AMAG PHARMACEUTICALS INC. Form 10-Q May 06, 2010 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, 2010
OR
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGI ACT OF 1934

For the transition period from $% \left\{ \mathbf{r}^{\prime}\right\} =\mathbf{r}^{\prime}$ to

Commission File Number 0-14732

AMAG PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

04-2742593 (IRS Employe

(State or Other Jurisdiction of Incorporation or Organization)

(IRS Employer Identification No.)

100 Hayden Avenue
Lexington, Massachusetts
(Address of Principal Executive Offices)

02421 (Zip Code)

(617) 498-3300

(Registrant s Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). **Yes o No** o

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

Large accelerated filer x

Accelerated filer o

Non-accelerated filer o (Do not check if a smaller reporting company)

Smaller reporting company o

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

As of May 3, 2010 there were 21,011,472 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)	
Item 1.	Financial Statements	
	Condensed Consolidated Balance Sheets as of March 31, 2010 and December 31, 2009	4
	Condensed Consolidated Statements of Operations for the three months ended March 31,	
	2010 and 2009	5
	Condensed Consolidated Statements of Comprehensive Loss for the three months ended	
	March 31, 2010 and 2009	6
	Condensed Consolidated Statements of Cash Flows for the three months ended	
	March 31, 2010 and 2009	7
	Notes to Condensed Consolidated Financial Statements	8
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	26
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	45
<u>Item 4.</u>	Controls and Procedures	45
PART II.	OTHER INFORMATION	
Item 1.	Legal Proceedings	46
Item 1A.	Risk Factors	46
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	70
Item 6.	<u>Exhibits</u>	71
<u>SIGNATURES</u>		
CERTIFICATIONS		

2

T	`al	ole	of	Contents	

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

Table of Contents

AMAG PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

(<u>Unaudited</u>)

	March 31, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents \$	212,747	\$ 50,126
Short-term investments	21,044	29,578
Settlement rights	788	788
Accounts receivable, net	15,004	27,350
Inventories	12,041	9,415
Receivable from collaboration	60,000	
Prepaid and other current assets	4,900	5,472
Total current assets	326,524	122,729
Property, plant and equipment, net	12,064	12,417
Long-term investments	48,432	49,013
Restricted cash	460	460
Total assets \$	387,480	\$ 184,619
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable \$	4,146	\$ 5,432
Accrued expenses	20,515	21,931
Deferred revenues	14,258	10,198
Total current liabilities	38,919	37,561
Long-term liabilities:		
Deferred revenues	55,000	1,000
Other long-term liabilities	3,011	3,081
Total liabilities	96,930	41,642
Commitments and contingencies (Note K & L)		
Stockholders equity:		
Preferred stock, par value \$0.01 per share, 2,000,000 shares authorized; none issued		
Common stock, par value \$0.01 per share, 58,750,000 shares authorized; 20,993,285		
and 17,362,710 shares issued and outstanding at March 31, 2010 and December 31,		
2009, respectively	210	174
Additional paid-in capital	603,140	432,414
Accumulated other comprehensive loss	(8,061)	(7,925)
Accumulated deficit	(304,739)	(281,686)
Total stockholders equity	290,550	142,977
Total liabilities and stockholders equity \$	387,480	\$ 184,619

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

4

Table of Contents

AMAG PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE DATA)

$(\underline{Unaudited})$

	Three Months Ended March 31, 2010 2009		
Revenues:			
Product sales, net	\$ 13,295	\$	393
License fees			516
Royalties	11		47
Total revenues	13,306		956
Costs and expenses:			
Cost of product sales	1,010		61
Research and development expenses	12,368		11,072
Selling, general and administrative expenses	23,456		17,750
Total costs and expenses	36,834		28,883
Other income (expense):			
Interest and dividend income, net	471		1,256
Gains on investments, net	4		992
Fair value adjustment of settlement rights			(923)
Total other income (expense)	475		1,325
Net loss before income taxes	(23,053)		(26,602)
Income tax benefit			179
Net loss	\$ (23,053)	\$	(26,423)
Net loss per share:			
Basic and diluted	\$ (1.15)	\$	(1.55)
Weighted average shares outstanding used to compute net loss per share:			
Basic and diluted	19,985		17,021

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

(IN THOUSANDS)

$(\underline{Unaudited})$

	Three Months Ended March 31,				
	2	010		2009	
Net loss	\$	(23,053)	\$	(26,423)	
Other comprehensive income (loss):					
Unrealized gains (losses) on securities:					
Holding (losses) gains arising during period, net of tax		(136)		2,201	
Reclassification adjustment for losses and gains, net, included in net loss				4	
Net unrealized (losses) gains		(136)		2,205	
Total comprehensive loss	\$	(23,189)	\$	(24,218)	

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

6

Table of Contents

AMAG PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

 $(\underline{Unaudited})$

	Three Months Ended March 31,			
		2010		2009
Net loss	\$	(23,053)	\$	(26,423)
Cash flows from operating activities:				
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation		570		442
Non-cash equity-based compensation expense		4,301		3,502
Amortization of premium/discount on purchased securities		33		204
Fair value adjustment of settlement rights				923
Gains on investments, net		(4)		(992)
Changes in operating assets and liabilities:				
Accounts receivable		12,346		171
Inventories		(2,500)		38
Prepaid and other current assets		572		1,396
Accounts payable and accrued expenses		(2,702)		(1,283)
Deferred revenues		(1,940)		(403)
Other long-term liabilities		(70)		
Total adjustments		10,606		3,998
Net cash used in operating activities		(12,447)		(22,425)
Cash flows from investing activities:				
Proceeds from sales or maturities of available-for-sale investments		8,950		26,595
Purchase of available-for-sale investments				(310)
Capital expenditures		(217)		(192)
Change in restricted cash				61
Net cash provided by investing activities		8,733		26,154
Cash flows from financing activities:				
Proceeds from the exercise of stock options		776		77
Proceeds from the issuance of common stock, net of underwriting discount and other				
expenses		165,559		
Net cash provided by financing activities		166,335		77
Net increase in cash and cash equivalents		162,621		3,806
Cash and cash equivalents at beginning of the period		50,126		64,182
Cash and cash equivalents at end of the period	\$	212,747	\$	67,988

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

Table of Contents

AMAG PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2010

(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 iron deficiency anemia, or IDA, and novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. We currently manufacture and sell two approved products, Feraheme® (ferumoxytol) Injection for intravenous, or IV, use and GastroMARK®.

On June 30, 2009, *Feraheme* was approved for marketing in the U.S. by the U.S. Food and Drug Administration, or the FDA, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with chronic kidney disease, or CKD. We market and sell *Feraheme* through our own commercial organization and began shipping *Feraheme* to our customers in July 2009.

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

We are subject to risks common to companies in the pharmaceutical industry including, but not limited to, our sole dependence on the success of *Feraheme*, development by us or our competitors of new technological and product innovations, uncertainty regarding market acceptance of our products, uncertainties related to insurance coverage, coding and third-party reimbursement for our products, our limited experience commercializing and distributing a pharmaceutical product, our reliance on Takeda to commercialize *Feraheme* in certain territories outside of the U.S., our potential inability to operate our manufacturing facility in compliance with current good manufacturing practices, our potential inability to obtain raw materials and manufacture sufficient quantities of our products, the potential fluctuation of our operating results, potential differences between actual future results and the estimates or assumptions used by us in preparation of our condensed consolidated financial statements, the volatility of our stock price, our potential inability to become profitable in the future, our potential inability to obtain additional financing, if necessary, on acceptable terms, the current credit and financial market conditions, our potential inadvertent failure to comply with reporting and payment obligations under government pricing programs, our potential inadvertent failure to comply with the regulations of the FDA or other government agencies, uncertainty of the regulatory approval process for our other *Feraheme* indications or for any indications outside of the U.S., uncertainty of the results of our clinical trials, our ability to manage growth, our ability to enter into and successfully maintain favorable collaborations and in-licensing arrangements, our dependence on key personnel, and uncertainties related to the protection of proprietary technology, product liability, potential legislative and regulatory changes, and potential costs and liabilities associated with currently pending or future litigati

Throughout this Quarterly Report on Form 10-Q, AMAG Pharmaceuticals, Inc. and our consolidated subsidiaries are collectively referred to as the Company, we, us, or our.

Basis of Presentation and Summary of Significant Accounting Policies

7D 1	1	c		
1 21	\mathbf{n}	nt.	('0'	ntents

В.

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 the financial position and results of operations of the Company for the interim periods presented. Such adjustments consisted only of normal recurring items. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America.
In accordance with accounting principles generally accepted in the United States of America for interim financial reports and the instructions for Form 10-Q and the rules of the Securities and Exchange Commission, 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, 2009. 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, 2009.
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, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The most significant estimates and assumptions are used in, but are not limited to, revenue recognition and related sales allowances, assessing investments for potential other-than-temporary impairment and determining values of investments, reserves for doubtful accounts, accrued expenses, income taxes and equity-based compensation expense. Actual results could differ materially from those estimates.

Principles of Consolidation

The accompanying condensed consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiaries, AMAG Securities Corporation and AMAG Europe Limited. AMAG Europe Limited was incorporated in October 2009 in London, England. AMAG Securities Corporation is a Massachusetts corporation that was formed in August 2007. All significant intercompany account balances and transactions between the companies have been eliminated.

Fair Value of Financial Instruments

Under current accounting standards, fair value is defined 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 must maximize the use of observable inputs and minimize the use of unobservable inputs.

In January 2010, we adopted a newly issued accounting standard which requires additional disclosure about the amounts of and reasons for significant transfers in and out of Level 1 and Level 2 fair value measurements. This standard also clarifies existing disclosure requirements related to the level of disaggregation of fair value measurements for each class of assets and liabilities and disclosures about inputs and valuation techniques used to measure fair value for both recurring and nonrecurring Level 2 and Level 3 measurements. As this newly issued accounting standard only requires enhanced disclosure, the adoption of this standard did not impact our financial position or results of operations. In addition, effective for interim and annual periods beginning after December 15, 2010, this standard will require

Table of Contents

additional disclosure and require an entity to present disaggregated information about activity in Level 3 fair value measurements on a gross basis, rather than as one net amount.

Current accounting guidance establishes a hierarchy used to categorize how fair value is measured and 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.

We hold 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, as defined below. The following tables represent the fair value hierarchy for those assets that we measure at fair value on a recurring basis as of March 31, 2010 and December 31, 2009 (in thousands):

		Qı	nir Value Measurements at I noted Prices in Active Markets for Identical Assets	Signif Obser	icant Other vable Inputs		ignificant observable Inputs
	Total		(Level 1)	(1	Level 2)	((Level 3)
Money market funds	\$ 207,168	\$	207,168	\$		\$	
Corporate debt securities	3,855				3,855		
U.S. treasury and government							
agency securities	8,657				8,657		
Auction rate securities	56,964						56,964
Settlement rights	788						788
-	\$ 277,432	\$	207,168	\$	12,512	\$	57,752

	Fair Value Measurements at December 31, 2009 Using: Quoted Prices in Active Significant						
	Total	M	larkets for Identical Assets (Level 1)	Obse	nificant Other ervable Inputs (Level 2)	Unobservable Inputs (Level 3)	
Money market funds	\$ 46,451	\$	46,451	\$		\$	
Corporate debt securities	9,804				9,804		
U.S. treasury and government							
agency securities	11,247				11,247		
Auction rate securities	57,540					57,540)

Settlement rights	788			788
-	\$ 125,830	\$ 46,451	\$ 21,051	\$ 58,328

With the exception of our ARS and Settlement Rights, which are valued using Level 3 inputs, as discussed below, the fair value of our non-money market fund investments is primarily determined from independent pricing services which use Level 2 inputs for the determination of fair value. Independent pricing services normally derive security prices from recently reported trades for identical or similar

Table of Contents

securities, making adjustments based upon other significant observable market transactions at fair value. At each reporting period, we perform quantitative and qualitative analyses on prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analyses, we did not adjust or override any fair value measurements provided by our pricing services as of March 31, 2010. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the three months ended March 31, 2010.

We also analyze when the volume and level of activity for an asset or liability have significantly decreased and when circumstances indicate that a transaction may not be considered orderly. In order to determine whether the volume and level of activity for an asset or liability have significantly decreased, we assess current activity with normal market activity for the asset or liability. We rely on many factors such as trading volume, trading frequency, the levels at which market participants indicate their willingness to buy and sell our securities, as reported by market participants, and current market conditions. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if there has been a significant decrease in the volume and level of activity for an asset or group of similar assets. Similarly, in order to identify transactions that are not orderly, we take into consideration the activity in the market which can influence the determination and occurrence of an orderly transaction. Also, we inquire as to whether there may have been restrictions on the marketing of the security to a single or limited number of participants. Where possible, we assess the financial condition of the seller to determine whether observed transactions may have been forced. If the trading price for a security held by us is significantly out of line when compared to the trading prices of similar recent transactions, we consider whether this disparity is an indicator of a disorderly trade. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if the evidence suggests that a transaction or group of similar transactions is not orderly. Based upon these procedures, we determined that market activity for our non-ARS assets appeared normal and that transactions did not appear disorderly as of March 31, 2010.

In November 2008, we elected to participate in a rights offering by UBS AG, or UBS, one of our securities brokers, which provided 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. In November 2008, we elected the fair value option with respect to our Settlement Rights in accordance with accounting guidance related to the fair value option for financial assets and financial liabilities. We are required to assess the fair value of both the Settlement Rights and our ARS subject to Settlement Rights and record changes each period until the Settlement Rights are exercised and our ARS subject to Settlement Rights are redeemed. Although the Settlement Rights represent the right to sell the securities back to UBS at par, we are required to periodically assess the ability of UBS to meet that obligation in assessing the fair value of the Settlement Rights.

The following table presents assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) as of March 31, 2010 (in thousands):

Table of Contents

	Three Months Ended March 31, 2010
Balance at beginning of period	\$ 58,328
Transfers to Level 3	
Total gains (losses) (realized or unrealized):	
Included in earnings	4
Included in other comprehensive income (loss)	(30)
Purchases (settlements), net	(550)
Balance at end of period	\$ 57,752
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	\$ 4

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

Revenue Recognition

Net Product Sales

We recognize net product sales in accordance with current accounting guidance related to the recognition, presentation and disclosure of revenue in financial statements, which outlines the basic criteria that must be met to recognize revenue. We recognize revenue when:

- persuasive evidence of an arrangement exists;
- delivery of product has occurred or services have been rendered;
- the sales price charged is fixed or determinable; and
- collection is reasonably assured.

Because we only recently launched *Feraheme* in the U.S. there are a number of factors that make it particularly difficult to predict the magnitude of future *Feraheme* sales, including the magnitude and timing of adoption of *Feraheme* by physicians, dialysis clinics, hospitals and other healthcare payors and providers, the inventory levels maintained by *Feraheme* wholesalers, distributors and other customers, the frequency of re-orders by existing customers, and the pricing of products that compete with *Feraheme* and other actions taken by our competitors.

We record product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and other rebates, distributor, wholesaler and group purchasing organization, or GPO, fees, and product returns as a reduction of revenue in our condensed consolidated statement of operations at the time product sales are recorded. Calculating these gross-to-net sales adjustments involves estimates and judgments based primarily on actual *Feraheme* sales data and forecasted customer buying patterns blended with historical experience of products similar to *Feraheme* sold by others. In addition, we also monitor our distribution channel to determine the level of additional allowances or accruals required based on inventory in our sales channel. There were no product sales allowances or accruals for the three months ended March

12

Table of Contents

31, 2009. An analysis of our product sales allowances and accruals for the three months ended March 31, 2010 is as follows (in thousands):

	Ma	rch 31, 2010
Product sales allowances and accruals:		
Discounts and chargebacks	\$	742
Government and other rebates		3,001
Returns		244
Total product sales allowances and accruals	\$	3,987
Total net product sales	\$	13,295
Total gross product sales	\$	17,282
Total product sales allowances and accruals as a percent of total gross product sales		23%

Product sales allowances and accruals are primarily comprised of both direct and indirect fees, discounts and rebates and provisions for estimated product returns. Direct fees, discounts and rebates are contractual fees and price adjustments payable to wholesalers, specialty distributors and other customers that purchase products directly from us. Indirect fees, discounts and rebates are contractual price adjustments payable to healthcare providers and organizations, such as certain dialysis organizations, physicians, clinics, hospitals, and GPOs that typically do not purchase products directly from us but rather from wholesalers and specialty distributors. In accordance with guidance related to accounting for fees and consideration given by a vendor to a customer (including a reseller of a vendor s products), these fees, discounts and rebates are presumed to be a reduction of the selling price of Feraheme. Product sales allowances and accruals are based on definitive contractual agreements or legal requirements (such as Medicaid laws and regulations) related to the purchase and/or utilization of the product. Allowances and accruals are recorded in the same period that the related revenue is recognized and are estimated using either historical, actual and/or other data, including estimated patient usage, applicable contractual rebate rates, contract performance by the benefit providers, other current contractual and statutory requirements, historical market data based upon experience of other similar products to Feraheme, specific known market events and trends such as competitive pricing and new product introductions and current and forecasted customer buying patterns and inventory levels, including the shelf life of our products. As part of this evaluation, we also review changes to federal legislation, changes to rebate contracts, changes in the level of discounts, and changes in product sales trends. Reserve estimates are evaluated quarterly and may require adjustments to better align our estimates with actual results. During the three months ended March 31, 2010, our allowances for government and other rebates reflected a decrease of \$0.3 million relating to sales in the prior year. This adjustment was primarily the result of a reduction in our estimates of Medicaid utilization across Feraheme customer classes resulting from additional data, including information regarding Medicaid claims experience for comparable products, partially offset by an increase in estimated Medicaid allowances associated with the increase in statutory minimum rebate rates included in recent healthcare legislation. Although allowances and accruals are recorded at the time of product sale, certain rebates are typically paid out, on average, up to six months or longer after the sale. If actual future results vary from our estimates, we may need to adjust our previous estimates, which would affect our earnings in the period of the adjustment.

Deferred Revenue - Launch Incentive Program

During the third quarter of 2009, certain dialysis organizations purchased *Feraheme* from us under our Launch Incentive Program. These purchases were made under agreements which provided these customers

Table of Contents

with an opportunity to purchase *Feraheme* through September 30, 2009 at discounted pricing and further provided for extended payment terms and expanded rights of return. As a result, in accordance with current accounting guidance which requires that we defer recognition of revenues until we can reasonably estimate returns related to those purchases, we have deferred the recognition of revenues associated with these purchases until our customers report to us that such inventory has been utilized in their operations. Any purchases returned to us will not be recorded as revenue. Accordingly, as of March 31, 2010, we have a remaining balance of \$8.3 million in deferred revenues, which represents product purchased under the Launch Incentive Program which remained held by the dialysis organizations at March 31, 2010, net of any applicable discounts and estimated rebates, which are included in our commercial rebate accruals as of March 31, 2010. In addition, we have deferred the related cost of product sales of approximately \$0.2 million and recorded such amount as finished goods inventory held by others as of March 31, 2010. Because we are unable to reasonably estimate the amount of inventory that may be returned under this program, if any, we cannot provide any assurance that amounts reported as deferred revenue and associated with this program will be utilized by our customers and thereby recorded by us as product revenues in our future condensed consolidated statements of operations.

License Fee and Other Collaboration Revenues

The terms of product development agreements entered into between us and our collaborative partners may include non-refundable license fees, payments based on the achievement of certain milestones and performance goals and royalties on any product sales derived from those collaborations. We recognize license fee and research and development revenue under collaborative arrangements over the term of the applicable agreements on a straight-line basis or through the application of a proportional performance model where revenue is recognized equal to the lesser of the amount due under the agreements or the amount based on the proportional performance to date. In cases where project costs or other performance metrics are estimable, we recognize nonrefundable payments and fees for the licensing of technology or intellectual property rights over the related performance period or when there are no remaining performance obligations. In cases where project costs or other performance metrics are not estimable but there is an established contract period, revenues are recognized on a straight line basis over the term of the relevant agreement. Nonrefundable payments and fees are recorded as deferred revenue upon receipt and may require deferral of revenue recognition to future periods.

Multiple Element Arrangements

We evaluate revenue from arrangements that have multiple elements to determine whether the components of the arrangement represent separate units of accounting as defined in the accounting guidance related to revenue arrangements with multiple deliverables, which provides that an element of a contract can be accounted for separately if the delivered elements have stand-alone value and the fair value of any undelivered elements is determinable. If an element is considered to have standalone value but the fair value of any of the undelivered items cannot be determined, all elements of the arrangement are recognized as revenue over the period of performance for such undelivered items or services.

Concentrations and Significant Customer Information

As of March 31, 2010 we had approximately \$163.9 million of our total \$212.7 million cash and cash equivalents balance invested in a single institutional money market fund, which is collateralized solely by U.S. Treasury and U.S. government agency securities.

Our operations are located solely within the U.S. We are focused principally on developing, manufacturing and commercializing an IV iron replacement therapeutic agent and novel imaging agents.

14

Table of Contents

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, 2010 and 2009.

	Three Months End	led March 31,
	2010	2009
Metro Medical Supply, Inc.	36%	
AmerisourceBergen Drug Corporation	29%	
Guerbet S.A.	< 10%	33%
Covidien, Ltd.	< 10%	13%
Bayer Healthcare Pharmaceuticals		54%

Revenues from customers outside of the U.S., principally in Europe, amounted to less than 10.0% and 33.0% of our total revenues for the three months ended March 31, 2010 and 2009, respectively.

Subsequent Events

We did not have any material recognizable subsequent events.

C. Investments

At March 31, 2010 and December 31, 2009, the combined total of our short- and long-term investments was \$69.5 million and \$78.6 million, respectively, and consisted of securities classified as trading and available-for-sale in accordance with accounting standards which provide guidance related to accounting and classification of certain investments in debt and equity securities.

The following is a summary of our available-for-sale and trading securities at March 31, 2010 and December 31, 2009 (in thousands):

15

Table of Contents

		March 3	1, 201	0	
	Amortized Cost	Gross Unrealized Gains		Gross Unrealized Losses	Estimated Fair Value
Short-term investments:					
Corporate debt securities					
Due in one year or less	\$ 3,485	\$ 54	\$		\$ 3,539
Due in one to three years	305	11			316
U.S. treasury and government agency securities					
Due in one year or less	4,272	43			4,315
Due in one to three years	4,255	87			4,342
Auction rate securities - trading					
Due in one year or less					
Due after five years	8,532				8,532
Total short-term investments	\$ 20,849	\$ 195	\$		\$ 21,044
Long-term investments:					
Auction rate securities - available for sale					
Due in one year or less	\$ 55,600	\$	\$	(7,168)	\$ 48,432
Due after five years					
Total long-term investments	\$ 55,600	\$	\$	(7,168)	\$ 48,432
Total short and long-term investments	\$ 76,449	\$ 195	\$	(7,168)	\$ 69,476
	16				

Table of Contents

	December 31, 2009							
	A	Amortized		Gross Unrealized Gains	1	Gross Unrealized		Estimated Fair Value
Short-term investments:		Cost		Gains		Losses		vaiue
Corporate debt securities								
Due in one year or less	\$	8,580	\$	61	\$		\$	8,641
Due in one to three years	Ψ	1,117	Ψ	46	Ψ		Ψ	1,163
U.S. treasury and government agency								2,232
securities								
Due in one year or less		8,532		136				8,668
Due in one to three years		2,521		58				2,579
Auction rate securities - trading								
Due in one year or less								
Due after five years		8,527						8,527
Total short-term investments	\$	29,277	\$	301	\$		\$	29,578
Long-term investments:								
Auction rate securities - available for sale								
Due in one year or less	\$		\$		\$		\$	
Due after five years		56,150				(7,137)		49,013
Total long-term investments	\$	56,150	\$		\$	(7,137)	\$	49,013
Total short and long-term investments	\$	85,427	\$	301	\$	(7,137)	\$	78,591

Auction Rate Securities and UBS Settlement Rights

At March 31, 2010, we held a total of \$56.9 million in fair market value of ARS, reflecting a decline in value of approximately \$8.0 million compared to the par value of these securities of \$64.9 million. Of the \$8.0 million decline in value, approximately \$7.2 million was considered a temporary impairment and was reported as an unrealized loss in accumulated other comprehensive loss at March 31, 2010. The remaining \$0.8 million represented a trading loss associated with our UBS ARS, the recording of which is described below. Of our total ARS, \$48.4 million in fair market value are not subject to Settlement Rights and are classified as available-for-sale. The remaining \$8.5 million are subject to Settlement Rights and are classified as trading securities. At March 31, 2010, 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, 2010 by at least one of the major securities rating agencies and was primarily collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program. 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 since that time, we use a discounted cash flow analysis to value these securities as opposed to valuing them at par value. Our valuation analysis considers, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, credit ratings of the security by the major securities rating agencies, the ability or inability to sell the investment in an active market, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when call features may be exercised by the issuer.

Table of Contents

subject to Settlement Rights to be \$8.5 million at March 31, 2010 and, accordingly, we recorded realized gains of approximately \$4,000 during the three months ended March 31, 2010. In addition, based upon this methodology, we have estimated the fair value of our remaining ARS not subject to Settlement Rights to be \$48.4 million at March 31, 2010, and have recorded a \$7.2 million unrealized loss to accumulated other comprehensive loss as of March 31, 2010. As discussed in greater detail below, for all available-for-sale debt securities with unrealized losses, management performs an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security s decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded in our condensed consolidated statement of operations as an impairment loss. Regardless of our intent to sell a security, we perform additional analyses on all securities with unrealized losses to evaluate whether there could be a credit loss associated with the security. We did not recognize any credit losses related to our securities during the three months ended March 31, 2010. As of March 31, 2010, all of our ARS continue to pay interest according to their stated terms.

In November 2008, we elected to participate in a rights offering by UBS which provided 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.

Due to our belief that the market for ARS may take in excess of twelve months to fully recover, we have classified our portfolio of ARS not subject to Settlement Rights as long-term investments in our condensed consolidated balance sheet at March 31, 2010. As discussed in greater detail below, we believe that the temporary impairment related to our ARS not subject to Settlement Rights is primarily attributable to the lack of liquidity of these investments, coupled with the ongoing turmoil in the credit and capital markets, and we have no reason to believe that any of the underlying issuers of our ARS are presently at risk of default. Any future fluctuation in fair value related to our ARS not subject to Settlement Rights that we deem to be temporary, including any recoveries of previous write-downs, would be recorded to accumulated other comprehensive loss. If we determine that any future unrealized loss is other-than-temporary, we will record a charge to our condensed consolidated statement of operations. In the event that we need to access our investments in these securities, we will not be able to do so until a future auction is successful, the issuer calls the security pursuant to a mandatory tender or redemption prior to maturity, a buyer is found outside the auction process, or the securities mature. For all of our ARS, the underlying maturity date is in excess of one year, and the majority have final maturity dates of 30 to 40 years in the future. We believe we will ultimately be able to liquidate our investments without significant loss prior to the maturity dates noted above 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

Table of Contents

Impairments and Unrealized Gains and Losses on Investments

The following is a summary of the fair value of our investments with unrealized losses that are deemed to be temporarily impaired and their respective gross unrealized losses aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position at March 31, 2010 and December 31, 2009 (in thousands):

			Marc	h 31, 20	10			
	Less tha	n 12 Months	12 Months	or Grea	ater	To	tal	
	Fair	Unrealized	Fair	Ur	ırealized	Fair	Uı	ırealized
	Value	Losses	Value	,	Losses	Value		Losses
Auction rate securities	\$	\$	\$ 48,432	\$	(7,168)	\$ 48,432	\$	(7,168)
	\$	\$	\$ 48,432	\$	(7,168)	\$ 48,432	\$	(7,168)

			Decem	ber 31, 2	2009			
	Less tha	n 12 Months	12 Months	or Grea	iter	To	tal	
	Fair	Unrealized	Fair	Uı	realized	Fair	Uı	nrealized
	Value	Losses	Value		Losses	Value		Losses
Auction rate securities	\$	\$	\$ 49,013	\$	(7,137)	\$ 49,013	\$	(7,137)
	\$	\$	\$ 49,013	\$	(7,137)	\$ 49,013	\$	(7,137)

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

Based upon our evaluation, we did not consider the unrealized losses on our available-for-sale investments at March 31, 2010 and December 31, 2009 to be other-than-temporary impairments. Accordingly, no impairment losses were recognized in our condensed consolidated statement of operations related to available-for-sale securities during the three months ended March 31, 2010.

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

Realized Gains and Losses

Gains and losses are determined on the specific identification method and, accordingly, during the three months ended March 31, 2010 and 2009 we recorded gains of approximately \$4,000 and \$1.0 million, respectively, to our condensed consolidated statement of operations principally

related to our estimated valuation of ARS subject to Settlement Rights. We did not record any realized gains or losses related to the fair value adjustment of our Settlement Rights during the three months ended March 31, 2010. We recorded a realized loss related to the fair value adjustment of our Settlement Rights of \$0.9

Table of Contents

million to our condensed consolidated statement of operations during the three months ended March 31, 2009.

D. Accounts Receivable

Our accounts receivable were \$15.0 million and \$27.4 million at March 31, 2010 and December 31, 2009, respectively. At March 31, 2010 and December 31, 2009, our accounts receivable primarily represented amounts due from wholesalers and distributors to whom we sell *Feraheme* directly and customers who participated in the Launch Incentive Program. Accounts receivable are recorded net of reserves for estimated chargeback obligations, prompt payment discounts and any allowance for doubtful accounts. Reserves for other sales related allowances such as rebates, distribution and other fees, and product returns are included in accrued expenses in our condensed consolidated balance sheet.

Included within our accounts receivable balance at March 31, 2010 are \$2.1 million in receivables, which represent amounts due from dialysis organizations to whom we shipped *Feraheme* under the 2009 Launch Incentive Program. These shipments were made under agreements which provided these customers with an opportunity to purchase *Feraheme* through September 30, 2009 at discounted pricing and further provided for extended payment terms and expanded rights of return. As of March 31, 2010, we have a remaining balance of \$8.3 million in deferred revenues related to product purchased under the Launch Incentive Program which remained held by the dialysis organizations at March 31, 2010, net of any applicable discounts and estimated rebates.

As part of our credit management policy, we perform ongoing credit evaluations of our customers and we have not required collateral from any customer. To date, we have not experienced significant bad debts. Accordingly, we have not established an allowance for doubtful accounts at either March 31, 2010 or December 31, 2009. If the financial condition of any of our significant customers was to deteriorate and result in an impairment of their ability to make payments owed to us, an allowance for doubtful accounts may be required which could have a material affect on earnings in the period of any such adjustment. Customers which represented greater than 10% of our accounts receivable balance at March 31, 2010 and December 31, 2009 were as follows:

	March 31, 2010	December 31, 2009
Metro Medical Supply, Inc.	34%	20%
AmerisourceBergen Drug Corporation	30%	29%
Dialysis Clinics, Inc.	14%	15%
Liberty Dialysis, LLC		10%
Satellite Healthcare, Inc.*		10%

^{*} During 2009, our Chief Executive Officer was a member of the Board of Directors of Satellite Healthcare, Inc. but resigned from that position during the three months ended March 31, 2010.

E. Inventories

Our major classes of inventories were as follows at March 31, 2010 and December 31, 2009 (in thousands):

Table of Contents

	Marc	h 31, 2010	December 31, 2009
Raw materials	\$	1,496	\$ 1,584
Work in process		1,678	1,169
Finished goods		8,620	6,326
Finished goods held by others		247	336
Total inventories	\$	12,041	\$ 9,415

Finished goods inventory held by others primarily relates to inventories held by dialysis organizations to which we have shipped *Feraheme* under the Launch Incentive Program. Agreements entered into under this program provided certain customers with extended payment terms and expanded rights of return. As a result, in accordance with current accounting and reporting standards related to revenue recognition, we have deferred both the recognition of revenues and the costs of the inventory sold under this program and presented inventories held by others as a separate component of our overall inventory as of March 31, 2010 and December 31, 2009.

Equity-based compensation of \$0.2 million was capitalized into inventory for the three months ended March 31, 2010. There was no equity-based compensation capitalized into inventory for the three months ended March 31, 2009.

F. Property, Plant and Equipment

Property, plant and equipment consisted of the following at March 31, 2010 and December 31, 2009 respectively (in thousands):

	March 31, 2010	December 31, 2009
Land	\$ 360	\$ 360
Buildings and improvements	10,892	10,356
Laboratory and production equipment	6,917	6,839
Furniture and fixtures	4,409	4,345
Construction in process	833	1,294
Total property, plant and equipment	23,411	23,194
Less - accumulated depreciation	(11,347)	(10,777)
Property, plant and equipment, net	\$ 12,064	\$ 12,417

G. 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, 2010 we did not recognize any tax expense or benefit due to our continued net operating loss position. 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

Table of Contents

legislation passed in February 2009. 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.

H. 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 the vesting of 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 Endo	ed March 31,
	2010	2009
Options to purchase shares of common stock	2,845	2,671
Shares of common stock issuable upon the vesting of restricted stock units	273	217
Total	3,118	2,888

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

	Three Months E	nded Ma	arch 31,
	2010		2009
Net loss	\$ (23,053)	\$	(26,423)
Weighted average common shares outstanding	19,985		17,021
Net loss per share:			
Basic and diluted	\$ (1.15)	\$	(1.55)

I. Equity-Based Compensation

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

2007 Plan

As of March 31, 2010, we have granted options and restricted stock units covering 2,720,575 shares of common stock under our 2007 Plan, of which 321,013 stock options and 10,000 restricted stock units have expired or terminated, and of which 23,766 options have been exercised and 1,250 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, 2010 was 2,103,715 and 260,831, respectively. The remaining number of shares available for future grants as of March 31, 2010 was 395,023, 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

22

Table of Contents

2007 Plan have an exercise price equal to the closing price of our common stock on the grant date and a ten-year term.

2000 Plan

As of March 31, 2010, we have granted options and restricted stock units covering 2,182,700 shares of common stock under the 2000 Plan, of which 402,825 stock options and 750 restricted stock units have expired or terminated, and of which 994,268 stock options have been exercised and 31,000 shares of common stock were issued pursuant to restricted stock units that became fully vested. The remaining number of shares underlying outstanding options and restricted stock units pursuant to the 2000 Plan as of March 31, 2010 was 741,607 and 12,250, 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

Equity-based compensation expense, net of amounts capitalized into inventory, was as follows (in thousands):

		Three Months Ended March 31,				
	20)10		2009		
Cost of product sales	\$	75	\$			
Research and development		1,205		1,095		
Selling, general and administrative		3,021		2,407		
Total equity-based compensation expense	\$	4,301	\$	3,502		

Equity-based compensation of \$0.2 million was capitalized into inventory for the three months ended March 31, 2010. Capitalized equity-based compensation is recognized into cost of product sales when the related product is sold.

J. Common Stock Transactions

In January 2010, we sold 3.6 million shares of our common stock, \$0.01 par value per share, in an underwritten public offering at a price to the public of \$48.25 per share, resulting in gross proceeds of approximately \$173.7 million. Net proceeds to us after deducting fees, commissions and other expenses related to the offering were approximately \$165.6 million. The shares were issued pursuant to a shelf registration statement on Form S-3 which became effective upon filing.

K. Commitments and Contingencies

Legal Proceedings

A purported class action complaint was filed on March 18, 2010 in the United States District Court for the District of Massachusetts against us and our President and Chief Executive Officer, and Executive Vice President and Chief Financial Officer, entitled *Silverstrand Investments v. AMAG Pharm., Inc., et.*

23

Table of Contents

al., Civil Action No. 1:10-CV-10470-NMG. The complaint alleges that the defendants violated the federal securities laws, specifically Section 11 of the Securities Act of 1933, as amended, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff seeks unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. No trial date has been scheduled. We believe that the allegations contained in the complaint are without merit and intend to defend the case vigorously. We have not recorded an estimated liability associated with this legal proceeding as we do not believe that such a liability is probable or estimable.

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. Other than the complaint described above, we are not aware of any material claims against us at March 31, 2010.

L. Collaborative Agreements

On March 31, 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda Pharmaceutical Company Limited, or Takeda. Under the Takeda Agreement, we granted exclusive rights to Takeda to develop and commercialize Feraheme as a therapeutic agent in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey, or collectively, the Licensed Territory. As provided for under the Takeda Agreement, except under limited circumstances, we have retained the right to manufacture Feraheme and, accordingly, are responsible for supply of the product to Takeda. We are also responsible for conducting, and bearing the costs related to, certain predefined clinical studies with the costs of future modifications or additional studies to be allocated between the parties according to an agreed upon cost-sharing mechanism, which provides for a cap on such costs. We will receive a combination of upfront, regulatory approval and performance-based milestone payments, as well as defined payments for supply of the drug product and royalties on net product sales by Takeda in the Licensed Territory. The milestone payments may total over time up to approximately \$220.0 million, primarily dependent upon regulatory approvals and the attainment of specified annual sales levels. In accordance with the terms of the Takeda Agreement, in April 2010 we received a \$60.0 million upfront payment from Takeda which we have recorded as a receivable from collaboration in our condensed consolidated balance sheet as of March 31, 2010. We will recognize the upfront payment into revenues on a straight-line basis over ten years, which is our best estimate of the period over which we will perform our obligations under the Takeda Agreement. In addition, we are eligible to receive tiered double-digit royalties on net sales of Feraheme in the Licensed Territory. As of March 31, 2010, we have not recognized any significant revenues under the Takeda Agreement. In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, No. 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13. ASU 2009-13 amends existing revenue recognition accounting pronouncements. We are currently evaluating the potential impact of this standard on our condensed consolidated financial statements, specifically with respect to our accounting and disclosures related to the Takeda collaboration.

In 2008, we entered into Collaboration and Exclusive License Agreement, or the 3SBio License Agreement, and a Supply Agreement, or the 3SBio 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. The 3SBio License Agreement grants 3SBio an exclusive license for an initial term of thirteen years to develop and commercialize *Feraheme* as a therapeutic agent in China for an initial indication for the treatment of IDA in patients with CKD, and an option to expand into additional therapeutic indications. In consideration of the grant of the license, we received an upfront payment of \$1

Table of Contents

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 are eligible to receive certain other specified milestone payments upon regulatory approval of *Feraheme* in China for CKD and other indications. We are also entitled to receive tiered royalties of up to 25% based on sales of *Feraheme* by 3SBio in China. We retained all manufacturing rights for *Feraheme*. In addition, pursuant to the 3SBio Supply Agreement, 3SBio has agreed to purchase from us, and we have agreed to supply to 3SBio, *Feraheme* at a predetermined supply price for clinical and commercial use in connection with 3SBio s development and commercialization obligations described above for so long as the 3SBio License Agreement is in effect. To date we have not provided 3SBio with any product under the 3SBio Supply Agreement.

M. Recently Issued and Proposed Accounting Pronouncements

In February 2010, the FASB issued ASU No. 2010-09, Subsequent Events: Amendments to Certain Recognition and Disclosure Requirements, or ASU 2010-09, which amends Accounting Standards Codification, or ASC, 855 to address certain implementation issues related to an entity s requirement to perform and disclose subsequent events procedures. The amendments in ASU 2010-09 remove the requirement for an SEC filer to disclose a date through which subsequent events have been evaluated in both issued and revised financial statements. We adopted this guidance as of its issuance date and because this guidance only amends required disclosures in our condensed consolidated financial statements, it did not have an effect upon our financial position or results of operations.

In January 2010, the FASB issued ASU No. 2010-06, Improving Disclosures About Fair Value Measurements, or ASU 2010-06, which also amends ASC 820. ASU 2010-06 requires additional disclosure related to transfers in and out of Levels 1 and 2 and the activity in Level 3. This guidance requires a reporting entity to disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and describe the reasons for the transfers. In addition, this guidance requires a reporting entity to present separately information about purchases, sales issuances, and settlements in the reconciliation for fair value measurements using significant unobservable inputs (Level 3). This accounting standard was effective for interim and annual reporting periods beginning after December 31, 2009 other than for disclosures about purchases, sales, issuances and settlements in the roll forward of activity in Level 3 fair value measurements. Those disclosures will be effective for fiscal years beginning after December 31, 2010 and for interim periods within those fiscal years. We adopted all provisions of this pronouncement, except for those related to the disclosure of disaggregated Level 3 activity, during the first quarter of 2010 and because this guidance only amends required disclosures in our condensed consolidated financial statements, it did not have an effect upon our financial position or results of operations. We do not expect the adoption of the remaining provisions of this amendment to have a significant impact on our consolidated financial statements.

In October 2009, the FASB issued ASU No. 2009-13. ASU 2009-13 amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB ASC Subtopic 605-25 (previously included within Emerging Issues Task Force, or EITF, No. 00-21, Revenue Arrangements with Multiple Deliverables, or EITF 00-21). The consensus to EITF Issue No. 08-1, Revenue Arrangements with Multiple Deliverables, or EITF 08-1, provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management sestimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. EITF 00-21 previously required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was

Table of Contents

difficult to determine when the product was not individually sold because of its unique features. Under EITF 00-21, if the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011 will require us to apply this guidance retrospectively to January 1, 2010 and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. We are currently evaluating the potential impact of this standard on our condensed consolidated financial statements, specifically with respect to our accounting and disclosures related to the Takeda collaboration.

In December 2009, the FASB issued ASU No. 2009-16, Accounting for Transfers of Financial Assets, or ASU 2009-16. ASU 2009-16 relates to the accounting and disclosure requirements related to the servicing and transfer of financial assets. ASU 2009-16 enhances information reported to users of financial statements by providing greater transparency about transfers of financial assets and an entity s continuing involvement in transferred financial assets, including securitization transactions, where entities have continuing exposure to the risks related to transferred financial assets. It eliminates the concept of a qualifying special-purpose entity, changes the requirements for de-recognizing financial assets, and requires additional disclosures. This amendment is effective for fiscal years beginning after November 15, 2009. We adopted this pronouncement during the first quarter of 2010 which did not have a significant impact on our condensed consolidated financial statements.

In December 2009, the FASB issued ASU No. 2009-17, Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities, or ASU 2009-17. ASU 2009-17 relates to the accounting and disclosure requirements related to the consolidation of variable interest entities and changes how a reporting entity determines when an entity that is insufficiently capitalized or is not controlled through voting (or similar rights) should be consolidated. The determination of whether a reporting entity is required to consolidate another entity is based on, among other things, the other entity is purpose and design and the reporting entity is ability to direct the activities of the other entity that most significantly impact the other entity is economic performance. The reporting entity will be required to provide additional disclosures about its involvement and will be required to disclose how its involvement with a variable interest entity affects the reporting entity is financial statements. This amendment is effective for fiscal years beginning after November 15, 2009. We adopted this pronouncement during the first quarter of 2010 which did not have a significant impact on our condensed consolidated financial statements.

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, 2009.

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: our expectations regarding our intended development and commercialization of

Table of Contents

Feraheme® (ferumoxytol) Injection, our expectations regarding the success of our collaboration with Takeda Pharmaceutical Company Limited, the expected timing of the filing of our Marketing Authorization Application for Feraheme with the European Medicines Agency, our plan to conduct four pediatric studies and the expected timing and design of these studies, our plan to conduct and the intended timing and design of our planned global studies of Feraheme for the treatment of iron deficiency anemia in a broad range of patients, our plan to complete our Phase II study of Feraheme in vascular-enhanced magnetic resonance imaging later in 2010, our statement that our partner in China, 3SBio Inc., plans to conduct a Feraheme clinical study in China, our expectation that sales of GastroMARK will not change materially, our expectation regarding our future revenues, including expected Feraheme, Takeda Pharmaceutical Company Limited and 3SBio Inc. revenues and our expectation to partly fund our future operations with Feraheme revenues, our expectation that our reserves as a percentage of gross sales will increase during the remainder of 2010, our expectation regarding milestone payments we may receive from Takeda Pharmaceutical Company Limited, our expectation that during 2010 and into the future our net sales as a percentage of gross sales will be negatively affected as a result of recently enacted healthcare legislation, our expectation that our costs of product sales will increase, our expectation regarding our research and development expenses for the remainder of 2010, our expectations regarding the amount of external expenses and the timing of our planned research and development projects, our expectation regarding our selling, general and administrative expenses for the remainder of 2010, our expectation 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 expectation regarding our future cash flows, our belief that the decline in the value of our auction rate securities not subject to settlement right agreements is temporary and that we will ultimately be able to liquidate these investments without significant loss, our intention to sell our auction rate securities subject to settlement right agreements to UBS AG, our belief that the allegations asserted against us in the class action lawsuit are without merit, 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 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 United States 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 iron deficiency anemia, or IDA, and novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. We currently manufacture and sell two approved products, Feraheme® (ferumoxytol) Injection for intravenous, or IV, use and GastroMARK®.

On June 30, 2009, *Feraheme* was approved for marketing in the U.S. by the U.S. Food and Drug Administration, or the FDA, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with chronic kidney disease, or CKD. We market and sell *Feraheme* through our own commercial organization, including a specialized sales force and account management and reimbursement teams. We sell *Feraheme* primarily to authorized wholesalers and specialty distributors and began commercial sale of *Feraheme* in the U.S. in July 2009.

Table of Contents

For the three months ended March 31, 2010, we recognized net product sales of *Feraheme* of \$13.1 million, including approximately \$2.2 million of previously deferred product revenues. During the third quarter of 2009, shortly after the launch of *Feraheme*, we implemented a Launch Incentive Program under which certain dialysis organizations purchased *Feraheme* directly from us. This program provided certain customers with, among other things, discounted pricing and expanded rights of return. As a result, we deferred revenues associated with this program which we recognize as revenues as the participating organizations utilize their *Feraheme* inventory.

In December 2009, we submitted draft protocols for two proposed clinical trials to meet our FDA post-approval Pediatric Research Equity Act requirement to support pediatric labeling of *Feraheme*. In 2010, we intend to initiate these two randomized, active controlled pediatric studies in children with CKD and IDA. One study will be in dialysis dependent CKD patients, and the other will be in CKD patients not on dialysis. Each study will assess the safety and efficacy of *Feraheme* treatment as compared to oral iron in approximately 144 children.

We also plan to advance our *Feraheme* clinical development program in adults by initiating two Phase III multi-center clinical trials in mid-2010 to assess *Feraheme* for the treatment of IDA in a broad range of patients, which may include women with abnormal uterine bleeding, or AUB, patients with cancer and gastrointestinal diseases and postpartum women, for whom oral iron is unsatisfactory. One study will assess the efficacy and safety of two doses of 510 milligrams each of *Feraheme* compared to placebo in a total of approximately 800 patients with IDA. A second study will assess the efficacy and safety of two doses of 510 milligrams each of *Feraheme* compared to a total dose of 1,000 milligrams of an IV iron sucrose product in a total of approximately 600 patients with IDA. Further, we intend to initiate an open label extension study enrolling patients from the placebo controlled study who will be followed for six months and will be eligible to receive two doses of 510 milligrams each of *Feraheme* whenever they meet treatment criteria.

On March 31, 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda Pharmaceutical Company Limited, or Takeda. Under the Takeda Agreement, we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey, or collectively, the Licensed Territory. Under the Takeda Agreement we are initially responsible for the regulatory application for *Feraheme* in the EU, Switzerland and Canada with Takeda responsible for registrational filings in all other regions covered by the agreement.

In connection with our responsibilities under the Takeda Agreement, we expect to file a Marketing Authorization Application, or MAA, in mid-2010 for *Feraheme* for the treatment of IDA in CKD patients with the European Medicines Agency, or EMA. In the fourth quarter of 2009, we received approval from the EMA for our Pediatric Investigation Plan, which is a prerequisite for the submission of our *Feraheme* MAA. Our Pediatric Investigation Plan includes the two pediatric studies required to meet our Pediatric Research Equity Act requirement and two additional pediatric studies requested by the EMA. To further support our MAA, we have initiated a global, randomized, Phase IV multi-center, active controlled trial with approximately 150 adult CKD patients both on dialysis and not on dialysis. This study will assess the safety and efficacy of two doses of 510 milligrams each of *Feraheme* compared to a total dose of 1,000 milligrams of an IV iron sucrose product.

In addition, as part of our obligation under the Takeda Agreement, we are planning to advance our *Feraheme* clinical development program in adult patients with CKD by initiating a Phase IV multi-center

Table of Contents

clinical trial. This study will assess the safety and efficacy of repeat, episodic *Feraheme* administration for the treatment of persistent or recurrent IDA over a 12 month period. Subjects will receive an initial course of two doses of 510 milligrams each of *Feraheme*, and will receive subsequent courses of two doses of 510 milligrams of *Feraheme* whenever they meet treatment criteria. The study is expected to enroll a total of approximately 300 CKD patients with IDA including patients on dialysis (hemodialysis or peritoneal dialysis) and those not on dialysis, including post-kidney transplant recipients.

In December 2009, we filed a New Drug Submission for *Feraheme* to treat IDA in patients with CKD with the Therapeutic Products Directorate of Health Canada, the federal authority that regulates pharmaceutical drugs and medical devices for human use in Canada. This filing has been accepted and is currently under review. In addition, in December 2009, our partner in China, 3SBio Inc., or 3SBio, filed an application with the Chinese State Food and Drug Administration, or the SFDA, to obtain approval to begin a registrational clinical trial necessary to file for marketing approval in China. Once approved by the SFDA, 3SBio plans to commence a multi-center randomized efficacy and safety study in China involving approximately 200 CKD patients.

In addition to its use for the treatment of IDA, *Feraheme* may also be useful as a vascular enhancing agent in magnetic resonance imaging, or MRI. The FDA has granted Fast Track designation to *Feraheme* with respect to its development as a diagnostic agent for vascular-enhanced MRI for the assessment of peripheral arterial disease, or PAD, in patients with known or suspected CKD. We have enrolled over 90% of our 108 patient Phase II study of *Feraheme* in vascular-enhanced MRI for the detection of clinically significant arterial stenosis or occlusion, or the narrowing or blocking of arteries. We plan to complete the Phase II study later this year and will assess next steps for development based on the Phase II data.

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

In the past, we have devoted substantially all of our resources to our research and development programs and, more recently, we have also incurred substantial costs related to the commercialization of *Feraheme*. Prior to the commercial launch of *Feraheme*, we financed our operations primarily from the sale of our equity securities, cash generated by our investing activities, and payments from our strategic partners. At March 31, 2010, our accumulated deficit was approximately \$304.7 million. We expect to continue to incur significant expenses to manufacture, market and sell *Feraheme* as an iron replacement therapeutic in CKD patients in the U.S. and to further develop *Feraheme* for additional indications and in additional countries outside of the U.S. In the second half of 2009, we began to derive revenues from product sales of *Feraheme*. We currently expect to fund our future operations in part from the sale of *Feraheme* in addition to the sale of our equity securities, cash generated by our investing activities, and payments from our strategic partners.

In January 2010, we sold 3.6 million shares of our common stock, \$0.01 par value per share, in an underwritten public offering at a price to the public of \$48.25 per share, resulting in gross proceeds of approximately \$173.7 million. Net proceeds to us after deducting fees, commissions and other expenses related to the offering were approximately \$165.6 million. The shares were issued pursuant to a shelf registration statement on Form S-3 which became effective upon filing.

Table of Contents

Results of Operations for the Three Months Ended March 31, 2010 as Compared to the Three Months Ended March 31, 2009

Revenues

Total revenues were \$13.3 million and \$1.0 million for the three months ended March 31, 2010 and 2009, respectively, representing an increase of approximately \$12.3 million, or greater than 100%. The increase in revenues was primarily due to product sales of *Feraheme* following its FDA approval and commercial launch in mid-2009.

The following table sets forth customers who represented 10% or more of our revenues for the three months ended March 31, 2010 and 2009. No other company accounted for more than 10% of our total revenues for the three months ended March 31, 2010 and 2009.

	Three Months Ended M	arch 31,
	2010	2009
Metro Medical Supply, Inc.	36%	
AmerisourceBergen Drug Corporation	29%	
Guerbet S.A.	< 10%	33%
Covidien, Ltd.	< 10%	13%
Bayer Healthcare Pharmaceuticals		54%

Our revenues for the three months ended March 31, 2010 and 2009 consisted of the following (in thousands):

	Three Months Ended March 31,						
		2010		2009		\$ Change	% Change
Product sales, net	\$	13,295	\$	393	\$	12,902	>100%
License fees				516		(516)	-100%
Royalties		11		47		(36)	-77%
Total	\$	13,306	\$	956	\$	12,350	>100%

Net Product Sales

Net product sales for the three months ended March 31, 2010 and 2009 consisted of the following (in thousands):

	Three Months Ended March 31,					
	2010		2009		\$ Change	% Change
Feraheme	\$ 13,056	\$		\$	13,056	N/A
GastroMARK	239			393	(154)	-39%
Total	\$ 13,295	\$		393 \$	12,902	>100%

The \$12.9 million, or greater than 100%, increase in net product sales was primarily due to the FDA approval and subsequent U.S. commercial launch of *Feraheme* in mid-2009. Included in *Feraheme* product sales is \$2.2 million of product sales related to previously deferred revenues recorded under our Launch Incentive Program.

Table of Contents

Our product sales may fluctuate from period to period as a result of factors such as wholesaler demand forecasts and buying decisions as well as end user demand, which can create uneven purchasing patterns by our customers. Our product sales may also fluctuate as the result of changes or adjustments to our reserves or changes in government or customer rebates. For example, in March 2010, U.S. healthcare reform legislation was enacted which contains several provisions that impact our business. Although many provisions of the new legislation do not take effect immediately, several provisions became effective in the first quarter of 2010, including the following:

- an increase in the minimum statutory Medicaid rebate to states participating in the Medicaid program from 15.1% to 23.1%;
- an extension of the Medicaid rebate to drugs dispensed to Medicaid beneficiaries enrolled with managed care organizations; and
- an expansion of the 340(B) Public Health Services drug pricing program, which provides drugs at reduced rates, to include additional hospitals, clinics, and healthcare centers in an outpatient setting.

Beginning in 2011, we may incur our share of a new fee assessed on all branded prescription drug manufacturers and importers. This fee will be calculated based upon *Feraheme s* percentage share of total branded prescription drug sales to U.S. government programs (such as Medicare, Medicaid and VA and PHS discount programs) made during the previous year. The aggregated industry wide fee is expected to total \$28 billion through 2019, ranging from \$2.5 billion to \$4.1 billion annually. Presently, uncertainty exists as many of the specific determinations necessary to implement this new legislation have yet to be decided and communicated to industry participants. For example, determinations as to how the annual fee on branded prescription drugs will be calculated and allocated remain to be clarified, though, as noted above, this provision will not be effective until 2011.

We expect that during 2010 and into the future, our net sales as a percentage of gross sales will be negatively affected as a result of certain aspects of the recently enacted healthcare legislation, specifically, the increase in the minimum Medicaid rebates and the expansion to whom the rebates may potentially apply. It is possible that the effect of this legislation could further adversely impact our future revenues, however, we are still assessing the full extent of this legislation s future impact on our business.

We recognize net product sales in accordance with current accounting guidance related to the recognition, presentation and disclosure of revenue in financial statements, which outlines the basic criteria that must be met to recognize revenue and provides guidance for disclosure of revenue in financial statements. We recognize revenue when:

- persuasive evidence of an arrangement exists;
- delivery of product has occurred or services have been rendered;

- the sales price charged is fixed or determinable; and
- collection is reasonably assured.

We record product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and other rebates, distributor, wholesaler and group purchasing organization, or GPO, fees, and product returns as a reduction of revenue in our condensed consolidated statement of operations at the time product sales are recorded. Calculating these gross-to-net sales adjustments involves estimates and judgments based primarily on actual *Feraheme* sales data, forecasted customer buying patterns blended with historical experience of products similar to *Feraheme* sold by others, and other market research. In addition,

Table of Contents

we also monitor our distribution channel to determine the level of additional allowances or accruals required based on inventory in our sales channel. There were no product sales allowances or accruals for the three months ended March 31, 2009. For further details related to our revenue recognition and related sales allowances policy refer to our critical accounting policies included in Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations of our Annual Report on Form 10-K for the year ended December 31, 2009.

An analysis of our product sales allowances and accruals for the three months ended March 31, 2010 is as follows (in thousands):

	March 31, 2010
Product sales allowances and accruals:	
Discounts and chargebacks	\$ 742
Government and other rebates	3,001
Returns	244
Total product sales allowances and accruals	\$ 3,987
Total net product sales	\$ 13,295
Total gross product sales	\$ 17,282
Total product sales allowances and accruals as a percent of total gross product sales	23%

An analysis of the amount of, and change in, reserves for the three months ended March 31, 2010 is as follows (in thousands):

		Rebates and		
	Discounts	Fees	Returns	Total
Balance at January 1, 2010	\$ 499	\$ 5,194	\$ 463 \$	6,156
Current provisions relating to sales in current year	742	3,284	294	4,320
Other provisions relating to deferred revenue		(383)		(383)
Adjustments relating to sales in prior year		(283)	(50)	(333)
Payments/returns relating to sales in current year	(158)	(34)		(192)
Payments/returns relating to sales in prior year	(495)	(2,105)		(2,600)
Balance at March 31, 2010	\$ 588	\$ 5,673	\$ 707 \$	6,968

Product sales allowances and accruals are primarily comprised of both direct and indirect fees, discounts and rebates. Direct fees, discounts and rebates are contractual fees and price adjustments payable to wholesalers, specialty distributors and other customers that purchase products directly from us. Indirect fees, discounts and rebates are contractual price adjustments payable to healthcare providers and organizations, such as certain dialysis organizations, physicians, clinics, hospitals, and GPOs that typically do not purchase products directly from us but rather from wholesalers and specialty distributors. In accordance with guidance related to accounting for fees and consideration given by a vendor to a customer (including a reseller of a vendor s products), these fees, discounts and rebates are presumed to be a reduction of the selling price of *Feraheme*. Product sales allowances and accruals are based on definitive contractual agreements or legal requirements (such as Medicaid laws and regulations) related to the purchase and/or utilization of the product by these entities. Allowances and accruals are generally recorded in the same period that the related revenue is recognized and are estimated using either historical, actual and/or other data, including estimated patient

Table of Contents

usage, applicable contractual rebate rates, contract performance by the benefit providers, other current contractual and statutory requirements, historical market data based upon experience of other similar products to *Feraheme*, specific known market events and trends such as competitive pricing and new product introductions and current and forecasted customer buying patterns and inventory levels, including the shelf life of our products. As part of this evaluation, we also review changes to federal legislation, changes to rebate contracts, changes in the level of discounts, and changes in product sales trends. Reserve estimates are evaluated quarterly and may require adjustments to better align our estimates with actual results. During the three months ended March 31, 2010, our allowances for government and other rebates reflected a reduction in prior year Medicaid allowances which was primarily the result of a reduction in our estimates of Medicaid utilization across *Feraheme* customer classes resulting from additional data, including information regarding Medicaid claims experience for comparable products. This reduction was partially offset by an increase in estimated Medicaid allowances associated with the increase in statutory minimum rebate rates included in the legislation described above. Although allowances and accruals are recorded at the time of product sale, certain rebates are typically paid out, on average, up to six months or longer after the sale. If actual future results vary from our estimates, we may need to adjust our previous estimates, which would affect our earnings in the period of the adjustment.

There are several factors that make it difficult to predict future changes in our sales allowances and accruals as a percentage of gross product sales including, but not limited to, the following:

- variations in, and the success of, fee, rebate and discount structures implemented in our efforts to increase adoption of *Feraheme*;
- variations in our future customer mix:
- changes in legislation, such as the healthcare legislation discussed above;
- the percentage of total revenues in each period which are the result of utilization by customers who purchased *Feraheme* directly from us at the discounted pricing under our Launch Incentive Program; and
- adjustments and refinements to prior estimates and assumptions.

Overall, we expect that our reserves as a percent of gross sales will increase during the remainder of 2010 due primarily to our efforts to increase adoption and utilization of *Feraheme*, the increase in statutory minimum rebate rates noted above as well as customer mix assumptions, which will negatively affect our future net product sales.

Because we only recently launched *Feraheme* in the U.S. there are a number of factors that make it particularly difficult to predict the magnitude of future *Feraheme* sales, including the magnitude and timing of adoption of *Feraheme* by physicians, dialysis clinics, hospitals and other healthcare payors and providers, the inventory levels maintained by *Feraheme* wholesalers, distributors and other customers, the frequency of re-orders by existing customers, and the pricing of products that compete with *Feraheme* and other actions taken by our competitors.

Accordingly, our *Feraheme* net product revenues in previous quarters may not be indicative of future *Feraheme* net product revenues. As a result of these and other factors, future *Feraheme* sales could vary significantly from quarter to quarter.

Table of Contents

Deferred Revenue - Launch Incentive Program

During the third quarter of 2009 certain dialysis organizations purchased *Feraheme* from us under our Launch Incentive Program. These purchases were made under agreements which provided these customers with an opportunity to purchase *Feraheme* through September 30, 2009 at discounted pricing and further provided for extended payment terms and expanded rights of return. As a result, in accordance with current accounting guidance which requires that we defer recognition of revenues until we can reasonably estimate returns related to those purchases, we have deferred the recognition of revenues associated with these purchases until our customers report to us that such inventory has been utilized in their operations. Any purchases returned to us will not be recorded as revenue. Accordingly, as of March 31, 2010, we have a remaining balance of \$8.3 million in deferred revenues, which represents product purchased under the Launch Incentive Program which remained held by the dialysis organizations at March 31, 2010, net of any applicable discounts and estimated rebates, which are included in our commercial rebate accruals as of March 31, 2010. In addition, we have deferred the related cost of product sales of approximately \$0.2 million and recorded such amount as finished goods inventory held by others as of March 31, 2010. Because we are unable to reasonably estimate the amount of inventory that may be returned under this program, if any, we cannot provide any assurance that amounts reported as deferred revenue and associated with this program will be utilized by our customers and thereby recorded by us as product revenues in our future condensed consolidated statements of operations.

License Fee and Other Collaboration Revenues

There were no license fee revenues for the three months ended March 31, 2010. The \$0.5 million license fee revenues for the three months ended March 31, 2009 consisted solely of deferred revenues that were being amortized in connection with our agreements with Bayer Healthcare Pharmaceuticals, or Bayer, which were terminated in November 2008. In 1995, we entered into a License and Marketing Agreement and a Supply Agreement, or the Bayer Agreements, granting Bayer a product license and exclusive marketing rights to Feridex I.V.® in the U.S. and Canada. In connection with our decision to cease manufacturing *Feridex I.V.*, the Bayer Agreements were terminated in November 2008 by mutual agreement. Prior to the termination of the Bayer Agreements, we accounted for the revenues associated with the Bayer Agreements on a straight line basis over their 15 year contract term. Pursuant to the termination agreement, Bayer continued to sell any remaining *Feridex I.V.* inventory in its possession through April 1, 2009. As a result of the termination of these agreements, during the three months ended March 31, 2009 we recognized the remaining \$0.5 million of deferred revenues under the Bayer Agreements. No further significant obligation exists by either party.

On March 31, 2010, we entered into the Takeda Agreement. Under the Takeda Agreement, we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in the Licensed Territory. As provided for under the Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme* and, accordingly, are responsible for supply of the product to Takeda. We are also responsible for conducting, and bearing the costs related to, certain predefined clinical studies with the costs of future modifications or additional studies to be allocated between the parties according to an agreed upon cost-sharing mechanism, which provides for a cap on such costs. We will receive a combination of upfront, regulatory approval and performance-based milestone payments, as well as defined payments for supply of the drug product and royalties on net product sales by Takeda in the Licensed Territory. The milestone payments may total over time up to approximately \$220.0 million, primarily dependent upon regulatory approvals and the attainment of specified annual sales levels. In accordance with the terms of the Takeda Agreement, in April 2010 we received a \$60.0 million upfront payment from Takeda which we will recognize into revenues on a straight-line basis over ten years, which is our best estimate of the period over which we will perform our obligations under the Takeda Agreement. In addition, we are eligible to receive tiered double-digit royalties on net sales of *Feraheme* in the Licensed Territory. As of March 31, 2010, we have not recognized any significant

Table of Contents

revenues under the Takeda Agreement and have recorded \$6.0 million as short-term deferred revenue representing the amount of fees that will be amortized into revenues over the next twelve months. In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, No. 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13. ASU 2009-13 amends existing revenue recognition accounting pronouncements. We are currently evaluating the potential impact of this standard on our condensed consolidated financial statements, specifically with respect to our accounting and disclosures related to the Takeda collaboration.

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 upfront payment of \$1 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 2010.

Costs and Expenses

Cost of Product Sales

We incurred costs of \$1.0 million and less than \$0.1 million associated with product sales, or 8% and 16% of net product sales, during the three months ended March 31, 2010 and 2009, respectively. Our cost of product sales for the three months ended March 31, 2010 was comprised primarily of manufacturing costs associated with *Feraheme*. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the costs of *Feraheme* sold during the three months ended March 31, 2010 were expensed prior to the June 2009 FDA approval, and therefore are not included in the cost of product sales during this period. We continue to hold *Feraheme* inventory that has been previously expensed, and once such inventory has been fully depleted, we expect our cost of product sales as a percentage of net product sales will increase, reflecting the full manufacturing cost of our inventory. We cannot predict when such previously expensed materials will be exhausted, as this will be dependent on the timing and magnitude of *Feraheme* sales in the U.S. We also anticipate that costs of product sales will increase as sales volume increases.

In addition, as of March 31, 2010, we deferred approximately \$0.2 million of costs associated with product sales made under our Launch Incentive Program. These costs have been recorded as finished goods inventory held by others on our condensed consolidated balance sheet as of March 31, 2010. We recognize the cost of product sold under the Launch Incentive Program as, and to the extent that, inventory is utilized by our customers.

Research and Development Expenses

Research and development expenses include external expenses, such as costs of clinical trials, contract research and development expenses, certain manufacturing research and development 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. As discussed below, where possible, we track our external costs by major project. To the extent that external costs are not attributable to a specific project or activity, they are included in other external costs. Prior to the June 2009 regulatory approval of *Feraheme*, costs associated with manufacturing process

development and the manufacture of the drug product were recorded as research

Table of Contents

and development expenses. Subsequent to FDA approval, costs associated with the manufacture of *Feraheme* to be made commercially available in the U.S. are capitalized.

Research and development expenses for the three months ended March 31, 2010 and 2009 consisted of the following (in thousands):

	Three Months Ended March 31,					
	2010		2009		\$ Change	% Change
External Research and Development Expenses						
Feraheme to treat IDA regardless of the underlying cause	\$ 1,894	\$		\$	1,894	N/A
Feraheme to treat IDA in CKD patients	1,989				1,989	N/A
Feraheme as a therapeutic agent in AUB patients			1,287		(1,287)	-100%
Feraheme as a therapeutic agent, general	293		1,425		(1,132)	-79%
Feraheme as an imaging agent in PAD patients	582		323		259	80%
Feraheme manufacturing and materials	1,637		1,154		483	42%
Other external costs	327		216		111	51%
Total	\$ 6,722	\$	4,405	\$	2,317	53%
Internal Research and Development Expenses						
Compensation, payroll taxes, benefits and other expenses	4,441		5,572		(1,131)	-20%
Equity-based compensation expense	1,205		1,095		110	10%
Total	\$ 5,646	\$	6,667	\$	(1,021)	-15%
Total Research and Development Expenses	\$ 12,368	\$	11,072	\$	1,296	12%

Total research and development expenses incurred in the three months ended March 31, 2010 amounted to \$12.4 million, an increase of \$1.3 million, or 12%, from the three months ended March 31, 2009. The \$1.3 million increase reflects the costs incurred as we prepared and initiated new clinical trials and increased spending on ongoing clinical trials. The increase in total research and development expenses was partially offset by a reduction in costs associated with our then planned AUB trial, a reduction in expense related to the manufacture of *Feraheme* prior to approval for commercial sale, and a reduction in pre-approval costs incurred in the first quarter of 2009 to ready our manufacturing capabilities at our Cambridge, Massachusetts manufacturing facility.

Our external research and development expenses increased by \$2.3 million, or 53%, for the three months ended March 31, 2010 as compared to the three months ended March 31, 2009. The increase in our external expenses was due primarily to costs incurred as we began preparations for our Phase III clinical development program for *Feraheme* to treat IDA regardless of the underlying cause, which we plan to initiate in mid-2010, costs associated with the initiation of a global clinical study to support our MAA in Europe for the treatment of IDA in CKD patients, costs incurred as we progressed our Phase II study of *Feraheme* as a diagnostic agent for vascular-enhanced MRI for the assessment of PAD, and costs associated with research and development for new manufacturing processes. These increased external research and development expenses were partially offset by a reduction of costs associated with our AUB trial, which was discontinued in 2009, a reduction in costs incurred in connection with our efforts to address the manufacturing observations noted by the FDA during a 2008 inspection of our Cambridge, Massachusetts manufacturing facility and the capitalization to inventory of certain external *Feraheme* manufacturing and materials costs incurred post FDA approval.

Table of Contents

Our internal research and development expenses decreased by \$1.0 million, or 15%, for the three months ended March 31, 2010 as compared to the three months ended March 31, 2009. The decrease in internal costs was due primarily to the allocation of internal manufacturing costs to inventory in the three months ended March 31, 2010, whereas such costs were expensed in the three months ended March 31, 2009 because *Feraheme* had not been approved for sale by the FDA. At March 31, 2010, we had 57 full-time equivalents, or FTEs, in research and development as compared to 94 FTEs at March 31, 2009, a decrease of 39% due primarily to the reallocation of manufacturing personnel out of research and development following FDA approval of *Feraheme* in June 2009. The \$0.1 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 compared to current levels for the remainder of 2010 primarily as a result of our continued advancement and the initiation of our clinical development programs, including studies and activities required under the Takeda Agreement, as well as other research and development related functions and activities in support of *Feraheme*. Factors which will impact 2010 research and development expenses include the timing of initiation and pace of enrollment of our pediatric studies of *Feraheme*, our trial of *Feraheme* to support our MAA filing with the EMA, our safety and efficacy trial of repeat, episodic *Feraheme* administration for the treatment of persistent or recurrent IDA, and the design, timing and pace of enrollment of our other clinical trials of *Feraheme*, including our planned development program for *Feraheme* in a broad range of patients with IDA.

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 later of the completion of the last trial in the project or the last submission of a regulatory filing to the FDA or applicable foreign regulatory body. We have commenced or anticipate commencing the following two major research and development projects during 2010:

- <u>Feraheme</u> to treat IDA regardless of the underlying cause. This project currently includes: (1) a Phase III clinical study evaluating *Feraheme* treatment compared to treatment with placebo; (2) a second Phase III clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron; and (3) an extension study.
- <u>Feraheme</u> to treat IDA in CKD patients. This project includes: (1) a clinical study currently underway evaluating *Feraheme* treatment compared to treatment with another IV iron which will support our planned CKD MAA; (2) two pediatric studies to be conducted as part of our Phase IV Pediatric Research Equity Act requirement to support pediatric CKD labeling of *Feraheme*; (3) two additional pediatric studies in accordance with our approved Pediatric Investigation Plan to support our planned CKD MAA; and (4) a Phase IV multi-center clinical trial assessing the safety and efficacy of repeat, episodic *Feraheme* administration for the treatment of persistent or recurrent IDA over a 12 month period.

During the three months ended March 31, 2010, we incurred aggregate external research and development expenses of approximately \$1.9 million related to the development of *Feraheme* to treat IDA regardless of the underlying cause. We currently estimate that the total external costs associated with the efforts needed to complete this development project will be in the range of approximately \$55.0 to \$65.0 million over the next several years. This represents a decrease of approximately \$15.0 million from our expected range at December 31, 2009, which reflects the finalization of clinical study contracts with

Table of Contents

third-parties as well as actual expenses incurred during the three months ended March 31, 2010 in connection with this project.

During the three months ended March 31, 2010, we incurred aggregate external research and development expenses of approximately \$2.0 million related to the development of *Feraheme* to treat IDA in CKD patients. We currently estimate that the external costs associated with this development project will be in the range of approximately \$45.0 to \$55.0 million over the next several years. This represents an increase of approximately \$15.0 million from our expected range at December 31, 2009, which primarily reflects the addition of a Phase IV multi-center clinical trial assessing the safety and efficacy of repeat, episodic *Feraheme* administration for the treatment of persistent or recurrent IDA over a 12 month period partially offset by actual expenses incurred during the three months ended March 31, 2010 in connection with this project.

Conducting clinical trials involves a number of uncertainties, many of which are out of our control. Our estimates of external costs associated with our research and development projects could therefore vary from our current estimates for a variety of reasons including but not limited to the following: significant delays in our clinical trials due to slow enrollment, unexpected results from our clinical sites that affect our ability to complete the studies in a timely manner, inadequate performance or errors by third-party service providers, any deficiencies in the design or oversight of these studies by us, the need to conduct additional clinical trials or a delay in the submission of any applicable regulatory filing.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses include costs related to our commercial personnel, including our specialized sales force, medical education professionals, and other commercial support personnel, administrative personnel costs, external and facilities costs required to support the marketing and sale of *Feraheme* and other costs associated with our corporate-related activities.

Selling, general and administrative expenses for the three months ended March 31, 2010 and 2009 consisted of the following (in thousands):

	Three Months E	nded M	arch 31,			
	2010		2009	\$ C	hange	% Change
Compensation, payroll taxes and benefits	\$ 10,052	\$	8,421	\$	1,631	19%
Professional and consulting fees and other						
expenses	10,383		6,922		3,461	50%
Equity-based compensation expense	3,021		2,407		614	26%
Total	\$ 23,456	\$	17,750	\$	5,706	32%

The \$5.7 million, or 32%, increase in selling, general and administrative expenses for the three months ended March 31, 2010 as compared to the three months ended March 31, 2009 was due primarily to increased costs associated with the expansion of our commercial operations function and our general administrative infrastructure to support our growth as a commercial entity, including compensation and benefits costs related to increased headcount and increased advertising and promotion costs associated with the July 2009 U.S. commercial launch of *Feraheme*. In addition, during the three months ended March 31, 2010 we incurred legal and other consulting and professional fees in connection with our collaboration with Takeda. At March 31, 2010 we had 179 employees in our selling, general and administrative departments as compared to 171 employees at March 31, 2009, a 5% increase. The \$0.6 million increase in equity-based compensation expense was due primarily to increased equity awards to both new and existing employees.

Table of Contents

We expect selling, general and administrative expenses to remain generally consistent with current levels for the remainder of 2010 as we continue our U.S. commercialization efforts related to *Feraheme*, execute our marketing and promotional programs, and maintain our commercial and administrative infrastructure to support the commercialization of *Feraheme*.

Other Income (Expense)

Other income (expense) for the three months ended March 31, 2010 and 2009 consisted of the following (in thousands):

	Three Months	Ended M	larch 31,		
	2010		2009	\$ Change	% Change
Interest and dividend income, net	\$ 471	\$	1,256	\$ (785)	-63%
Gains on investments, net	4		992	(988)	-100%
Fair value adjustment of settlement rights			(923)	923	-100%
Total	\$ 475	\$	1,325	\$ (850)	-64%

Other income (expense) for the three months ended March 31, 2010 decreased by \$0.9 million, or 64%, as compared to the three months ended March 31, 2009. The \$0.9 million decrease was primarily attributable to a \$0.8 million decrease in interest and dividend income as the result of lower interest rates in the three months ended March 31, 2010 as compared to the three months ended March 31, 2009.

In November 2008, we elected to participate in a rights offering by UBS AG, or UBS, one of our securities brokers, which provided us with the right to sell to UBS \$9.3 million in par value of our auction rate securities, or ARS, 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 the accounting guidance related to fair value measurements. We elected the fair value option with respect to the Settlement Rights in accordance with current accounting guidance related to the fair value option for financial assets and financial liabilities. We have recorded an asset equal to our estimated fair value of the Settlement Rights of approximately \$0.8 million in our condensed consolidated balance sheet as of both March 31, 2010 and December 31, 2009, representing no change to the estimated fair value of our Settlement Rights from the estimated fair value at December 31, 2009. 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 \$8.5 million as of March 31, 2010 as trading securities. Accordingly, as of March 31, 2010, we have adjusted our estimated value of these trading securities by \$4,000 from the estimated value at December 31, 2009, which we have recorded as a gain on investments in other income (expense) in our condensed consolidated statement of operations.

We expect interest and dividend income to increase for the remainder of 2010 as a result of the investment of excess cash balances, principally as the result of our January 2010 sale of 3.6 million shares of our common stock at a public offering price of \$48.25 per share and which resulted in net proceeds to us of approximately \$165.6 million.

Table of Contents
Income Tax Benefit
During the three months ended March 31, 2010 we recognized no tax expense or benefit due to our continued net operating loss position as compared to a \$0.2 million tax benefit recognized during the three months ended March 31, 2009 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 \$23.1 million, or \$1.15 per basic and diluted share, for the three months ended March 31, 2010 as compared to a net loss of \$26.4 million, or \$1.55 per basic and diluted share, for the three months ended March 31, 2009.
Liquidity and Capital Resources
General
We finance our operations primarily from the sale of <i>Feraheme</i> , the sale of our common stock, cash generated from our investing activities, and payments from our strategic partners. Our long-term capital requirements will depend on many factors, including, but not limited to, the following:
• Our ability to successfully commercialize <i>Feraheme</i> in the U.S. as an IV iron replacement therapeutic agent;
• The magnitude of <i>Feraheme</i> sales and the timing of the receipt of cash from such sales;
• Our ability to achieve the various milestones and receive the associated payments under the Takeda Agreement;
• Costs associated with the U.S. commercialization of <i>Feraheme</i> , including costs associated with maintaining our commercial infrastructure, executing our promotional and marketing strategy for <i>Feraheme</i> and conducting post-marketing clinical studies;

•	Costs associated with our development of additional indications for <i>Feraheme</i> in the U.S.;
•	Costs associated with our pursuit of approval for Feraheme as an IV iron replacement therapeutic agent outside of the U.S.;
	Costs associated with commercial-scale manufacturing of <i>Feraheme</i> , including costs of raw materials and costs associated with g commercial inventory and qualifying additional manufacturing capacities and second source suppliers;
•	Costs associated with potential business development and in-licensing activities;
•	Our ability to liquidate our investments in ARS, in a timely manner and without significant loss;
•	The impact of the current state of the credit and capital markets upon the investments in our portfolio;
• necessary;	Our ability to maintain successful collaborations with our partners and/or to enter into additional alternative strategic relationships, in and
	40

Table of Contents

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

As of March 31, 2010, our investments consisted of corporate debt securities, U.S. treasury and government agency securities, and ARS. We place our cash and 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.

Cash and cash equivalents and investments at March 31, 2010 and December 31, 2009 consisted of the following (in thousands):

	March 31, 2010	I	December 31, 2009	\$ Change	% Change
Cash and cash equivalents	\$ 212,747	\$	50,126	\$ 162,621	>100%
Short-term investments	21,044		29,578	(8,534)	-29%
Long-term investments	48,432		49,013	(581)	-1%
Total cash, cash equivalents and investments	\$ 282,223	\$	128,717	\$ 153,506	119%

The increase in cash and cash equivalents and investments as of March 31, 2010 as compared to December 31, 2009 is primarily the result of net proceeds of \$165.6 million from our January 2010 public offering, cash received from *Feraheme* sales and interest income partially offset by cash used in operations.

As of March 31, 2010, we believe that our cash, cash equivalents, and short-term investments, combined with the \$60 million we received in April 2010 as an upfront payment pursuant to the Takeda Agreement, and the cash we currently expect to receive from sales of *Feraheme* and earnings on our investments, will be sufficient to satisfy our future cash flow needs for at least the next twelve months, including projected operating expenses related to our ongoing development and commercialization programs for *Feraheme*.

The ongoing uncertainty in the global financial markets has had an adverse impact on financial market activities world-wide, resulting in, among other things, volatility in security prices, diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. Although we invest our excess cash in investment grade securities, there can be no assurance that changing circumstances will not affect our future financial position, results of operations or liquidity.

Cash flows from operating activities

During the three months ended March 31, 2010, our use of \$12.4 million of cash in operations was due principally to our net loss of approximately \$23.1 million adjusted for the following:

Approximately \$10.0 million received in connection with sales deferred under our Launch Incentive Program;

- Additional costs of \$2.5 million capitalized to inventory as of March 31, 2010;
- A decrease of \$2.4 million in accounts receivable, excluding sales deferred under our Launch Incentive Program;

41

Table of Contents

• A decrease of \$2.7 million in accounts payable and accrued expenses, including an increase of \$0.7 million of reserves for commercial discounts and rebates;
• Non-cash operating items of \$4.9 million including equity-based compensation expense, depreciation and amortization, income tax benefit, and other non-cash items; and
• Changes in other operating assets and liabilities of \$1.4 million, which reflect timing differences between the receipt and payment of cash associated with certain transactions and when such transactions are recognized in our results of operations.
Our net loss for the three months ended March 31, 2010 was primarily the result of commercialization costs, including advertising and promotion costs, compensation and other expenses, research and development costs, including clinical trials, and general and administrative costs partially offset by net product revenues.
Cash flows from investing activities
Cash provided by investing activities was \$8.7 million during the three months ended March 31, 2010 and was primarily attributable to net proceeds from the sales and maturities of our investments.
Cash flows from financing activities
Cash provided by financing activities was \$166.3 million during the three months ended March 31, 2010. In January 2010, we sold 3.6 million shares of our common stock at a public offering price of \$48.25 per share and which resulted in net proceeds to us of approximately \$165.6 million.
Contractual Obligations
Our contractual obligations primarily consist of our obligations under non-cancellable operating leases and other purchase obligations as described in our Annual Report on Form 10-K for the year ended December 31, 2009. Other than as described below, there have been no significant changes in our contractual obligations since December 31, 2009.

On March 31, 2010, we entered into the Takeda Agreement. Under the Takeda Agreement, we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in the Licensed Territory. As provided for under the Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme* and, accordingly, are responsible for supply of the product to Takeda. We are also responsible for conducting, and bearing the costs related to, certain predefined clinical studies with the costs of future modifications or additional studies to be allocated between the parties according to an agreed upon cost-sharing mechanism, which provides for a cap on such costs. We will receive a combination of upfront, regulatory approval and performance-based milestone payments, as well as defined payments for supply of the drug product and royalties on net product sales by Takeda in the Licensed Territory.

Legal Proceedings

A purported class action complaint was filed on March 18, 2010 in the United States District Court for the District of Massachusetts against us and our President and Chief Executive Officer, and Executive Vice President and Chief Financial Officer, entitled *Silverstrand Investments v. AMAG Pharm., Inc., et.*

Table of Contents

al., Civil Action No. 1:10-CV-10470-NMG. The complaint alleges that the defendants violated the federal securities laws, specifically Section 11 of the Securities Act of 1933, as amended, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff seeks unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. No trial date has been scheduled. We believe that the allegations contained in the complaint are without merit and intend to defend the case vigorously.

Off-Balance Sheet Arrangements

As of March 31, 2010, 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, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The most significant estimates and assumptions are used in, but are not limited to, revenue recognition and related sales allowances, assessing investments for potential other-than-temporary impairment and determining values of investments, reserves for doubtful accounts, accrued expenses, income taxes and equity-based compensation expense. Actual results could differ materially from those estimates. In making these estimates and assumptions, management employs critical accounting policies. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the year ended December 31, 2009. There have been no significant changes to these critical accounting policies and estimates since December 31, 2009.

Impact of Recently Issued and Proposed Accounting Pronouncements

In February 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, No. 2010-09, Subsequent Events: Amendments to Certain Recognition and Disclosure Requirements, or ASU 2010-09, which amends Accounting Standards Codification, or ASC, 855 to address certain implementation issues related to an entity s requirement to perform and disclose subsequent events procedures. The amendments in ASU 2010-09 remove the requirement for an SEC filer to disclose a date through which subsequent events have been evaluated in both issued and revised financial statements. We adopted this guidance as of its issuance date and because this guidance only amends required disclosures in our condensed consolidated financial statements, it did not have an effect upon our financial position or results of operations.

In January 2010, the FASB issued ASU No. 2010-06, Improving Disclosures About Fair Value Measurements, or ASU 2010-06, which also amends ASC 820. ASU 2010-06 requires additional disclosure related to transfers in and out of Levels 1 and 2 and the activity in Level 3. This guidance requires a reporting entity to disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and describe the reasons for the transfers. In addition, this guidance requires a reporting entity to present separately information about purchases, sales issuances, and settlements in the reconciliation for fair value measurements using significant unobservable inputs (Level 3). This accounting standard was effective for interim and annual reporting periods beginning after December 31, 2009 other than for disclosures about purchases, sales, issuances and settlements in the roll forward of activity in Level 3 fair value measurements. Those disclosures will be effective for fiscal years beginning after December 31, 2010 and for interim periods within those fiscal years. We adopted all provisions of this

pronouncement, except for those related to the disclosure of disaggregated Level 3 activity, during the first quarter of 2010

Table of Contents

and because this guidance only amends required disclosures in our condensed consolidated financial statements, it did not have an effect upon our financial position or results of operations. We do not expect the adoption of the remaining provisions of this amendment to have a significant impact on our consolidated financial statements.

In October 2009, the FASB issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13. ASU 2009-13 amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB ASC Subtopic 605-25 (previously included within Emerging Issues Task Force, or EITF, No. 00-21, Revenue Arrangements with Multiple Deliverables, or EITF 00-21). The consensus to EITF Issue No. 08-1, Revenue Arrangements with Multiple Deliverables, or EITF 08-1, provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management s estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. EITF 00-21 previously required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under EITF 00-21, if the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011 will require us to apply this guidance retrospectively to January 1, 2010 and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. We are currently evaluating the potential impact of this standard on our condensed consolidated financial statements, specifically with respect to our accounting and disclosures related to the Takeda collaboration.

In December 2009, the FASB issued ASU No. 2009-16, Accounting for Transfers of Financial Assets, or ASU 2009-16. ASU 2009-16 relates to the accounting and disclosure requirements related to the servicing and transfer of financial assets. ASU 2009-16 enhances information reported to users of financial statements by providing greater transparency about transfers of financial assets and an entity s continuing involvement in transferred financial assets, including securitization transactions, where entities have continuing exposure to the risks related to transferred financial assets. It eliminates the concept of a qualifying special-purpose entity, changes the requirements for de-recognizing financial assets, and requires additional disclosures. This amendment is effective for fiscal years beginning after November 15, 2009. We adopted this pronouncement during the first quarter of 2010 which did not have a significant impact on our condensed consolidated financial statements.

In December 2009, the FASB issued ASU No. 2009-17, Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities, or ASU 2009-17. ASU 2009-17 relates to the accounting and disclosure requirements related to the consolidation of variable interest entities and changes how a reporting entity determines when an entity that is insufficiently capitalized or is not controlled through voting (or similar rights) should be consolidated. The determination of whether a reporting entity is required to consolidate another entity is based on, among other things, the other entity s purpose and design and the reporting entity s ability to direct the activities of the other entity that most significantly impact the other entity s economic performance. The reporting entity will be required to provide additional disclosures about its involvement and will be required to disclose how its involvement with a variable interest entity affects the reporting entity s financial statements. This amendment is effective for fiscal years beginning after November 15, 2009. We adopted this pronouncement during the

Table of Contents

first quarter of 2010 which 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, 2010, our short- and long-term investments totaled \$69.5 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, 2010, this would have resulted in a hypothetical decline in fair value of our investments, excluding ARS, which are described below, of less than \$0.1 million.

At March 31, 2010, we held a total of \$56.9 million in fair market value of ARS, reflecting a decline in value of approximately \$8.0 million compared to the par value of these securities of \$64.9 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 since that time, we use a discounted cash flow analysis to value these securities as opposed to valuing them at par value. Our valuation analysis considers, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, credit ratings of the security by the major securities rating agencies, the ability or inability to sell the investment in an active market, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when call features may be exercised by the issuer. Based upon this methodology, we have recorded a \$7.2 million unrealized loss related to our ARS, other than those subject to Settlement Rights, to accumulated other comprehensive loss as of March 31, 2010. In November 2008, we elected to participate in a rights offering by UBS which provides us with rights to sell to UBS \$9.3 million in par value of our ARS portfolio, at par value, at any time during a two-year sale period beginning June 30, 2010. In accordance with current accounting guidance related to the fair value option for financial assets and financial liabilities, we have recorded an asset equal to the estimated fair value of the Settlement Rights of approximately \$0.8 million in our condensed consolidated balance sheet at March 31, 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 \$1.2 million as of March 31, 2010. 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 \$1.5 million as of March 31, 2010.

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 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 Securities Exchange Act of 1934, as amended,

is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely

Table of Contents

decisions regarding required disclosure, and is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission s rules and forms. It should be noted that any system of controls is designed to provide reasonable, but not absolute, assurances that the system will achieve its stated goals under all reasonably foreseeable circumstances. Our principal executive officer and principal financial officer have each concluded that our disclosure controls and procedures as of the end of the period covered by this report are effective at a level that provides such reasonable assurances.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended March 31, 2010 that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

A purported class action complaint was filed on March 18, 2010 in the United States District Court for the District of Massachusetts against us and our President and Chief Executive Officer, and Executive Vice President and Chief Financial Officer, entitled *Silverstrand Investments v*. *AMAG Pharm., Inc., et. al.*, Civil Action No. 1:10-CV-10470-NMG. The complaint alleges that the defendants violated the federal securities laws, specifically Section 11 of the Securities Act of 1933, as amended, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff seeks unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. No trial date has been scheduled. We believe that the allegations contained in the complaint are without merit and intend to defend the case vigorously.

Item 1A. Risk Factors

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

We are solely dependent on the success of Feraheme.

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

We intend to dedicate significant resources to our *Feraheme* development efforts; however, we may not be successful in expanding the potential indications or developing new applications for *Feraheme*. Although we are pursuing or have commenced additional clinical trials for *Feraheme* in indications other than chronic kidney disease, or CKD, and as an imaging agent, we are not currently conducting or sponsoring research to

Table of Contents

expand our product development pipeline beyond *Feraheme* and therefore our revenues and operations will not be as diversified as some of our competitors which have multiple products or product candidates. Any failure by us to acquire, develop and commercialize additional products and product candidates or gain approval for additional indications or uses for *Feraheme* could limit long-term shareholder value and would adversely affect the future prospects of 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, the commercial opportunity for Feraheme will be adversely impacted.

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

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

In addition to the foregoing currently marketed products, there are several iron replacement therapy products in various stages of clinical and commercial development in the U.S. and abroad, including Monofer® (iron isomaltoside 1000), an injectable iron preparation which in December 2009 received a positive recommendation in 22 European countries and a final marketing authorization in Denmark, Iceland and the Netherlands for the treatment of IDA, Injectafer®, which is known as Ferinject® in Europe and is approved for marketing in 19 European Union countries, and soluble ferric pyrophosphate, a form of iron given as part of the hemodialysis procedure.

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

Table of Contents

with the U.S. Food and Drug Administration, or FDA, which is under expedited review. Companies that manufacture generic products typically invest far less resources in research and development than the manufacturer of a branded product and can therefore price their products significantly lower than those already on the market. It remains unclear if and when a generic product will enter this market.

If any of these product candidates are approved for marketing and sale by the FDA, our efforts to market and sell *Feraheme* and our ability to generate additional revenues and achieve profitability could be adversely affected.

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

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

- Our ability to demonstrate to the medical community, particularly nephrologists, hematologists, dialysis clinics, hospitals 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 ability of physicians and other providers to be adequately reimbursed for *Feraheme* in a timely manner 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 relative price of *Feraheme* as compared to alternative iron replacement therapeutic agents;
- The actual or perceived convenience and ease of administration of *Feraheme* as compared to alternative iron replacement therapeutic agents;
- The effectiveness of our sales and marketing organizations and our distribution network; and
- The development of unanticipated adverse reactions to Feraheme resulting in safety concerns among prescribers.

We market and sell *Feraheme* for use by both dialysis and non-dialysis CKD patients. The dialysis market is the largest and most established market for IV iron replacement therapies, with two companies serving a significant majority of all dialysis patients in the U.S. Fresenius and DaVita, Inc., or DaVita, together treat approximately two-thirds of the U.S. dialysis population. If we are unable to successfully market and sell *Feraheme* to physicians who treat dialysis dependent CKD patients in clinics controlled by either or both of Fresenius and DaVita, our ability to realize and grow revenues from sales of *Feraheme* could be limited. In addition, if we are unable to successfully market and sell *Feraheme* to a significant number of the dialysis clinics that treat the remaining one-third of the U.S. dialysis population, our potential profitability and our future business prospects could be materially adversely impacted.

Table of Contents

In September 2008, Fresenius finalized an exclusive sublicense agreement with Luitpold, the U.S. licensing partner of Vifor Pharma, a subsidiary of Galenica Ltd., to manufacture, sell and distribute Venofer® 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 addition, Galenica Ltd., Vifor Pharma and Fresenius entered into a strategic joint-venture, which became effective on January 1, 2009, to market and distribute the IV iron products Venofer® and Ferinject® in the dialysis market in Europe, the Middle East, Africa and Latin America. Fresenius has significant experience selling and distributing dialysis equipment and supplies to outpatient dialysis clinics which, together with these agreements, make it difficult for us to penetrate the dialysis market, particularly at its clinics.

Another key component of our commercialization strategy is to market and sell *Feraheme* for use by non-dialysis CKD patients. The current non-dialysis market is comprised primarily of three segments: hospitals, hematology clinics and nephrology clinics. Our ability to effectively market and sell *Feraheme* in the hospital market depends in part upon our ability to achieve acceptance of *Feraheme* onto hospital formularies. In addition, since many hospitals are members of group purchasing organizations, which leverage the purchasing power of a group of entities to obtain discounts based on the collective bargaining power of the group, our ability to attract customers in the hospital market also depends in part on our ability to effectively promote *Feraheme* within group purchasing organizations. In addition, IV iron therapeutic products are not currently widely used by certain physicians who treat non-dialysis CKD patients due to safety concerns and the inconvenience and often impracticability of administering IV iron therapeutic products. It is often difficult to change physicians existing treatment paradigms even when supportive clinical data is available. If we are not successful in securing and maintaining formulary coverage for *Feraheme* or are significantly delayed in doing so or if we are not successful in effectively promoting *Feraheme* to physicians who treat non-dialysis CKD patients, we will have difficulty achieving market acceptance of *Feraheme* in the non-dialysis market and our ability to generate revenues and achieve and maintain profitability, and our long-term business prospects, could be adversely affected.

Our ability to generate future revenues from Feraheme depends heavily on the ability of end-users to receive adequate reimbursement for the use of Feraheme in a timely manner.

The commercial success of *Feraheme* substantially depends on the availability and extent of reimbursement for *Feraheme* from third-party payors, including governmental payors, such as Medicare and Medicaid, and private payors. *Feraheme* is purchased by hospitals, clinics, dialysis centers, physicians and other users, each of which generally relies on third-party payors to reimburse them or their patients for pharmaceutical products administered in the hospital, clinic, dialysis center and physician-office settings. Public and private insurance coverage and reimbursement plans are therefore central to new product acceptance, with customers unlikely to use *Feraheme* if they do not receive adequate reimbursement in a timely manner. If *Feraheme* is not reimbursed at an adequate level, our ability to generate revenues from sales of *Feraheme*, our potential profitability and our future business prospects would be adversely affected.

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 adversely impact the available reimbursement for, and therefore our ability to sell Feraheme profitably.

In the U.S., both federal and state agencies continue to promote efforts to reduce healthcare costs. For example, among other things, the recently enacted federal healthcare legislation requires pharmaceutical manufacturers to be responsible for higher minimum Medicaid rebates owed to state Medicaid agencies, extends the rebate provisions to Medicaid managed care organizations, and expands the 340(b) Public Health Services drug pricing program. As a result of these and other reimbursement and legislative proposals, and the trend toward managed health care in the U.S., third-party payors, including government

Table of Contents

and private payors, are also increasingly attempting to contain health care costs by limiting the coverage and the level of reimbursement of new drugs. These cost-containment methods may include, but are not limited to, using formularies, which are lists of approved or preferred drugs, requiring prior authorization or step therapy, which is a program to encourage using lower cost alternative treatments, basing payment amounts on the least costly alternative treatment, or refusing to provide coverage of approved products for medical indications other than those for which the FDA has granted marketing approval. Cost control initiatives could adversely affect the commercial opportunity or decrease the price of *Feraheme* and may impede the ability of potential *Feraheme* users to obtain reimbursement, any of which could have a material adverse effect on our profitability and future business prospects.

Medicare currently reimburses for physician-administered drugs in the hospital outpatient, dialysis center and physician clinic settings at a rate of 106% of the drug s average selling price, or ASP. If the Centers for Medicare & Medicaid Services, or CMS, or one of its local contractors, 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. In addition, in July 2008, Congress enacted the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, which created a Medicare-expanded bundled payment system for the treatment of end stage renal disease, or ESRD, to be implemented by January 1, 2011. MIPPA requires CMS to move 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. The ESRD expanded bundle is to be phased in beginning on January 1, 2011, and the phase-in must be completed by January 1, 2014. In September 2009, in compliance with the statutory requirements of MIPPA, CMS proposed a new prospective payment system for dialysis services provided to Medicare beneficiaries who have ESRD. CMS has stated that it intends to issue a final rule on the prospective payment system later in 2010 in order to meet the legislative requirements of implementation by January 1, 2011. 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 the MIPPA ESRD provisions apply only to Medicare, Medicare payment policy can also influence pricing and reimbursement in the non-Medicare markets, as private third-party payors and state Medicaid plans frequently adopt Medicare principles in setting reimbursement methodologies, particularly in the ESRD setting. 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.

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 payor 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.

Significant safety or drug interaction problems could arise with respect to Feraheme, resulting in recalls, restrictions in Feraheme s label, withdrawal of Feraheme from the market, or cause us to alter or terminate future Feraheme clinical development programs.

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. New safety or drug interaction issues may arise as *Feraheme* is used over longer periods of time by a wider group of patients

Table of Contents

taking numerous other medicines and with additional underlying health problems. In addition, as we conduct additional clinical trials for Feraheme, new safety problems may be identified which could negatively impact both our ability to successfully complete these studies and the use and/or regulatory status of Feraheme for the treatment of IDA in patients with CKD. These new safety or drug interaction issues may require us to provide additional warnings on the Feraheme label, directly alert healthcare providers of new safety information, narrow our approved indications, or alter or terminate future trials planned for additional uses of Feraheme, any of which could reduce the market acceptance of Feraheme. In addition, if significant safety or drug interaction issues arise, FDA approval for Feraheme could be withdrawn, and the FDA could require the recall of all existing Feraheme in the marketplace. The FDA also has the authority to require the recall of our products if there is contamination or other problems with manufacturing, transport or storage of the product. A government-mandated recall or a voluntary recall could divert managerial and financial resources, could be difficult and costly to correct, could result in the suspension of sales of Feraheme, and could have a severe adverse impact on our potential profitability and the future prospects of our business.

We may also be required to conduct certain post-approval clinical studies to assess known or suspected significant risks associated with *Feraheme*. The Food and Drug Administration Amendments Act of 2007 expanded the FDA is authority. Under the Food and Drug Administration Amendments Act of 2007, 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 Management 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 could have a material adverse impact on our ability to generate revenues from sales of *Feraheme*, or require us to expend significant additional funds on clinical studies.

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

Prior to our commercialization of *Feraheme*, we have never independently marketed or sold a drug product as we had relied on our corporate partners to market and sell our previously approved products. We have established an internal sales and marketing infrastructure to market and sell *Feraheme*, and if we are unsuccessful in maintaining an effective sales and marketing function or experience a high level of turnover, then the commercialization of *Feraheme* could be severely impaired. Any failure by us to successfully execute our commercialization plans for *Feraheme* could have a material adverse impact on our ability to generate revenues, our ability to achieve profitability, and the future prospects for our business.

We have limited experience independently distributing a pharmaceutical product, and our Feraheme commercialization plans could suffer if we fail to effectively manage and maintain our supply chain and distribution network.

We do not have significant experience in managing and maintaining a supply chain and distribution network, and we are placing substantial reliance on third-parties to perform product supply chain services for us. Such services include packaging, warehousing, inventory management, storage and distribution of *Feraheme*. We have contracted with Integrated Commercialization Services, Inc., or ICS, to be our exclusive third party logistics provider to perform a variety of functions related to the sale and distribution of *Feraheme*, including services related to warehousing and inventory management, distribution, chargeback processing, accounts receivable management and customer service call center management. As

Table of Contents

a result, most of our inventory is stored at a single warehouse maintained by ICS. In addition, we have contracted with Catalent Pharma Solutions, LLC, or Catalent, to provide certain labeling and packaging services for final *Feraheme* drug product. If ICS or Catalent are unable to provide uninterrupted supply chain services or labeling and packaging services, respectively, we may incur substantial losses of sales to wholesalers or other purchasers of *Feraheme*.

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

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

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

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

We currently manufacture *Feraheme* for commercial use and for use in human clinical trials in our Cambridge, Massachusetts manufacturing facility. Although we are working to establish and qualify second source manufacturing facilities, we currently have only one facility at which we produce *Feraheme*. Our ability to manufacture *Feraheme* in sufficient quantities to meet commercial demand and our clinical development needs at acceptable costs is dependent on the uninterrupted and efficient operation of our manufacturing facility. If there are any difficulties, disruptions or delays in the *Feraheme* manufacturing process, including quality control problems, we may experience manufacturing failures which could result

Table of Contents

in product defects or shipment delays, recall or withdrawal of products previously shipped for commercial or clinical purposes, inventory write-offs or the inability to meet commercial demand for *Feraheme* in a timely and cost-effective manner. Furthermore, if we fail to continue to attract and retain key members of our manufacturing or quality departments, we may be unable to manufacture sufficient quantities of *Feraheme* in a timely manner, which could delay or impair our product sales and development efforts.

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

If we are unable to produce sufficient quantities of *Feraheme* to meet demand or we experience any manufacturing difficulties at our Cambridge, Massachusetts manufacturing facility, we will be required to enter into arrangements with third-party manufacturers. We are currently working to establish and qualify second source manufacturing facilities for *Feraheme*, however we may not be able to enter into agreements with manufacturers whose facilities and procedures comply with cGMP, regulations and other regulatory requirements on terms that are favorable to us, if at all. Even if we were to reach agreement, the transition of the manufacturing process to a third party could take a significant amount of time. Any prolonged interruption in our manufacturing operations could result in cancellations of orders or loss of product in the manufacturing process. Furthermore, use of second-source manufacturing facilities may increase the risk of certain problems, including cost overruns, process reproducibility, stability issues, the inability to deliver required quantities of product that conform to specifications in a timely manner, or the inability to manufacture *Feraheme* in accordance with cGMP. If we are unable to consistently manufacture our products on a timely basis because of these or other factors, we may not be able to meet commercial demand or our clinical development needs for *Feraheme*. As a result, we may lose sales and fail to generate increased revenues and our clinical development programs may be delayed, which could have an adverse impact on our potential profitability and future business prospects.

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

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

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

•	Regulatory requirements or action;		
•	Adverse financial developments at or affecting the supplier; or		
•	Import or export problems.		
If any of our third-party suppliers cease to supply our raw materials for any reason, we will be unable to manufacture <i>Feraheme</i> or unable to manufacture <i>Feraheme</i> in sufficient quantities until we are able to			
	53		

Table of Contents

qualify an alternative source, which would adversely affect our ability to satisfy commercial demand and our clinical development needs for *Feraheme*.

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

Even if we are able to obtain raw materials from an alternative source, if these raw materials are not available in a timely manner or on commercially reasonable terms, we would be unable to manufacture *Feraheme*, both for commercial sale and for use in our clinical trials, on a timely and cost-effective basis. Any such difficulty in obtaining raw materials would severely hinder our ability to manufacture *Feraheme* and would have a material adverse impact on our ability to generate additional revenues and to achieve profitability.

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

We have commenced or are pursuing additional clinical trials and plan to seek regulatory approval to market *Feraheme* in indications other than CKD in the U.S. 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.

The FDA imposes substantial requirements on the development and production of all drug products. Before obtaining regulatory approval for the commercial marketing and sale of *Feraheme* for additional indications, we must demonstrate through extensive human clinical trials that *Feraheme* is safe and efficacious for these new uses and in these new patient populations. Conducting clinical trials is a complex, time-consuming and expensive process that requires adherence to a wide range of regulatory requirements. The FDA has substantial discretion in the approval process and may decide that the results of our clinical trials are insufficient for approval or that *Feraheme* is not effective or safe in indications other than CKD. Clinical and other data is often susceptible to varying interpretations, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products.

The FDA could also determine that our clinical trials and/or our manufacturing processes were not properly designed, were not conducted in accordance with federal laws and regulations, or were otherwise not properly managed. In addition, under the FDA s current good clinical practices regulations, or cGCP, we are responsible for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA may conduct inspections of clinical investigator sites which are involved in our clinical development programs to ensure their compliance with cGCP regulations. If the FDA determines that we, our contract research organizations or our study sites fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may disqualify certain data generated from those sites or require us to perform additional clinical trials before approving our marketing applications,

Table of Contents

which could adversely impact our ability to obtain approval for *Feraheme* in indications other than CKD. Any such deficiency in the design, implementation or oversight of our clinical development programs could cause us to incur significant additional costs, experience significant delays in our efforts to obtain regulatory approval for *Feraheme* in indications other than CKD, or even prevent us from obtaining regulatory approval for *Feraheme* for additional indications. This would, in turn, materially adversely impact our cash position, our ability to increase revenues, our ability to achieve profitability, and the future prospects of our business.

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

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

Any failure by us to obtain approval for additional *Feraheme* indications in the U.S. in a timely manner may limit the commercial success of *Feraheme* and our ability to grow our revenues.

We are substantially dependent upon our collaboration with Takeda Pharmaceutical Company Limited, or Takeda, to commercialize Feraheme in certain regions outside of the U.S., and if Takeda fails to fulfill its obligations or our collaboration is terminated, our plans to commercialize Feraheme outside of the U.S. may be adversely affected.

On March 31, 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda. Under the Takeda Agreement, we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey, or collectively, the Licensed Territory. We are highly dependent on Takeda for the commercialization and certain regulatory filings outside of the U.S. for *Feraheme*. If Takeda fails to perform its obligations under the Takeda Agreement or is ineffective in its commercialization of *Ferahame* in the Licensed Territory or if we fail to effectively manage our relationship with Takeda, our ability to and the extent to which we commercialize and obtain certain regulatory approvals of *Feraheme* outside of the U.S. would be significantly harmed. Further, if we fail to fulfill certain of our obligations under the Takeda Agreement, Takeda has the right to assume the responsibility of clinical development of *Feraheme* in the Licensed Territory, which would increase the cost of and delay the *Feraheme* development program outside of the U.S.

In addition, Takeda has the right to terminate the agreement under certain conditions. If Takeda terminates the Takeda Agreement, we would be required to either enter into alternative arrangements with third parties to develop and commercialize *Feraheme* in the Licensed Territories, which we may be unable to do, or to increase our internal sales and marketing infrastructure, both of which would likely result in significant additional expense and delay or termination of our *Feraheme* clinical development programs outside of the U.S.

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

Table of Contents

In order for Takeda, 3SBio Inc., or us to market and sell *Feraheme* in any country outside of the U.S, it will be necessary to obtain regulatory approval from the appropriate regulatory authorities. The requirements for regulatory approval vary widely from country to country and may in some cases be more rigorous than requirements in the U.S. Certain foreign regulatory authorities may require additional studies or studies designed with different clinical endpoints and/or comparators than those which we have already completed. The time required for approval may also be longer or shorter than in the U.S. In addition, in order to increase the number of patients available for enrollment in our clinical trials, we will conduct trials in geographies outside the U.S. We have no experience conducting clinical trials outside the U.S., and, therefore, we will need to expend substantial time and resources to identify and familiarize ourselves with the regulatory requirements of such foreign countries.

Any failure by us, Takeda or 3SBio Inc. to obtain approval for *Feraheme* in any countries outside of the U.S. in a timely manner may limit the commercial success of *Feraheme* and our ability to grow our revenues.

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

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

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

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

- The timing and magnitude of our recognition of revenues from sales of *Feraheme*;
- The timing and magnitude of our recognition of revenues from sales of *Feraheme* associated with purchases made under our Launch Incentive Program, and the possibility that such purchases will be returned and never recognized as revenue by us;
- The timing and magnitude of costs associated with the commercialization of Feraheme in the U.S., including costs associated with maintaining our commercial infrastructure and executing our promotional and marketing strategy;

• Changes in buying patterns and inventory levels of our wholesalers or distributors;

Table of Contents

our revenue and results of operations.

• The timing and magnitude of costs associated with our ongoing and planned clinical studies of <i>Feraheme</i> in connection with our pursuit of additional indications and our development of <i>Feraheme</i> in countries outside of the U.S;
• The timing and magnitude of milestone payments received under the Takeda Agreement;
• The timing and magnitude of costs associated with commercial-scale manufacturing of <i>Feraheme</i> , including costs of raw materials and costs associated with maintaining commercial inventory and qualifying additional manufacturing capacities and second source suppliers;
• Actual or anticipated difficulties, disruptions or delays associated with our manufacturing facility, packager, or supply chain and distribution network;
• Changes in laws and regulations concerning reimbursement for <i>Feraheme</i> , from government health administration authorities, private health insurers and other third-party payors;
• The outcome of any material litigation to which we are a party; 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.
Wholesaler and distributor buying patterns and other factors may cause our quarterly results to fluctuate, and these fluctuations may adversely affect our short-term results.
Our results of operations, including, in particular, product sales revenues, may vary from period to period due to a variety of factors, including

the buying patterns of our wholesalers and distributors, which vary from quarter to quarter. In the event wholesalers and distributors with whom we do business determine to limit their purchases of our products, sales of our products could be adversely affected. For example, in advance of an anticipated price increase, customers may order *Feraheme* in larger than normal quantities which could cause sales of *Feraheme* to be lower in subsequent quarters than they would have been otherwise. Further, any changes in purchasing patterns, inventory levels, increases in returns of *Feraheme*, delays in purchasing products or delays in payment for products by one of our distributors could also have a negative impact on

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

Our condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us, and the related disclosure of contingent assets and liabilities. On an ongoing basis, our management evaluates our critical and other significant estimates and judgments, including among others, those related to revenue recognition and related sales allowances, investments, reserves for doubtful accounts, equity-based compensation, accrued expenses and income taxes. We base our estimates on market data, our observance of trends in our industry, and on various other assumptions that we believe to be reasonable under the circumstances. If

Table of Contents

actual results differ from these estimates, there could be a material adverse effect on our financial results and the performance of our stock. For instance, the recently enacted federal healthcare legislation requires pharmaceutical manufacturers to be responsible for higher minimum Medicaid rebates owed to state Medicaid agencies, extends the rebate provisions to Medicaid managed care organizations, and expands the 340(b) Public Health Services drug pricing program. We are still assessing the full extent of this legislation s future impact on our business.

As part of our revenue recognition policy, our estimates of product returns, rebates and chargebacks, fees and other discounts require subjective and complex judgments due to the need to make estimates about matters that are inherently uncertain. Any significant differences between our actual results and our estimates could negatively affect our financial position, results of operations and cash flows. In addition, to determine the required quantities of our products and the related manufacturing schedule, we 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. For example, the level of our access to wholesaler and distributor inventory levels and sales data, which varies based on the wholesaler or distributor, affects our ability to accurately estimate certain reserves included in our financial statements. 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 results of operation.

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 \$31.90 and \$58.23 in the fifty-two week period through May 3, 2010. 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 include, among others:

- Our ability to successfully commercialize Feraheme in the U.S.;
- The timing and magnitude of Feraheme revenue and actual or anticipated fluctuations in our operating results;
- Changes in or our failure to meet financial estimates published by securities analysts;
- The availability of reimbursement coverage for *Feraheme* or changes in the reimbursement policies of governmental or private payors;
- Public announcements of regulatory actions with respect to Feraheme or products or product candidates of our competitors;

General market conditions;

Actual or perceived safety concerns related to Feraheme or products or product candidates of our competitors;

58

Table of Contents

Sales of large blocks of our common stock;			
• The status or results of clinical trials for <i>Feraheme</i> or products or product candidates of our competitors;			
• The acquisition or development of technologies, product candidates or products by us or our competitors;			
• Developments in patents or other proprietary rights by us or our competitors;			
• The outcome of any material litigation to which we are a party; and			
• Significant collaboration, acquisition, joint venture or similar agreements by us or our competitors.			
Thus, as a result of events both within and beyond our control, our stock price could fluctuate significantly or lose value rapidly.			
If securities analysts downgrade our stock, cease coverage of us, or if our operating results do not meet analysts forecasts and expectations, our stock price could decline.			
The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us and our business. Currently, ten financial analysts publish reports about us and our business. We do not control these or any other analysts. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. In addition, our future operating results are subject to substantial uncertainty, and our stock price could decline significantly if we fail to meet or exceed analysts—forecasts and expectations, especially with respect to the timing and magnitude of <i>Feraheme</i> revenues, including the recognition of net product revenues associated with purchases made under our Launch Incentive Program, which were initially deferred as of September 30, 2009. 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.			
We have a history of net losses, and we may not be able to generate sufficient revenues to achieve and maintain profitability in the future.			

We have a history of significant operating losses, and we may not be profitable in the future or if we attain profitability, it may not be sustainable. In the past, we have financed our operations primarily from the sale of our equity securities, cash generated by our investing

activities, and payments from our strategic partners. As of March 31, 2010, we had an accumulated deficit of approximately \$304.7 million. Our losses are primarily the result of costs incurred in research and development, including costs associated with our *Feraheme* and other development programs, costs associated with establishing and maintaining our sales and marketing infrastructure, and other selling, general and administrative costs. We expect to continue to incur significant expenses to manufacture, market and sell *Feraheme* as an IV iron replacement therapeutic in CKD patients in the U.S. and to further develop *Feraheme* for additional indications and in additional countries outside of the U.S. As a result, we will need to generate sufficient revenues in future periods to achieve and maintain profitability. We anticipate that the vast majority of any revenue we generate in the near future will be from sales of *Feraheme* as an IV iron replacement therapeutic agent for CKD patients in the U.S. We have never independently marketed or sold any products, and we may not be successful in marketing or selling *Feraheme*. If we are not successful in marketing and selling *Feraheme*, if revenues grow more slowly than we anticipate or if our operating expenses exceed our expectations, our business,

Table of Contents

results of operations and financial condition could be materially adversely affected. In addition, if we are unable to achieve, maintain or increase profitability on a quarterly or annual basis, the market price of our common stock may decline.

We may need additional capital to achieve our business objectives.

We have expended and will continue to expend substantial funds to successfully commercialize and develop *Feraheme*. As a result, we anticipate that our expenses will increase and that our cash-burn rate will continue to increase in the near- and long-term. Our long-term capital requirements will depend on many factors, including, but not limited to:

- The magnitude of *Feraheme* sales and the timing of our receipt of cash from such sales;
- Our ability to achieve the various milestones and receive the associated payments under the Takeda Agreement;
- Costs associated with the U.S. commercialization of *Feraheme*, including costs associated with maintaining our commercial infrastructure and distribution network and executing our promotional and marketing strategy for *Feraheme*;
- Costs associated with our development of additional indications for *Feraheme* in the U.S.;
- Costs associated with our pursuit of approval for *Feraheme* as an IV iron replacement therapeutic agent outside of the U.S.;
- Costs associated with potential business development and in-licensing activities;
- Costs associated with commercial-scale manufacturing of *Feraheme*, including costs of raw materials and costs associated with maintaining commercial inventory and qualifying additional manufacturing capacities and second source suppliers;
- Our ability to liquidate our investments in a timely manner and without significant loss;

- The impact of the current state of the credit and capital markets upon the investments in our portfolio;
- Our ability to maintain successful collaborations with our partners and/or to enter into additional alternative strategic relationships, if necessary; and
- Our ability to raise additional capital on terms and within a timeframe acceptable to us, if necessary.

We estimate that our cash resources at March 31, 2010, combined with the \$60.0 million upfront payment we received from Takeda in April 2010, cash we currently expect to receive from sales of *Feraheme* and from earnings on our investments, will be sufficient to finance our currently planned operations for at least the next twelve months. Thereafter, we may require additional funds or need to establish additional alternative strategic arrangements to execute our business plans. We may seek needed funding through additional 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.

Table of Contents

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 commercialization and development activities, any of which would have a material adverse effect on our business, financial condition and future business prospects.

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

At March 31, 2010, we had \$212.7 million in cash and cash equivalents, \$21.0 million in short-term investments, \$48.4 million in long-term investments, and \$0.8 million in Settlement Rights with respect to certain of our auction rate securities, or ARS. These investments are subject to general credit, liquidity, market and interest rate risks, which have been and may continue to be exacerbated by the U.S. sub-prime mortgage defaults and the ensuing fallout. The recent disruptions in the credit and financial markets have negatively affected many industries, including those in which we invest, and we may realize losses in the fair value of certain of our investments or a complete loss of these investments, which would have an adverse effect on our results of operations, liquidity and financial condition.

At March 31, 2010, we held a total of \$56.9 million in fair market value of ARS, reflecting a decline in value of approximately \$8.0 million compared to the par value of these securities of \$64.9 million. Of the \$8.0 million decline in value, approximately \$7.2 million was considered a temporary impairment and was reported as an unrealized loss in accumulated other comprehensive loss at March 31, 2010. The remaining \$0.8 million represented a trading loss which was recognized in our consolidated statements of operations. In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions. Since that time, 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 will recognize the credit-related portion of the loss to our consolidated statement of operations, which could be material. In addition, failed auctions will adversely impact the liquidity of our investments. Based on our ability to access our cash and other short-term investments, our expected operating cash flows, and our other sources of cash, we do not anticipate that the current lack of liquidity with respect to these securities will materially affect our ability to operate our business in the ordinary course in the short term, however, we are uncertain when the current liquidity issues relating to ARS will improve, if at all.

The condition of the credit markets remains dynamic and unpredictable. As a result, we may experience a reduction in value or loss of liquidity with respect to our investments. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. Further, as part of our determination of the fair value of our investments, we consider credit ratings provided by independent investment rating agencies as of the valuation date. These ratings are subject to change. For example, in 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

Table of Contents

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 ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income may be limited as a result of the sale of shares of our common stock in our January 2010 public offering or other past or future transactions involving our common stock.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an ownership change is subject limitations on its ability to utilize its pre-change net operating losses and certain other tax assets to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders lowest percentage ownership during the testing period, which is generally three years. An ownership change could limit our ability to utilize our net operating loss and tax credit carryforwards for taxable years including or following such ownership change. It is possible that the issuance of shares of our common stock in our January 2010 public offering, together with certain other transactions involving our common stock within the testing period, will result in an ownership change. Even if the issuance of our common stock in our recent offering does not result in an ownership change, this offering would significantly increase the likelihood that there would be an ownership change in the future (which ownership change could occur as a result of transactions involving our common stock that are outside of our control, such as sales by existing stockholders). Limitations imposed on the ability to use net operating losses and tax credits to offset future taxable income could require us to pay U.S. federal income taxes earlier than we have estimated would otherwise be required if such limitations were not in effect and could cause such net operating losses and tax credits to expire unused, in each case reducing or eliminating the benefit of such net operating losses and tax credits and potentially adversely affecting our financial position. Similar rules and limitations may apply for state income tax purposes.

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

Over the past two years, the U.S. and global economies have taken a dramatic downturn as a result of the volatility of 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 taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If the actions taken by the U.S. and other governments are not successful, the continued economic decline may continue to negatively affect the liquidity of our investments, significantly impact our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all, and cause our investments to substantially decline in value. Any of these could have a material adverse effect on our liquidity, cash position and the potential future prospects of our business.

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

Table of Contents

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

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

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

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

- FDA Warning Letters;
- Civil or criminal penalties;
- Suspension or withdrawal of regulatory approvals;
- Temporary or permanent closing of our manufacturing facilities;
- Requirements to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, or other issues involving *Feraheme*;
- FDA-imposed label changes;

•	Implementation of an FDA-mandated REMS;
•	Restrictions on our continued manufacturing, marketing or sale of <i>Feraheme</i> ; or
•	Recalls or a refusal by the FDA to consider or approve applications for additional indications.
An	y of these sanctions would have a material adverse impact on our ability to generate revenues and to achieve profitability.
	ve market or distribute our products in a manner that violates federal or state healthcare fraud and abuse laws, marketing disclosure laws other federal or state laws and regulations, we may be subject to civil or criminal penalties.
	63

Table of Contents

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

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

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

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

As part of our business strategy, we intend to pursue collaboration and in-licensing opportunities, acquisitions of products or businesses, and/or strategic alliances that we believe would be complementary to our existing business. We have limited experience with respect to these business development activities. Any such strategic transactions by us could result in large and immediate write-offs or the incurrence of debt and contingent liabilities, any of which would adversely impact our operating results. Management of a license arrangement, collaboration, or other strategic arrangement and/or integration of an acquired asset or company may also disrupt our ongoing business, require management resources that otherwise would be available for ongoing development of our existing business and our U.S. commercialization of *Feraheme*. We may not identify or complete any such transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated financial benefits of any such transaction. In addition, to finance any such strategic transactions, we may choose to issue shares of our common or preferred stock as consideration, which would result in dilution to our stockholders. Alternatively, it may be necessary for us

Table of Contents

to raise additional funds through public or private financings, and such additional funds may not be available on terms that are favorable to us, if at all. 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.

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

We have experienced significant growth, which has placed and may continue to place a substantial strain on our management, employees, facilities and resources. In anticipation of the approval and U.S. commercialization of *Feraheme*, we rapidly expanded our marketing, sales, manufacturing, regulatory, medical affairs, finance, development, and compliance capabilities. As our operations continue to expand, we will also need to manage additional relationships with various collaborative partners, suppliers and other third parties. In addition, we will need to continue to improve our operational and financial systems, train and manage our expanding workforce, and maintain close coordination among our various departments. We may not be able to accomplish these tasks, and our failure to accomplish any one of them could prevent us from successfully commercializing *Feraheme*, pursuing new business opportunities, or expanding our business, any one of which could adversely impact our future business prospects.

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

Because of the specialized nature of our business, our success depends to a significant extent on the continued service of our Chief Executive Officer and President, Brian J.G. Pereira, MD, our other executive officers and on our ability to continue to attract, retain and motivate qualified managerial, scientific, medical and sales personnel. We have entered into employment agreements with 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 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. Our failure to attract and retain such personnel or to develop such expertise could impose significant limits on our business operations and hinder our ability to successfully and efficiently commercialize *Feraheme* and complete our development projects.

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

We rely on a combination of patents, trademarks, copyrights and trade secrets in the conduct of our business. The patent positions of pharmaceutical and biopharmaceutical firms are generally uncertain and involve complex legal and factual questions. We may not be successful or timely in obtaining any patents for which we submit applications. The breadth of the claims obtained in our patents may not provide significant protection for our technology. The degree of protection afforded by patents for licensed technologies or for future discoveries may

not be adequate to protect our proprietary technology. The patents issued to us may not provide us with any competitive advantage. In addition, there is a risk that

Table of Contents

others will independently develop or duplicate similar technology or products or circumvent the patents issued to us.

Our U.S. *Feraheme* patents are currently scheduled to expire in 2020. These and any other patents issued to us may be contested or invalidated. Future patent interference proceedings involving our patents may harm our ability to commercialize *Feraheme*. Claims of infringement or violation of the proprietary rights of others may be asserted against us. If we are required to defend against such claims or to protect our own proprietary rights against others, it could result in substantial costs to us and the distraction of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling *Feraheme*, limit our development and commercialization of *Feraheme*, or harm our competitive position and result in additional significant costs. In addition, any successful claim of infringement asserted against us could subject us to monetary damages or injunction preventing us from making or selling *Feraheme*. We also may be required to obtain licenses to use the relevant technology. Such licenses may not be available on commercially reasonable terms, if at all.

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

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

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

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

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

If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose

Table of Contents

reliability of our financial statements, which could lead to a decline in our stock price. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the Securities and Exchange Commission, NASDAQ or other regulatory authorities.

An adverse determination, if any, in the class action lawsuit in which we are a defendant could have a material adverse affect on us.

A purported class action complaint was filed on March 18, 2010 in the United States District Court for the District of Massachusetts against us and our President and Chief Executive Officer, and Executive Vice President and Chief Financial Officer, entitled *Silverstrand Investments v. AMAG Pharm., Inc., et. al.*, Civil Action No. 1:10-CV-10470-NMG. The complaint alleges that the defendants violated the federal securities laws, specifically Section 11 of the Securities Act of 1933, as amended, by making certain alleged false and misleading statements and omissions in our registration statement filed in January 2010. The plaintiff seeks unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. We believe that the allegations contained in the complaint are without merit and intend to defend the case vigorously. However, whether or not the plaintiff s claims are successful, this type of litigation is often expensive and diverts management s attention and resources, which could adversely affect the operation of our business. If we are ultimately required to pay significant defense costs, damages or settlement amounts, such payments could adversely affect our operations. We maintain liability insurance, however, if any costs or expenses associated with this litigation exceed the insurance coverage, we may be forced to bear some or all of these costs and expenses directly, which could be substantial.

We are exposed to a number of different potential liability claims.

The administration of our products to humans, whether in clinical trials or after approved commercial usage, may expose us to liability claims. Although we maintain product liability insurance coverage for claims arising from the use of our products in clinical trials and commercial use, coverage is expensive and we may not be able to maintain sufficient insurance at a reasonable cost, if at all. Product liability claims, whether or not they have merit, could decrease demand for *Feraheme*, subject us to product recalls or harm our reputation, all of which could damage our position in the stock market at a time when the market in general has experienced extreme price and volume fluctuations.

Further, the market prices of securities of companies in the biopharmaceutical industry have been extremely volatile and have experienced fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. These fluctuations could adversely affect the market price of our common stock. In the past, securities class action litigation has often been brought against companies following periods of volatility in the market prices of their securities. For example, a purported class action complaint was filed on March 18, 2010 against us and our President and Chief Executive Officer, and Executive Vice President and Chief Financial Officer alleging that the defendants violated the federal securities laws, specifically Section 11 of the Securities Act of 1933, as amended, by making certain alleged false and misleading statements and omissions in our registration statement filed in January 2010. We may be the target of similar litigation in the future. Securities litigation could result in substantial costs and divert our management s attention and resources, which could cause serious harm to our business, operating results and financial condition.

Our shareholder rights plan, certain provisions in our charter and by-laws, certain contractual relationships and certain Delaware law provisions could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current members of our Board of Directors.

Table of Contents

In 2009 we adopted a shareholder rights plan, the provisions of which are intended to deter a hostile takeover by making any proposed hostile acquisition of us more expensive and less desirable to a potential acquirer by enabling our shareholders (other than the potential hostile acquiror) to purchase significant amounts of additional shares of our common stock at dilutive prices. The rights issued pursuant to our shareholder rights plan become exercisable generally upon the earlier of 10 days after a person or group acquires 20% or more of our outstanding common stock or 10 business days after the announcement by a person or group of an intention to acquire 20% of our outstanding common stock via tender offer or similar transaction. The shareholder rights plan could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices.

In addition, certain provisions in our certificate of incorporation and our by-laws may discourage, delay or prevent a change of control or takeover attempt of our company by a third-party as well as substantially impede the ability of our stockholders to benefit from a change of control or effect a change in management and board of directors. These provisions include:

- The ability of our Board of Directors to increase or decrease the size of the Board without stockholder approval;
- Advance notice requirements for the nomination of candidates for election to our Board of Directors and for proposals to be brought before our annual meeting of stockholders;
- The authority of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval;
- Non-cumulative voting for directors; and
- Limitations on the ability of our stockholders to call special meetings of stockholders.

As a Delaware corporation, we are subject to the provisions of Section 203 of the Delaware General Corporation Law which prevents us from engaging in any business combination with any interested stockholder, which is defined generally as a person that acquires 15% or more of a corporation s outstanding voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the manner prescribed in Section 203. These provisions could have the effect of delaying or preventing a change of control, whether or not it is desired by, or beneficial to, our stockholders.

In addition to the above factors, an acquisition of our company could be made more difficult by employment agreements we have in place with our executive officers, as well as a company-wide change of control policy which provide for severance benefits as well as the full acceleration of vesting of any outstanding options or restricted stock units in the event of a change of control and subsequent termination of employment. Further, our Amended and Restated 2007 Equity Incentive Plan generally permits our Board of Directors to provide for the acceleration of vesting of options granted under that plan in the event of certain transactions that result in a change of control.

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

Table of Contents

Because we use certain hazardous materials in the production of our products, we are subject to various federal, state and local environmental laws and regulations that govern our operations, including the import, handling and disposal of non-hazardous and hazardous wastes, and emissions and discharges into the environment. Failure to comply with these laws and regulations could result in costs for corrective action, penalties or the imposition of other liabilities. We also are subject to laws and regulations that impose 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.

Table of Contents

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, 2010.

Tab]	le of	Contents

Item 6. Exhibits.

(a) List of Exhibits

Exhibit
Number Description

- 3.1, 4.1 + Restated Certificate of Amendment of the Company.
 - 10.1 + License, Development and Commercialization Agreement by and between AMAG Pharmaceuticals, Inc. and Takeda Pharmaceutical Company Limited, dated March 31, 2010 (portions of this exhibit have been omitted and filed separately with the Commission pursuant to a request for confidential treatment).
 - 31.1 + Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
 - 31.2 + Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
 - 32.1 ++ Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
 - 32.2 ++ Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- + Exhibits marked with a plus sign (+) are filed herewith.
- ++ Exhibits marked with a double plus sign (++) are furnished herewith.

71

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, 2010

AMAG PHARMACEUTICALS, INC.

By: /s/ David A. Arkowitz

David A. Arkowitz,

Executive Vice President, Chief Financial Officer and

Chief Business Officer

Date: May 6, 2010

72

Table of Contents

EXHIBIT INDEX

Exhibit Number

Description

- 3.1, 4.1 + Restated Certificate of Amendment of the Company.
 - 10.1 + License, Development and Commercialization Agreement by and between AMAG Pharmaceuticals, Inc. and Takeda Pharmaceutical Company Limited, dated March 31, 2010 (portions of this exhibit have been omitted and filed separately with the Commission pursuant to a request for confidential treatment).
 - 31.1 + Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
 - 31.2 + Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
 - 32.1 ++ Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
 - 32.2 ++ Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- + Exhibits marked with a plus sign (+) are filed herewith.
- ++ Exhibits marked with a double plus sign (++) are furnished herewith.

73