AMAG PHARMACEUTICALS INC.
Form 10-Q
May 03, 2012
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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, 2012

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number 001-10865

AMAG Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-2742593**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
100 Hayden Avenue Lexington, Massachusetts	**02421**
(Address of Principal Executive Offices)	(Zip Code)

(617) 498-3300

(Registrant s Telephone Number, Including Area Code)

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

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

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

Large accelerated filer o	Accelerated filer x
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 Act). **Yes** o **No** x

As of April 27, 2012, there were 21,358,395 shares of the registrant s common stock, par value $0.01 per share, outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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AMAG PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

(Unaudited)

	March 31, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 37,619	$ 63,474
Short-term investments	162,833	148,703
Accounts receivable, net	6,278	5,932
Inventories	14,255	15,206
Receivable from collaboration	370	428
Prepaid and other current assets	5,740	6,288
Total current assets	227,095	240,031
Property, plant and equipment, net	8,702	9,206
Long-term investments	17,409	17,527
Restricted cash	460	460
Total assets	$ 253,666	$ 267,224
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,398	$ 3,732
Accrued expenses	27,986	28,916
Deferred revenues	6,346	6,346
Total current liabilities	37,730	38,994
Long-term liabilities:		
Deferred revenues	43,672	45,196
Other long-term liabilities	2,341	2,438
Total liabilities	83,743	86,628
Commitments and contingencies (Notes I & J)		
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; 21,358,395 and 21,306,413 shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively	213	213
Additional paid-in capital	626,799	625,133
Accumulated other comprehensive loss	(4,765)	(4,842)
Accumulated deficit	(452,324)	(439,908)
Total stockholders equity	169,923	180,596
Total liabilities and stockholders equity	$ 253,666	$ 267,224

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

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AMAG PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

(Unaudited)

	Three Months Ended March 31,	
	2012	**2011**
Revenues:		
Product sales, net	$ 13,708	$ 11,022
License fee and other collaboration revenues	1,753	2,327
Royalties	19	36
Total revenues	15,480	13,385
Costs and expenses:		
Cost of product sales	2,646	3,041
Research and development expenses	12,462	13,566
Selling, general and administrative expenses	13,181	19,634
Total costs and expenses	28,289	36,241
Other income (expense):		
Interest and dividend income, net	393	560
Gains on investments, net		1
Total other income (expense)	393	561
Net loss	$ (12,416)	$ (22,295)
Net loss per share:		
Basic and diluted	$ (0.58)	$ (1.05)
Weighted average shares outstanding used to compute net loss per share:		
Basic and diluted	21,349	21,144

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

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AMAG PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(IN THOUSANDS)

(Unaudited)

	Three Months Ended March 31,	
	2012	**2011**
Net loss	$ (12,416)	$ (22,295)
Other comprehensive income (loss):		
Unrealized gains (losses) on securities:		
Holding gains (losses) arising during period, net of tax	77	(111)
Reclassification adjustment for (gains) losses included in net loss		
Net unrealized gains (losses) on securities	77	(111)
Total comprehensive loss	$ (12,339)	$ (22,406)

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

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AMAG PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

(Unaudited)

	Three Months Ended March 31,	
	2012	**2011**
Cash flows from operating activities:		
Net loss	$ (12,416)	$ (22,295)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	551	642
Non-cash equity-based compensation expense	1,685	4,475
Amortization of premium/discount on purchased securities	766	868
Gains on investments, net		(1)
Changes in operating assets and liabilities:		
Accounts receivable, net	(346)	(724)
Inventories	2,131	313
Receivable from collaboration	58	(410)
Prepaid and other current assets	548	1,208
Accounts payable and accrued expenses	(2,463)	(3,508)
Deferred revenues	(1,524)	(1,710)
Other long-term liabilities	(97)	(83)
Total adjustments	1,309	1,070
Net cash used in operating activities	(11,107)	(21,225)
Cash flows from investing activities:		
Proceeds from sales or maturities of available-for-sale investments	37,504	35,327
Purchase of available-for-sale investments	(52,205)	(49,364)
Capital expenditures	(47)	(76)
Net cash used in investing activities	(14,748)	(14,113)
Cash flows from financing activities:		
Proceeds from the exercise of stock options		10
Net cash provided by financing activities		10
Net decrease in cash and cash equivalents	(25,855)	(35,328)
Cash and cash equivalents at beginning of the period	63,474	112,646
Cash and cash equivalents at end of the period	$ 37,619	$ 77,318

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

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AMAG PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2012

(Unaudited)

A. Description of Business

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a biopharmaceutical company focused on the development and commercialization of a therapeutic iron compound to treat iron deficiency anemia, or IDA. Our principal source of revenue is from the sale of Feraheme® (ferumoxytol) Injection for Intravenous, or IV, use, which was approved for marketing in the U.S. in June 2009 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* in the U.S. through our own commercial organization and began shipping *Feraheme* to our customers in July 2009.

In December 2011, *Feraheme* was granted marketing approval in Canada for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. In April 2012, the Committee for Medicinal Products for Human Use of the European Medicines Agency issued a positive opinion for ferumoxytol for the treatment of IDA in adult patients with CKD. We expect a final decision on our Marketing Authorization Application by the European Commission in mid-2012. Under an agreement with Takeda Pharmaceutical Company Limited, or Takeda, Takeda has an exclusive license to market and sell *Feraheme* in Canada and the European Union, or EU. We expect Takeda to launch *Feraheme* in Canada in the second quarter of 2012 and in the EU, under the trade name Rienso , in the second half of 2012. In addition, we are currently pursuing a marketing application with Takeda for *Feraheme* in Switzerland, under the trade name Rienso , for the treatment of IDA in CKD patients.

GastroMARK®, which is marketed and sold under the trade name Lumirem® outside of the U.S*,* is our oral contrast agent used for delineating the bowel in magnetic resonance imaging, and is approved and marketed in the U.S., Europe and other countries through our licensees. In April 2012, we entered into an agreement with our U.S. licensee for *GastroMARK* to terminate that license effective immediately.

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*, our potential inability to become profitable in the future, the potential development of significant safety or drug interaction problems with respect to *Feraheme*, uncertainties regarding market acceptance of *Feraheme*, uncertainties related to patient insurance coverage and third-party reimbursement for *Feraheme*, uncertainties related to the impact of current and future healthcare initiatives and legislation, competition in our industry, uncertainties related to our recent publicly announced process of evaluating strategic alternatives, our limited experience commercializing and distributing a pharmaceutical product, our dependence on key personnel, our reliance on our licensees to commercialize *Feraheme* in certain territories outside of the U.S., our potential inability to operate our manufacturing facilities in compliance with current good manufacturing practices, our potential inability to obtain raw or other materials and manufacture sufficient quantities of *Feraheme*, uncertainty of the regulatory approval process for the broader *Feraheme* indication, both in and outside of the U.S. or for potential alternative manufacturing facilities and processes, the potential fluctuation of our operating results, our reliance on a limited number of customers, 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 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 federal,

state or foreign government agencies, uncertainties related to the actions of activist stockholders, uncertainties related to

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the protection of proprietary technology, potential product liability, potential legislative and regulatory changes, and potential costs and liabilities associated with pending or future litigation.

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.

B. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

These condensed consolidated financial statements are unaudited and, in the opinion of management, include all adjustments necessary for a fair statement of 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, 2011. 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, 2011.

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 related to product sales and collaboration agreements, product sales allowances and accruals, assessing investments for potential other-than-temporary impairment and determining values of investments, reserves for doubtful accounts, accrued expenses, reserves for legal matters, 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, Alamo Acquisition Sub, Inc., AMAG Europe Limited, and AMAG Securities Corporation. Alamo Acquisition Sub, Inc. was incorporated in Delaware in July 2011. AMAG Europe Limited was incorporated in October 2009 in London, England. AMAG Securities Corporation is a Massachusetts corporation which was incorporated in August 2007. All 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.

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Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

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 third 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 and short- and long-term investments. The following tables represent the fair value hierarchy as of March 31, 2012 and December 31, 2011 for those assets that we measure at fair value on a recurring basis (in thousands):

		Fair Value Measurements at March 31, 2012 Using:		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 31,546	$ 31,546	$	$
Corporate debt securities	97,581		97,581	
U.S. treasury and government agency securities	58,270		58,270	
Commercial paper	6,982		6,982	
Auction rate securities	17,409			17,409
	$ 211,788	$ 31,546	$ 162,833	$ 17,409

		Fair Value Measurements at December 31, 2011 Using:		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 55,995	$ 55,995	$	$
Corporate debt securities	94,626		94,626	
U.S. treasury and government agency securities	48,086		48,086	
Commercial paper	5,991		5,991	
Auction rate securities	17,527			17,527

$ 222,225	$ 55,995	$ 148,703	$ 17,527

With the exception of our auction rate securities, or ARS, which are valued using Level 3 inputs, as discussed below, and our money market funds, the fair value of our investments is primarily determined from independent pricing services which use Level 2 inputs to determine fair value. Independent pricing services normally derive security prices from recently reported trades for identical or similar securities,

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making adjustments based upon other significant observable market transactions. At the end of each reporting period, we perform quantitative and qualitative analyses of 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 either March 31, 2012 or December 31, 2011. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the three months ended March 31, 2012.

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 as compared to 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, group of similar assets or liabilities. 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 there is a significant disparity between the trading price for a security held by us as 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, 2012.

Because there is currently no active market for trading the ARS that we hold, we value these securities using a discounted cash flow model. The assumptions used in preparing this model consist of unobservable inputs, including estimates for interest rates, timing and amount of cash flows and the average expected term over which we expect our ARS to be outstanding. In the process of developing these assumptions, we review the characteristics of each individual ARS, including the frequency of coupon payments, the credit rating of the individual security, the quality of the underlying collateral, the final maturity of each security, the approximate repayment time for student loans underlying the security and any pre-maturity redemption or prepayments for comparable securities. We prepare a discounted cash flow model for three expected term scenarios and then apply a weighted average probability formula to each scenario. We estimate the amount of cash flows for each security by utilizing market forecasts of interest rates to calculate the maximum amount of future interest payments. We then apply a discount rate to these estimated cash flows in order to arrive at a discounted cash flow value for each ARS. We calculate this discount rate by using a base index plus two additional factors which address the current lack of liquidity in the ARS market and the difference in credit risk associated with the specific ARS that we own. A significant increase or decrease in the interest rates used to forecast expected cash flows would result in a significantly higher or lower fair value measurement of our ARS. A significant increase or decrease in the discount rate used to discount these cash flows would result in a significantly lower or higher fair value measurement of our ARS. A significant increase or decrease in the expected term assumption would result in a significantly lower or higher fair value measurement.

The following table provides quantitative information on the unobservable inputs of our fair value measurements for our Level 3 assets for the three months ended March 31, 2012 (in thousands):

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		Quantitative Information about Level 3 Fair Value Measurements		
	Estimated Fair Value at March 31, 2012	Valuation Technique	Unobservable Inputs	Range (Weighted Average)
Auction rate securities	$ 17,409	Discounted cash flow	Coupon rate (%)	0.55% - 1.72% (0.85%)
			Discount rate (%)	4.00% - 7.00% (5.14%)
			Expected term (in years)	3 - 10 (4.7)

The following table provides a rollforward of Level 3 assets for the three months ended March 31, 2012 (in thousands):

	Three Months Ended March 31, 2012
Balance at beginning of period	$ 17,527
Transfers to Level 3	
Total gains (losses) (realized or unrealized):	
Included in earnings	
Included in other comprehensive income (loss)	(18)
Purchases, issuances, sales and settlements:	
Purchases	
Issuances	
Sales	
Settlements	(100)
Balance at end of period	$ 17,409
The amount of total gains (losses) for the period included in earnings attributable to the change in unrealized gains (losses) relating to assets still held at end of period	$

Gains and losses (realized or 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 and provides guidance for disclosure of revenue in financial statements.

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, we also monitor our distribution channel to determine whether additional allowances or accruals are required

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based on inventory in our sales channel. An analysis of our product sales allowances and accruals for the three months ended March 31, 2012 and 2011 is as follows (in thousands):

	Three Months Ended March 31,	
	2012	2011
Product sales allowances and accruals		
Discounts and chargebacks	$ 5,892	$ 2,220
Government and other rebates	1,460	2,534
Returns	(266)	299
Total provision for product sales allowances and accruals	$ 7,086	$ 5,053
Total gross product sales	$ 20,794	$ 16,075
Total provision for product sales allowances and accruals as a percent of total gross product sales	34%	31%

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 physicians, clinics, hospitals, GPOs, and dialysis organizations 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 and are recorded in the same period that the related revenue is recognized. We estimate product sales allowances and accruals 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 *Feraheme* and other products similar 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, and the shelf life of *Feraheme*. As part of this evaluation, we also review changes to federal and other legislation, changes to rebate contracts, changes in the level of discounts, and changes in product sales trends. 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.

We generally offer our wholesalers, specialty distributors and other customers a limited right to return product purchased directly from us, principally based on the product s expiration date which, once packaged, is currently four years. Reserves for product returns are recorded in the period the related revenue is recognized, resulting in a reduction to product sales. We evaluate our estimated product returns rate each period based on the historical return patterns and known or expected changes in the marketplace. Due to the extended period between the sale of *Feraheme* and when the limited right of return is allowable, which could be several years, we currently have limited actual returns data and therefore are not able to solely rely on our actual returns experience. During the first quarter of 2012, we reversed approximately $0.5 million of previously reserved product returns allowance due to the lapse of the product return period on certain manufactured *Feraheme* lots that carried a two year expiration period. As a result, the product returns reserve against gross sales for the three months ended March 31, 2012 was ($0.3) million as compared to $0.3 million in the three months ended March 31, 2011.

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Concentrations and Significant Customer Information

Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash, cash equivalents, investments, and accounts receivable. As of March 31, 2012, our cash, cash equivalents and investments amounted to approximately $217.9 million. We currently invest our excess cash primarily in U.S. government and agency money market funds, and investments in corporate debt securities, U.S. treasury and government agency securities, commercial paper and ARS. As of March 31, 2012 we had approximately $31.5 million of our total $37.6 million cash and cash equivalents balance invested in institutional money market funds, of which $16.0 million was invested in a single fund, which is collateralized solely by U.S. treasury and government agency securities.

Our operations are located solely within the U.S. We are focused principally on developing, manufacturing, and commercializing *Feraheme*. 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 total revenues for the three months ended March 31, 2012 and 2011.

	Three Months Ended March 31,	
	2012	**2011**
AmerisourceBergen Drug Corporation	45%	38%
McKesson Corporation	20%	18%
Cardinal Health, Inc.	15%	13%
Takeda Pharmaceuticals Company Limited	11%	17%

In addition, approximately 35% of our end-user demand during the three months ended March 31, 2012 was generated by members of a single GPO with which we have contracted. Revenues from customers outside of the U.S. amounted to approximately 11% and 18% of our total revenues for the three months ended March 31, 2012 and 2011, respectively, and were principally related to collaboration revenue recognized in connection with our collaboration agreement with Takeda, which is based in Japan.

C. Investments

As of March 31, 2012 and December 31, 2011, the combined total of our short- and long-term investments equaled $180.2 million and $166.2 million, respectively, and consisted of securities classified as 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 short- and long-term investments as of March 31, 2012 and December 31, 2011 (in thousands):

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	March 31, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	$ 53,623	$ 120	$ (21)	$ 53,722
Due in one to three years	43,795	93	(29)	43,859
U.S. treasury and government agency securities				
Due in one year or less	17,474	72	(1)	17,545
Due in one to three years	40,584	159	(18)	40,725
Commercial paper				
Due in one year or less	3,999		(1)	3,998
Due in one to three years	2,992		(8)	2,984
Total short-term investments	$ 162,467	$ 444	$ (78)	$ 162,833
Long-term investments:				
Auction rate securities				
Due after five years	19,800		(2,391)	17,409
Total long-term investments	$ 19,800	$	$ (2,391)	$ 17,409
Total short and long-term investments	$ 182,267	$ 444	$ (2,469)	$ 180,242

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	December 31, 2011			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	$ 74,687	$ 81	$ (115)	$ 74,653
Due in one to three years	19,950	73	(50)	19,973
U.S. treasury and government agency securities				
Due in one year or less	26,770	67	(7)	26,830
Due in one to three years	21,028	228		21,256
Commercial paper				
Due in one year or less	5,997		(6)	5,991
Total short-term investments	$ 148,432	$ 449	$ (178)	$ 148,703
Long-term investments:				
Auction rate securities				
Due after five years	19,900		(2,373)	17,527
Total long-term investments	$ 19,900	$	$ (2,373)	$ 17,527
Total short and long-term investments	$ 168,332	$ 449	$ (2,551)	$ 166,230

Auction Rate Securities

As of March 31, 2012, we held a total of $17.4 million in fair market value of ARS, reflecting a reduction of approximately $2.4 million from the par value of these securities of approximately $19.8 million. As of March 31, 2012, all of our ARS were municipal bonds with an auction reset feature and were classified as available-for-sale. The majority of our ARS portfolio was rated AAA as of March 31, 2012 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. As of March 31, 2012, all of our ARS continue to pay interest according to their stated terms.

In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions since that time. As a result of the lack of significant observable ARS market activity since February 2008, we use a discounted cash flow methodology to value these securities as opposed to valuing them at their 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 or to the issuer, 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. In addition, 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. In the event that we intend to sell a security, or may be required to do so, the decline in fair value of the security would be deemed to be other-than-temporary and the full amount of the unrealized loss would be recorded in our condensed consolidated statement of operations as an impairment loss. Regardless of our intent to sell a security, we perform additional

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analyses on all securities with unrealized losses to evaluate whether there could be a credit loss associated with the security. Based on the methodology and the analysis above, we have estimated the fair value of our ARS to be $17.4 million and have recorded the $2.4 million reduction in fair value as an unrealized loss to accumulated other comprehensive loss as of March 31, 2012.

Due to our belief that the market for ARS will likely take in excess of twelve months to fully recover, we have classified our portfolio of ARS as long-term investments in our condensed consolidated balance sheet as of March 31, 2012. We believe that the impairment related to our ARS is primarily attributable to the lack of liquidity of these investments, coupled with the ongoing uncertainty 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. All of our ARS have final maturity dates which occur approximately 20 to 35 years in the future. We believe we will ultimately be able to liquidate our investments in ARS without significant loss prior to their maturity dates primarily due to the collateral securing most of our ARS. However, it could take until final maturity of the ARS to realize the par value of our remaining ARS investments. As a result, we believe the decline in value of our ARS is a temporary impairment and similarly, any future fluctuation in fair value related to our ARS 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. In the event we are forced to seek a buyer outside the auction process, we may realize a significant loss on the sale of these securities. In addition, as part of our determination of the fair value of our investments, we consider credit ratings provided by independent investment rating agencies as of the valuation date. These ratings are subject to change, and we may be required to adjust our future valuation of these ARS which may adversely affect the value of these investments. Based upon the various analyses described above, we did not recognize any unrealized credit losses related to our securities during the three months ended March 31, 2012.

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 as of March 31, 2012 and December 31, 2011 (in thousands):

	March 31, 2012					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	$ 23,682	$ (50)	$	$	$ 23,682	$ (50)
U.S. treasury and government agency securities	14,937	(19)			14,937	(19)
Commercial paper	6,982	(9)			6,982	(9)
Auction rate securities			17,409	(2,391)	17,409	(2,391)
	$ 45,601	$ (78)	$ 17,409	$ (2,391)	$ 63,010	$ (2,469)

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	December 31, 2011					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	$ 34,097	$ (161)	$ 4,124	$ (4)	$ 38,221	$ (165)
U.S. treasury and government agency securities	8,841	(7)			8,841	(7)
Commercial paper	5,991	(6)			5,991	(6)
Auction rate securities			19,900	(2,373)	19,900	(2,373)
	$ 48,929	$ (174)	$ 24,024	$ (2,377)	$ 72,953	$ (2,551)

We did not recognize any other-than-temporary impairment losses in our condensed consolidated statements of operations related to our securities during either as of March 31, 2012 or 2011. 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 entire 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 on Investments

Gains and losses are determined on the specific identification method. Realized gains were insignificant during both the three months ended March 31, 2012 and 2011.

D. Accounts Receivable

Our accounts receivable were $6.3 million and $5.9 million as of March 31, 2012 and December 31, 2011, respectively, and primarily represented amounts due from wholesalers and distributors to whom we sell *Feraheme* directly. 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 sheets.

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, 2012 or December 31, 2011. If the financial condition of any of our significant customers was to deteriorate and result in an impairment of its ability to make payments owed to us, an allowance for doubtful accounts may be required which could have a material effect on earnings in the period of any such adjustment.

Customers which represented greater than 10% of our accounts receivable balances as of March 31, 2012 and December 31, 2011were as follows:

	March 31, 2012	December 31, 2011
AmerisourceBergen Drug Corporation	48%	44%
McKesson Corporation	27%	33%
Cardinal Health, Inc.	18%	15%

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E. Inventories

Our major classes of inventories were as follows as of March 31, 2012 and December 31, 2011 (in thousands):

	March 31, 2012	December 31, 2011
Raw materials	$ 2,224	$ 1,892
Work in process	1,758	3,696
Finished goods	10,273	9,618
Total inventories	$ 14,255	$ 15,206

Included in work in process and finished goods inventories as of March 31, 2012 and December 31, 2011 was approximately $2.4 million and $3.0 million, respectively, of *Feraheme* produced in third-party manufacturing facilities and using processes for which we have not yet received regulatory approval. We believe future regulatory approval of these facilities and processes is probable and that this inventory is fully realizable. During the quarter ended March 31, 2012, we wrote-off $0.6 million of pre-approved inventory which we no longer believed was suitable for sale.

On a quarterly basis, we analyze our inventory levels to determine whether we have any obsolete, expired, or excess inventory. If any inventory is expected to expire prior to being sold, has a cost basis in excess of its net realizable value, is in excess of expected sales requirements as determined by internal sales forecasts, or fails to meet commercial sale specifications, the inventory is written-down through a charge to cost of goods sold. The determination of whether inventory costs will be realizable requires estimates by management. A critical input in this determination is future expected inventory requirements, based on internal sales forecasts. Once packaged, *Feraheme* currently has a shelf-life of four years in the U.S., and as a result of comparison to internal sales forecasts, we expect to fully realize the carrying value of our current *Feraheme* inventory. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. Charges for inventory write-downs are not reversed if it is later determined that the product is saleable.

F. Income Taxes

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

For the three months ended March 31, 2012 and 2011, we did not recognize any tax expense or benefit due to our continued net operating loss position. Due to the uncertainty surrounding the realization of favorable tax attributes in future tax returns, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets.

G. Net Loss per Share

We compute basic net loss per share by dividing net loss by the weighted average number of common shares outstanding during the relevant period. The following table sets forth the potential common shares issuable upon the exercise of outstanding options and 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):

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	Three Months Ended March 31,	
	2012	2011
Options to purchase shares of common stock	1,717	2,213
Shares of common stock issuable upon the vesting of restricted stock units	679	701
Total	2,396	2,914

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

	Three Months Ended March 31,	
	2012	2011
Net loss	$ (12,416)	$ (22,295)
Weighted average common shares outstanding	21,349	21,144
Net loss per share:		
Basic and diluted	$ (0.58)	$ (1.05)

H. Equity-Based Compensation

We currently maintain several equity compensation plans, including our Second Amended and Restated 2007 Equity Incentive Plan, or the 2007 Plan, our Amended and Restated 2000 Stock Plan, or the 2000 Plan, and our 2010 Employee Stock Purchase Plan.

Second Amended and Restated 2007 Equity Incentive Plan

As of March 31, 2012, we have granted options and restricted stock units covering 4,089,775 shares of common stock under our 2007 Plan, of which 1,534,008 stock options and 286,293 restricted stock units have expired or terminated, and of which 35,338 options have been exercised and 228,525 shares of common stock have been 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, 2012 was 1,326,698 and 678,913, respectively. The remaining number of shares available for future grants as of March 31, 2012 was 1,315,108, 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 stock options granted under our 2007 Plan have an exercise price equal to the closing price of a share of our common stock on the grant date and a ten-year term.

Amended and Restated 2000 Stock Plan

As of March 31, 2012, the number of shares underlying outstanding options which were issued pursuant to our 2000 Plan was 390,742. There were no restricted stock units outstanding as of March 31, 2012. 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.

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Equity-based compensation expense

Equity-based compensation expense, excluding amounts that have been capitalized into inventory, for the three months ended March 31, 2012 and 2011 consisted of the following (in thousands):

	Three Months Ended March 31,	
	2012	2011
Cost of product sales	$ 78	$ 195
Research and development	422	642
Selling, general and administrative	1,185	3,638
Total equity-based compensation expense	$ 1,685	$ 4,475

We reduce the compensation expense being recognized to account for estimated forfeitures, which we estimate based primarily on historical experience. Under the current accounting guidance, forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

I. Commitments and Contingencies

Legal Proceedings

A purported class action complaint was originally filed on March 18, 2010 in the United States District Court for the District of Massachusetts, entitled Silverstrand Investments et. al. v. AMAG Pharm., Inc., et. al., Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Executive Vice President and Chief Financial Officer, our Board of Directors, and certain underwriters in our January 2010 offering of common stock violated certain federal securities laws, specifically Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, and that our former President and Chief Executive Officer and former Executive Vice President and Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff sought 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. On August 11, 2011, the Court issued an Opinion and Order dismissing the SAC in its entirety for failure to state a claim upon which relief could be granted. A separate Order of Dismissal was filed on August 15, 2011. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the United States Court of Appeals for the First Circuit, or the Court of Appeals. Plaintiffs appeal brief was filed on February 1, 2012. The defendants responding briefs were filed on March 5, 2012, and the plaintiffs reply brief was filed on March 16, 2012. The Court of Appeals has scheduled oral argument on the appeal for May 11, 2012. We are currently unable to predict the outcome or reasonably estimate the range of potential loss associated with this matter, if any, and have therefore not recorded any potential estimated liability as we do not believe that such a liability is probable nor do we believe that a range of loss is currently estimable.

In February 2010, we submitted to FINRA Dispute Resolution, Inc. an arbitration claim against our broker-dealer, Jefferies & Company, Inc., or Jefferies, and two former Jefferies employees, Anthony J. Russo, and Robert A. D Addario, who managed our cash account with Jefferies. We alleged that Jefferies, Russo and D Addario wrongfully marketed and sold a balance of $54.1 million in unsuitable ARS to us from September 2007 through January 2008. We further alleged that Jefferies, Russo and D Addario misrepresented or omitted material facts

concerning the nature and risks of ARS, which were inconsistent with our investment objectives to maintain liquidity and flexibility in our portfolio. In February 2012, we

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entered into a settlement agreement whereby the parties agreed to dismiss all claims related to this matter with prejudice.

We may periodically become subject to legal proceedings and claims arising in connection with ongoing 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 above actions, we are not aware of any material claims against us at March 31, 2012. We expense legal costs as they are incurred.

Contractual Obligations

In July 2011, we entered into an Agreement and Plan of Merger and Reorganization, or the Allos Merger Agreement, with Alamo Acquisition Sub, Inc., a Delaware corporation and our wholly-owned subsidiary, and Allos Therapeutics, Inc., or Allos, which was amended in August 2011. In October 2011, pursuant to the terms of the Allos Merger Agreement, we terminated the Allos Merger Agreement and paid Allos an expense reimbursement fee of $2.0 million in connection with such termination. In addition, we will be required to pay Allos a termination fee of $12.0 million (in addition to the $2.0 million expense reimbursement fee we paid to Allos in October 2011) if we enter into a definitive agreement for an Acquisition Transaction, as defined in the Allos Merger Agreement, on or before October 21, 2012 or such a transaction is consummated on or before such date.

J. Collaborative Agreements

Our commercial strategy includes the formation of collaborations with other pharmaceutical companies to facilitate the sale and distribution of our products, primarily outside of the U.S. As of March 31, 2012, we were a party to the following collaborations:

Takeda

In March 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda under which 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, except under limited circumstances, we have retained the right to manufacture *Feraheme* and, accordingly, are responsible for supply of *Feraheme* to Takeda at a fixed price per unit, which is capped. We are also responsible for conducting, and bearing the costs related to, certain pre-defined 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. In connection with the execution of the Takeda Agreement, we received a $60.0 million upfront payment from Takeda in April 2010, which we recorded as deferred revenue. We may also receive a combination of regulatory approval and performance-based milestone payments, reimbursement of certain out-of-pocket regulatory and clinical supply costs, defined payments for supply of *Feraheme,* and tiered double-digit royalties on net product sales in the Licensed Territory under the Takeda Agreement. The milestone payments we may be entitled to receive under the agreement could over time equal approximately $220.0 million, including up to an aggregate of $33.0 million upon the commercial launch of *Feraheme* in Canada and the

regulatory approval and commercial launch of *Feraheme* in the EU. Of the $220.0 million in potential milestone payments, we have determined that any payments which may become due upon approval by certain regulatory agencies will be deemed substantive milestones and, therefore, will be accounted for as revenue in the period in which they are

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achieved. All remaining milestone payments will be accounted for in accordance with our revenue attribution method for the upfront payment as defined below.

We have determined that the Takeda Agreement includes four deliverables: the license, access to future know-how and improvements to the *Feraheme* technology, regulatory and clinical research activities, and the manufacturing and supply of product. Pursuant to the accounting guidance in effect when we signed the Takeda Agreement, and which governed revenue recognition on multiple element arrangements, we evaluated the four deliverables under the Takeda Agreement and determined that our obligation to provide manufacturing supply of product meets the criteria for separation and is therefore treated as a single unit of accounting, which we refer to as the supply unit of accounting. Further, we concluded that the license is not separable from the undelivered future know-how and technological improvements or the undelivered regulatory and clinical research activities. Accordingly, these deliverables are being combined and also treated as a single unit of accounting, which we refer to as the combined unit of accounting.

With respect to the combined unit of accounting, our obligation to provide access to our future know-how and technological improvements is the final deliverable and is an obligation which exists throughout the term of the Takeda Agreement. Because we cannot reasonably estimate the total level of effort required to complete the obligations under the combined deliverable, we are recognizing the entire $60.0 million upfront payment, the $1.0 million reimbursed to us in 2010 for certain expenses incurred prior to entering the agreement, as well as any milestone payments that are achieved and not deemed to be substantive milestones into revenues on a straight-line basis over a period of ten years from March 31, 2010, the date on which we entered the Takeda Agreement, which represented the then current patent life of *Feraheme* and our best estimate of the period over which we will substantively perform our obligations. The potential milestone payments that may be received in the future will be recognized into revenue on a cumulative catch up basis when they become due and payable.

Under the terms of the Takeda Agreement, Takeda is responsible for reimbursing us for certain out-of-pocket regulatory and clinical trial supply costs associated with carrying out our regulatory and clinical research activities under the collaboration agreement. Because we are acting as the principal in carrying out these services, any reimbursement payments received from Takeda will be recorded in license fee and other collaboration revenues in our condensed consolidated statement of operations to match the costs that we incur during the period in which we perform those services.

Revenues related to the combined unit of accounting and any reimbursement revenues are recorded in license fee and other collaboration revenues in our condensed consolidated statement of operations. During the three months ended March 31, 2012, we recorded $1.5 million associated with the upfront payment and $0.2 million associated with other reimbursement revenues received from Takeda. Payments to be received for supply of the drug product and royalties will be recorded in product sales and royalties in our condensed consolidated statement of operations.

3SBio

In 2008, we entered into a Collaboration and Exclusive License Agreement, or the 3SBio License Agreement, and a Supply Agreement, or the 3SBio Supply Agreement, with 3SBio for 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 $1.0 million, the recognition of which has been deferred and is being recognized under the proportional performance methodology as we supply

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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 net sales of *Feraheme* by 3SBio in China. We retained all manufacturing rights for *Feraheme* under these agreements. 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 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 commercial product under this agreement.

K. Restructuring

In November 2011, we initiated a corporate restructuring, including a workforce reduction plan, which included an approximate 25% reduction in positions. During the fourth quarter of 2011, we recorded $3.5 million of restructuring related costs, primarily related to employee severance and benefits. The workforce reduction was substantially completed by the end of 2011, and we expect that the majority of our restructuring charges will be paid by the end of 2012.

The following table outlines the components of our restructuring expenses which were recorded in operating expenses and current liabilities for the three months ended March 31, 2012 (in thousands):

	Three Months Ended March 31, 2012
Accrued restructuring, beginning of period	$ 2,366
Employee severance, benefits and related costs	85
Payments	(609)
Other adjustments	(79)
Accrued restructuring, end of period	$ 1,763

L. Recently Issued and Proposed Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board, or FASB, issued amended guidance on the presentation of comprehensive income in financial statements. This amendment provides companies the option to present the components of net income and other comprehensive income either as one continuous statement of comprehensive income or as two separate but consecutive statements. It eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders equity. The provisions of this guidance are effective for interim and annual periods in 2012. We have adopted all provisions of this pronouncement by including other comprehensive income as a part of our condensed consolidated statements of comprehensive loss and such adoption did not have a significant impact on our condensed consolidated financial statements.

In May 2011, the FASB issued an amendment to the accounting guidance for fair value measurements and related disclosures. This amendment clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable inputs, or Level 3 measurements. This guidance is effective for interim and annual periods beginning after December 15, 2011. We have adopted all provisions of this pronouncement and such adoption did not have a significant impact on our

condensed consolidated financial statements.

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Item 2. Management s Discussion and Analysis Of Financial Condition and Results of Operations

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2011.

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 expectation that we will receive a final decision on our Marketing Authorization Application by the European Commission in mid-2012, our expectation that Takeda Pharmaceutical Company Limited, or Takeda, will launch Feraheme in Canada in the second quarter of 2012 and in the European Union in the second half of 2012, our expectation of revenue sources to fund our future operations, our expectations regarding the success of our collaboration with Takeda, including any potential milestone payments or royalties we may receive, our expectation that we will submit our Feraheme Supplemental New Drug Application in the U.S. for the treatment of anemia in all adult patients with iron deficiency anemia in 2012, our expectation that Takeda plans to file a Type II Variation with the European Medicines Agency in 2013 for the treatment of anemia in all adult patients with iron deficiency anemia, the design of our two pediatric studies to be conducted to meet our Pediatric Research Equity Act requirement, our intention to conduct two additional pediatric studies included in our pediatric investigation plan, our plan to conduct a post-approval trial to determine the safety and efficacy of repeat doses of Feraheme for the treatment of iron deficiency anemia and the design of such trial, our plan to conduct a magnetic resonance imaging study to evaluate the potential for iron deposits in the body following treatment with IV iron, our expectation that Feraheme will be sold in the European Union under the trade name Rienso , our expectation of the timing of a decision from Swissmedic on our Rienso Marketing Authorization Application, our statement that our licensee in China, 3SBio Inc., or, 3SBio, plans to begin a Feraheme clinical study in China in 2012, our expectation that sales of GastroMARK® will not materially increase, our expectation that we will manufacture Feraheme drug substance and drug product for use in the European Union at our third-party manufacturers, our expectation that the majority of our November 2011 restructuring charges will be paid by the end of 2012, our expectations regarding our future revenues, including expected Feraheme revenues under our Takeda and 3SBio collaborations, our expectation that our reserves as a percentage of gross sales will increase during the remainder of 2012, our expectation regarding future license fee revenues from 3SBio and Takeda, our expectation that our costs of product sales as a percentage of net product sales will remain relatively stable during the remainder of 2012, our expectation that our research and development expenses will decrease during the remainder of 2012, our expectations regarding the amount of external expenses we expect to incur and the timing of our planned research and development projects, our expectation that selling, general and administrative expenses will remain relatively stable during the remainder of 2012, 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 expectations regarding our future cash flows, our belief that the decline in the value of our auction rate securities is temporary and that we will ultimately be able to liquidate these investments without significant loss, our belief regarding the potential impact of the

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adoption of newly issued and future accounting guidance on our financial statements, our expectations that our cash and cash equivalents will remain relatively stable as compared to 2011, 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 risks discussed in Part II, Item 1A below under Risk Factors in this Quarterly Report on Form 10-Q and in Part 1, Item 1A in our Annual Report on Form 10-K for the year ended December 31, 2011. 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 these forward-looking statements.

Overview

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a biopharmaceutical company focused on the development and commercialization of a therapeutic iron compound to treat iron deficiency anemia, or IDA. Our principal source of revenue is from the sale of Feraheme® (ferumoxytol) Injection for Intravenous, or IV, use, which was approved for marketing in the U.S. in June 2009 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* in the U.S. through our own commercial organization, including a specialized sales force. We began commercial sale of *Feraheme* in the U.S. in July 2009 and sell *Feraheme* primarily to authorized wholesalers and specialty distributors.

In December 2011, *Feraheme* was granted marketing approval in Canada for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. In April 2012, the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, issued a positive opinion for ferumoxytol for the treatment of IDA in adult patients with CKD. We expect a final decision on our Marketing Authorization Application, or MAA, by the European Commission in mid-2012. Under an agreement with Takeda Pharmaceutical Company Limited, or Takeda, Takeda has an exclusive license to market and sell *Feraheme* in Canada and the European Union, or EU. We expect Takeda to launch *Feraheme* in Canada in the second quarter of 2012 and in the EU, under the trade name Rienso , in the second half of 2012. In addition, we are currently pursuing a marketing application with Takeda for *Feraheme* in Switzerland, under the trade name Rienso , for the treatment of IDA in CKD patients.

In November 2011, we announced that we hired Jefferies & Company, Inc., or Jefferies, as our financial advisor to explore whether a sale of our company is a viable strategy for value maximization at this time while we simultaneously establish a solid foundation from which to drive profitability and deliver stockholder value if a sale is not pursued. We are conducting a strategic review with Jefferies to determine the optimal strategy for growth, which involves an evaluation of all business strategies to enhance our portfolio, including in-licensing and acquisition opportunities.

Prior to the FDA approval and commercial launch of *Feraheme* in 2009, we devoted substantially all of our resources to our research and development programs. Since then, we have incurred substantial costs related to the commercialization and development of *Feraheme*. We expect to continue to incur significant expenses to manufacture, market and sell *Feraheme* as an IV iron replacement therapeutic for

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use in adult CKD patients in the U.S., to further develop and seek marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients, and to obtain marketing approval for *Feraheme* in countries outside of the U.S. 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 licensees. Since 2009, our revenues have been primarily attributable to product sales of *Feraheme,* along with license fee payments from Takeda. We currently expect to fund our future operations from cash from sales of *Feraheme* in the U.S., milestone payments we expect to receive from Takeda upon the commercial launch of *Feraheme* in Canada and regulatory approval and commercial launch of *Feraheme* in the EU, royalties we may receive with respect to sales of *Feraheme* in Canada and in the EU, cash generated by our investing activities, and the sale of our equity securities, if necessary. As of March 31, 2012, we had an accumulated deficit of approximately $452.3 million and a cash, cash equivalents and investments balance of approximately $217.9 million.

Takeda Collaboration

In March 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda under which 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 may be entitled to receive milestone payments over time equaling approximately $220.0 million, including up to an aggregate of $33.0 million upon the commercial launch of *Feraheme* in Canada and the regulatory approval and commercial launch of *Feraheme* in the EU.

Clinical Development and Regulatory Status of Feraheme

During the first quarter of 2012, we completed enrollment in our global registrational program for *Feraheme* in patients with IDA regardless of the underlying cause. This program consists of two Phase III multi-center clinical trials to assess *Feraheme* for the treatment of IDA in a broad range of patients for whom treatment with oral iron is unsatisfactory, including women with abnormal uterine bleeding, or AUB, patients with cancer or gastrointestinal diseases, postpartum women and other causes.

In March 2012, we reported preliminary results from the first of the two Phase III studies in our global IDA registrational program. This study was an open label, active controlled trial that compared treatment with *Feraheme* to treatment with IV iron sucrose and enrolled 605 patients at 74 sites in Europe, Asia Pacific and Australia. The patients enrolled in the study had a history of unsatisfactory oral iron therapy and had IDA associated with various conditions including AUB, cancer, gastrointestinal disorders or other causes.

The study enrolled patients to receive a one gram IV course of either *Feraheme* or iron sucrose and was designed to demonstrate non-inferiority on the efficacy of *Feraheme* as compared to iron sucrose. Of the 605 patients enrolled in the study, 406 patients were randomly assigned to receive *Feraheme* and 199 were randomly assigned to receive iron sucrose. The demographics and all baseline parameters of patients who participated in the study were well balanced between the two treatment groups. The primary efficacy endpoint of the study was the mean change in hemoglobin from the date of determination of each patient s baseline hemoglobin level to the fifth week following administration of the study drug or the proportion of patients who achieved a greater than or equal to 2.0 gram per deciliter increase in hemoglobin at any time from the date of determination of their baseline hemoglobin level to the fifth week following administration of the study drug, depending on the regulatory authority.

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In this study, *Feraheme* achieved the predefined criteria for non-inferiority on both primary efficacy endpoints. Patients treated with *Feraheme* achieved a mean increase in hemoglobin at week five of 2.7 grams per deciliter as compared to a mean increase of 2.4 grams per deciliter in patients treated with IV iron sucrose. An increase of 2.0 grams per deciliter or more in hemoglobin at any time from baseline to week five was achieved in 84% of patients treated with *Feraheme* as compared to 81% of patients treated with IV iron sucrose.

No new safety signals were observed with *Feraheme* and the types of reported adverse events, or AEs, were consistent with those seen in previous studies and those contained in the U.S. package insert for *Feraheme*. Overall, AEs experienced by patients in the two treatment groups were comparable, with AEs reported in 41.4% of *Feraheme*-treated patients as compared to 44.2% of patients treated with IV iron sucrose. Patients in both treatment groups experienced protocol-defined adverse events of special interest, including moderate to severe hypotension or hypersensitivity reactions, ranging from fever alone to an anaphylactoid reaction. Cardiovascular AEs were comparable between the two treatment groups. Serious adverse events, or SAEs, were reported in 4.2% of *Feraheme*-treated patients as compared to 2.5% of patients treated with IV iron sucrose. The SAEs reported in two *Feraheme* treated patients, or 0.5%, were reported as related to treatment by the applicable investigators in the study, compared to none that were deemed related to study drug by the investigator in the iron sucrose group.

The second Phase III trial in our global IDA registrational program is a double blind, placebo-controlled study to 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. We completed enrollment in this trial during the first quarter of 2012 and we expect to submit a Supplemental New Drug Application, or sNDA, in the U.S. seeking marketing approval for *Feraheme* for the treatment of anemia in all adult patients with IDA with a history of unsatisfactory oral iron therapy during the second half of 2012. In addition, we expect that Takeda will file a Type II Variation, which is the equivalent of a sNDA in the U.S., seeking marketing approval for *Feraheme* for the treatment of anemia in all adult patients with IDA with a history of unsatisfactory oral iron therapy with the EMA in 2013.

Further, we have completed enrollment in an open label extension study for patients from the placebo-controlled study described above. Patients in this study 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.

We have also initiated two randomized, active-controlled pediatric studies of *Feraheme* for the treatment of IDA in pediatric CKD patients to meet our FDA post-approval Pediatric Research Equity Act requirement to support pediatric labeling of *Feraheme.* One study is in dialysis-dependent CKD pediatric patients, and the other is 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 pediatric patients. Both of these pediatric studies are currently open for enrollment.

Our pediatric investigation plan, which was a requirement for submission of our MAA, was approved by the EMA in December 2009 and includes the two pediatric studies needed to meet the requirements of the Pediatric Research Equity Act in the U.S. described above, and two additional pediatric studies requested by the EMA. These studies include a rollover study in pediatric CKD patients and a study in pediatric patients with IDA regardless of the underlying cause. The rollover study is open for enrollment. The Pediatric IDA study will commence once the appropriate dose of *Feraheme* is determined from the study data resulting from the two ongoing pediatric studies of *Feraheme* for the treatment of IDA in pediatric CKD patients, described above.

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As part of our obligations under the Takeda Agreement, we are also required to initiate a multi-center clinical trial to determine the safety and efficacy of repeat doses of *Feraheme* for the treatment of IDA in patients with hemodialysis dependent CKD. This study will be modified to include a treatment arm with iron sucrose, and will serve to meet a commitment we made to the EMA as a condition of the approval of our MAA for *Feraheme* in the EU. Final study design and timing of this trial is subject to further discussions with Takeda, however we currently expect enrollment to begin in the fourth quarter of 2012.

In addition, as part of the post-approval commitment we made to the EMA as a condition of the approval of our MAA for *Feraheme* in the EU, we plan to conduct a magnetic resonance imaging, or MRI, study to evaluate the potential for iron to deposit in the body following treatment with IV iron, specifically in the heart and liver, and, where possible, other major organs following repeated IV iron administration for the treatment of IDA in patients with CKD over a two year period.

In August 2010, Takeda filed an MAA with Swissmedic, the Swiss Agency for Therapeutic Products, seeking marketing approval for *Feraheme* for the treatment of IDA in CKD patients. We have received a positive pre-decision from Swissmedic and expect the final decision during the second or third quarter of 2012.

In December 2009, our licensee 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 of *Feraheme* in China. If approved by the SFDA, 3SBio plans to commence a multi-center randomized efficacy and safety study of *Feraheme* in China involving approximately 200 CKD patients in 2012.

Other information

GastroMARK® , which is marketed and sold under the trade name Lumirem® outside of the U.S, is our oral contrast agent used for delineating the bowel in MRI and is approved and marketed in the U.S., Europe, and other countries through our licensees. Sales of *GastroMARK* by our licensees have been at approximately their current levels for many years, and we do not expect sales of *GastroMARK* to materially increase. In addition, in April 2012, we entered into an agreement with our U.S. licensee for *GastroMARK* to terminate that license effective immediately.

Results of Operations for the Three Months Ended March 31, 2012 as Compared to the Three Months Ended March 31, 2011

Revenues

Our total revenues for the three months ended March 31, 2012 and 2011 consisted of the following (in thousands):

	Three Months Ended March 31,

	2012	2011	$ Change	% Change
Product sales, net	$ 13,708	$ 11,022	$ 2,686	24%
License fee and other collaboration revenues	1,753	2,327	(574)	-25%
Royalties	19	36	(17)	-47%
Total	$ 15,480	$ 13,385	$ 2,095	16%

Our total revenues during the three months ended March 31, 2012 and 2011 were approximately $15.5 million and $13.4 million, respectively. Our revenues during the three months ended March 31,

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2012 reflect a $2.7 million increase in our net product sales and a $0.6 million decrease in our license fee and other collaboration revenues as compared to the three months ended March 31, 2011, as discussed in greater detail below.

The following table sets forth customers who represented 10% or more of our total revenues for the three months ended March 31, 2012 and 2011.

	Three Months Ended March 31,	
	2012	2011
AmerisourceBergen Drug Corporation	45%	38%
McKesson Corporation	20%	18%
Cardinal Health, Inc.	15%	13%
Takeda Pharmaceuticals Company Limited	11%	17%

Net Product Sales

Net product sales for the three months ended March 31, 2012 and 2011 consisted of the following (in thousands):

	Three Months Ended March 31,			
	2012	2011	$ Change	% Change
Feraheme	$ 13,626	$ 10,861	$ 2,765	25%
GastroMARK	82	161	(79)	-49%
Total	$ 13,708	$ 11,022	$ 2,686	24%

Our total net product sales increased by $2.7 million, or 24%, during the three months ended March 31, 2012 as compared to the three months ended March 31, 2011. The $2.7 million increase was primarily due to increased sales of *Feraheme* as the result of an increase in provider demand in the first quarter of 2012 as compared to the first quarter of 2011 as well as a $0.5 million reversal of previously reserved returns due to the lapse of the return period. However, we also offered higher average customer discounts, chargebacks and rebates to our end-users during the three months ended March 31, 2012 as compared to the three months ended March 31, 2011, which partially offset the increase in gross product sales for the quarter ended March 31, 2012 as compared to the same period in 2011. During the first quarter of 2012, we reduced our gross product sales by recording allowances of $7.1 million as compared to allowances of $5.1 million recorded during the first quarter of 2011.

Our net product sales may fluctuate from period to period as a result of a number of factors, including but not limited to the following:

- Wholesaler demand forecasts and buying decisions as well as end-user demand, which can create uneven purchasing patterns by our customers;

- Changes or adjustments to our reserves or changes in the timing or availability of government or customer discounts, rebates and incentives;

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- The impact of any pricing strategies we may implement related to *Feraheme,* including the magnitude of rebates and/or discounts we may offer;

- Changes in the actual or perceived safety and efficacy profile of *Feraheme*, or products that compete with *Feraheme,* which could cause customers to reduce, discontinue or increase their use of *Feraheme*;

- The introduction of new products into the market that compete with *Feraheme,* such as Nulecit or, if approved, Injectafer®;

- The enactment of or changes in legislation that impact third-party reimbursement coverage and pricing; and

- Any expansion or contraction of the overall size of the IV iron market, which could result from a number of factors including but not limited to, changes in treatment guidelines or practices related to IDA.

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, 2011.

An analysis of our product sales allowances and accruals for the three months ended March 31, 2012 and 2011 is as follows (in thousands):

	Three Months Ended March 31,	
	2012	2011
Product sales allowances and accruals		
Discounts and chargebacks	$ 5,892	$ 2,220
Government and other rebates	1,460	2,534
Returns	(266)	299
Total provision for product sales allowances and accruals	$ 7,086	$ 5,053
Total gross product sales	$ 20,794	$ 16,075
Total provision for product sales allowances and accruals as a percent of total gross product sales	34%	31%

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 physicians, clinics, hospitals, GPOs, and dialysis organizations 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.

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Product sales 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 *Feraheme* and other products similar 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, and the shelf life of *Feraheme*. As part of this evaluation, we also review changes to federal and other 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 changes to our estimates to better align our estimates with actual results. 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.

We are subject to reimbursement arrangements with state Medicaid programs for which we estimate and record rebate reserves. We determine our estimates for Medicaid rebates based on market research data related to utilization rates by various end-users, and actual *Feraheme* sales data and forecasted customer buying patterns blended with historical experience of products similar to *Feraheme* sold by others. If we determine in future periods that our actual rebate experience is not indicative of expected claims or if other factors affect estimated claims rates, we may be required to change our current estimated Medicaid accumulated reserve, which would affect our earnings in the period of the change and could be significant.

We generally offer our wholesalers, specialty distributors and other customers a limited right to return product purchased directly from us, principally based on the product s expiration date which, once packaged, is currently four years. Reserves for product returns are recorded in the period the related revenue is recognized, resulting in a reduction to product sales. We evaluate our estimated product returns rate each period based on the historical return patterns and known or expected changes in the marketplace. Due to the extended period between the sale of *Feraheme* and when the limited right of return is allowable, which could be several years, we currently have limited actual returns data and therefore are not able to solely rely on our actual returns experience. During the first quarter of 2012, we reversed approximately $0.5 million of previously reserved product returns allowance due to the lapse of the product return period on certain manufactured *Feraheme* lots that carried a two year expiration period. As a result, the product returns reserve applied to gross product sales for the three months ended March 31, 2012 was ($0.3) million as compared to $0.3 million in the three months ended March 31, 2011.

An analysis of the amount of, and change in, reserves for the three months ended March 31, 2012 and 2011 is as follows (in thousands):

	Discounts	Rebates and Fees	Returns	Total
Balance at January 1, 2012	$ 1,822	$ 3,101	$ 2,842	$ 7,765
Current provisions relating to sales in current year	5,892	1,554	255	7,701
Adjustments relating to sales in prior years		(94)	(521)	(615)
Payments/returns relating to sales in current year	(3,976)	(156)		(4,132)
Payments/returns relating to sales in prior years	(1,859)	(1,562)	(199)	(3,620)
Balance at March 31, 2012	$ 1,879	$ 2,843	$ 2,377	$ 7,099

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	Discounts	Rebates and Fees	Returns	Total
Balance at January 1, 2011	$ 1,148	$ 8,218	$ 1,797	$ 11,163
Current provisions relating to sales in current year	2,443	2,601	299	5,343
Other provisions relating to deferred revenue		(13)		(13)
Adjustments relating to sales in prior years	(223)	(67)		(290)
Payments/returns relating to sales in current year	(1,185)	(73)		(1,258)
Payments/returns relating to sales in prior years	(925)	(4,088)		(5,013)
Balance at March 31, 2011	$ 1,258	$ 6,578	$ 2,096	$ 9,932

During the three months ended March 31, 2012 and 2011, we decreased our product sales allowances and accruals by approximately $0.6 million and $0.3 million, respectively, for changes in estimates relating to sales in prior years. The $0.6 million adjustments in the first quarter of 2012 were primarily caused by the reversal of $0.5 million of previously reserved returns due to the lapse of the return period. The $0.3 million adjustments in the first quarter of 2011 were primarily caused by differences between actual customer utilization and claims experience to date as compared to our initial estimates. Product return rights for additional lots of *Feraheme* will expire throughout the second and third quarters of 2012, and it is possible there will be additional reductions in our returns reserve as we continue to gain actual returns experience.

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 pricing, fee, rebate and discount structures implemented in our efforts to increase adoption of *Feraheme*;

- Variations in our customer mix;

- Changes in legislation, such as the Health Care and Education Affordability Reconciliation Act, or the Health Care Reform Act, the Budget Control Act of 2011 or any future legislation;

- Adjustments and refinements to our prior estimates and assumptions; and

- The impact of and any actions taken by us or our competitors to address pricing and reimbursement considerations related to *Feraheme* or products that compete with *Feraheme.*

Overall, we expect that our reserves as a percentage of gross sales will increase during the remainder of 2012 due primarily to our efforts to continue to increase adoption and utilization of *Feraheme*, our efforts to address continuing reimbursement and competitive pricing pressures, as well as the expected customer mix and utilization rates, all of which will negatively affect the future average net selling price of *Feraheme*.

There are a number of factors that make it difficult to predict the magnitude of future *Feraheme* sales, including but not limited to, the following:

- The magnitude and timing of adoption of *Feraheme* by physicians, hospitals and other healthcare payors and providers;

- Any expansion or contraction of the overall size of the IV iron market, which could result from a number of factors including but not limited to, changes in treatment guidelines or practices related to IDA;

- The effect of federal and other legislation such as the Health Care Reform Act and the Budget Control Act of 2011;

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- The inventory levels maintained by *Feraheme* wholesalers, distributors and other customers;

- The frequency of re-orders by existing customers;

- The impact of any actual or perceived safety or efficacy issues with *Feraheme;* and

- The impact of and any actions taken by us or our competitors to address pricing and reimbursement considerations related to *Feraheme* or products that compete with *Feraheme*.

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

License Fee and Other Collaboration Revenues

License fee and other collaboration revenues for the three months ended March 31, 2012 and 2011 consisted of the following (in thousands):

	Three Months Ended March 31,			
	2012	2011	$ Change	% Change
Deferred license fee revenues from Takeda	$ 1,524	$ 1,524	$	0%
Reimbursement revenues primarily from Takeda	229	803	(574)	-71%
Total	$ 1,753	$ 2,327	$ (574)	-25%

Most of our license fee and other collaboration revenues for the three months ended March 31, 2012 and 2011 related to revenue recognized under the Takeda Agreement. During each of the three months ended March 31, 2012 and 2011 we recorded $1.5 million of revenues associated with the amortization of $61.0 million of deferred revenues recorded in connection with the Takeda Agreement. The $61.0 million of deferred revenues was comprised of a $60.0 million upfront payment which we received from Takeda in April 2010, as well as approximately $1.0 million reimbursed to us during 2010 for certain expenses incurred prior to entering the agreement, which we considered an additional upfront payment. As of March 31, 2012, we had approximately $48.8 million remaining in deferred revenues related to the $61.0 million upfront payments received from Takeda.

In addition, under the terms of the Takeda Agreement, Takeda is responsible for reimbursing us for certain out-of-pocket regulatory and clinical trial supply costs we incur in the conduct of certain regulatory and clinical research activities we manage under the agreement. Because we are acting as the principal in carrying out these activities, any reimbursement payments received from Takeda are recorded in license fee and other collaboration revenues in our condensed consolidated statement of operations and offsets the costs that we incur during the period in which we perform those services. During the three months ended March 31, 2012 and 2011, we recorded $0.2 million and $0.8 million, respectively, of

revenues associated with the reimbursement of out-of pocket regulatory and clinical supply costs in connection with the Takeda Agreement.

We anticipate that our license fee and other collaboration revenues will increase for the remainder of 2012 due to our expected receipt of $33.0 million in milestone payments from Takeda upon the commercial launch of *Feraheme* in Canada and the regulatory approval and commercial launch of *Feraheme* in the EU, a portion of which will be deferred and reflected in our license fee and other collaboration revenues.

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Costs and Expenses

Cost of Product Sales

Cost of product sales for the three months ended March 31, 2012 and 2011 consisted of the following (in thousands):

	Three Months Ended March 31, 2012	2011	$ Change	% Change
Cost of Product Sales	$ 2,646	$ 3,041	$ (395)	-13%
Percentage of Net Product Sales	19%	28%		

Our cost of product sales are primarily comprised of manufacturing costs associated with *Feraheme*. Our cost of product sales decreased by $0.4 million, or 13%, during the three months ended March 31, 2012 as compared to the same period in 2011, primarily due to a lower average production cost of certain vials sold in the first quarter of 2012 as compared to vials sold in the first quarter of 2011 due to the sale of certain inventory in the first quarter of 2012 that had lower associated carrying value because it was produced prior to regulatory approval.

We expect our cost of product sales as a percentage of net product sales to remain relatively stable for the remainder of 2012.

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, regulatory filing fees, 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. 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 initial regulatory approval of our products or development of new manufacturing processes, costs associated with manufacturing process development and the manufacture of drug product are recorded as research and development expenses. Subsequent to initial regulatory approval, costs associated with the manufacture of our products for commercial sale are capitalized in inventory and recorded as cost of product sales when sold.

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Research and development expenses for the three months ended March 31, 2012 and 2011 consisted of the following (in thousands):

	Three Months Ended March 31, 2012	2011	$ Change	% Change
External Research and Development Expenses				
Feraheme to treat IDA regardless of the underlying cause	$ 6,781	$ 5,736	$ 1,045	18%
Feraheme to treat IDA in CKD patients	730	2,499	(1,769)	-71%
Feraheme as a therapeutic agent, general	88	60	28	47%
Feraheme manufacturing process development and materials	883	422	461	>100%
Other external costs	56	35	21	60%
Total	$ 8,538	$ 8,752	$ (214)	-2%
Internal Research and Development Expenses				
Compensation, payroll taxes, benefits and other expenses	3,502	4,172	(670)	-16%
Equity-based compensation expense	422	642	(220)	-34%
Total	$ 3,924	$ 4,814	$ (890)	-18%
Total Research and Development Expenses	$ 12,462	$ 13,566	$ (1,104)	-8%

Total research and development expenses incurred in the three months ended March 31, 2012 decreased by $1.1 million, or 8%, as compared to the three months ended March 31, 2011. The $1.1 million decrease was due to reduced external costs resulting from decreased clinical trial activity in our CKD related trials, partially offset by an increase in external research and development expenses in connection with our Phase III clinical development program for *Feraheme* to treat IDA regardless of the underlying cause. In addition, the $1.1 million decrease in total research and development expenses was due to reduced internal research and development expenses primarily as the result of lower compensation related costs, as discussed in greater detail below.

Our external research and development expenses decreased by $0.2 million, or 2%, for the three months ended March 31, 2012 as compared to the three months ended March 31, 2011. The decrease in our external expenses was due primarily to decreased costs incurred in connection with our global clinical program to support our MAA in the EU for the treatment of IDA in CKD patients, which was completed in 2012, our post-approval clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron, which was completed in 2011, and the current pace of enrollment in our on-going pediatric studies of *Feraheme,* partially offset by increased external costs related to our Phase III clinical development program for *Feraheme* to treat IDA regardless of the underlying cause. In addition, our *Feraheme* manufacturing process development and materials costs were $0.5 million higher in the first quarter of 2012 as compared to the same period in 2011 due to the write-off of pre-approved inventory which we no longer believed was suitable for sale.

Our internal research and development expenses decreased by $0.9 million, or 18%, for the three months ended March 31, 2012 as compared to the three months ended March 31, 2011. The decrease in internal costs was primarily attributable to the net decrease of other compensation-related benefits following our November 2011 corporate restructuring, which resulted in lower headcount in our research and development departments and the reduction of equity-based compensation expense.

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Research and Development Activities

We expect research and development expenses to continue to decrease for the remainder of 2012 primarily due to the completion of our clinical development program of *Feraheme* for the treatment of IDA regardless of the underlying cause and our study to support our *Feraheme* MAA in the EU for the treatment of IDA in CKD patients, partially offset by costs related to the preparation and submission of our planned regulatory filings in 2012, including our *Feraheme* sNDA in the U.S. to treat IDA regardless of the underlying cause, costs associated with certain *Feraheme* clinical studies we have committed to conduct as a condition of approval of our *Feraheme* MAA by the EMA, such as the MRI trial discussed above, as well as other miscellaneous research and development related activities in support of our *Feraheme* development programs.

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 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. The following two major research and development projects are currently ongoing:

- *Feraheme* 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 Phase III clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron; and (3) an extension study.

- *Feraheme* to treat IDA in CKD patients. This project currently includes: (1) a post-approval clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron to support our MAA submission; (2) two ongoing pediatric studies that are being conducted as part of our post-approval Pediatric Research Equity Act requirement to support pediatric CKD labeling of *Feraheme*; (3) two additional pediatric studies to be conducted in accordance with our approved pediatric investigation plan to support our MAA submission; (4) a multi-center clinical trial to be conducted to determine the safety and efficacy of repeat doses of *Feraheme* for the treatment of IDA in patients with hemodialysis dependent CKD; and (5) a MRI study to evaluate the potential for iron to deposit in the body following treatment with IV iron, specifically in the heart and liver, and, where possible, other major organs following repeated IV iron administration for the treatment of IDA in patients with CKD over a two year period.

Through March 31, 2012, we have incurred aggregate external research and development expenses of approximately $52.1 million related to our current program for the development of *Feraheme* to treat IDA regardless of the underlying cause. We currently estimate that the total remaining external costs associated with the efforts needed to complete this development project will be in the range of approximately $8.0 to $13.0 million, the majority of which will be incurred by the end of 2012.

Through March 31, 2012, we have incurred aggregate external research and development expenses of approximately $21.5 million related to our current program for the development of *Feraheme* to treat IDA in CKD patients. We currently estimate that the total remaining external costs associated with this development project will be in the range of approximately $28.0 to $38.0 million over the next several years.

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: delays in our clinical trials due to slow enrollment, unexpected results from our clinical sites that affect our

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ability to complete the studies in a timely manner, unanticipated adverse reactions to *Feraheme* either in commercial use or in a clinical trial setting, 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 any adverse regulatory action or delay in the submission of any applicable regulatory filing. As a result, we are unable to reasonably estimate the specific timing of any expected net cash inflows resulting from these projects, provided however, as the result of recent regulatory decisions on our marketing applications for *Feraheme* in the CKD indication from the CHMP and HealthCanada, we expect that *Feraheme* will be launched commercially in Canada and the EU during 2012, at which point we will receive an aggregate of $33.0 million of milestone payments and we will begin receiving royalty payments in accordance with the Takeda Agreement.

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, pharmacovigilance and safety monitoring and other commercial support personnel, costs related to our administrative personnel, including our legal, finance and executive personnel, external and facilities costs required to support the marketing and sale of *Feraheme* and other costs associated with our corporate activities.

Selling, general and administrative expenses for the three months ended March 31, 2012 and 2011 consisted of the following (in thousands):

	Three Months Ended March 31,			
	2012	2011	$ Change	% Change
Compensation, payroll taxes and benefits	$ 6,807	$ 8,408	$ (1,601)	-19%
Sales and marketing consulting, professional fees, and other expenses	2,532	4,664	(2,132)	-46%
General and administrative consulting, professional fees and other expenses	2,657	2,924	(267)	-9%
Equity-based compensation expense	1,185	3,638	(2,453)	-67%
Total	$ 13,181	$ 19,634	$ (6,453)	-33%

Total selling, general and administrative expenses incurred in the three months ended March 31, 2012 decreased by $6.5 million, or 33%, as compared to the three months ended March 31, 2011. Compensation, payroll taxes and benefits decreased by $1.6 million during the first quarter of 2012 as compared to the same period in 2011 primarily as a result of reduced headcount resulting from our November 2011 corporate restructuring. In addition, sales and marketing consulting, professional fees, and other expenses decreased by $2.1 million during the three months ended March 31, 2012 as compared to the same period in 2011 due primarily to reduced costs related to advertising and marketing materials, and certain other general marketing costs. The $2.5 million decrease in equity-based compensation expense during three months ended March 31, 2012 as compared to the three months ended March 31, 2011 was due primarily to a $1.4 million reduction of equity-based compensation expense associated with the 2011 departures of certain of our executive officers, including each of our former chief financial officer, chief executive officer and chief commercial officer, and the impact of our November 2011 corporate workforce reduction, partially offset by the expense associated with equity awards to new employees and additional equity awards to existing employees.

We expect total selling, general and administrative expenses will remain relatively stable for the remainder of 2012.

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Other Income (Expense)

Other income (expense) for the three months ended March 31, 2012 and 2011 consisted of the following (in thousands):

	Three Months Ended March 31,			
	2012	2011	$ Change	% Change
Interest and dividend income, net	$ 393	$ 560	$ (167)	-30%
Gains on investments, net		1	(1)	-100%
Total	$ 393	$ 561	$ (168)	-30%

Other income (expense) for the three months ended March 31, 2012 decreased by $0.2 million as compared to the three months ended March 31, 2011. This decrease was primarily attributable to a slight decrease in interest and dividend income as the result of lower average cash balances in the first quarter of 2012 as compared to the first quarter of 2011.

We expect interest and dividend income to remain relatively consistent with current levels for the remainder of 2012.

Net Loss

For the reasons stated above, we incurred a net loss of $12.4 million, or $0.58 per basic and diluted share, for the three months ended March 31, 2012 as compared to a net loss of $22.3 million, or $1.05 per basic and diluted share, for the three months ended March 31, 2011.

Liquidity and Capital Resources

General

We finance our operations primarily from the sale of *Feraheme*, payments from our licensees, cash generated from our investing activities, and the sale of our common stock. We expect to continue to incur significant expenses to manufacture, market and sell *Feraheme* as an IV iron replacement therapeutic for use in adult CKD patients in the U.S., Canada and the EU, and to further develop and seek regulatory approval for *Feraheme* for the treatment of IDA in a broad range of patients and in countries outside of the U.S.

Our long-term capital requirements will depend on many factors, including, but not limited to, the following:

- Our ability to successfully commercialize *Feraheme* in the U.S. and Takeda s ability to successfully commercialize *Feraheme* in its licensed territories outside of the U.S.;

- The magnitude of U.S. *Feraheme* sales and royalties we may receive under the Takeda Agreement on *Feraheme* sales outside of the U.S.;

- Our ability to obtain U.S. regulatory approval for *Feraheme* to treat IDA regardless of the underlying cause and our ability to obtain final marketing approval for *Feraheme* outside the U.S., particularly in the EU;

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- 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, executing our promotional and marketing strategy for *Feraheme* and conducting our required pediatric clinical trials and our post-marketing clinical studies;

- Costs associated with our development of *Feraheme* for the treatment of IDA in a broad range of patients in the U.S.;

- The outcome of and costs associated with any material litigation to which we are or may become a party;

- Our ability to liquidate our investments in auction rate securities, or ARS, in a timely manner and without significant loss;

- Our ability to maintain successful collaborations with our licensees and/or to enter into additional strategic relationships or acquisitions, if necessary; and

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

As of March 31, 2012, our investments consisted of corporate debt securities, U.S. treasury and government agency securities, commercial paper and ARS. We place our cash and investments in instruments that meet high credit quality and diversification standards, as specified in our investment policy. Our investment policy also limits the amount of our credit exposure to any one issue or issuer, excluding U.S. government entities, and seeks to manage these assets to achieve our goals of preserving principal, maintaining adequate liquidity at all times, and maximizing returns.

Cash, cash equivalents and investments as of March 31, 2012 and December 31, 2011 consisted of the following (in thousands):

	March 31, 2012	December 31, 2011	$ Change	% Change
Cash and cash equivalents	$ 37,619	$ 63,474	$ (25,855)	-41%
Short-term investments	162,833	148,703	14,130	10%
Long-term investments	17,409	17,527	(118)	-1%
Total	$ 217,861	$ 229,704	$ (11,843)	-5%

The $11.8 million decrease in cash, cash equivalents and investments as of March 31, 2012 from December 31, 2011 was primarily due to cash expended to fund our operations partially offset by cash received from *Feraheme* sales and interest income.

We expect that our cash, cash equivalents and investments balances, in the aggregate, will increase from their current balances during the remainder of 2012. Our expectation assumes our continued investment in the development and commercialization of *Feraheme,* the continued realignment of our cost structure following our November 2011 corporate restructuring, and the expected receipt of $33.0 million in milestone payments from Takeda. We believe that our cash, cash equivalents, and short-term

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investments as of March 31, 2012 and the cash we currently expect to receive from sales of *Feraheme*, earnings on our investments, and potential milestone and royalty payments from Takeda will be sufficient to satisfy our cash flow needs for at least the next twelve months, including projected operating expenses related to our ongoing development and commercialization programs for *Feraheme*.

In November 2011, in order to align our operating expenses with our near-term revenue projections for *Feraheme*, we initiated a corporate restructuring, including a workforce reduction plan, which included an approximate 25% reduction in positions. During the fourth quarter of 2011, we recorded $3.5 million of restructuring related costs as operating expenses, primarily related to employee severance and benefits. The workforce reduction was substantially completed by the end of 2011, and we expect that the majority of our restructuring charges will be paid by the end of 2012.

In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions since that time. As a result of the lack of significant observable ARS market activity since February 2008, we use a discounted cash flow methodology to value these securities as opposed to valuing them at their 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 or to the issuer, 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. We believe we will ultimately be able to liquidate our investments in ARS without significant loss prior to their maturity dates primarily due to the collateral securing most of our ARS. Our ARS balance has declined from a par value of $105.4 million at December 31, 2007 to a par value of $19.8 million at March 31, 2012 without the recognition of a material loss. However, it could take until final maturity of the ARS to realize the par value of our remaining ARS investments. 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. In the event we are forced to seek a buyer outside the auction process, we may realize a significant loss on the sale of these securities.

As of March 31, 2012, we held a total of $17.4 million in fair market value of ARS, reflecting a reduction of approximately $2.4 million from the par value of these securities of approximately $19.8 million. As of March 31, 2012, all of our ARS were municipal bonds with an auction reset feature and were classified as available-for-sale. The majority of our ARS portfolio was rated AAA as of March 31, 2012 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. As of March 31, 2012, all of our ARS continue to pay interest according to their stated terms.

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, periodic 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, 2012, our use of $11.1 million of cash in operations was attributable principally to our net loss of approximately $12.4 million, adjusted for the following:

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- Non-cash operating items of $3.0 million including equity-based compensation expense, depreciation, income tax benefit, and other non-cash items;

- A decrease in deferred revenues and other long-term liabilities of $1.6 million, which reflects timing differences between the receipt and payment of cash associated with certain transactions and the recognition of such amounts in our results of operations;

- A combined decrease of $2.4 million in accounts receivable, prepaid assets and inventories; and

- A decrease of $2.5 million in accounts payable and accrued expenses.

Our net loss of $12.4 million was primarily the result of commercialization expenses, including marketing and promotion costs, compensation and other expenses, research and development costs, including costs associated with our clinical trials, and general and administrative costs, partially offset by net product and collaboration revenues.

Cash flows from investing activities

Cash used in investing activities was $14.7 million during the three months ended March 31, 2012 and was primarily attributable to the purchases of investments partially offset by proceeds from the sales and maturities of our investments.

Contractual Obligations

In July 2011, we entered into an Agreement and Plan of Merger and Reorganization, or the Allos Merger Agreement, with Alamo Acquisition Sub, Inc., a Delaware corporation and our wholly-owned subsidiary, and Allos Therapeutics, Inc., or Allos, which was amended in August 2011. In October 2011, pursuant to the terms of the Allos Merger Agreement, we terminated the Allos Merger Agreement and paid Allos an expense reimbursement fee of $2.0 million in connection with such termination. Under the terms of the Allos Merger Agreement, we are required to pay Allos a termination fee of $12.0 million (in addition to the $2.0 million expense reimbursement fee we paid Allos in October 2011) in the event that we enter into certain acquisition transactions on or prior to October 21, 2012 or such a transaction is consummated on or before such date.

Off-Balance Sheet Arrangements

As of March 31, 2012, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

Critical Accounting Policies

Our management s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements 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 related to product sales and collaboration agreements, product sales allowances and accruals, assessing investments for potential other-than-temporary impairment and determining values of investments, accrued expenses and equity-based compensation expense. Actual results could differ materially from those estimates. In

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making these estimates and assumptions, management employs critical accounting policies. Our critical accounting policies include revenue recognition and related sales allowances, valuation of investments and equity-based compensation. For a detailed description, 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, 2011.

Impact of Recently Issued and Proposed Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board, or FASB, issued amended guidance on the presentation of comprehensive income in financial statements. This amendment provides companies the option to present the components of net income and other comprehensive income either as one continuous statement of comprehensive income or as two separate but consecutive statements. It eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders equity. The provisions of this guidance are effective for interim and annual periods in 2012. We have adopted all provisions of this pronouncement and such adoption did not have a significant impact on our condensed consolidated financial statements.

In May 2011, the FASB issued an amendment to the accounting guidance for fair value measurements and related disclosures. This amendment clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable inputs, or Level 3 measurements. This guidance is effective for interim and annual periods beginning after December 15, 2011. We have adopted all provisions of this pronouncement and such adoption 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, 2012, our investments equaled $180.2 million and were invested in corporate debt securities, U.S. treasury and government agency securities, commercial paper and auction rate securities. 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, 2012, this would have resulted in a hypothetical decline in fair value of our investments, excluding ARS, which are described below, of approximately $0.9 million.

As of March 31, 2012, we held a total of $17.4 million in fair market value of auction rate securities, reflecting an impairment of approximately $2.4 million compared to the par value of these securities of $19.8 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 inability to sell the investment in an active market or to the issuer, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when call features may be exercised by the issuer. Based upon this methodology, we have estimated the fair value of our ARS to be $17.4 million at March 31, 2012 and have recorded the $2.4 million reduction in fair value as an unrealized loss related to our ARS to accumulated other comprehensive loss as of March 31, 2012.

We believe there are several significant assumptions that are utilized in our ARS valuation analysis, the two most critical of which are the discount rate and the average expected term. Holding all other

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factors constant, if we were to increase the discount rate utilized in our ARS 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 $0.4 million as of March 31, 2012. Similarly, holding all other factors constant, if we were to increase the average expected term utilized in our fair value calculation by one year, this change would have the effect of reducing the fair value of our ARS by approximately $0.6 million as of March 31, 2012.

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 decisions regarding required disclosure, and is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission 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, 2012 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 originally filed on March 18, 2010 in the United States District Court for the District of Massachusetts, entitled Silverstrand Investments et. al. v. AMAG Pharm., Inc., et. al., Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Executive Vice President and Chief Financial Officer, our Board of Directors, and certain underwriters in our January 2010 offering of common stock violated certain federal securities laws, specifically Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, and that our former President and Chief Executive Officer and former Executive Vice President and Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff sought 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. On August 11, 2011, the Court issued an Opinion and Order dismissing the SAC in its entirety for failure to state a claim upon which relief could be granted. A separate Order of Dismissal was filed on August 15, 2011. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the United States Court of

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Appeals for the First Circuit, or the Court of Appeals. Plaintiffs appeal brief was filed on February 1, 2012. The defendants responding briefs were filed on March 5, 2012, and the plaintiffs reply brief was filed on March 16, 2012. The Court of Appeals has scheduled oral argument on the appeal for May 11, 2012.

In February 2010, we submitted to FINRA Dispute Resolution, Inc. an arbitration claim against our broker-dealer, Jefferies & Company, Inc., or Jefferies, and two former Jefferies employees, Anthony J. Russo, and Robert A. D Addario, who managed our cash account with Jefferies. We alleged that Jefferies, Russo and D Addario wrongfully marketed and sold a balance of $54.1 million in unsuitable ARS to us from September 2007 through January 2008. We further alleged that Jefferies, Russo and D Addario misrepresented or omitted material facts concerning the nature and risks of ARS, which were inconsistent with our investment objectives to maintain liquidity and flexibility in our portfolio. In February 2012, we entered into a settlement agreement whereby the parties agreed to dismiss all claims related to this matter with prejudice.

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.

We currently derive and expect to continue to derive substantially all of our revenue from sales of *Feraheme* by us in the U.S. and by our licensees, including Takeda Pharmaceutical Company Limited, or Takeda, outside of the U.S. and, therefore, our ability to become profitable is solely dependent on our and our licensees successful commercialization and development of *Feraheme.* We currently sell only one other product, *GastroMARK* in certain foreign jurisdictions through our licensees. However, sales of *GastroMARK* have been at approximately their current levels for many years, and we do not expect sales of *GastroMARK* to materially increase. In addition, we recently agreed with our U.S. licensee for *GastroMARK* to terminate that license effective immediately. 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 continue to dedicate significant resources to our *Feraheme* development efforts. However, we may not be successful in our efforts to expand the *Feraheme* package insert to include additional indications or obtain marketing approval for *Feraheme* in additional geographies. Although we have completed enrollment in our global registration program for *Feraheme* for the treatment of iron deficiency anemia, or IDA, regardless of the underlying cause, we are not currently conducting or sponsoring research to expand our product development pipeline beyond *Feraheme* and therefore our revenues and operations will not be as diversified as some of our competitors which have multiple products or product candidates. Any failure by us to gain marketing approval for *Feraheme* for the treatment IDA regardless of the underlying cause, gain marketing approval for *Feraheme* in new geographies, or acquire, develop and commercialize additional products and product candidates, could limit long-term shareholder value and adversely affect the future prospects of our business.

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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, we may not be profitable in the future, and if we do attain profitability, such profitability may not be sustainable. In the past, we have financed our operations primarily from the sale of our equity securities, cash from sales of *Feraheme*, cash generated by our investing activities, and payments from our licensees. As of March 31, 2012, we had an accumulated deficit of approximately $452.3 million. Our losses were primarily the result of costs incurred in our efforts to manufacture, market and sell *Feraheme*, including costs associated with maintaining our commercial infrastructure and marketing and promotion costs, research and development costs, such as costs associated with our clinical trials, and selling, general and administrative costs. We expect to continue to incur significant expenses to manufacture, market and sell *Feraheme* as an intravenous, or IV, iron replacement therapeutic for use in adult chronic kidney disease, or CKD, patients in the U.S., and to further develop and seek marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients. 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 use in adult CKD patients in the U.S., milestone payments we expect to receive from Takeda upon commercial launch of *Feraheme* in Canada and regulatory approval and commercial launch of *Feraheme* in the European Union, or EU, and royalties we may receive with respect to sales of *Feraheme* in Canada and in the EU under our License, Development and Commercialization Agreement, or the Takeda Agreement, which we entered into with Takeda in 2010. We have never independently marketed or sold any products prior to *Feraheme*, and we or Takeda may not be successful in marketing or selling *Feraheme*. If we or Takeda are not successful in marketing and selling *Feraheme*, if revenues grow more slowly than we anticipate or if our operating expenses exceed our expectations, our business, results of operations and financial condition could be materially adversely affected. In addition, if we are unable to achieve, maintain or increase profitability on a quarterly or annual basis, the market price of our common stock may decline.

Significant safety or drug interaction problems could arise with respect to Feraheme, which could result in restrictions in Feraheme s label, recalls, withdrawal of Feraheme from the market, an adverse impact on Feraheme sales, or cause us to alter or terminate current or future Feraheme development programs, any of which would adversely impact our future business prospects.

Significant safety or drug interaction problems could arise with respect to *Feraheme*, including an increase in the severity or frequency of known problems or the discovery of previously unknown problems, and may result in a variety of adverse regulatory actions. In the U.S., under the Food and Drug Administration Amendments Act of 2007, the U.S. Food and Drug Administration, or the FDA, has broad authority to force drug manufacturers to take any number of actions if safety or drug interaction problems arise, including, but not limited to: (i) requiring manufacturers to conduct post-approval clinical studies to assess known risks or signals of serious risks, or to identify unexpected serious risks; (ii) mandating labeling changes to a product based on new safety information; or (iii) requiring manufacturers to implement a Risk Evaluation Mitigation Strategy where necessary to assure safe use of the drug. Similar laws and regulations exist in countries outside of the U.S. In addition, previously unknown safety or drug interaction problems could result in product recalls, restrictions on the product s permissible uses, or withdrawal of the product from the U.S. and/or foreign markets.

For example, in November 2010, following discussions with the FDA, we revised the *Feraheme* package insert to include bolded warnings and precautions that describe events that have been reported after *Feraheme* administration in the post-marketing environment, including life-threatening hypersensitivity reactions and clinically significant hypotension. We also directly alerted healthcare providers of the changes to the *Feraheme* package insert. During June 2011, we made further changes to the *Feraheme* package insert based on additional post-marketing data. These or any future changes to the *Feraheme* package insert could adversely impact our or Takeda s ability to successfully compete in the IV iron market and could have an adverse impact on potential sales of *Feraheme* and our future business

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prospects. In addition, as more data become available and an increased number of patients are treated with *Feraheme*, we may be required to make further changes to the *Feraheme* package insert in the U.S. or other territories, including the inclusion of a boxed warning in the U.S. or similar warnings outside of the U.S., directly alert healthcare providers of new safety information, narrow our approved indications, alter or terminate current or planned trials for additional uses of *Feraheme*, or even remove *Feraheme* from the market.

The data submitted to both the FDA as part of our New Drug Application, or NDA, and to the European Medicines Agency, or EMA, as part of our Marketing Authorization Application, or MAA, for *Feraheme* in the CKD indication 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 some of whom may be taking numerous other medicines or by patients with additional underlying health problems. In addition, as we conduct and complete other clinical trials for *Feraheme*, new safety issues may be identified which could negatively impact our ability to successfully complete these studies, the use and/or regulatory status of *Feraheme* for the treatment of IDA in patients with CKD in the U.S., EU or other territories, and the prospects for approval of future supplemental New Drug Applications, or sNDAs, such as our planned 2012 sNDA submission for *Feraheme* for the treatment of IDA regardless of the underlying cause. New safety or drug interaction issues may require us to, among other things, provide additional warnings and/or restrictions on the *Feraheme* package insert, including a boxed warning in the U.S. or similar warnings outside of the U.S., directly alert healthcare providers of new safety information, narrow our approved indications, alter or terminate current or planned trials for additional uses of *Feraheme*, or even remove *Feraheme* from the market, any of which could have a significant adverse impact on potential sales of *Feraheme* or require us to expend significant additional funds.

Feraheme may not be widely adopted by physicians, hospitals, patients, or healthcare payors, which would adversely impact our potential profitability and future business prospects.

The commercial success of *Feraheme* in the U.S. and in other territories depends upon its level of market adoption by physicians, hospitals, patients, and healthcare payors, including managed care organizations and group purchasing organizations, or GPOs. If *Feraheme* does not achieve an adequate level of market adoption for any reason, our potential profitability and our future business prospects will be severely adversely impacted. *Feraheme* represents an alternative to other products and might not be adopted if perceived to be no safer, less safe, no more effective, less effective, no more convenient, or less convenient than currently available products. In addition, the pricing and/or reimbursement for *Feraheme* may not be viewed as attractive as the pricing and/or reimbursement of alternative IV iron products. The degree of market acceptance of *Feraheme* in the U.S. and abroad depends on a number of factors, including but not limited to the following:

- Our and Takeda s ability to demonstrate to healthcare providers, particularly hematologists, oncologists, hospitals, nephrologists, and others who may purchase or prescribe *Feraheme*, the clinical efficacy and safety of *Feraheme* as an alternative to currently marketed IV iron products which treat IDA in CKD patients;

- Our and Takeda s ability to convince physicians and other healthcare providers to use IV iron, and *Feraheme* in particular, rather than oral iron, which is the current treatment of choice of most physicians for treating IDA in CKD patients.

- The actual or perceived safety and efficacy profile of *Feraheme* compared to alternative iron replacement therapeutic agents, particularly if unanticipated adverse reactions to *Feraheme* result in further changes to or restrictions in the *Feraheme* package insert and/or otherwise create safety concerns among potential prescribers;

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- The results of our two Phase III multi-center clinical trials to assess *Feraheme* in patients with IDA regardless of the underlying cause, including the results of the first of such trials which we announced in March 2012, which could impact the actual or perceived safety profile of *Feraheme* compared to alternative iron replacement therapeutic agents;

- The relative level of available reimbursement for *Feraheme* from payors, including government payors, such as Medicare and Medicaid in the U.S., and private payors as compared to the level of available reimbursement for alternative IV iron products;

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

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

- The effectiveness of our and Takeda s commercial organizations and distribution networks.

We are approved to market and sell *Feraheme* for use in both dialysis and non-dialysis adult CKD patients in the U.S. However, *Feraheme* sales in the U.S. dialysis market have become insignificant due, in large part, to the 2011 implementation of the prospective payment system for end stage renal disease, or ESRD, drugs like *Feraheme*, which has made it far less likely that dialysis providers would choose to use higher priced products like *Feraheme* in treating their dialysis patients. Accordingly, we expect sales of *Feraheme* in the U.S. dialysis market to represent an insignificant portion of our total U.S. sales going forward. As a result, unless we capture a significant share of the U.S. non-dialysis CKD market, potential U.S. *Feraheme* sales, our potential profitability and our future business prospects will be materially adversely impacted.

The key component of our U.S. commercialization strategy is to market and sell *Feraheme* for use in non-dialysis adult CKD patients. The current U.S. non-dialysis CKD market is comprised primarily of three sites of care where a substantial number of CKD patients are treated: hematology and oncology clinics, hospitals, and nephrology clinics. IV iron therapeutic products are not currently widely used by certain physicians who treat non-dialysis CKD patients in the U.S., particularly nephrologists, due to safety concerns and the inconvenience and often impracticability of administering IV iron therapeutic products in their offices. It is often difficult to change physicians existing treatment paradigms even when supportive clinical data is available. In addition, our ability to effectively market and sell *Feraheme* in the U.S. hospital market depends in part upon our ability to achieve acceptance of *Feraheme* onto hospital formularies. Since many hospitals and hematology, oncology and nephrology practices are members of GPOs, 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 these sites of care also depends in part on our ability to effectively promote *Feraheme* to and enter into contracts with GPOs. If we are not successful in effectively promoting *Feraheme* to physicians who treat non-dialysis CKD patients in the U.S. or if we are not successful in securing and maintaining formulary coverage for *Feraheme* or are significantly delayed in doing so, we will have difficulty achieving wide-spread U.S. market acceptance of *Feraheme* in the non-dialysis CKD market and our ability to generate revenues and achieve and maintain profitability, and our long-term business prospects could be adversely affected.

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We depend, to a significant degree, on the availability and extent of reimbursement from third-party payors for the use of Feraheme, and a reduction in the extent of reimbursement could adversely affect our Feraheme sales revenues and results of operations.

In both the U.S. and foreign markets, our and Takeda s ability to successfully commercialize *Feraheme* is and will be dependent, in significant part, on the availability and extent of reimbursement to end-users from third-party payors for the use of *Feraheme*, including governmental payors, managed care organizations, private health insurers and other third-party payors. Reimbursement by a third-party payor depends on a number of factors, including the third-party s determination that the product is competitively priced, safe and effective, appropriate for the specific patient, and cost-effective. Third-party payors are increasingly challenging the prices charged for pharmaceutical products and have instituted and continue to institute cost containment measures to control or significantly influence the purchase of pharmaceutical products. If these entities do not provide coverage and reimbursement for *Feraheme* or provide an insufficient level of coverage and reimbursement, physicians and other healthcare providers may choose to use alternative IV iron replacement products, which would have an adverse affect on our ability to generate revenues.

In addition, U.S. and foreign governments continue to propose and pass legislation designed to reduce the cost of health care. In the U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the Health Care Reform Act, was enacted in March 2010 and includes certain cost containment measures including an increase to the minimum rebates for products covered by Medicaid programs and the extension of such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations as well as the expansion of the 340(B) Public Health Services drug discount program. More recently, in August 2011, the President of the United States signed into law the Budget Control Act of 2011, which is expected to result in significant federal spending cuts including cuts in Medicare and other health related spending, such as a potential 27.4% reduction in payment rates for physician services. The full impact on our business of these new laws is uncertain. In recent years some states have also passed legislation to control the prices of drugs as well as begun a move toward managed care to relieve some of their Medicaid cost burden. These and any other future changes in government regulations or private third-party payors reimbursement policies may reduce the extent of reimbursement for *Feraheme* and adversely affect our future operating results.

The phase-in of the ESRD expanded prospective payment system began in the U.S. on January 1, 2011, and must be completed by January 1, 2014. This bundled approach to reimbursement has and will likely continue to alter the utilization of physician-administered drugs in the ESRD market as well as put downward pressure on the prices pharmaceutical companies can charge ESRD facilities for such drugs, particularly where alternative products are available. In the U.S., *Feraheme* is sold at a price that is substantially higher than alternative IV iron products in the dialysis setting, and as a result, the demand for *Feraheme* in the dialysis setting has largely disappeared. While the prospective payment system provisions apply only to Medicare, Medicare is the predominant payor in the ESRD market, and Medicare payment policy, in time, 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. Further changes in the Medicare reimbursement rate, particularly with respect to ESRD patients who are not on dialysis, which result in lower payment rates from either or both Medicare and non-Medicare payors, would further limit our ability to successfully market and sell *Feraheme* in the U.S.

In addition, in the hospital in-patient setting, *Feraheme* is reimbursed by Medicare under a diagnosis related group payment system, which provides a fixed reimbursement based on the diagnosis and/or procedure rather than actual costs incurred in patient treatments, thereby increasing the incentive for a hospital to limit or control expenditures. As a result, *Feraheme* has not been nor do we expect it to be broadly used in the hospital in-patient setting.

In countries outside of the U.S., 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

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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 or allow sales of *Feraheme* to be profitable in those countries. Any such limitations on the reimbursement for *Feraheme* in countries outside of the U.S. would have an adverse impact on Takeda s ability to generate product sales of *Feraheme* in such territories, which would, in turn, limit the amount of royalties we may receive under our agreement with Takeda.

In the U.S. there have been, and we expect there will continue to be, a number of federal and state healthcare initiatives implemented to reform the healthcare system in ways that could adversely impact our business and our ability to sell Feraheme profitably.

In the U.S., there have been, and we expect there will continue to be, a number of legislative and regulatory proposals aimed at changing the U.S. healthcare system. For example, the Health Care Reform Act contains a number of provisions that significantly impact the pharmaceutical industry and may negatively affect our potential *Feraheme* revenues. Among other things, the Health Care Reform Act increased the minimum Medicaid drug rebates for pharmaceutical companies, extended the rebate provisions to Medicaid managed care organizations, and expanded the 340(b) Public Health Services drug pricing program. Substantial new provisions affecting compliance have also been added, which may require us to modify our business practices with healthcare providers and potentially incur additional costs. While we are continuing to evaluate this legislation and its potential impact on our business, this legislation may adversely affect the demand for *Feraheme* in the U.S. or cause us to incur additional expenses and therefore adversely affect our financial position and results of operations.

In addition, various healthcare reform proposals have emerged at the state level in the U.S. We cannot predict the impact that newly enacted laws or any future legislation or regulation will have on us. We expect that there will continue to be a number of U.S. federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs. These efforts could adversely affect our business by, among other things, limiting the prices that can be charged for *Feraheme* or the amount of reimbursement available from governmental agencies or third-party payors, limiting the profitability of *Feraheme*, increasing our rebate liability or limiting the commercial opportunity for *Feraheme*.

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 and reimbursement than Feraheme, the commercial opportunity for Feraheme in the U.S. and abroad will be adversely impacted.

The pharmaceutical and biopharmaceutical industries are subject to intense competition and rapid technological change. We and Takeda have competitors both in the U.S. and internationally, and many may have greater financial and other resources, and more experienced trade, sales, reimbursement and manufacturing organizations than we or Takeda do. In addition, many of our and Takeda s competitors have significant name recognition, more established positions in the IV iron 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 and reimbursement than *Feraheme*.

Feraheme currently competes with several IV iron replacement therapies in the U.S., including Venofer®, which is marketed in the U.S. by Fresenius Medical Care North America and American Regent Laboratories, Inc., or American Regent, a subsidiary of Luitpold Pharmaceuticals, Inc., or Luitpold, Ferrlecit®, which is marketed by Sanofi-Aventis U.S. LLC, Nulecit , a generic version of Ferrlecit®, which

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is marketed by Watson Pharmaceuticals, Inc., or Watson, INFeD®, an iron dextran product marketed by Watson, and Dexferrum®, an iron dextran product marketed by American Regent.

Feraheme will also compete with a number of branded IV iron replacement products outside of the U.S., including Venofer®, Ferrlecit®, Monofer®, Ferinject® (the brand name for Injectafer® outside the U.S.) and certain other iron dextran and iron sucrose products. Monofer® is an injectable iron preparation developed by Pharmacosmos A/S, which is currently approved for marketing in approximately 23 countries for the treatment of IDA. Ferinject® is currently approved for marketing in approximately 38 countries, including approximately 30 countries within Europe, for the treatment of iron deficiency where oral iron is ineffective or cannot be used. Venofer® and Ferrlecit® have been marketed in many countries throughout the world, including most of Europe and Canada, for many years. *Feraheme* will compete primarily with Venofer®, Ferinject® and Ferrlecit® in both the Canadian and European markets. If Takeda is unable to convince physicians and other healthcare providers to switch from using the competing IV iron products to *Feraheme,* our ability to generate revenues from royalties we expect to receive from Takeda will be limited and our operating results will be negatively affected. In addition, all other IV iron products currently approved and marketed and sold in the EU are approved for marketing to all patients with IDA. Upon approval of our MAA, we expect *Feraheme* to be approved only for use in CKD patients, which could put *Feraheme* at a competitive disadvantage unless and until it receives approval for a broader indication.

In addition to the currently marketed products described above, *Feraheme* may also compete in the U.S. with Injectafer®, which is known as Ferinject® in Europe, which is in development in the U.S. for a variety of anemia-related indications, including the treatment of IDA in CKD patients, whether or not on dialysis. In October 2011, Luitpold submitted an NDA to the FDA seeking marketing approval for Injectafer® for the treatment of IDA. The FDA has since notified Luitpold that it has assigned a Prescription Drug User Fee Act target action date of August 3, 2012. The Injectafer® NDA includes data and information from two new large randomized controlled clinical trials investigating the cardiovascular risk profile of high dose Injectafer®. If approved in the U.S., Injectafer® will be marketed by American Regent, the current distributor of Venofer®. If Injectafer® or any other iron replacement therapy product is approved for marketing and sale in the U.S. or is successful in obtaining a broader IDA indication than *Feraheme*, our efforts to market and sell *Feraheme* in the U.S. and our ability to generate additional revenues and achieve profitability could be adversely affected.

The market opportunity for *Feraheme* in the U.S. and abroad could also be negatively affected by approved generic IV iron replacement therapy products that achieve commercial success. For example, in 2011, Watson launched Nulecit , a generic version of Ferrlecit® in the U.S. Nulecit is approved for marketing in the U.S. for the treatment of IDA in adult patients and in pediatric patients age six years and older undergoing chronic hemodialysis who are receiving supplemental epoetin therapy. There are also a number of approved generic IV iron products in countries outside the U.S. which will directly compete with *Feraheme*, including a generic version of Venofer®. Companies that manufacture generic products typically invest far less resources in research and development than the manufacturers of branded products and can therefore price their products significantly lower than those already on the market. Therefore, competition from generic IV iron products could limit our U.S. sales and any royalties we may receive from Takeda, which would have an adverse impact on our business and results of operations.

The iron replacement therapy market is highly sensitive to several factors including, but not limited to, the actual and perceived safety and efficacy profile of the available products, the ability to obtain appropriate insurance coverage and reimbursement, price competitiveness, and product characteristics such as convenience of administration and dosing regimens. *Feraheme* may not receive the same level of market acceptance as competing iron replacement therapy products, especially since most of these products have been on the market longer and are currently widely used by physicians in the U.S. and abroad. In addition, certain of the IV iron products that we compete with are approved for the treatment of iron deficiency

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anemia in a broader group of patients than *Feraheme*. We or Takeda may not be able to convince physicians and other healthcare providers or payers to switch from using the other IV iron therapeutic products to *Feraheme*. If we or Takeda are not able to differentiate *Feraheme* from other marketed IV iron products, our ability to generate revenues and achieve and maintain profitability, and our long-term business prospects could be adversely affected.

The outcome of our publicly announced process of evaluating strategic alternatives to maximize stockholder value is uncertain, may not result in a transaction or may result in the disruption of our business, a decrease in our profitability, dilution to our stockholders investment or the incurrence by us of debt or significant additional expense, any of which could have a material adverse affect on the future prospects of our business and on our stock price.

In late 2011, we hired Jefferies & Company, Inc., or Jefferies, as our financial advisor to assist us in identifying and evaluating various strategies to maximize stockholder value and leverage our core assets, including the potential sale of our company and the acquisition or in-license of additional companies or assets. While we intend to complete our evaluation expeditiously, there is no guarantee that the process will result in a sale of the company or other transaction or outcome that creates stockholder value. In addition, our announcement that we are evaluating various strategic alternatives may make it more difficult to recruit, retain and motivate our employees, may cause a disruption in our relationship with our vendors or customers or may deter potential vendors or customers from entering into any business transaction with us until we have announced a final outcome.

As part of our strategic review, we are evaluating certain options including the sale of our company, 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, contingent liabilities, or significant additional expenses, including but not limited to the payment of $12.0 million (in addition to the $2.0 million expense reimbursement fee we paid to Allos in October 2011) we may be required to pay as a result of the termination of our merger agreement with Allos Therapeutics, Inc., or Allos, if we enter into a definitive agreement for an Acquisition Transaction, as defined in the merger agreement with Allos, on or before October 21, 2012 or such a transaction is consummated on or before such date, 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 or a sale of our company may also disrupt our ongoing business, create uncertainty among our employees and investors, and require management resources that otherwise would be available for ongoing development of our existing business and the global 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 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, acquisition or sale 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.

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We have limited experience independently commercializing a pharmaceutical product, and any failure on our part to effectively execute our Feraheme commercial plans in the U.S., particularly in light of our recent restructuring, would have an adverse impact on our business.

Prior to our commercialization of *Feraheme* in the U.S., we had never independently marketed or sold a drug product as we had relied on our licensees to market and sell our previously approved products. We have an internal commercial infrastructure to market and sell *Feraheme* in the U.S., and if we are unsuccessful in maintaining an effective commercial function or experience a high level of turnover, then the commercialization of *Feraheme* could be severely impaired. We reduced our workforce by approximately 25% of our positions in November 2011 as part of an overall corporate restructuring, including certain positions within our commercial function. In November 2011, we also announced the departure of our chief executive officer and our chief commercial officer. This workforce reduction, together with the departure of our chief executive officer and our chief commercial officer, or any future reductions or departures, could harm our ability to attract and retain qualified personnel, which could prevent us from successfully commercializing *Feraheme* in the U.S., impair our ability to maintain sales levels and/or impair our ability to support potential sales growth and sales of *Feraheme* for any additional indications we may commercialize in the future. Any failure by us to successfully execute our commercialization plans for *Feraheme* in the U.S. could have a material adverse impact on our ability to generate revenues, our ability to achieve profitability, and the future prospects for our business.

Our success depends on our ability to attract and retain key employees, including the hiring of a permanent chief executive officer.

Because of the specialized nature of our business, our success depends to a significant extent on the continued service of our executive officers and on our ability to continue to attract, retain and motivate qualified executive, sales, manufacturing, managerial, scientific, and medical personnel. We have entered into employment agreements with our current 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. 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.

In November 2011, we initiated a corporate restructuring, including a workforce reduction plan, which included an approximate 25% reduction in positions and the departure of our chief executive officer and our chief commercial officer. We are currently seeking a permanent chief executive officer, however, we may not be able to find qualified candidates in a timely manner, or at all. In addition, in November 2011, we announced that we hired Jefferies to help us conduct a strategic review to determine the optimal strategy for our growth. The uncertainty regarding the outcome of our strategic review, our November 2011 workforce reduction, recent executive departures, and any future reductions or departures, could harm our ability to attract and retain qualified key personnel. If we are unable to attract such personnel, or we lose the services of our key personnel for any reason, our *Feraheme* development and commercialization efforts could be adversely impacted.

We are substantially dependent upon our collaboration with Takeda to commercialize Feraheme in certain regions outside of the U.S., including Canada and the EU, and if Takeda fails to successfully fulfill its obligations, or is ineffective in its commercialization of Feraheme in the licensed territories, or if our collaboration is terminated, our plans to commercialize Feraheme outside of the U.S. may be adversely affected.

In March 2010, we entered into the Takeda Agreement with Takeda, under which 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 certain regulatory filings outside of the U.S. with respect to *Feraheme* and the commercialization of *Feraheme* outside of the U.S., including in Canada and the EU. If Takeda fails to perform its obligations under the Takeda Agreement, delays the commercial launch of *Feraheme* in the Licensed

Territory, or is

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ineffective in its commercialization of *Feraheme* in the Licensed Territory or if we fail to effectively manage our relationship with Takeda, our ability to and the extent to which we obtain regulatory approvals for *Feraheme* and our *Feraheme* commercialization efforts outside of the U.S. would be significantly harmed, which would have an adverse affect on milestone payments and royalties we expect to receive under the Takeda Agreement. 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.

Takeda has the unilateral right to terminate the Takeda Agreement under certain conditions, including without cause. If Takeda terminates the agreement, we would be required to either enter into alternative arrangements with third parties to commercialize *Feraheme* in the Licensed Territory, which we may be unable to do, or to increase our internal infrastructure, both of which would likely result in significant additional expense and delay or termination of our *Feraheme* clinical development programs and commercial efforts outside of the U.S. In addition, such a termination would prevent us from receiving the milestone payments and royalties we expect to receive under the Takeda Agreement.

Our recent corporate restructuring could disrupt our business, which could have a material adverse effect on our business.

Our restructuring plan may be disruptive to our operations. For example, cost saving measures may distract management from our core business, harm our reputation, or yield unanticipated consequences, such as attrition beyond planned reductions in workforce, increased difficulties in our day-to-day operations, reduced employee productivity and a deterioration of employee morale. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, manufacturing and commercial personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully commercializing and developing *Feraheme*, impair our ability to maintain sales levels and/or support potential sales growth, and result in unexpected delays in our development programs and our anticipated regulatory filings, including our planned sNDA for *Feraheme* for a broad IDA indication.

Moreover, although we believe it is necessary to reduce the cost of our operations to improve our performance, these initiatives may preclude us from making potentially significant expenditures that could improve our competitiveness over the longer term. We cannot guarantee that the cost reduction measures, or other measures we may take in the future, will result in the expected cost savings, or that any cost savings will be unaccompanied by these or other unintended consequences.

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* in the U.S., including services related to warehousing and inventory management, distribution, chargeback processing, accounts receivable management and customer service call center management. As a result, a significant amount of our U.S. 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 U.S. *Feraheme* drug product. If ICS or Catalent are unable to provide

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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* in the U.S. and abroad requires significant coordination among our and Takeda s 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 U.S. or foreign commercial demand could 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 in a timely manner, 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 operations.

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

Our Cambridge, Massachusetts manufacturing facility and our third-party contract manufacturing facilities are subject to current good manufacturing practices, or cGMP, regulations enforced by the FDA and equivalent foreign regulatory agencies through periodic inspections to confirm such compliance. We and our contract manufacturers must continually expend time, money and effort in production, record-keeping and quality assurance and control to ensure that these manufacturing facilities meet applicable regulatory requirements. Failure to maintain ongoing compliance with cGMP regulations and other applicable manufacturing requirements of various U.S. or foreign regulatory agencies could result in, among other things, the issuance of warning letters, fines, the withdrawal or recall of *Feraheme* from the marketplace, total or partial suspension of *Feraheme* production, the loss of *Feraheme* inventory, suspension of the review of any future sNDAs or equivalent foreign filings, enforcement actions, injunctions or criminal prosecution. 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. In addition, if any U.S. or foreign regulatory agency inspects any of these manufacturing facilities and determines that they are not in compliance with cGMP regulations or we or our contract manufacturers otherwise determine that we or they are not in compliance with these regulations, we or our contract manufacturers could experience an inability to manufacture sufficient quantities of *Feraheme* to meet U.S. or foreign 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.

Any difficulties, disruptions or delays in the Feraheme manufacturing process, including our transition to alternative source manufacturing facilities, could increase our costs, or adversely affect our profitability and future business prospects.

We manufacture *Feraheme* for commercial use in the U.S. and for use in human clinical trials in our Cambridge, Massachusetts manufacturing facility. In April 2011, the FDA also approved certain of our

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third-party contract manufacturers to produce *Feraheme* drug substance and drug product for the U.S. market.

We manufacture *Feraheme* drug substance and drug product for use in the Canadian market at our Cambridge facility. Upon approval of our MAA by the EMA, we expect to manufacture *Feraheme* drug substance and drug product for use in the EU market at certain of our third-party contract manufacturers. Although we are working to establish and qualify alternative source manufacturing facilities for the production of *Feraheme* for Canada and the EU, we will not have such alternative source manufacturing facilities available upon initial commercial launch of *Feraheme* in those geographies.

Our ability to manufacture *Feraheme* or have *Feraheme* manufactured in sufficient quantities and at acceptable costs to meet our commercial demand and clinical development needs is dependent on the uninterrupted and efficient operation of these manufacturing facilities. Any difficulties, disruptions or delays in the *Feraheme* manufacturing process, particularly with respect to our facilities where we will manufacture *Feraheme* for Canadian and European supply, where we will not immediately have an approved back-up supplier, could result in product defects or shipment delays, recall or withdrawal of product previously shipped for commercial or clinical purposes, inventory write-offs or the inability to meet commercial demand for *Feraheme* in a timely and cost-effective manner.

In addition, the transition of the manufacturing processes to third-party contract manufacturers and the oversight of such third-parties could take a significant amount of time and 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 *Feraheme* or have *Feraheme* manufactured 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* or may not be able to manufacture *Feraheme* in a cost-effective manner, particularly in light of the fixed price at which we are required to supply *Feraheme* to Takeda under the Takeda Agreement. As a result, we may lose sales, fail to generate increased revenues, our clinical development programs may be delayed and/or we may lose money on our supply of *Feraheme* to Takeda, any of which could have an adverse impact on our potential profitability and future business prospects.

Our inability to obtain raw and other materials used in the manufacture of Feraheme could adversely impact our ability to manufacture sufficient quantities of Feraheme, which would have an adverse impact on our business.

We currently purchase certain raw and other materials used to manufacture *Feraheme* from third-party suppliers and at present do not have any long-term supply contracts with these third parties. These third-party suppliers may cease to produce the raw or other materials used in *Feraheme* or otherwise fail to supply these materials to us or fail to supply sufficient quantities of these materials to us in a timely manner for a number of reasons, including but not limited to the following:

- Unexpected demand for or shortage of raw or other materials;

- Labor disputes or shortages;

- Manufacturing difficulties;

- Regulatory requirements or action;

- Adverse financial developments at or affecting the supplier; or

- Import or export problems.

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If any of our third-party suppliers cease to supply certain raw or other materials to us for any reason we could be unable to manufacture *Feraheme* in sufficient quantities, on a timely basis, or in a cost-effective manner until we are able to qualify an alternative source, which could 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 or other 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 or other materials, we may not be able to obtain these 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 or other materials from an alternative source, if these raw or other 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, which could cause us to lose money on our supply of *Feraheme* to Takeda, which we are required to supply at a pre-negotiated fixed price. Any such difficulty in obtaining raw or other materials could severely hinder our ability to manufacture *Feraheme* and could 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 could be limited if we do not obtain approval, or if we experience significant delays in our efforts to obtain approval, in the U.S. to market and sell Feraheme for the treatment of IDA in a broad range of patients.

We have recently completed enrollment in certain Phase III clinical trials to support our global registrational program to assess *Feraheme* for the treatment of IDA in a broad range of patients. Before obtaining regulatory approval in the U.S. for the commercial marketing and sale of *Feraheme* for the broad IDA indication, we must demonstrate through extensive human clinical trials that *Feraheme* is safe and effective for use in this broader patient population. In March 2012 we announced results from the first of our two Phase III multi-center clinical trials to assess *Feraheme* in patients with IDA. 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. There is no guarantee that the FDA will determine that the results of our clinical trials, including the recently announced results from one of our trials in our global registrational program for *Feraheme* in a broad range of patients with IDA, will adequately demonstrate that *Feraheme* is safe and effective in such a patient population to grant approval.

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 clinical 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

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those sites or require us to perform additional clinical trials before approving our marketing application, which could adversely impact our ability to obtain marketing approval for *Feraheme* in the broad IDA indication. 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 or prevent us from obtaining marketing approval for *Feraheme* for the broad IDA indication. In addition, any failure by us to obtain approval for the broad IDA indication could adversely affect the commercialization of *Feraheme* in its current indication. If, for any of these reasons, we do not obtain approval, or if we experience significant delays in our efforts to obtain approval to market and sell *Feraheme* in the U.S. for the treatment of IDA in a broad range of patients, our cash position, our ability to increase revenues, our ability to achieve profitability, and the future prospects of our business could be materially adversely affected.

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

In order for Takeda, 3SBio Inc., or 3SBio, or us to market and sell *Feraheme* for any indication in any country outside of the U.S., including in the EU, it will be necessary to obtain regulatory approval from the appropriate foreign regulatory authorities, which approval must include approval of our proposed manufacturing processes and facilities. The requirements and timing for regulatory approval vary widely from country to country and may in some cases be different than or more rigorous than requirements in the U.S. For example, our MAA submitted to the EMA, for the approval of *Feraheme* for the treatment of IDA in CKD patients, is largely supported by data from the clinical trials we conducted to support our U.S. NDA filing for the approval of *Feraheme* for the treatment of IDA in CKD patients. For example, upon final approval of our MAA, we will be required to perform certain additional studies for the CKD indication in the EU.

In addition, in March 2012 we announced results from the first of our two Phase III multi-center clinical trials to assess *Feraheme* in patients with IDA. The EMA has substantial discretion in the approval process and may decide that the results of our clinical trials are insufficient for approval the broader IDA indication. Clinical and other data is often susceptible to varying interpretations, and there is no guarantee that the EMA will determine that the results of our clinical trials will adequately demonstrate that *Feraheme* is safe and effective in the broader IDA patient population to support approval. In addition, any adverse regulatory action taken by the FDA with respect to *Feraheme* in the U.S. may affect the regulatory requirements or decisions made by certain foreign regulatory bodies with regard to the regulatory approval of *Feraheme* outside of the U.S.

Any failure to obtain regulatory approval outside of the U.S. for *Feraheme* for the treatment of IDA in CKD patients or in a broad range of patients would prevent us from receiving expected milestone payments and royalties from Takeda and could limit the commercial success of *Feraheme* and our ability to grow our revenues.

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

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 in the conduct of our business. 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 or suppliers. For example, our distributors, customers or suppliers may experience difficulty in obtaining the liquidity necessary to purchase inventory or raw or other materials, may begin to maintain lower inventory levels or may become

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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.

In addition, we have contracted and we plan to continue to contract with certain third-parties to provide certain services, including site selection, enrollment, monitoring, data management and other services, in connection with the conduct of our clinical trials and the preparation and filing of our regulatory applications, including our planned sNDA for the broad IDA indication in the U.S. We have limited experience conducting clinical trials outside the U.S., and, therefore, we are also largely relying on third-parties such as clinical research organizations to manage, monitor and carry out these clinical trials outside of the U.S. 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 or our regulatory submissions are compromised due to poor quality or 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 and planned regulatory submissions both in and outside of the U.S., including our planned sNDA for the broad IDA indication in 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 magnitude of *Feraheme* sales*;*

- Any expansion or contraction of the overall size of the IV iron market, which could result from a number of factors including but not limited to, changes in treatment guidelines or practices related to IDA;

- The impact of any pricing strategies we may implement related to *Feraheme,* including the magnitude of rebates and/or discounts we may offer;

- 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;

- The timing and magnitude of milestone payments and royalties we may receive under the Takeda Agreement;

- Any adverse impact on our financial results stemming from our recent corporate restructuring;

- The timing and magnitude of costs associated with our ongoing and planned clinical studies of *Feraheme* in connection with our pediatric program, our pursuit of additional indications and our development of *Feraheme* in countries outside of the U.S;

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- The timing and magnitude of costs associated with commercial-scale manufacturing of *Feraheme*, including costs of raw and other materials and costs associated with maintaining commercial inventory and qualifying additional manufacturing capacities and alternative suppliers;

- The magnitude of costs incurred in connection with business development activities, including legal and other costs associated with our previously announced process to evaluate strategic alternatives;

- Changes in laws and regulations affecting *Feraheme* from federal, state and foreign legislative and regulatory authorities, government health administration authorities, private health insurers and other third-party payors;

- The initiation or outcome of any material litigation to which we are or become a party and the magnitude of costs associated with such litigation; and

- The 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.

We derive a substantial amount of our revenue from a limited number of customers and the loss of one or more of these customers or a decline in revenue from one or more of these customers could have an adverse impact on our results of operations and financial condition.

In the U.S., we sell *Feraheme* primarily to wholesalers and specialty distributors and therefore a significant portion of our revenues is generated by a small number of customers. Four customers accounted for 91% of our product sales revenue during the three months ended March 31, 2012 and three customers accounted for 93% of our accounts receivable balance at March 31, 2012. In addition, a significant portion of our U.S. *Feraheme* sales are generated through a small number of contracts with GPOs. For example, approximately 35% of our end-user demand in the first quarter of 2012 was generated by members of a single GPO with which we have contracted. The loss of, material reduction in sales volume to, or a significant adverse change in our relationship with any of our key wholesalers, distributors or GPOs could have a material adverse effect on our revenue in any given period and may result in significant annual or quarterly revenue fluctuations.

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 U.S. wholesalers and distributors, which vary from quarter to quarter. In the event wholesalers and distributors with whom we do business in the U.S. determine to limit their purchases of *Feraheme*, sales of *Feraheme* could be adversely affected. For example, in advance of an anticipated price increase or a reduction in expected rebates or discounts, 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 our revenue and results of operations.

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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 associated with revenue recognition related to collaboration agreements and product sales, product sales allowances and accruals, our assessment of investments for potential other-than-temporary impairment and our determination of the value of our investments, reserves for doubtful accounts, accrued expenses, reserves for legal matters, income taxes and equity-based compensation expense. We base our estimates on market data, our observance of trends in our industry, and various other assumptions that we believe to be reasonable under the circumstances. If actual results differ from these estimates, there could be a material adverse effect on our financial results and the performance of our stock.

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 materially 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, forecasts from our licensees, including Takeda, and other factors. Because of the inherent nature of estimates, there could be significant differences between our and Takeda s estimates and the actual amount of product need. For example, the level of our access to wholesaler and distributor inventory levels and sales data in the U.S., 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 operations.

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 $12.65 and $19.62 in the fifty-two week period through April 27, 2012. 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. and Takeda s ability to successfully commercialize *Feraheme* in territories outside of the U.S.;

- The timing and magnitude of *Feraheme* revenue and actual or anticipated fluctuations in our operating results;

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- Changes in or our failure to meet financial estimates published by securities analysts or our own publicly disclosed financial guidance;

- Any announcements or speculation regarding the status or result of our previously announced process of evaluating strategic alternatives available to us;

- Any announcement regarding the results of our ongoing clinical trials of *Feraheme* in the broad IDA indication;

- The availability of reimbursement coverage for *Feraheme* or changes in the reimbursement policies of U.S. or foreign governmental or private payors;

- Public announcements of U.S. or foreign regulatory actions with respect to *Feraheme* or products or product candidates of our competitors;

- Actual or perceived safety concerns related to *Feraheme* or products or product candidates of our competitors, including any actions taken by U.S. or foreign regulatory authorities in connection with such concerns;

- The status or results of clinical trials for *Feraheme* or products or product candidates of our competitors;

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

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

- The initiation or outcome of any material litigation to which we are a party;

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

- Shareholder activism and attempts to disrupt our strategy by activist investors;

- Any announcement by us naming a permanent chief executive officer;

- General market conditions; and

- Sales of large blocks of our common stock.

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, nine 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

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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. 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 any of these analysts engage in speculation about the outcome of our publicly announced strategic review process, our stock price could become volatile and decline significantly if the outcome of the process does not align with their expectations. In addition, if these analysts cease coverage of our company, we could lose visibility in the market, which in turn could also cause our stock price to decline.

If our operating results do not meet our own publicly disclosed financial guidance our stock price could decline.

In January and May 2012, we publicly provided 2012 financial guidance, including expected 2012 *Feraheme* product revenue, estimated operating expenses and estimated year-end cash balance. If we fail to realize any element of our publicly disclosed financial guidance or other expectations about our business, our stock price could decline in value.

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*. Our long-term capital requirements will depend on many factors, including, but not limited to:

- Our ability to successfully commercialize *Feraheme* in the U.S. and Takeda s ability to successfully commercialize *Feraheme* in its licensed territories outside of the U.S.;

- The magnitude of U.S. *Feraheme* sales and royalties we may receive under the Takeda Agreement on *Feraheme* sales outside of the U.S.;

- Our ability to obtain U.S. regulatory approval for *Feraheme* to treat IDA regardless of the underlying cause and our ability to obtain regulatory approval for *Feraheme* outside the U.S., particularly in the EU;

- 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, executing our promotional and marketing strategy for *Feraheme,* and conducting our required pediatric clinical studies and any post-marketing clinical studies;

- Costs associated with our development of *Feraheme* for the treatment of IDA in a broad range of patients in the U.S.;

- Costs associated with any acquisition or in-license transactions that we may engage in;

- The outcome of and costs associated with any material litigation to which we are or may become a party;

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- Our ability to liquidate our investments in auction rate securities, or ARS, in a timely manner and without significant loss;

- Our ability to maintain successful collaborations with our licensees 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 as of March 31, 2012, combined with cash we currently expect to receive from sales of *Feraheme,* from earnings on our investments, and potential milestone and royalty payments we expect to receive from Takeda 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 collaborators through public or private equity or debt financings. We may not be able to obtain financing or to secure alternative strategic arrangements on acceptable terms or within an acceptable timeframe, if at all.

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

As of March 31, 2012, we had $37.6 million in cash and cash equivalents, $162.8 million in short-term investments, and $17.4 million in long-term investments. 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. and global financial crisis which has been occurring over the past several years. The ongoing 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.

As of March 31, 2012, we held a total of $17.4 million in fair market value of ARS reflecting a reduction in value of approximately $2.4 million from the par value of these securities of approximately $19.8 million. 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 condensed consolidated statement of operations, which could be material. In addition, failed auctions will adversely impact the liquidity of our investments.

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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. As the ratings of our ARS change we may be required to adjust our future valuation of our ARS which may adversely affect the value of these investments. These market risks associated with our investment portfolio may have an adverse effect on our results of operations, cash position, liquidity and overall financial condition.

We are subject to increasingly complex corporate governance, public disclosure and accounting requirements that could adversely affect our business and financial results.

We are subject to changing rules and regulations of U.S. federal and state government as well as the stock exchange on which our common stock is listed. These entities, including the Public Company Accounting Oversight Board, the NASDAQ Global Select Market, and the U.S. Securities and Exchange Commission, or SEC, have issued a significant number of new and increasingly complex requirements and regulations over the last several years and continue to develop additional regulations and requirements in response to laws enacted by Congress. For example, in July 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act, some of which the SEC has recently implemented by adopting additional rules and regulations in areas such as executive compensation, or say on pay . Our efforts to comply with these requirements have resulted in, and are likely to continue to result in, an increase in our expenses and a diversion of management s time from other business activities.

Our ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income may be limited as a result of 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 to 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. 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.

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

As a condition of reimbursement by various U.S. federal and state healthcare programs for *Feraheme*, we are required to calculate and report certain pricing information to U.S. federal and state healthcare agencies. For example, we are required to provide average selling price information to the Centers for Medicare and Medicaid Services on a quarterly basis in order to compute Medicare payment rates. Price

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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. In addition, the Health Care Reform Act modified the rules related to certain price reports and expanded the scope of pharmaceutical product sales to which Medicaid rebates apply, among other things. 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. This uncertainty in the interpretation of the legislation increases the chances of an error in price reporting, which could in turn lead to a legal challenge or investigation. 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 operations.

We are subject to ongoing U.S. and foreign regulatory obligations and oversight of Feraheme, and any failure by us to maintain compliance with applicable regulations may result in several adverse consequences including the suspension of the manufacturing, marketing and sale of Feraheme, the incurrence of significant additional expense and other limitations on our ability to commercialize Feraheme.

We are subject to ongoing regulatory requirements and review both in the U.S. and in certain cases, foreign jurisdictions, pertaining to *Feraheme s* manufacture, labeling, packaging, adverse event reporting, storage, marketing, promotion and record keeping. Failure to comply with such regulatory requirements or the later discovery of previously unknown problems with *Feraheme* or our manufacturing facilities may result in restrictions on our ability to manufacture, market or sell *Feraheme*, including its withdrawal from the market. Any such restrictions could result in a decrease in *Feraheme* sales, damage to our reputation or the initiation of lawsuits against us. We may also be subject to additional sanctions, including but not limited to:

- Warning letters;
- Civil or criminal penalties;
- Suspension or withdrawal of regulatory approvals;
- Temporary or permanent closing of our manufacturing facilities or those of our third party contract manufacturers;
- Requirements to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, or other issues involving *Feraheme;*
- Changes to the *Feraheme* package insert;

- Implementation of risk mitigation programs;

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

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

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Any of the above sanctions could have a material adverse impact on our ability to generate revenues and to achieve profitability and cause us to incur significant additional expenses.

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

In addition to FDA and related regulatory requirements in the U.S. and abroad, we are subject to extensive additional federal, state and foreign healthcare regulation, which includes but is not limited to, the Federal False Claims Act, the Federal Anti-Kickback Statute, the Foreign Corrupt Practices Act and similar laws in countries outside of the U.S. 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. The Foreign Corrupt Practices Act and similar foreign anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Similar laws and regulations exist in many other countries throughout the world in which we intend to commercialize *Feraheme* through Takeda and our other licensees. 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, state and foreign regulations. If we, our representatives, or our licensees, including Takeda, fail to comply with any of these laws or regulations, a range of fines, penalties and/or other sanctions could be imposed on us and/or Takeda, including, but not limited to, restrictions on how we and/or Takeda 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 operations.

In recent years, several U.S. states have enacted legislation requiring pharmaceutical companies to establish marketing and promotional compliance programs or codes of conduct and/or to 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, Congress and foreign governments. In addition, as part of the Health Care Reform Act, the federal government has enacted the Physician Payment Sunshine Act and related regulations. Beginning in 2013, manufacturers of drugs will be required to publicly report gifts and payments made to physicians and teaching hospitals. 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, time consuming and costly, 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 operations.

If we fail to comply with any federal, state or foreign 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 operations.

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Our business could be negatively affected as a result of the actions of activist shareholders.

Proxy contests have been waged against many companies in the biopharmaceutical industry over the last few years. In 2011, MSMB Capital Management LLC, or MSMB Capital, filed a preliminary consent solicitation statement with the SEC seeking to remove and replace all of our current directors with MSMB Capital s nominees. The review, consideration and response to MSMB Capital s efforts to gain control of our Board of Directors, or Board, may require the expenditure of significant time and resources by us and may be a significant distraction for our management and employees. MSMB Capital s efforts to replace our current Board members may also create uncertainty for our employees, and this uncertainty may adversely affect our ability to retain and attract key employees, including a permanent chief executive officer. The impact of MSMB Capital s efforts due to these or other factors may undermine our business and have a material adverse effect on our results of operations. MSMB Capital has not yet formally commenced its proposed consent solicitation.

If faced with a proxy contest, we may not be able to successfully defend against the contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest for the following reasons:

- Responding to proxy contests and other actions by activist shareholders may be costly and time-consuming and may disrupt our operations and divert the attention of management and our employees;

- Perceived uncertainties as to our future direction may result in our inability to consummate potential acquisitions, collaborations or in-licensing opportunities and may make it more difficult to attract and retain qualified personnel, including a permanent chief executive officer; and

- If individuals are elected to our Board with a specific agenda different from ours, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

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

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

Our *Feraheme* patents are currently scheduled to expire in 2020. These and any other patents issued to us may be contested or invalidated. For example, in July 2010, Sandoz GmbH, or Sandoz, filed an opposition to one of our patents which covers *Feraheme* in the EU with the European Patent Office, or EPO. Although we believe that the subject patent is valid, there is a possibility that the EPO could invalidate or require us to

narrow the claims contained in our patent. We believe the Sandoz patent opposition is without merit and intend to defend against the opposition vigorously, however, this or future patent interference proceedings involving our patents may result in substantial costs to us, distract our management, prevent us or Takeda from marketing and selling *Feraheme*, increase the risk that a generic version of *Feraheme* could enter the market to compete with *Feraheme*, limit our development and commercialization of *Feraheme* or otherwise harm our competitive position and our ability to commercialize *Feraheme*.

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In addition, 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*, increase the risk that a generic version of *Feraheme* could enter the market to compete with *Feraheme*, limit our development and commercialization of *Feraheme*, or otherwise 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, which could prevent us or Takeda 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 for *Feraheme*, such as in China, where we license certain development and commercial rights to *Feraheme* to 3SBio, 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 licensees, 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, particularly in China, where we license certain development and commercial rights to *Feraheme* to 3SBio. 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 public 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 public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements, which could lead to a decline in our stock price. Failure to comply

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with reporting requirements could also subject us to sanctions and/or investigations by the SEC, the NASDAQ Global Select Market or other regulatory authorities.

An adverse determination in any current or future lawsuits in which we are a defendant, including the class action lawsuit to which we are currently a party, could have a material adverse affect on us.

A purported class action complaint was originally filed on March 18, 2010 in the United States District Court for the District of Massachusetts, entitled Silverstrand Investments et. al. v. AMAG Pharm., Inc., et. al., Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Executive Vice President and Chief Financial Officer, our Board, and certain underwriters in our January 2010 offering of common stock violated certain federal securities laws by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff sought 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. On August 11, 2011, the Court issued an Opinion and Order dismissing the SAC in its entirety for failure to state a claim upon which relief could be granted. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the United States Court of Appeals for the First Circuit. Whether or not the plaintiff s appeal is 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 may also be the target of similar litigation in the future. Any future 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. We maintain liability insurance, however, if any costs or expenses associated with this or any other litigation exceed our insurance coverage, we may be forced to bear some or all of these costs and expenses directly, which could be substantial.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of Feraheme.

The administration of *Feraheme* to humans, whether in clinical trials or after approved for commercial use, may expose us to liability claims, whether or not *Feraheme* is actually at fault for causing an injury. As *Feraheme* is used over longer periods of time by a wider group of patients taking numerous other medicines or by patients with additional underlying health problems, the likelihood of adverse drug reactions or unintended side effects, including death, may increase. 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 also decrease demand for *Feraheme*, subject us to product recalls or harm our reputation, cause us to incur substantial costs, and divert management s time and attention.

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.

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 stockholders (other than the potential hostile acquiror) to purchase

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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 our Board. These provisions include:

- The ability of our Board 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 and for proposals to be brought before our annual meeting of stockholders;

- The authority of our Board 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, or Section 203, 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.

As a result of the termination of our merger agreement with Allos, we may be required to pay Allos a fee of $12.0 million (in addition to the $2.0 million expense reimbursement fee we paid to Allos in October 2011) if we enter into a definitive agreement for an Acquisition Transaction, as defined in the Agreement and Plan of Merger and Reorganization we entered into with Allos, on or before October 21, 2012 or such a transaction is consummated on or before such date. Such potential payment could delay or discourage transactions involving an actual or potential change in control of our company.

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 Second Amended and Restated 2007 Equity Incentive Plan generally permits our Board 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.

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

Because we use certain hazardous materials in the production of our products, 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.

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, 2012.

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Item 6. Exhibits

(a) List of Exhibits

Exhibit Number		Description
31.1	+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	++	The following materials from AMAG Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, formatted in Extensible Business Reporting Language (XBRL), (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text.

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

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

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SIGNATURES

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

AMAG PHARMACEUTICALS, INC.

By: /s/ Frank E. Thomas
Frank E. Thomas
Executive Vice President, Chief Operating Officer, and Interim President and Chief Executive Officer

Date: May 3, 2012

AMAG PHARMACEUTICALS, INC.

By: /s/ Scott A. Holmes
Scott A. Holmes
Chief Accounting Officer, Vice President and Controller

Date: May 3, 2012

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