AMAG PHARMACEUTICALS INC.
Form 10-Q
May 06, 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 March 31, 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 **02421**
(Address of Principal Executive Offices) (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 Smaller reporting company o
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o **No** x

As of May 1, 2009 there were 17,024,284 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

PART I.	**FINANCIAL INFORMATION (Unaudited)**	3
Item 1.	Financial Statements	3
	Condensed Consolidated Balance Sheets as of March 31, 2009 and December 31, 2008	3
	Condensed Consolidated Statements of Operations for the three months ended March 31, 2009 and 2008	4
	Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2009 and 2008	5
	Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2009 and 2008	6
	Notes to Condensed Consolidated Financial Statements	7
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	22
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	36
Item 4.	Controls and Procedures	37
PART II.	**OTHER INFORMATION**	37
Item 1A.	Risk Factors	37
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	57
Item 5.	Other Information	57
Item 6.	Exhibits	59

SIGNATURES

CERTIFICATIONS

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

AMAG PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

AS OF MARCH 31, 2009 AND DECEMBER 31, 2008

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

(Unaudited)

	March 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 67,988	$ 64,182
Short-term investments	68,318	94,914
Accounts receivable	237	408
Inventories	58	96
Prepaid and other current assets	3,314	4,710
Total current assets	139,915	164,310
Property, plant and equipment:		
Land	360	360
Buildings and improvements	10,016	9,986
Laboratory equipment	6,041	5,994
Furniture and fixtures	3,490	3,474
Construction in process	373	298
Total property, plant and equipment	20,280	20,112
Less - accumulated depreciation	(9,306)	(8,889)
Net property, plant and equipment	10,974	11,223
Settlement rights	643	1,566
Long-term investments	57,639	54,335
Restricted cash	460	521
Total assets	$ 209,631	$ 231,955
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,641	$ 2,305
Accrued expenses	10,952	11,571
Deferred revenue		516
Total current liabilities	12,593	14,392
Long-term liabilities:		
Deferred revenue and rent expense	4,262	4,149
Total liabilities	16,855	18,541
Commitments and contingencies (Note J)		
Stockholders equity:		
Preferred stock, par value $.01 per share, 2,000,000 shares authorized; none issued		
Common stock, par value $.01 per share, 58,750,000 shares authorized; 17,024,284 and 17,018,159 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively	170	170
Additional paid-in capital	415,118	411,538
Accumulated other comprehensive loss	(7,754)	(9,959)
Accumulated deficit	(214,758)	(188,335)
Total stockholders equity	192,776	213,414
Total liabilities and stockholders equity	$ 209,631	$ 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 MONTHS ENDED

MARCH 31, 2009 AND 2008

(IN THOUSANDS, EXCEPT PER SHARE DATA)

(Unaudited)

	Three Months Ended March 31,	
	2009	2008
Revenues:		
License fees	$ 516	$ 184
Royalties	47	36
Product sales	393	392
Total revenues	956	612
Costs and expenses:		
Cost of product sales	61	44
Research and development expenses	11,072	4,823
Selling, general and administrative expenses	17,750	8,385
Total costs and expenses	28,883	13,252
Other income (expense):		
Interest and dividend income, net	1,256	3,267
Gains on investments, net	992	72
Fair value adjustment of settlement rights	(923)	
Total other income (expense)	1,325	3,339
Net loss before income taxes	(26,602)	(9,301)
Income tax benefit	179	
Net loss	$ (26,423)	$ (9,301)
Net loss per share:		
Basic and diluted	$ (1.55)	$ (0.55)
Weighted average shares outstanding used to compute net loss per share:		
Basic and diluted	17,021	16,970

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 MONTHS ENDED

MARCH 31, 2009 AND 2008

(IN THOUSANDS)

(Unaudited)

	Three Months Ended March 31,	
	2009	2008
Net loss	$ (26,423)	$ (9,301)
Other comprehensive income (loss):		
Unrealized gains (losses) on securities:		
Holding gains (losses) arising during period	2,201	(2,642)
Reclassification adjustment for losses and gains, net, included in net loss	4	72
Net unrealized gains (losses)	2,205	(2,570)
Total comprehensive loss	$ (24,218)	$ (11,871)

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 THREE MONTHS ENDED

MARCH 31, 2009 AND 2008

(IN THOUSANDS)

(Unaudited)

	Three Months Ended March 31,	
	2009	2008
Net loss	$ (26,423)	$ (9,301)
Cash flows from operating activities:		
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	442	235
Non-cash equity-based compensation expense	3,502	2,694
Amortization of premium/discount on purchased securities	204	(19)
Fair value adjustment on settlement rights	923	
Gains on investments, net	(992)	(72)
Changes in operating assets and liabilities:		
Accounts receivable	171	(235)
Inventories	38	30
Prepaid and other current assets	1,396	(448)
Accounts payable and accrued expenses	(1,283)	(1,196)
Deferred revenue and rent expense	(403)	(214)
Total adjustments	3,998	775
Net cash used in operating activities	(22,425)	(8,526)
Cash flows from investing activities:		
Proceeds from sales or maturities of available-for-sale investments	26,595	126,068
Purchase of available-for-sale investments	(310)	(93,470)
Capital expenditures	(192)	(389)
Restricted cash	61	
Net cash provided by investing activities	26,154	32,209
Cash flows from financing activities:		
Proceeds from the exercise of stock options	77	514
Net cash provided by financing activities	77	514
Net increase in cash and cash equivalents	3,806	24,197
Cash and cash equivalents at beginning of the period	64,182	28,210
Cash and cash equivalents at end of the period	$ 67,988	$ 52,407

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

6

Table of Contents

AMAG PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 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 have one product candidate, Feraheme (ferumoxytol injection), and two approved products, Feridex I.V.® and GastroMARK®.

Feraheme is being developed for use as an intravenous, or IV, iron replacement therapeutic agent for the treatment of iron deficiency anemia, or IDA, and as a diagnostic agent for vascular enhanced magnetic resonance imaging, or MRI, to assess peripheral arterial disease, or PAD. In December 2007, we submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or the FDA, for marketing approval of *Feraheme* for the treatment of IDA in chronic kidney disease, or CKD, patients. In October 2008, we received a Complete Response letter from the FDA with respect to our NDA for *Feraheme* requesting certain additional clinical information, information regarding certain observations noted during an FDA inspection at one of our Phase III clinical sites, and resolution of certain observations noted during a recent FDA inspection of our Cambridge, Massachusetts manufacturing facility. We submitted a response in October 2008, and in December 2008 we received a second Complete Response letter from the FDA requesting data to clarify a specific chemistry, manufacturing and controls question, resolution of the observations noted during the recent FDA inspection of our manufacturing facility, and finalization of labeling discussions for *Feraheme*. We have been engaged in active dialogue with the FDA and have recently been informed that the observations noted during the recent FDA inspection of our manufacturing facility have been adequately addressed and that a re-inspection of our manufacturing facility will not be required as a condition to approval of *Feraheme*. We will need to resolve all of the issues raised by the FDA in the Complete Response letters in a timely manner in order to obtain approval to market and sell *Feraheme* in the U.S.

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

Feridex I.V., our liver contrast agent, is approved and has been sold in the U.S., Europe and other countries. 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

Table of Contents

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.

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 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 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 March 31, 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 Statement of Financial Accounting Standards, or SFAS, No. 115 Accounting for Certain Investments in Debt and Equity Securities, or SFAS 115. The determination of the appropriate classification by us is based on a variety of factors, including management s intent at the time of purchase. As of March 31, 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

Table of Contents

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 our condensed consolidated statements of operations. In November 2008, we elected to participate in a rights offering by UBS AG, or UBS, one of our 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, or the Settlement Rights. 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.

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

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. The standard describes a fair value hierarchy to measure fair value which is based on three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

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

Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of March 31, 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 March 31, 2009 and December 31, 2008 (in thousands):

Table of Contents

		Fair Value Measurements at March 31, 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	$ 66,546	$ 66,546	$	$
Corporate debt securities	44,006		44,006	
U.S. treasury and government agency securities	24,312		24,312	
Auction rate securities	57,639			57,639
Settlement rights	643			643
	$ 193,146	$ 66,546	$ 68,318	$ 58,282

		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 investments is generally determined from quoted market prices based upon either quoted prices from active markets or other significant observable market transactions at fair value.

In November 2008, we 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 UBS Settlement Rights and as of March 31, 2009, we have recorded an asset equal to the estimated fair value of the Settlement Rights of approximately $0.6 million in our condensed consolidated balance sheet. This represents a decrease of approximately $0.9 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 UBS ARS with a par value of $9.3 million and an estimated fair value of $8.6 million as of March 31, 2009 as trading securities. Accordingly, as of March 31, 2009, we have adjusted our estimated value of these trading securities by approximately $1.0 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. We will be 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 will be required to periodically assess the economic 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, which include our ARS and Settlement Rights as of March 31, 2009 and our ARS only as of March 31, 2008 (in thousands):

Table of Contents

	Three Months Ended March 31, 2009	2008
Balance at beginning of period	$ 55,901	$
Transfers to Level 3		80,725
Total gains (losses) (realized or unrealized):		
Included in earnings	65	
Included in other comprehensive income (loss)	2,316	(3,561)
Purchases (settlements), net		(8,400)
Balance at end of period	$ 58,282	$ 68,764
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	$	$

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.

Equity-Based Compensation

We account for our equity-based compensation arrangements with our employees and non-employee directors under SFAS No. 123R, Share-Based Payment, or SFAS 123R, and its related implementation guidance as promulgated by both the Financial Accounting Standards Board, or the FASB, and the SEC Staff Accounting Bulletin 107. Under these pronouncements, equity-based compensation cost is required to be measured at the grant date (based upon an estimate of the fair value of the compensation granted) and recorded to expense over the requisite service period, which generally is the vesting period. Because equity-based compensation expense is based on awards ultimately expected to vest, we must make certain judgments about whether employees and directors will complete the requisite service period. Accordingly, we have reduced the compensation expense being recognized for estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on historical experience. If factors change and we employ different assumptions in the application of SFAS 123R in future periods, the compensation expense that we record under SFAS 123R may differ significantly from what we have recorded in the current period.

We estimate the fair value of equity-based compensation involving stock options based on the Black-Scholes option pricing model. We estimate the fair value of our restricted stock units whose vesting is contingent upon market conditions using the Monte-Carlo simulation model. These models require the input of several factors such as the expected option term, the expected risk-free interest rate over the expected option term, the expected volatility of our stock price over the expected option term, and the expected dividend yield over the expected option term and are subject to various assumptions. The fair value of awards whose fair values are calculated using the Black-Scholes option pricing model are generally being amortized on a straight line basis based on the proportionate amount of the requisite service period that has been rendered to date for each respective performance period. The fair value of awards with market conditions are being amortized based upon the estimated derived service period. We believe our valuation methodologies are appropriate for estimating the fair value of equity awards we grant to employees and directors, which are subject to SFAS 123R requirements. Our equity award valuations are estimates and thus may not be reflective of actual future results or amounts ultimately realized by recipients of these grants. These amounts, and the amounts applicable to future quarters, are also subject to future quarterly adjustments

Table of Contents

based upon a variety of factors, which include, but are not limited to, changes in estimated forfeiture rates and the issuance of new options and other equity-based awards. The fair value of restricted stock units granted to employees and directors is determined based upon the quoted closing market price per share on the date of grant, adjusted for assumed forfeitures. As with any accounting policy that applies judgments and estimates, actual results could significantly differ from those estimates and our financial results could be materially and adversely impacted.

Equity-based compensation to certain non-employees is accounted for in accordance with SFAS 123R, utilizing the measurement guidance of the Emerging Issues Task Force, or EITF, 96-18 Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.

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.

Reclassifications

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

C. Investments

At March 31, 2009 and December 31, 2008, our short- and long-term investments totaled $126.0 million and $149.2 million, respectively, and consisted of securities classified as available-for-sale and trading in accordance with SFAS No. 115.

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

Table of Contents

	March 31, 2009			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	$ 39,278	$ 100	$ (205)	$ 39,173
Due in one to three years	4,811	50	(28)	4,833
U.S. treasury and government agency securities				
Due in one year or less	12,160	217		12,377
Due in one to three years	11,624	311		11,935
Total short-term investments	$ 67,873	$ 678	$ (233)	$ 68,318
Long-term investments:				
Auction rate securities - available for sale				
Due in one year or less	$	$	$	$
Due after five years	57,200		(8,199)	49,001
Auction rate securities - trading				
Due in one year or less				
Due after five years	8,638			8,638
Total long-term investments	$ 65,838	$	$ (8,199)	$ 57,639
Total short and long-term investments	$ 133,711	$ 678	$ (8,432)	$ 125,957

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

At March 31, 2009, we held a total of $57.6 million in fair market value of ARS, reflecting an impairment of approximately $8.9 million compared to the par value of these securities of $66.5 million. Of the $8.9 million impairment, approximately $8.2 million is considered a temporary impairment and is reported as an unrealized loss at March 31, 2009. The remaining $0.7 million represents an impairment associated with our UBS ARS, the recording of which is described below. Of our total ARS, $49.0 million in fair market value are not subject to Settlement Rights and are classified as available-for-sale. The remaining $8.6 million are subject to Settlement Rights and are classified as trading securities. At March 31, 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 March 31, 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 to a discounted cash flow analysis as opposed to valuing them at par value. Our valuation analyses

Table of Contents

consider, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, 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 UBS ARS subject to Settlement Rights to be $8.6 million at March 31, 2009 and, accordingly, during the three months ended March 31, 2009, recorded a realized gain of approximately $1.0 million. In addition, based upon this methodology, we have estimated the fair value of our remaining ARS which are not subject to Settlement Rights to be $49.0 million at March 31, 2009, and have recorded an $8.2 million unrealized loss to accumulated other comprehensive loss as of March 31, 2009. We believe that the temporary impairment related to these ARS is primarily attributable to the limited liquidity of these investments, coupled with the recent turmoil in the credit and capital markets. As of March 31, 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, one of our brokers, 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. We elected the SFAS 159 fair value option in November 2008 with respect to the UBS Settlement Rights, and as of March 31, 2009, we have recorded an asset equal to the estimated fair value of the Settlement Rights of approximately $0.6 million in our condensed consolidated balance sheet. This represents a decrease of approximately $0.9 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. 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 $8.6 million as of March 31, 2009, as trading securities as we are likely to sell these investments to UBS. Accordingly, as of March 31, 2009, we have recognized a gain of approximately $1.0 million to other income (expense) in our condensed consolidated statement of operations during the three months ended March 31, 2009. We will be 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 will be required to periodically assess the economic ability of UBS to meet that 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 entire ARS portfolio as long-term investments in our condensed consolidated balance sheet at March 31, 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, 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 ARS, other than those subject to Settlement Rights that we deem to be temporary, including any

Table of Contents

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 earnings as appropriate. In the event that we need to access our investments in these securities, we will not be able to do so until a future auction is successful, the issuer calls the security pursuant to a mandatory tender or redemption prior to maturity, a buyer is found outside the auction process, or the securities mature. For all of our ARS, the underlying maturity date is in excess of one year, and 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.

Gains and losses are determined on the specific identification method and, accordingly, during the three months ended March 31, 2009, we recorded a realized gain of $1.0 million to our condensed consolidated statement of operations related to our estimated valuation of ARS that were subject to Settlement Rights. In addition, we recorded a realized loss related to the fair value adjustment of our Settlement Rights of $0.9 million to our condensed consolidated statement of operations.

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 March 31, 2009 and December 31, 2008 (in thousands):

	March 31, 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	$ 12,628	$ (153)	$ 5,057	$ (80)	$ 17,685	$ (233)
Auction rate securities			49,001	(8,199)	49,001	(8,199)
	$ 12,628	$ (153)	$ 54,058	$ (80)	$ 66,686	$ (8,432)

	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)

With the exception of the ARS discussed above, the unrealized losses on our investments at March 31, 2009 and December 31, 2008 were primarily caused by the recent uncertainty in the capital credit markets and changes in interest rates. Since the decline in market value is primarily attributable to changes in these factors, and we have the ability and intent to hold these investments until a recovery of fair value, we do not consider these investments to be other-than-temporarily impaired at March 31, 2009.

Table of Contents

D. Inventories

The major classes of inventories were as follows at March 31, 2009 and December 31, 2008 (in thousands):

	March 31, 2009	December 31, 2008
Raw materials	$ 12	$ 9
Work in process	37	57
Finished goods	9	30
Total inventories	$ 58	$ 96

Prior to regulatory approval of *Feraheme*, we incur expenses for the manufacture of drug product that could potentially be available to support the commercial launch of this product candidate. Until the necessary regulatory approvals have been received, we charge all such amounts to research and development expenses.

E. Income Taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using 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 three months ended March 31, 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 was no other income tax provision or benefit for the three months ended March 31, 2009 given our continued net operating loss position. Due to the uncertainty surrounding realization of favorable tax attributes in future tax returns, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets.

F. Net Loss per Share

We compute basic net loss per share by dividing net loss by the weighted average number of common shares outstanding during the relevant period. The following table sets forth the potential common shares issuable upon the exercise of outstanding options and restricted stock units (prior to consideration of the treasury stock method), 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):

	Three Months Ended March 31,	
	2009	2008
Options to purchase shares of common stock	2,671	1,734
Shares of common stock issuable upon the vesting of restricted stock units	217	29
Total	2,888	1,763

Table of Contents

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

	Three Months Ended March 31,	
	2009	2008
Net loss	$ (26,423)	$ (9,301)
Weighted average common shares outstanding	17,021	16,970
Net loss per share:		
Basic and diluted	$ (1.55)	$ (0.55)

G. Equity-Based Compensation

We maintain several equity compensation plans, including our 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.

As of March 31, 2009, we have granted options and restricted stock units covering 1,946,081 shares of common stock under our 2007 Plan, of which 157,290 stock options and 6,000 restricted stock units have expired or terminated, and of which no options have been exercised and no shares of common stock were issued pursuant to restricted stock units that became fully vested. The number of options and restricted stock units outstanding under this plan as of March 31, 2009 was 1,589,291 and 193,500, respectively. The remaining number of shares available for future grants as of March 31, 2009 was 390,384, not including shares subject to outstanding awards under the 2000 Plan, which will be added to the total number of shares available for issuance under the 2007 Plan to the extent that such awards expire or terminate for any reason prior to exercise. All outstanding options granted under our 2007 Plan have an exercise price equal to the closing price of our common stock on the grant date and a ten-year term.

As of March 31, 2009, we have granted options and restricted stock units covering 2,182,700 shares of common stock under the 2000 Plan, of which 355,125 stock options and 750 restricted stock units have expired or terminated, and of which stock options and restricted stock units covering 701,770 and 20,250 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 March 31, 2009 was 1,081,805 and 23,000, 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):

Table of Contents

	Three Months Ended March 31, 2009	2008
Research and development	$ 1,095	$ 709
Selling, general and administrative	2,407	1,985
Total equity-based compensation expense	$ 3,502	$ 2,694

Equity-based compensation expense for the three months ended March 31, 2009 and 2008 included approximately $0.2 million and $0.7 million, respectively, in equity-based compensation expense associated with grants subject to market or performance conditions.

At March 31, 2009, the amount of unrecorded equity-based compensation expense attributable to future periods was approximately $43.2 million, of which $36.7 million was associated with stock options and $6.5 million was associated with restricted stock units. Such amounts will be amortized, in varying amounts, primarily to research and development or selling, general and administrative expense, generally on a straight line basis over weighted average amortization periods of approximately 3.1 and 2.9 years, respectively. These future estimates are subject to change based upon a variety of future events, which include, but are not limited to, changes in estimated forfeiture rates, and the issuance of new options and other equity-based awards.

H. 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 three months ended March 31, 2009 and 2008. No other company accounted for more than 10% of our total revenues for the three months ended March 31, 2009 and 2008.

	Three Months Ended March 31, 2009	2008
Bayer	54%	30%
Guerbet	33%	64%
Covidien	13%	<10%

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

Revenues from customers outside of the U.S., principally in Europe, amounted to 33% and 64% of our total revenues for the three months ended March 31, 2009 and 2008, respectively.

I. Recently Issued Accounting Pronouncements

In April 2009, the FASB issued FASB Staff Position, or 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 FASB Statement No. 107, Disclosure About Fair Value of Financial Investments, and APB 28, Interim Financial Reporting, to require disclosures

Table of Contents

about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FAS 107-1 and APB 28-1 will be effective for interim reporting periods ending after June 15, 2009. We are evaluating the impact that FSP 107-1 and APB 28-1 will have on our condensed consolidated financial statements.

In April 2009, the FASB issued FSP 115-2, FSP 124-2, and EITF 99-20-2, Recognition and Presentation of Other-Than-Temporary Impairments, or FSP 115-2, FSP 124-2, and EITF 99-20-2, respectively, which provide additional guidance to provide greater clarity to the credit and noncredit component of an other-than-temporary impairment event and to more effectively communicate when an other-than-temporary impairment event has occurred. FSP 115-2, FSP 124-2, and EITF 99-20-2 will be effective for interim and annual reporting periods ending after June 15, 2009. We are evaluating the impact that FSP 115-2, FSP 124-2, and EITF 99-20-2 will have on our condensed consolidated financial statements.

In April 2009, the FASB issued FSP 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 FASB 157 when the volume and level of activity for the asset or liability has significantly decreased. FSP 157-4 will be effective for interim and annual reporting periods ending after June 15, 2009. We are evaluating the impact that FSP 157-4 will have on our condensed consolidated financial statements.

Effective January 1, 2009, we adopted FSP EITF No. 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities, or EITF 03-6-1. EITF 03-6-1 addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting and therefore need to be included in the earnings allocation in calculating earnings per share under the two-class method described in SFAS No. 128, Earnings per Share. EITF 03-6-1 requires companies to treat unvested share-based payment awards that have non-forfeitable rights to dividend or dividend equivalents as a separate class of securities in calculating earnings per share. The adoption of EITF 03-6-1 did not have a significant impact on our condensed consolidated financial statements.

Effective January 1, 2009, we adopted SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133, or SFAS 161. SFAS 161 is intended to improve financial standards for derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity s financial position, financial performance, and cash flows. Entities are required to provide enhanced disclosures about: (a) how and why an entity uses derivative instruments; (b) how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations; and (c) how derivative instruments and related hedged items affect an entity s financial position, financial performance, and cash flows. Because we do not have any material derivative instruments requiring additional disclosure, the adoption of SFAS 161 did not have a significant impact on our condensed consolidated financial statements.

Effective January 1, 2009, we adopted SFAS No. 141 (revised 2007), Business Combinations, or SFAS 141R. SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest in the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. Because we did not enter into any business combinations during the three months ended March 31, 2009, the adoption of SFAS 141R did not have a significant impact on our condensed consolidated financial statements.

Effective January 1, 2009, we adopted EITF 07-01, Accounting for Collaborative Arrangements, or EITF 07-01, which addresses how the parties to a collaborative agreement should account for costs incurred

Table of Contents

and revenues generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure questions. The adoption of EITF 07-01 did not have a significant impact on our condensed consolidated financial statements.

Effective January 1, 2009, we adopted FSP SFAS No. 157-2, Effective Date of FASB No. 157, or FSP 157-2. FSP 157-2 delayed the effective date of SFAS 157 to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years, for nonfinancial assets and nonfinancial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The adoption of FSP 157-2 did not have a significant impact on our condensed consolidated financial statements.

J. 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 March 31, 2009.

K. Subsequent Events

At our Annual Meeting of Stockholders held on May 5, 2009, a proposal to amend and restate 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, was approved by a vote of our stockholders.

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 potential approval of Feraheme (ferumoxytol injection) in the U.S. and outside of the U.S., statements regarding our belief that we will not need to conduct any additional clinical trials prior to approval of Feraheme, our belief that we have adequately addressed the observations noted during a recent FDA inspection of our manufacturing facility and that a re-inspection of our manufacturing facility will not be required as a condition to approval of Feraheme, our plan to launch Feraheme, the progress of our intended development and commercialization of Feraheme, 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, future revenues (including expected future 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 have one product candidate, Feraheme (ferumoxytol injection), and two approved products, Feridex I.V.® and GastroMARK®.

Table of Contents

Feraheme is being developed for use as an intravenous, or IV, iron replacement therapeutic agent for the treatment of iron deficiency anemia, or IDA, and as a diagnostic agent for vascular enhanced magnetic resonance imaging, or MRI, to assess peripheral arterial disease, or PAD. In December 2007, we submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or the FDA, for marketing approval of *Feraheme* for the treatment of IDA in patients with chronic kidney disease, or CKD. In October 2008, we received a Complete Response letter from the FDA with respect to our NDA for *Feraheme* requesting certain additional clinical information, information regarding certain observations noted during an FDA inspection at one of our Phase III clinical sites, and resolution of certain observations noted during a recent FDA inspection of our Cambridge, Massachusetts manufacturing facility. We submitted a response to the Complete Response letter in October 2008, and in December 2008 we received a second Complete Response letter from the FDA requesting data to clarify a specific chemistry, manufacturing and controls question, resolution of the observations noted during the recent FDA inspection of our manufacturing facility, and finalization of labeling discussions for *Feraheme*. We are working with the FDA to address the December 2008 Complete Response letter and believe that we will not need to conduct any additional clinical trials of *Feraheme* prior to FDA approval of *Feraheme*. In addition, we have been engaged in active dialogue with the FDA and have recently been informed that the observations noted during the recent FDA inspection of our manufacturing facility have been adequately addressed and that a re-inspection of our manufacturing facility will not be required as a condition to approval of *Feraheme*. We will need to resolve all of the issues raised by the FDA in the Complete Response letters in a timely manner in order to obtain approval to market and sell *Feraheme* in the U.S.

Following discussions with the FDA regarding the proposed design of our Phase III oncology program, we decided to pursue a broad Phase III clinical development program to treat IDA in a wide range of patient populations and in multiple disease states rather than pursue individual indications. As a result, we decided not to commence enrollment in our previously planned Phase III studies of *Feraheme* in women with IDA and abnormal uterine bleeding, or AUB, and not to advance our plans for a separate Phase III clinical development program for *Feraheme* in patients with IDA and cancer. 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 subject to the completion of discussions with the FDA and final protocol review.

In addition to its use for the treatment of IDA, *Feraheme* may also be useful as a vascular enhancing agent in MRI. In August 2008, we announced that the FDA granted Fast Track designation to *Feraheme* for its development as a diagnostic agent for vascular-enhanced MRI for the assessment of PAD. We have initiated 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.

If approved for the treatment of IDA in CKD patients, we will market and sell *Feraheme* in the U.S. through our own commercial organization. We have built an internal sales and marketing function, including a direct sales force, in preparation for the planned U.S. commercial launch of *Feraheme* as an IV iron replacement therapeutic agent in CKD patients.

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

Table of Contents

reimbursement, patient access to dialysis, the role of iron in medical treatment protocols in each country, 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.

GastroMARK, our oral contrast agent used for delineating the bowel in MRI, is approved and marketed in the U.S., Europe, and other countries. 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, is approved and has been sold in the U.S., Europe and other countries. 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 March 31, 2009 as Compared to the Three Months Ended March 31, 2008

Revenues

Total revenues were $1.0 million and $0.6 million for the three months ended March 31, 2009 and 2008, respectively, representing an increase of approximately 56%. The increase in revenues was primarily the result of an increase in license fee revenues, as discussed below.

Our revenues for the three months ended March 31, 2009 and 2008 consisted of the following (in thousands):

	Three Months Ended March 31, 2009	2008	$ Change	% Change
Revenues:				
License fees	$ 516	$ 184	$ 332	>100%
Royalties	47	36	11	31%
Product sales	393	392	1	0%
Total	$ 956	$ 612	$ 344	56%

The following table sets forth customers who represented 10% or more of our revenues for the three months ended March 31, 2009 and 2008. No other company accounted for more than 10% of our total revenues in either period.

	Three Months Ended March 31, 2009	2008
Bayer	54%	30%
Guerbet	33%	64%
Covidien	13%	<10%

License Fee Revenues

License fee revenues were $0.5 million and $0.2 million for the three months ended March 31, 2009 and 2008, respectively, and consisted solely of deferred license fee 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 1996, the parties agreed to remove Canada from the territories subject to the Bayer Agreements. In connection with our decision in November 2008 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

Table of Contents

these agreements, during the three months ended March 31, 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 2009.

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 March 31, 2009 and 2008 consisted of the following (in thousands):

	Three Months Ended March 31,			
	2009	2008	$ Change	% Change
GastroMARK	$ 393	$ 157	$ 236	>100%
Feridex I.V.		235	(235)	-100%
Total	$ 393	$ 392	$ 1	0%

Total product sale revenues for the three months ended March 31, 2009 remained relatively stable as compared to the three months ended March 31, 2008 and reflect an increase in sales of *GastroMARK* to our marketing partners, offset by a decrease in sales of *Feridex I.V.* as the result of our November 2008 decision to cease the manufacture and commercialization of *Feridex I.V.* Product sales may fluctuate from period to period. Fluctuations in our product sales are primarily attributable to unpredictable annual product demand by end users and the batch sizes in which our products are manufactured and shipped, which create uneven purchasing patterns by our marketing partners. Due to our decision to cease the manufacture and commercialization of *Feridex I.V.* in November 2008, we do not expect that revenues from our currently marketed products will materially change during the remainder of 2009.

Costs and Expenses

Cost of Product Sales

We incurred costs associated with product sales during the three months ended March 31, 2009 and 2008 of approximately $61,000 and $44,000, respectively. These costs represented approximately 16% and 11% of product sales during the three months ended March 31, 2009 and 2008, respectively. The cost of product sales and therefore our gross margins are dependent on the mix of customers, prices we charge for our products, product mix, changes in unit volume and production efficiencies, none of which had a material impact during the three months ended March 31, 2009 or 2008.

Table of Contents

Research and Development Expenses

Research and development expenses include external expenses, such as costs of clinical trials, contract research and development expenses, commercial manufacturing preparation and related materials costs, consulting and professional fees and expenses, and internal expenses, such as compensation of employees engaged in research and development activities, the manufacture of 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 in other external costs. Manufacturing costs are expensed as incurred until a product has received the necessary initial regulatory approval.

Research and development expenses for the three months ended March 31, 2009 and 2008 consisted of the following (in thousands):

	Three Months Ended March 31,			
	2009	2008	$ Change	% Change
External Research and Development Expenses				
Feraheme as an IV iron replacement therapeutic agent in CKD patients	$ 1,425	$ 158	$ 1,267	>100%
Feraheme as an IV iron replacement therapeutic agent in AUB patients	1,287	18	1,269	>100%
Feraheme as an imaging agent in PAD patients	323		323	N/A
Feraheme manufacturing and materials	1,154	576	578	>100%
Other external costs	216	227	(11)	-5%
Total	$ 4,405	$ 979	$ 3,426	>100%
Internal Research and Development Expenses				
Compensation, payroll taxes, benefits and other expenses	5,572	3,135	2,437	78%
Equity-based compensation expense	1,095	709	386	54%
Total	$ 6,667	$ 3,844	$ 2,823	73%
Total Research and Development Expenses	$ 11,072	$ 4,823	$ 6,249	>100%

Total research and development expenses incurred in the three months ended March 31, 2009 amounted to $11.1 million, an increase of $6.2 million, or 130%, from the three months ended March 31, 2008. The $6.2 million increase was primarily attributable to costs associated with increased headcount, our AUB and PAD clinical development programs, and activities necessary to address the manufacturing issues raised during the recent FDA inspection of our Cambridge, Massachusetts manufacturing facility and to prepare for commercial scale manufacturing of *Feraheme*.

Our external research and development expenses increased by $3.4 million, or 350%, for the three months ended March 31, 2009 as compared to the three months ended March 31, 2008. The $3.4 million increase in our external expenses was due primarily to spending on our clinical development programs for AUB and PAD, costs associated with our efforts to address the manufacturing issues raised by the FDA during a recent inspection of our Cambridge, Massachusetts manufacturing facility, costs incurred with respect to production materials and supplies, and second source manufacturing and other activities related to preparation for commercial scale manufacturing.

Our internal research and development expenses increased by $2.8 million, or 73%, for the three months ended March 31, 2009 as compared to the three months ended March 31, 2008. The $2.8 million increase in

Table of Contents

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 planned commercialization of *Feraheme*. At March 31, 2009, we had 94 employees in research and development as compared to 50 employees at March 31, 2008, an increase of 88%. 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 increase as we advance our clinical development programs, continue commercial manufacturing preparations, purchase additional *Feraheme* materials and supplies and continue other research and development related functions and activities in support of *Feraheme*. If *Feraheme* receives approval from the FDA, we will record materials, supplies and other costs associated with manufacturing *Feraheme* as inventory in accordance with our capitalization policies.

We do not track our internal costs by project since our research and development personnel work on a number of projects concurrently and much of our fixed costs benefit multiple projects or our operations in general. We track our external costs on a major project by major project basis, in most cases through the NDA submission to the FDA with respect to such project. In December 2007, we submitted an NDA for *Feraheme* as an IV iron replacement therapeutic agent in CKD patients and therefore do not intend to track additional external costs related to that project.

During 2008, we began incurring costs related to our AUB clinical development program. However, following discussions with the FDA regarding the proposed design of our Phase III oncology program, 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 decided not to begin enrollment in our previously planned Phase III studies of *Feraheme* in women with IDA and AUB and not to advance our plans for a separate Phase III clinical development program for *Feraheme* in patients with IDA and cancer. During the three months ended March 31, 2009, we incurred costs associated with the AUB clinical development program of $1.3 million. We do not expect to incur any significant additional future costs associated with the AUB clinical development program but will 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.

At this time, due to the numerous risks and uncertainties inherent in the clinical development and regulatory approval process, including significant and changing government regulation, and given the current stage of our development of our additional indications for *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 obtaining FDA approval of *Feraheme* and the subsequent planned 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

Table of Contents

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.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended March 31, 2009 and 2008 consisted of the following (in thousands):

	Three Months Ended March 31,			
	2009	2008	$ Change	% Change
Compensation, payroll taxes and benefits	$ 8,421	$ 2,549	$ 5,872	>100%
Professional and consulting fees and other expenses	6,922	3,851	3,071	80%
Equity-based compensation expense	2,407	1,985	422	21%
Total	$ 17,750	$ 8,385	$ 9,365	>100%

The $9.4 million, or 112%, increase in selling, general and administrative expenses for the three months ended March 31, 2009 as compared to the three months ended March 31, 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 preparing for the planned U.S. commercial launch of *Feraheme*, and the expansion of our general administrative infrastructure. At March 31, 2009, we had 171 employees in our selling, general and administrative departments as compared to 47 employees at March 31, 2008, an increase of 264%. The increase in equity-based compensation expense in the three months ended March 31, 2009 as compared to the three months ended March 31, 2008 was primarily attributable to increased equity awards to both new and existing employees partially offset by a net decrease in expense of $0.7 million associated with performance-based awards recognized during the three months ended March 31, 2008 for which there was no expense in 2009.

We expect selling, general and administrative expenses to continue to increase during the remainder of 2009. We continue to incur significant expense related to maintaining our sales force, developing our marketing infrastructure, executing related marketing and promotional programs and hiring consultants in preparation for the planned commercialization of *Feraheme* in the U.S. as an IV iron replacement therapeutic agent in patients with CKD.

Other Income (Expense)

Other income (expense) for the three months ended March 31, 2009 and 2008 consisted of the following (in thousands):

Table of Contents

	Three Months Ended March 31,			
	2009	2008	$ Change	% Change
Interest and dividend income, net	$ 1,256	$ 3,267	$ (2,011)	-62%
Gains on investments, net	992	72	920	>100%
Fair value adjustment of settlement rights	(923)		(923)	N/A
Total	$ 1,325	$ 3,339	$ (2,014)	-60%

The $2.0 million, or 60%, decrease in other income (expense) for the three months ended March 31, 2009, as compared to the three months ended March 31, 2008 was primarily attributable to a $2.0 million decrease in interest and dividend income as the result of a lower average amount of invested funds and lower interest rates in the three months ended March 31, 2009 as compared to the three months ended March 31, 2008.

In November 2008, we elected to participate in a rights offering by UBS AG, or UBS, one of our brokers, 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, or the Settlement Rights. 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 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 UBS Settlement Rights and as of March 31, 2009, we have recorded an asset equal to our estimated fair value of the Settlement Rights of approximately $0.6 million in our condensed consolidated balance sheet. This represents a decrease of approximately $0.9 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 $8.6 million as of March 31, 2009 as trading securities. Accordingly, as of March 31, 2009, we have adjusted our estimated value of these trading securities by approximately $1.0 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.

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 the commercial, clinical, and manufacturing activities noted above. We will be 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 will be required to periodically assess the economic ability of UBS to meet that obligation in assessing the fair value of the Settlement Rights.

Table of Contents

Income Tax Benefit

During the three months ended March 31, 2009, we recognized a tax benefit of $0.2 million associated with U.S. research and development tax credits against which we had previously provided a valuation allowance, but which became refundable as a result of legislation passed in February 2009.

Net Loss

For the reasons stated above, we incurred a net loss of $26.4 million, or $1.55 per basic and diluted share, for the three months ended March 31, 2009 compared to a net loss of $9.3 million, or $0.55 per basic and diluted share, for the three months ended March 31, 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 obtain regulatory approval in the U.S. for *Feraheme* as an IV iron replacement therapeutic agent in a timely manner;

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

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

- Costs associated with commercial-scale manufacturing of *Feraheme,* including costs associated with building 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 of potential business development activities;

Table of Contents

- 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 auction rate securities, or 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;

- 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 March 31, 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 March 31, 2009, we held a total of $57.6 million in fair market value of ARS, reflecting an impairment of approximately $8.9 million compared to the par value of these securities of $66.5 million. Of the $8.9 million impairment, approximately $8.2 million is considered a temporary impairment and is reported as an unrealized loss at March 31, 2009. The remaining $0.7 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 $8.6 million. The substantial majority of our ARS portfolio was rated AAA as of March 31, 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, one of our brokers, 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 will be required to periodically assess the economic ability of UBS to meet that obligation in

assessing the fair value of the Settlement Rights.

We believe that the $8.2 million temporary impairment related to our other ARS 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

Table of Contents

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 earnings as appropriate. In the event that we need to access our investments in these securities, we will not be able to do so until a future auction is successful, the issuer calls the security pursuant to a mandatory tender or redemption prior to maturity, a buyer is found outside the auction process, or the securities mature. For all of our ARS, the underlying maturity date is in excess of one year, and 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 our other sources of cash, we do not anticipate that the current lack of liquidity with respect to our ARS will materially affect our ability to operate our business in the ordinary course over 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 March 31, 2009 and December 31, 2008 consisted of the following (in thousands):

	March 31, 2009	December 31, 2008	$ Change	% Change
Cash and cash equivalents	$ 67,988	$ 64,182	$ 3,806	6%
Short-term investments	68,318	94,914	(26,596)	-28%
Long-term investments	57,639	54,335	3,304	6%
Total cash, cash equivalents and investments	$ 193,945	$ 213,431	$ (19,486)	-9%

The decrease in cash and cash equivalents and investments as of March 31, 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 March 31, 2009, we believe that our cash, cash equivalents, and short-term investments, combined with cash we currently expect to receive from earnings on our investments, will be sufficient to satisfy our future cash flow needs for at least the next twelve months.

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 three months ended March 31, 2009, our use of $22.4 million of cash in operations was due principally to our net loss of approximately $26.4 million partially offset by approximately $4.1 million in equity-based compensation and other non-cash expenses. Our net loss includes compensation-related expenses associated with additional employees hired for research and development and commercial operating activities, payments for activities in preparation for the planned commercialization

Table of Contents

of *Feraheme* as an IV iron replacement therapeutic agent, and costs associated with clinical trials in indications other than CKD.

We anticipate cash used in operating activities will increase in 2009 over current levels as we continue to advance our ongoing commercialization efforts for *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 planned *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 expenses and the timing and progress of the regulatory approval of *Feraheme* and our development, sales and marketing efforts.

Cash flows from investing activities

Cash provided by investing activities was $26.2 million during the three months ended March 31, 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 $0.1 million during the three months ended March 31, 2009 and was primarily attributable to the proceeds from the exercise of stock options.

Operating and Facility Lease Obligations

We have entered into certain operating leases, including leases of certain automobiles and certain laboratory and office equipment, which are in effect through 2011. We lease approximately 110 automobiles for our field-based employees. This lease requires a minimum lease term of 12 months per automobile. We expect our monthly expense related to this operating lease to be approximately $60,000. We are also responsible for certain disposal costs in the event of termination of the lease.

In May 2008, we entered into a lease agreement for certain real property located at 100 Hayden Avenue, Lexington, Massachusetts for use as our principal executive offices. The term of the lease began on May 22, 2008 and will continue until August 31, 2016 with two successive five year extension terms at our option. The aggregate size of rentable floor area for the offices is 55,924 square feet, and the rent for the initial term commenced in February 2009.

Off-Balance Sheet Arrangements

As of March 31, 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 not limited to, assessing

Table of Contents

investments for potential impairment and determining values of investments, accrued expenses, income taxes and equity-based compensation expense. Actual results could differ 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.

Impact of Recently Issued Accounting Pronouncements

In April 2009, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position, or 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 amends FASB Statement No. 107, Disclosure About Fair Value of Financial Investments, and APB 28, Interim Financial Reporting, to require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FAS 107-1 and APB 28-1 will be effective for interim reporting periods ending after June 15, 2009. We are evaluating the impact that FSP 107-1 and APB 28-1 will have on our condensed consolidated financial statements.

In April 2009, the FASB issued FSP 115-2, FSP 124-2, and EITF 99-20-2, Recognition and Presentation of Other-Than-Temporary Impairments, or FSP 115-2, FSP 124-2, and EITF 99-20-2, respectively, which provide additional guidance to provide greater clarity to the credit and noncredit component of an other-than-temporary impairment event and to more effectively communicate when an other-than-temporary impairment event has occurred. FSP 115-2, FSP 124-2, and EITF 99-20-2 will be effective for interim and annual reporting periods ending after June 15, 2009. We are evaluating the impact that FSP 115-2, FSP 124-2, and EITF 99-20-2 will have on our condensed consolidated financial statements.

In April 2009, the FASB issued FSP 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 FASB 157 when the volume and level of activity for the asset or liability has significantly decreased. FSP 157-4 will be effective for interim and annual reporting periods ending after June 15, 2009. We are evaluating the impact that FSP 157-4 will have on our condensed consolidated financial statements.

Effective January 1, 2009, we adopted FSP EITF No. 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities, or EITF 03-6-1. EITF 03-6-1 addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting and therefore need to be included in the earnings allocation in calculating earnings per share under the two-class method described in SFAS No. 128, Earnings per Share. EITF 03-6-1 requires companies to treat unvested share-based payment awards that have non-forfeitable rights to dividend or dividend equivalents as a separate class of securities in calculating earnings per share. The adoption of EITF 03-6-1 did not have a significant impact on our condensed consolidated financial statements.

Effective January 1, 2009, we adopted SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133, or SFAS 161. SFAS 161 is intended to improve financial standards for derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity s financial position, financial performance, and cash flows. Entities are required to provide enhanced disclosures about: (a) how and why an entity uses derivative instruments; (b) how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations; and (c) how derivative instruments and related

Table of Contents

hedged items affect an entity s financial position, financial performance, and cash flows. Because we do not have any material derivative instruments requiring additional disclosure, the adoption of SFAS 161 did not have a significant impact on our condensed consolidated financial statements.

Effective January 1, 2009, we adopted SFAS No. 141 (revised 2007), Business Combinations, or SFAS 141R. SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest in the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. Because we did not enter into any business combinations during the three months ended March 31, 2009, the adoption of SFAS 141R did not have a significant impact on our condensed consolidated financial statements.

Effective January 1, 2009, we adopted EITF 07-01, Accounting for Collaborative Arrangements, or EITF 07-01, which addresses how the parties to a collaborative agreement should account for costs incurred and revenues generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure questions. The adoption of EITF 07-01 did not have a significant impact on our condensed consolidated financial statements.

Effective January 1, 2009, we adopted FSP SFAS No. 157-2, Effective Date of FASB No. 157, or FSP 157-2. FSP 157-2 delayed the effective date of SFAS 157 to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years, for nonfinancial assets and nonfinancial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The adoption of FSP 157-2 did not have a significant impact on our condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As of March 31, 2009, our short- and long-term investments totaled $126.0 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 March 31, 2009, this would have resulted in a hypothetical decline in fair value of our investments, excluding ARS, which are described below, of approximately $0.2 million.

At March 31, 2009, we held a total of $57.6 million in fair market value of ARS, reflecting an impairment of approximately $8.9 million compared to the par value of these securities of $66.5 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 analyses consider, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, 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 an $8.2 million unrealized loss related to our ARS, other than those subject to Settlement Rights, to accumulated other

Table of Contents

comprehensive loss as of March 31, 2009. In November 2008, we elected to participate in a rights offering by UBS, one of our 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.

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 March 31, 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 $1.6 million as of March 31, 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 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, or SEC s rules and forms. It should be noted that any system of controls is designed to provide reasonable, but not absolute, assurances that the system will achieve its stated goals under all reasonably foreseeable circumstances. Our principal executive officer and principal financial officer have 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 three months ended March 31, 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.

Table of Contents

We are solely dependent on the success of Feraheme.

We are currently investing most of our efforts and financial resources in the development and commercialization of *Feraheme*. Our ability to generate future revenues is solely dependent on our ability to obtain marketing approval for and successfully commercialize *Feraheme* as an IV iron replacement therapeutic agent in the U.S. If we are unable to generate revenues from *Feraheme*, our financial condition will be materially adversely affected and our business prospects will be very limited.

Although we have dedicated significant resources to development efforts in the past, we may not be successful in developing new applications for our existing technology or in expanding the potential indications for *Feraheme*. Although we have commenced or are pursuing additional clinical trials for *Feraheme* in indications other than CKD in an effort to expand the potential indications for *Feraheme*, we are not currently conducting or sponsoring research to expand our product development pipeline beyond *Feraheme*. Any failure by us to acquire, develop and commercialize additional products and product candidates or additional indications for *Feraheme* would limit long-term shareholder value and would adversely affect the future prospects of our business.

We currently have two products, *Feridex I.V.* and *GastroMARK*, approved for marketing and sale in the U.S. and in certain foreign jurisdictions. However, we recently ceased the manufacture of *Feridex I.V.* and have terminated all of our agreements with our marketing partners for *Feridex I.V.* throughout the world. In addition, 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 materially increase.

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

FDA approval of *Feraheme* may be significantly delayed or may never occur for a variety of reasons, including but not limited to the following:

- The FDA may determine that *Feraheme* is not safe or efficacious;

- We may not be able to adequately address the issues raised in the December 2008 Complete Response letter received by the FDA in a timely manner, if at all;

- The FDA may identify deficiencies in the design, implementation or oversight of our clinical development program or manufacturing operations, which we may not be able to adequately address in a timely manner, if at all; or

- The FDA may require additional information which we may not be able to provide in a timely manner, if at all.

The FDA imposes substantial requirements on the development, production and commercial introduction of all drug products. Before obtaining regulatory approval for the commercial marketing and sale of *Feraheme*, we must demonstrate through extensive pre-clinical testing and human clinical trials that *Feraheme* is safe and efficacious. In December 2007, we submitted our NDA to the FDA for marketing approval of *Feraheme* for the treatment of IDA in CKD patients. In October 2008, we received a Complete Response letter from the FDA with respect to our NDA for *Feraheme* requesting certain additional clinical information, information regarding certain observations noted during an FDA inspection at one of our Phase III clinical sites, and resolution of certain observations noted during a recent FDA inspection of our Cambridge, Massachusetts manufacturing facility. In December 2008 we

Table of Contents

received a second Complete Response letter from the FDA requesting data to clarify a specific chemistry, manufacturing and controls question, resolution of the observations noted during the recent FDA recent inspection of our manufacturing facility, and finalization of labeling discussions for *Feraheme*. If we are unable to adequately address the issues raised or provide the information requested by the FDA with respect to our NDA in a timely manner, we may experience significant delays in our efforts to obtain approval for *Feraheme* or *Feraheme* may not receive approval at all.

The FDA has substantial discretion in the approval process and may decide that the data in our NDA, including any information we provide in our reply to the December 2008 Complete Response letter, is insufficient for approval. The FDA may review our data and determine that *Feraheme* is not efficacious and/or does not have an acceptable safety profile. 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 pre-clinical studies, our clinical trials and/or our manufacturing processes were not properly designed, were not conducted in accordance with federal laws and regulations, or were otherwise not properly managed.

In addition, under the FDA s current good clinical practices, or cGCP, regulations, we are responsible for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA may conduct inspections of clinical investigator sites, which were involved in our clinical development programs to ensure their compliance with cGCP regulations. If the FDA determines that we, our contract research organizations or our study sites 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.*

Any such deficiency in the design, implementation or oversight of our clinical development program identified by the FDA could cause us to incur significant additional costs, experience significant delays in our efforts to obtain regulatory approval for *Feraheme*, or even prevent us from obtaining regulatory approval for *Feraheme*. 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.

We may not be able to continue to operate our manufacturing facility in compliance with current good manufacturing practices, or cGMP, and other FDA regulations, which could result in a substantial delay in the approval of Feraheme, a suspension of our ability to manufacture Feraheme, the loss of our existing Feraheme inventory, a delay in our anticipated Feraheme launch, 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. Failure to operate in compliance with cGMP regulations and other applicable manufacturing requirements of various regulatory agencies could result in the FDA s issuance of Warning Letters, fines, product recalls, total or partial suspension of production, suspension of the FDA s review of an NDA or future supplemental NDAs, enforcement actions, injunctions or criminal prosecution and could impair our ability to obtain product approvals, generate product sales and continue our development efforts. In addition to the foregoing regulatory actions that may be taken by the FDA, any failure on our part to

Table of Contents

continuously operate our manufacturing facility in accordance with cGMP requirements could result in a substantial delay in the approval of *Feraheme,* a suspension of our ability to manufacture *Feraheme*, the loss of our existing *Feraheme* inventory, a delay in our anticipated *Feraheme* launch, our inability to manufacture sufficient quantities of *Feraheme* to meet demand, or other unanticipated compliance expenditures, any of which would have an adverse impact on our potential profitability and the future prospects of our business.

In addition, if the FDA decides to re-inspect our manufacturing facility to confirm the remedial measures we have implemented are adequate, the FDA may identify new or additional deficiencies with respect to our compliance with cGMP regulations. If the FDA were to identify additional cGMP deficiencies, the FDA could take one or more of the regulatory actions described above, which could result in a substantial delay in the approval of *Feraheme,* a suspension of our ability to manufacture *Feraheme*, the loss of our existing *Feraheme* inventory, a delay in our anticipated *Feraheme* launch, our inability to manufacture sufficient quantities of *Feraheme* to meet demand, or other unanticipated compliance expenditures, any of which would have an adverse impact on our potential profitability and the future prospects of our business.

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

We currently manufacture *GastroMARK* for commercial sale and *Feraheme* for potential commercial use and for use in human clinical trials in our Cambridge, Massachusetts manufacturing facility. We also intend to use this facility to manufacture *Feraheme* for commercial sale if and when it is approved by the FDA. Although we are working to establish and qualify second source manufacturing facilities for *Feraheme*, we currently have only one manufacturing facility at which we produce limited quantities of *Feraheme*. As we manufacture *Feraheme* in larger volumes for commercial sale, we could experience higher than anticipated material, labor and overhead costs per unit. Additionally, manufacturing and quality control problems may arise as we increase our level of production. If we are not able to use our existing *Feraheme* inventory to satisfy demand at launch, we may not be able to increase our manufacturing capacity in a timely and cost-effective manner to meet demand for *Feraheme* if and when it is approved by the FDA, and we may experience delays in manufacturing *Feraheme*, which could result in a shortage in the supply of *Feraheme*. Furthermore, we will need to continue to recruit, train and retain additional qualified manufacturing and quality control personnel as we prepare for production of *Feraheme* on a commercial scale. 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.

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

Although we are working to establish and qualify second source manufacturing facilities for *Feraheme*, 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. Furthermore, use of second-source manufacturing facilities may increase the risk of certain problems,

Table of Contents

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 demand for *Feraheme*. As a result, we may lose sales and fail to generate increased revenues, which would have a severe adverse impact on our potential profitability and future business prospects.

Our inability to obtain raw materials and our reliance on sole source suppliers could adversely impact our ability to manufacture sufficient quantities of 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 the raw materials;
- Labor disputes or shortages;
- Manufacturing difficulties;
- Regulatory requirements or action;
- Adverse financial developments at or affecting the supplier; or
- Import or export problems.

If any of our third-party suppliers cease to supply our raw materials for any reason, we would be unable to manufacture *Feraheme* or unable to manufacture *Feraheme* in sufficient quantities until we are able to qualify an alternative source.

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

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

For a variety of reasons, many of which are beyond our control, *Feraheme* may not achieve market acceptance among physicians, patients, or healthcare payors or providers, including dialysis clinics. If *Feraheme* does not achieve an adequate level of market acceptance for any reason, our potential profitability and our future business prospects would be severely adversely impacted. *Feraheme* will represent an alternative to existing products and might not be adopted by the medical community if perceived to be no safer or more effective than currently available products. The degree of market acceptance of *Feraheme* will depend on a number of factors, including:

- Our ability to demonstrate to the medical community, particularly nephrologists, hematologists, dialysis clinics and others who may purchase or prescribe *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 timing of market entry of *Feraheme* relative to competitive treatments;

- 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 therapeutic agents;

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

- The *Feraheme* labeling and product insert required by the FDA;

- The availability of generic iron preparations; and

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

Currently IV iron therapeutic products are not widely used by physicians who treat non-dialysis CKD patients in the physician s office setting due to safety concerns and the inconvenience and often impracticability of administering currently approved IV iron therapeutic products in that setting. A key component of our commercialization strategy is to develop a market for IV iron replacement therapeutics, specifically *Feraheme*, in the non-dialysis CKD market. Therefore, if approved, it will be critical for us to successfully market and sell *Feraheme* to physicians who treat non-dialysis CKD patients in the physician s office setting. It is often difficult to change physicians existing treatment paradigms even when supportive clinical data is available. If we are not successful in marketing and selling *Feraheme*, if and when approved,

Table of Contents

to physicians who treat non-dialysis CKD patients in the physician s office setting, our ability to generate revenues, achieve and maintain profitability, and long-term business prospects would be adversely affected.

The dialysis market is the largest and most established market for IV iron replacement therapies, with two companies serving a significant majority of all dialysis patients in the U.S. Fresenius Medical Care North America, or 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* will be severely limited, which would have a material adverse impact on our potential profitability, and our future business prospects. In addition, in September 2008, Fresenius finalized an exclusive sublicense agreement with Luitpold Pharmaceuticals, Inc, or Luitpold,, 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. Luitpold retains the right to sell Venofer® in the U.S. to any other customer. In 2008, Galenica, Vifor Pharma and Fresenius also 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 this agreement, it may be more difficult for us to penetrate the dialysis market, in particular at Fresenius clinics.

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

Our ability to successfully commercialize *Feraheme* will depend on the adequacy of insurance coverage, coding, and 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*. We expect that *Feraheme* will be purchased by hospitals, clinics, dialysis centers, physicians and other users, each of which generally relies on third-party payors to reimburse them or their patients for pharmaceutical products administered in the hospital, clinic, dialysis center and physician-office settings. Public and private insurance coverage and reimbursement plans are therefore central to new product acceptance, with customers unlikely to use *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 adequately reimbursed. This could result in lower sales of *Feraheme*, which would have a material adverse effect on us and the results of our operations.

In the U.S. there have been, and we expect there will continue to be, a number of federal and state proposals to reform the healthcare system in ways that could impact our ability to sell *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, utilizing variable co-payments, or refusing to provide coverage of approved products for medical indications other than those for which the FDA has granted marketing approval.

Table of Contents

With respect to *Feraheme*, 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 highly uncertain whether the ASP reimbursement methodology will continue to apply if and when *Feraheme* is approved by the FDA, and any changes in reimbursement policies may have a negative impact on the level of reimbursement available for *Feraheme*. On July 15, 2008, Congress enacted The Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, which created a bundled payment system for the treatment of end stage renal disease, or ESRD, to take effect on January 1, 2011. MIPPA requires CMS to begin a process of moving from a system in which it pays separately for physician-administered drugs for dialysis patients to a 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, for providers to obtain reimbursement for *Feraheme* from Medicare, Medicaid and certain third-party payers, select codes must be submitted by the provider with each claim. These codes are issued to manufacturers at the discretion of CMS. Certain codes may also be issued by CMS at the request of a provider or Medicare Administrative Contractor. There is no guarantee that we will be successful in obtaining the appropriate codes for *Feraheme*, and our inability to obtain these codes 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 marketing and sales experience, 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 marketed or sold a drug product as we have relied on our corporate partners to market and sell our current approved products, *Feridex I.V.* and *GastroMARK*. In preparation for the planned U.S. commercial launch of *Feraheme* as an IV iron replacement therapeutic agent in CKD patients, we have built an internal sales and marketing function, including a direct sales force, in the U.S. Developing an internal marketing team and sales force is expensive and time-consuming. In addition, we have and continue to expend substantial amounts of capital to prepare for the U.S. commercial launch of *Feraheme* before we know whether the FDA has approved the marketing and sale of *Feraheme*. If *Feraheme* is not approved by the FDA or is not approved in a timely manner, we may not have the ability to redeploy the sales force, and we will have no way to recoup the capital expended in building the sales force and commercial organization.

Table of Contents

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

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

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

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

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

Any delay or failure in our commercial product launch of *Feraheme* would have a material adverse impact on our ability to generate revenues, our ability to achieve profitability, and the future prospects for our business.

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

The pharmaceutical and biopharmaceutical industries are subject to intense competition and rapid technological change. Most of our competitors which are developing iron replacement therapeutic products have greater financial resources, experience and expertise in product development, manufacturing, marketing and sales than we do. Our *Feraheme* commercial opportunity will be reduced or eliminated if our competitors develop and commercialize 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*. In addition, any significant delays in FDA approval or U.S. commercial launch of *Feraheme* could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize *Feraheme*.

There are currently two options for treating IDA in CKD patients: oral iron supplements and IV iron. We anticipate that, if approved, *Feraheme* will primarily compete with existing IV iron replacement therapies, including Venofer®, which is marketed by Fresenius and American Regent Laboratories, Inc., a subsidiary of Luitpold, Ferrlecit®, which is marketed by Watson Pharmaceuticals, Inc., and certain oral iron products. These competing iron replacement therapy products may receive greater market acceptance than *Feraheme*, especially since these products are already on the market and are currently widely used by physicians. We may not be able to convince physicians to switch from using the currently approved IV iron therapeutic products to *Feraheme*. The iron replacement therapy market is highly sensitive to several factors

including, but not limited to, the ability to obtain appropriate insurance coverage, coding and

Table of Contents

reimbursement, price competitiveness, and product characteristics such as convenience of administration and dosing regimens. In particular, the IV iron replacement market is extremely sensitive to the perceived relative safety profiles of the various IV iron replacement therapeutics, and it will be critical that *Feraheme* s safety profile is or is perceived to be comparable to that of other products in order to be competitive in the marketplace. To date, we have not conducted any head-to-head clinical studies comparing the relative safety profiles of *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 soluble ferric pyrophosphate, or SFP, a form of iron given as part of the hemodialysis procedure.

Galenica, through its Vifor (International) Inc. subsidiary, exclusively licenses Injectafer® to Luitpold and American Regent for the United States and Canada. Injectafer® is in development for a variety of anemia-related indications, including the treatment of anemia in CKD patients, whether or not on dialysis. In addition, Luitpold is sponsoring ongoing Phase III trials for Ferinject® in cardiology (chronic heart failure), irritable bowel disease, orthopedic surgery and post partum anemia. In June 2007, the UK Medicines and Healthcare Products Regulatory Agency approved the registration of Ferinject®, and it was simultaneously registered in a total of 18 EU countries. Ferinject® is currently marketed in eight European countries. In March 2008, Luitpold received a non-approvable letter from the FDA for Injectafer® for the treatment of IDA in postpartum women and women with heavy uterine bleeding in the U.S. Luitpold has expanded ongoing clinical trials and is initiating three further clinical trials to provide additional data addressing the concerns of the FDA. Luitpold expects these trials to take two years to complete prior to filing an NDA in the U.S.

Rockwell Medical Technologies, Inc., or Rockwell, is developing an iron supplemented dialysate product, SFP, a form of iron given as part of the hemodialysis procedure to be used as a treatment for anemia in dialysis patients. Rockwell has completed enrollment for its ongoing Phase IIb clinical trials and is sponsoring an on-going study funded by the National Institutes of Health. We do not know when an NDA for SFP might be submitted to the FDA for approval or when SFP may be marketed in the U. S. SFP, if shown to be safe and effective for the treatment of IDA, could compete with IV iron products, including *Feraheme*.

Pharmacosmos A/S has also completed a non-comparative open-label Phase III study of IV iron oligosaccharide in CKD patients. No additional studies are known to be on-going, and their future development plans have not been publicly disclosed.

In addition to competition from currently approved products and products known by us to be currently under development, the market opportunity for *Feraheme* would be negatively affected if generic IV iron replacement therapy products were to be approved and achieve commercial success. For example, in June 2008, Hospira, Inc. reported opening a bioequivalence study for a generic iron sucrose. As of January 2009, the study was not complete and was not actively recruiting patients. 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. It remains unclear whether a generic product will enter this market. If any of these product candidates are approved for marketing and sale by the FDA our efforts to market and sell *Feraheme*, if approved, and our ability to generate additional revenues and achieve profitability would be adversely affected.

Table of Contents

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

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

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 FDA as part of our NDA was obtained in controlled clinical trials of limited duration. If approved, new safety or drug interaction issues may arise as *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 would have a severe adverse impact on our potential profitability and the future prospects of our business.

We may also be required to conduct certain post-approval clinical studies to assess known or suspected significant risks associated with *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 Risk Evaluation and Mitigation Strategy, or 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 would 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.

Table of Contents

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 $55.00 in the fifty-two week period through May 1, 2009. The stock market has from time to time experienced extreme price and volume fluctuations, particularly in the biotechnology and pharmaceuticals sectors, which have often been unrelated to the operating performance of particular companies. Various factors and events, many of which are beyond our control, may have a significant impact on the market price of our common stock. Factors which may affect the market price of our common stock, among others, include:

- General market conditions;
- Public announcements of regulatory actions with respect to *Feraheme* or products or product candidates of our competitors;
- The availability of reimbursement coverage for *Feraheme* and changes in the reimbursement policies of governmental or private payors;
- Actual or anticipated fluctuations in our operating results;
- Changes in financial estimates or recommendations by securities analysts;
- Sales of large blocks of our common stock;
- Loss of any of our key scientific or management personnel;
- The results of clinical trials for *Feraheme* or potentially competitive products or product candidates;
- The acquisition or development of technologies, product candidates or products by us or our competitors;

- Developments in patents or other proprietary rights by us or our competitors;
- Public concern regarding the safety of *Feraheme* or products or product candidates of 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.

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

Table of Contents

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 rely on third-parties, including our clinical research organizations, third-party manufacturers, 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 of our third-party contractors and suppliers. 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.

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

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

- Protocol design;
- Timing of regulatory and institutional review board approval;
- Availability of clinical study material; and

- The rate of patient enrollment.

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

Table of Contents

trials outside the U.S. and therefore such trials will require substantial time and resources to identify and familiarize ourselves with the regulatory requirements of such foreign countries.

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.

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. 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 fulfill their obligations to us on a timely and satisfactory basis or if the quality and accuracy of our clinical trial data is compromised due to failure to adhere to our protocols or regulatory requirements or if such third-parties otherwise fail to meet deadlines, our development plans may be delayed or terminated.

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

At March 31, 2009, we had $68.0 million in cash and cash equivalents, $68.3 million in short-term investments, $57.6 million in long-term investments, and $0.6 million in settlement rights. We have historically invested our funds in institutional money market funds, corporate debt securities, commercial paper, U.S. Treasury and government agency securities, municipal debt securities, and auction rate securities, or ARS, in accordance with the criteria set forth in our investment policy. These investments are subject to general credit, liquidity, market and interest rate risks, which may be exacerbated by the U.S. sub-prime mortgage defaults and the ensuing fallout, which have affected various sectors of the financial markets and caused credit and liquidity issues. We may realize losses in the fair value of these investments or a complete loss of these investments, which would have an adverse effect on our results of operations, liquidity and financial condition.

At March 31, 2009, we held a total of $57.6 million in fair market value of ARS, reflecting an impairment of approximately $8.9 million compared to the par value of these securities of $66.5 million. Of the $8.9 million impairment, approximately $8.2 million is considered a temporary impairment and is reported as an unrealized loss at March 31, 2009. The remaining $0.7 million represents an impairment which is recognized in our consolidated statement of operations at March 31, 2009. The substantial majority of our ARS portfolio was rated AAA as of March 31, 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

Table of Contents

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 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. 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. 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. 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.

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

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

Table of Contents

are not successful in defending ourselves, such actions could have a significant adverse impact on our business.

Legislative or regulatory changes may adversely impact our business.

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

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

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

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

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

- The timing and magnitude of costs associated with our preparations for the planned U.S. commercial launch of *Feraheme*, including costs associated with building and maintaining our commercial infrastructure and executing our promotional and marketing strategy for *Feraheme*, if approved;

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

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

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

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

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

Table of Contents

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

Because of the specialized nature of our business, our success depends to a significant extent on the continued service of our Chief Executive Officer and President, Brian J.G. Pereira, MD, our other executive officers and on our ability to continue to attract, retain and motivate qualified personnel. We have entered into employment agreements with the majority of our senior executives but such agreements do not guarantee that these executives will remain employed by us for any significant period of time, or at all. 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.

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 employees, management, facilities and resources. In anticipation of the potential approval and U.S. commercial launch of *Feraheme*, we have rapidly expanded our regulatory, medical affairs, marketing, sales, manufacturing, finance, development, and compliance capabilities. As our operations expand, we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. In addition, we will need to continue to improve our operational and financial systems, train and manage our expanding workforce, and maintain close coordination among our various departments. We may not be able to accomplish these tasks, and our failure to accomplish any one of them could prevent us from successfully commercializing *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 planned U.S. commercial launch 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

Table of Contents

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.

We may need additional capital to achieve our business objectives.

We have expended and will continue to expend substantial funds to complete development, clinical trials, commercial launch preparations, and other activities necessary to successfully commercialize *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:

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

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

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

- Costs associated with commercial-scale manufacturing of *Feraheme*, including costs associated with building 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 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 ARS investments in a timely manner and without significant loss;

- The impact of the current deterioration in the credit and capital markets upon the investments in our portfolio;

- Our ability to establish additional development and marketing arrangements or to enter into alternative strategic relationships, if necessary; and

- Our ability to raise additional capital on terms and within a timeframe acceptable to us, if necessary.

Table of Contents

We estimate that our existing cash resources, combined with cash we currently expect to receive from earnings on our investments, will be sufficient to finance our operations for at least the next twelve months. Thereafter, we may require additional funds or need to establish alternative strategic arrangements to continue our *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.

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

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

Moreover, patents issued to us may be contested or invalidated. Future patent interference proceedings involving our patents may harm our ability to commercialize *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.

We currently hold a number of U.S. and foreign patents, which expire between the years 2009 and 2020, some of which may be subject to extension under FDA regulations. Because certain patents that cover our products will begin to expire in the coming years, the protection provided by these patents will also begin to expire. Our inability to commercialize our products prior to the expiration of our patents could have a material adverse effect on our business, financial condition and prospects as the expiration of such patents could permit generic drug manufacturers to manufacture, market and sell lower cost drugs that compete with our products and product candidates. In the future, we may be required to obtain additional licenses to patents or other proprietary rights of others in order to commercialize our products or continue with our development efforts. Such licenses may not be available on acceptable terms, if at all. The failure to obtain

Table of Contents

such licenses could result in delays in marketing our products or our inability to proceed with the development, manufacture or sale of our products or product candidates requiring such licenses.

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

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

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

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

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

Table of Contents

result in costs for corrective action, penalties or the imposition of other liabilities. We also are subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment. Under certain of these laws and regulations, a current or previous owner or operator of property may be liable for the costs of remediating the release or spill of hazardous substances or petroleum products on or from its property, without regard to whether the owner or operator knew of, or caused, the contamination, and such owner or operator may incur liability to third parties impacted by such contamination. The presence of, or failure to remediate properly the release or spill of, these substances could adversely affect the value of, and our ability to transfer or encumber, our real property.

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

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

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

There were no purchases by us, or any affiliated purchaser, of our equity securities which are registered pursuant to Section 12 of the Exchange Act during the three months ended March 31, 2009.

Item 5. Other Information.

On May 5, 2009, the Board voted to amend each outstanding stock option grant agreement between us and each of our current non-employee directors to provide that, in the event the non-employee director ceases to be a member of the Board for any reason, the period for exercising any unexercised portion of such stock option which was otherwise exercisable on the date of termination of his membership on the Board or other service to the Company, will be extended from three months to twelve months of such date, but in no event beyond the ten-year option term.

Michael D. Loberg, a Board member since 1997, did not stand for re-election at our Annual Meeting of Stockholders held on May 5, 2009. Dr. Loberg was also a member of our Audit Committee. The reasons for Dr. Loberg s decision to not stand for re-election were not the result of any disagreement with us.

On May 5, 2009, the Board approved an amended and restated non-employee director compensation policy, which amends and restates in its entirety the policy previously amended and restated on February 25, 2009, and effective December 19, 2008. Under the amended and restated non-employee director policy, our non-employee directors will receive the following compensation:

- Each non-employee director, other than the Chairman of the Board, will receive an aggregate annual retainer fee of $30,000, payable in four equal quarterly installments;

- The Chairman of the Board, provided that he is a non-employee director, will receive an aggregate annual retainer fee of $60,000, payable in four equal quarterly installments;

Table of Contents

- Each member of each of the Audit, Compensation and Nominating and Corporate Governance Committees, other than the Chairman of each committee, will receive an additional aggregate annual retainer fee of $5,000, payable in four equal quarterly installments;

- The Chairman of each of the Audit, Compensation and Nominating and Corporate Governance Committees will receive an additional aggregate annual retainer fee of $10,000, payable in four equal quarterly installments;

- Commencing in May 2010, each non-employee director will be granted an annual option to purchase 5,000 shares, or in the case of the Chairman of the Board, provided that he is a non-employee director, an annual option to purchase 10,000 shares, of our common stock. The May 2010 annual grant will be pro-rated to reflect the number of quarters of continuous Board service performed by each non-employee director since the last annual grant to such director. The foregoing options will vest in twelve equal monthly installments beginning on the first day of the first full month following our Annual Meeting of Stockholders and continuing on the first day of each of the following eleven months thereafter, have an exercise price equal to the fair market value of a share of our common stock on the date of grant, and have a ten-year term;

- Each newly-elected or appointed director will be granted an option to purchase 10,000 shares of our common stock on the date of his or her appointment or election to the Board. The foregoing options will vest in equal annual installments over a four-year period beginning on the first anniversary of his or her appointment or election to the Board, have an exercise price equal to the fair market value of a share of our common stock on the date of grant, and have a ten-year term; and

- In addition, and in lieu of the annual grant to non-employee directors described above, for his or her first year of service on the Board, each newly-elected director joining the Board subsequent to the Annual Meeting of Stockholders will be granted an option to purchase 5,000 shares of our common stock on the date of his or her appointment or election to the Board if such appointment or election occurs during the same quarter as the Annual Meeting of Stockholders, 3,750 shares of our common stock if his or her appointment or election to the Board occurs in the first quarter following the quarter in which the Annual Meeting of Stockholders is held; 2,500 shares of our common stock if his or her appointment or election to the Board occurs in the second quarter following the quarter in which the Annual Meeting of Stockholders is held; and 1,250 shares of our common stock if his or her appointment or election to the Board occurs in the third quarter following the quarter in which the Annual Meeting of Stockholders is held. The foregoing options will vest in equal monthly installments beginning on the first day of the first full month following the appointment or election of the newly-elected director and continuing on the first day of each month thereafter through the first day of the month in which the next Annual Meeting of Stockholders is to be held, have an exercise price equal to the fair market value of a share of our common stock on the date of grant, and have a ten-year term.

Effective as of May 5, 2009, the Board also reconstituted the membership of its Audit and Compensation Committees. Effective immediately, the Audit Committee is comprised of Davey S. Scoon (Chair), Mark Skaletsky, and Robert J. Perez, and the Compensation Committee is comprised of Michael Narachi (Chair), Mark Skaletsky, and Robert J. Perez.

Table of Contents

Item 6. Exhibits.

(a) List of Exhibits

Exhibit Number		Description
10.1	+	Amended and Restated Non-Employee Director Compensation Policy
10.2	+	Form of Option Agreement (Nonqualified Option) for Annual Director Grants.
10.3	+	AMAG Pharmaceuticals, Inc. Amended and Restated 2007 Equity Incentive Plan
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: May 6, 2009

AMAG PHARMACEUTICALS, INC.

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

Date: May 6, 2009

Table of Contents

EXHIBIT INDEX

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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.