these securities of $66.3 million. Of the $7.4 million impairment, approximately $6.9 million is considered a temporary impairment and is reported as an unrealized loss at June 30, 2009. The remaining $0.5 million represents an impairment which is recognized in our consolidated statement of operations at June 30, 2009. A substantial majority of our ARS portfolio was rated AAA as of June 30, 2009 by at least one of the major securities rating agencies, and greater than 90% of our ARS 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. Prior to February 2008, these ARS typically reset through an auction process every 7 or 28 days, which generally allowed existing investors to either roll over their holdings and continue to own their

51

Table of Contents

securities or liquidate their holdings by selling their securities at par value. In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions. As a result of the lack of observable ARS 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 almost all 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. These auctions may continue to fail indefinitely, and there could be a further 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 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, failed auctions will 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 in the short term, 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 and unpredictable. As a result, we may experience a reduction in value or loss of liquidity with respect to our investments. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. Further, as part of our determination of the fair value of our investments, we consider credit ratings provided by independent investment rating agencies as of the valuation date. These ratings are subject to change. For example, in late February 2009 three of our ARS with a total par value of $8.7 million and one of our ARS with a par value of $5.0 million were downgraded by one of the major credit rating agencies to A3 and Baa1, respectively, from their previous rating of Aaa. In contrast, the ARS having a par a value of $5.0 million was re-affirmed as AAA by a different major rating agency in January 2009. As the ratings of our ARS change we may be required to adjust our future valuation of our ARS which may adversely affect the value of these investments. 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 quarters, the U.S. and global economies have taken a dramatic downturn as a 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. and other governments are not successful, the continued economic decline may continue to negatively affect the liquidity of our investments, significantly impact our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all, and cause our investments to substantially decline in value. Any of these 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 continue to rely on third-parties, including our clinical research organizations, third-party manufacturers, third party logistics provider, packaging and labeling provider,

Table of Contents

wholesale distributors and certain other important vendors and consultants. As a result of the current volatile and unpredictable global economic situation, there may be a disruption or delay in the performance or satisfaction of commitments to us by our third-party contractors and suppliers. For example, as a result of the current economic climate, our distributors, customers or suppliers may experience difficulty in obtaining the liquidity necessary to purchase inventory or raw materials, may begin to maintain lower inventory levels or could become insolvent. If such third-parties are unable to adequately satisfy their contractual commitments to us in a timely manner, our business could be severely adversely affected.

If we fail to comply with our reporting and payment obligations under governmental pricing programs, we could be required to reimburse government programs for underpayments and could be required to pay penalties, sanctions and fines which could have a material adverse effect on our business, financial condition and results of operation.

As a condition of reimbursement by various federal and state healthcare programs, we are required to calculate and report certain pricing information to federal and state healthcare agencies. For example, we are required to provide ASP information to CMS on a quarterly basis in order to compute Medicare payment rates. Price reporting and payment obligations are highly complex and vary among products and programs. Our processes for estimating amounts due under these governmental pricing programs will involve subjective decisions, and as a result, our price reporting calculations will remain subject to the risk of errors and our methodologies for calculating these prices could be challenged under the Federal False Claims Act or other laws. If we become subject to investigations or other inquiries concerning our compliance with price reporting laws and regulations, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operation.

We are subject to ongoing regulatory review of Feraheme, 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 Feraheme.

We are subject to ongoing FDA regulatory requirements and review pertaining to *Feraheme s* manufacture, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. Failure to comply with such regulatory requirements or the later discovery of previously unknown problems with *Feraheme* or our manufacturing facility may result in restrictions on our ability to market and sell *Feraheme*, including withdrawal from the market. We may also be subject to additional sanctions, including but not limited to:

- FDA warning letters;
- Civil or criminal penalties;
- 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, or other issues involving *Feraheme;*

- FDA-imposed label changes;

- Implementation of an FDA-mandated Risk Evaluation and Mitigation Strategy, or REMS;

- Restrictions on our continued manufacturing, marketing or sale of *Feraheme;* or

Table of Contents

- Recalls or a refusal by the FDA to consider or approve applications for additional indications.

Any of these sanctions would have a material adverse impact on our ability to generate revenues and to achieve profitability.

If we market or distribute products in a manner that violates federal or state healthcare fraud and abuse laws, marketing disclosure laws or other federal or state laws and regulations, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to extensive federal and state healthcare regulation, including but not limited to, the federal false claims act, and the federal anti-kickback statute. False claims laws prohibit anyone from knowingly presenting, or causing to be presented for payment to third-party payors, including Medicare and Medicaid, false or fraudulent claims for reimbursed drugs or services, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Anti-kickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug, that is reimbursed by a state or federal program. We have developed and implemented a corporate compliance program based on what we believe are current best practices in the pharmaceuticals industry, but we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all 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, restrictions on how we market and sell *Feraheme*, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation, or other sanctions. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition and results of operation.

In recent years, several states and localities have enacted legislation requiring pharmaceutical companies to establish marketing and promotional compliance programs or codes of conduct and/or file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered by additional states and by Congress. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Compliance with these laws is difficult and time consuming, and if we are found to not be in full compliance with these laws, we may face enforcement actions, fines and other penalties, and we could receive adverse publicity which could have an adverse effect on our business, financial condition and results of operation.

If we fail to comply with any federal or state laws or regulations governing our industry, we could be subject to a range of regulatory actions that could affect our ability to commercialize *Feraheme*, harm or prevent sales of *Feraheme*, or substantially increase the costs and expenses of commercializing and marketing *Feraheme,* all of which could have a material adverse effect on our business, financial condition and results of operation.

Significant safety or drug interaction problems could arise for Feraheme even after FDA approval, resulting in recalls, restrictions in Feraheme s label, or withdrawal of Feraheme 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

Table of Contents

FDA as part of our NDA was obtained in controlled clinical trials of limited duration. New safety or drug interaction issues may arise as *Feraheme* 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 the *Feraheme* label or narrow our approved indications, each of which could reduce the market acceptance of *Feraheme*. In addition, if significant safety or drug interaction issues arise, FDA approval for *Feraheme* could be withdrawn, and the FDA could require the recall of all existing *Feraheme* in the marketplace. The 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 *Feraheme*, and could 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 *Feraheme*. 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 a REMS where necessary to assure safe use of the drug. If we are required to conduct post-approval clinical studies or implement a REMS, or if the FDA changes the label for *Feraheme* to include additional discussion of potential safety issues, such requirements or restrictions could have a material adverse impact on our ability to generate revenues from sales of *Feraheme*, or require us to expend significant additional funds on clinical studies.

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

The FDA imposes substantial requirements on the development and production of all drug products. We have recently commenced and are pursuing additional clinical trials and plan to seek regulatory approval to market *Feraheme* in indications other than CKD. Before obtaining regulatory approval for the commercial marketing and sale of *Feraheme* in additional indications, we must demonstrate through extensive human clinical trials that *Feraheme* is safe and efficacious for these new uses and in these new patient populations. Conducting clinical trials is a complex, time-consuming and expensive process that requires adherence to a wide range of regulatory requirements. The FDA has substantial discretion in the approval process and may decide that the results of our clinical trials are insufficient for approval or that *Feraheme* is not effective or safe in indications other than CKD. 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 could also determine that 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. 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 are involved in our clinical development programs to ensure their compliance with cGCP regulations. If the FDA determines that we, our contract research

Table of Contents

organizations or our study sites failed 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, which could adversely impact our ability to obtain approval for *Feraheme* in indications other than CKD. Any such deficiency in the design, implementation or oversight of our clinical development program could cause us to incur significant additional costs, experience significant delays in our efforts to obtain regulatory approval for *Feraheme* indications other than CKD, or even prevent us from obtaining regulatory approval for *Feraheme* in additional indications. 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. 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 *Feraheme* to be safe and effective in such uses and/or patient populations.

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

- Our ability to reach agreement with the FDA on a trial design in a timely manner;
- Our ability to identify and enter into contracts with prospective clinical sites in a timely manner;
- The rate of patient enrollment; and
- The ability of our contract research organizations to perform their oversight responsibilities and meet expected deadlines.

To the extent we wish to manufacture, market or sell *Feraheme* 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. In addition, in order to increase the number of patients available for enrollment in our clinical trials, we may conduct trials in geographies outside the U.S. We have no experience conducting clinical trials outside the U.S., and, therefore, we will need to expend substantial time and resources to identify and familiarize ourselves with the regulatory requirements of such foreign countries.

Any failure by us to obtain approval for additional *Feraheme* indications in the U.S. or any failure to obtain approval for any indications outside the U.S. in a timely manner may limit the commercial success of *Feraheme* 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 continue 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

Table of Contents

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 adequately discharge their responsibilities or meet deadlines, our development plans may be delayed or terminated.

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

We have experienced significant growth, which has placed and may continue to place a substantial strain on our management, employees, facilities and resources. In anticipation of the approval and U.S. commercialization of *Feraheme*, we rapidly expanded our regulatory, medical affairs, marketing, sales, manufacturing, finance, development, and compliance capabilities. As our operations continue to expand, we will also 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 *Feraheme*, pursuing new business opportunities, or expanding our business, any one of which could adversely impact our future business prospects.

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 and 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 U.S. commercialization of *Feraheme*. 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 for these arrangements, and we may not be able to enter into such arrangements on acceptable terms or at all.

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 managerial, scientific, medical and sales personnel. 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

57

Table of Contents

significant period of time, or at all. If we are unable to retain these personnel, or we lose the services of our key personnel for any reason, our *Feraheme* development and commercialization efforts could be severely adversely impacted.

Furthermore, our expansion into areas and activities requiring additional expertise, such as commercial scale manufacturing, marketing and sales, and late-stage development 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 commercialize *Feraheme* and complete our development projects.

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.

Our primary U.S. *Feraheme* patent is currently scheduled to expire in 2020. This and any other patents issued to us may be contested or invalidated. Future patent interference proceedings involving our patents may harm our ability to commercialize *Feraheme*. 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 *Feraheme*, limit our development and commercialization of *Feraheme*, 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.

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 *Feraheme*, 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 might be independently discovered by our

Table of Contents

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 *Feraheme*, thereby substantially reducing the value of our proprietary rights.

If we identify a material weakness in our internal controls over financial reporting, our ability to meet reporting obligations and the trading price of our stock could be negatively affected.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we, or our independent registered accounting firm, determine that our internal controls over our financial reporting are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial results, and the price of our common stock could be negatively affected.

If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements, which could lead to a decline in our stock price. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC or NASDAQ or other regulatory authorities.

We are exposed to a number of different potential liability claims, and we may not be able to maintain or obtain sufficient insurance coverage to protect our cash and other assets.

The administration of our products to humans, whether in clinical trials or after approved commercial usage, may expose us to liability claims. Although we maintain product liability insurance coverage for claims arising from the use of our products in clinical trials and commercial use, coverage is expensive and we may not be able to maintain sufficient insurance at a reasonable cost, if at all. Product liability claims, whether or not they have merit, could decrease demand for *Feraheme*, divert the attention of our management and key personnel from our core business, require us to spend significant time and money in litigation or to pay significant damages, all of which could prevent or interfere with the commercialization of *Feraheme* and adversely affect our business. Claims of this nature could also subject us to product recalls or harm our reputation, which could damage our position in the market.

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

Because we use certain hazardous materials in the production of our products, we are subject to various federal, state and local environmental laws and regulations that govern our operations, including the import, 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

Table of Contents

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.

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

There were no purchases by us, or any affiliated purchaser, of our equity securities which are registered pursuant to Section 12 of the Exchange Act during the six months ended June 30, 2009.

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

On May 5, 2009, we held our Annual Meeting of Stockholders.

Votes for represented affirmative votes and did not include abstentions or broker non-votes. In cases where a signed proxy was submitted without designation, the shares represented by the proxy were voted FOR the proposal in the manner described in the Proxy Statement delivered to the holders of shares of our common stock on the record date established for the meeting, which was March 9, 2009. On the record date, 17,024,284 shares of our common stock were issued and outstanding.

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

Table of Contents

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

	For	Withheld
Joseph V. Bonventre, MD, PhD	14,154,621	35,193
Michael Narachi	10,601,384	3,588,430
Brian J.G. Pereira, MD	14,154,621	35,193
Robert J. Perez	14,154,220	35,594
Davey S. Scoon	14,154,202	35,612
Mark Skaletsky	13,162,470	1,027,344
Ron Zwanziger	13,530,208	659,606

2. An amendment to our 2007 Equity Incentive Plan to, among other things, increase the number of shares of our common stock available for issuance thereunder by 600,000 shares. Voting results were as follows:

For	Against	Abstain	Broker Non Votes
6,707,996	2,870,580	4,812	4,606,427

3. Ratification of the appointment of PricewaterhouseCoopers LLP as our independent auditor for the year ending December 31, 2009. Voting results were as follows:

For	Against	Abstain	Broker Non Votes
14,157,222	24,720	7,871	

Table of Contents

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.

Table of Contents

SIGNATURES

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

AMAG PHARMACEUTICALS, INC.

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

Date: August 5, 2009

AMAG PHARMACEUTICALS, INC.

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

Date: August 5, 2009

Table of Contents

EXHIBIT INDEX

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.