AMAG PHARMACEUTICALS INC.
Form 10-Q
August 07, 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 June 30, 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 July 30, 2012, there were 21,390,188 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)

	June 30, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 30,678	$ 63,474
Short-term investments	176,571	148,703
Accounts receivable, net	5,778	5,932
Inventories	13,580	15,206
Receivable from collaboration	15,133	428
Prepaid and other current assets	4,202	6,288
Total current assets	245,942	240,031
Property, plant and equipment, net	7,831	9,206
Long-term investments		17,527
Restricted cash	460	460
Total assets	$ 254,233	$ 267,224
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,757	$ 3,732
Accrued expenses	23,351	28,916
Deferred revenues	6,346	6,346
Total current liabilities	33,454	38,994
Long-term liabilities:		
Deferred revenues	42,148	45,196
Other long-term liabilities	2,239	2,438
Total liabilities	77,841	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; 21,390,188 and 21,306,413 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively	214	213
Additional paid-in capital	628,508	625,133
Accumulated other comprehensive loss	(3,325)	(4,842)
Accumulated deficit	(449,005)	(439,908)
Total stockholders equity	176,392	180,596
Total liabilities and stockholders equity	$ 254,233	$ 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 PER SHARE DATA)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Revenues:				
Product sales, net	$ 14,420	$ 13,081	$ 28,128	$ 24,103
License fee and other collaboration revenues	16,592	2,288	18,345	4,615
Royalties		33	19	69
Total revenues	31,012	15,402	46,492	28,787
Costs and expenses:				
Cost of product sales	3,224	2,082	5,870	5,123
Research and development expenses	7,671	16,695	20,133	30,261
Selling, general and administrative expenses	15,101	16,826	28,282	36,460
Restructuring expenses	1,058		1,058	
Total costs and expenses	27,054	35,603	55,343	71,844
Other income (expense):				
Interest and dividend income, net	338	452	731	1,012
Losses on investments, net	(1,471)	(209)	(1,471)	(208)
Total other income (expense)	(1,133)	243	(740)	804
Net income (loss) before income taxes	2,825	(19,958)	(9,591)	(42,253)
Income tax benefit	494	396	494	396
Net income (loss)	$ 3,319	$ (19,562)	$ (9,097)	$ (41,857)
Net income (loss) per share:				
Basic	$ 0.16	$ (0.92)	$ (0.43)	$ (1.98)
Diluted	$ 0.15	$ (0.92)	$ (0.43)	$ (1.98)
Weighted average shares outstanding used to compute net income (loss) per share:				
Basic	21,370	21,167	21,359	21,156
Diluted	21,649	21,167	21,359	21,156

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 INCOME (LOSS)

(IN THOUSANDS)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Net income (loss)	$ 3,319	$ (19,562)	$ (9,097)	$ (41,857)
Other comprehensive income (loss):				
Unrealized gains (losses) on securities:				
Holding gains (losses) arising during period, net of tax	(31)	1,380	46	1,269
Reclassification adjustment for (gains) losses included in net income (loss)	1,471	210	1,471	210
Net unrealized gains (losses) on securities	1,440	1,590	1,517	1,479
Total comprehensive income (loss)	$ 4,759	$ (17,972)	$ (7,580)	$ (40,378)

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)

	Six Months Ended June 30,	
	2012	**2011**
Cash flows from operating activities:		
Net loss	$ (9,097)	$ (41,857)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,422	1,317
Non-cash equity-based compensation expense	3,262	7,096
Non-cash income tax benefit	(494)	(396)
Amortization of premium/discount on purchased securities	1,463	1,841
Losses on investments, net	1,471	208
Changes in operating assets and liabilities:		
Accounts receivable, net	154	972
Inventories	2,276	1,028
Receivable from collaboration	(14,705)	(430)
Prepaid and other current assets	2,086	2,382
Accounts payable and accrued expenses	(6,546)	1,413
Deferred revenues	(3,048)	(3,305)
Other long-term liabilities	(199)	(172)
Total adjustments	(12,858)	11,954
Net cash used in operating activities	(21,955)	(29,903)
Cash flows from investing activities:		
Proceeds from sales or maturities of available-for-sale investments	85,234	71,033
Purchase of available-for-sale investments	(96,178)	(73,912)
Capital expenditures	(47)	(212)
Net cash used in investing activities	(10,991)	(3,091)
Cash flows from financing activities:		
Proceeds from the exercise of stock options		10
Proceeds from the issuance of common stock under ESPP	150	294
Net cash provided by financing activities	150	304
Net decrease in cash and cash equivalents	(32,796)	(32,690)
Cash and cash equivalents at beginning of the period	63,474	112,646
Cash and cash equivalents at end of the period	$ 30,678	$ 79,956

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

JUNE 30, 2012

(Unaudited)

A. Description of Business

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a specialty pharmaceutical company focused on the development and commercialization of Feraheme® (ferumoxytol) Injection for Intravenous, or IV, use to treat iron deficiency anemia, or IDA. Currently, our principal source of revenue is from the sale of *Feraheme*, which was approved for marketing in the U.S. in June 2009 by the U.S. Food and Drug Administration 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, ferumoxytol was granted marketing approval in Canada, under the trade name *Feraheme*, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. In June 2012, the European Commission granted marketing authorization for ferumoxytol, under the trade name Rienso® 30mg/ml solution for Injection, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. Under an agreement with Takeda Pharmaceutical Company Limited, or Takeda, Takeda has an exclusive license to market and sell ferumoxytol in Canada and in the European Union, or EU. The EU marketing authorization triggered a $15.0 million milestone payment to us from Takeda, which we received in July 2012. We expect Takeda to launch *Feraheme/Rienso* in Canada and the EU in the second half of 2012. In addition, we are currently pursuing a marketing application with Takeda for ferumoxytol in Switzerland, under the trade name *Rienso*, for the treatment of IDA in CKD patients.

GastroMARK®, which has been 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 the second quarter of 2012, we terminated our commercial license agreements for *GastroMARK*. Following the completion of our obligations under these agreements, we no longer intend to commercially manufacture or sell *GastroMARK*. Pursuant to the terms of the respective termination agreements, during the three months ended June 30, 2012, we paid our licensees termination fees of $1.6 million, which we recorded in selling, general and administrative expenses in our condensed consolidated statement of operations.

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.

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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. 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.

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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 June 30, 2012 and December 31, 2011 for those assets that we measure at fair value on a recurring basis (in thousands):

	Total	Fair Value Measurements at June 30, 2012 Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 27,417	$ 27,417	$	$
Corporate debt securities	110,218		110,218	
U.S. treasury and government agency securities	58,876		58,876	
Commercial paper	7,477		7,477	
	$ 203,988	$ 27,417	$ 176,571	$

	Total	Fair Value Measurements at December 31, 2011 Using: 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 money market funds and, previously, our auction rate securities, or ARS, which we sold in June 2012, and which were valued using Level 3 inputs, as discussed below, 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, 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 June 30, 2012 or December 31, 2011. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the six months ended June 30, 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

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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 assets appeared normal and that transactions did not appear disorderly as of June 30, 2012.

In June 2012, we sold our remaining ARS portfolio, with a par value of $19.8 million, for proceeds of $18.3 million.

The following table provides a rollforward of Level 3 assets for the six months ended June 30, 2012 (in thousands):

		Six Months Ended June 30, 2012
Balance at beginning of period	$	17,527
Transfers to Level 3		
Total gains (losses) (realized or unrealized):		
Included in earnings		(1,471)
Included in other comprehensive income (loss)		2,373
Purchases, issuances, sales and settlements:		
Purchases		
Issuances		
Sales		(18,329)
Settlements		(100)
Balance at end of period	$	
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 organizations, 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

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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 based on inventory in our sales channel. An analysis of our product sales allowances and accruals for the three and six months ended June 30, 2012 and 2011 is as follows (in thousands):

	Three Months Ended June 30,	
	2012	2011
Product sales allowances and accruals		
Discounts and chargebacks	$ 6,846	$ 3,579
Government and other rebates	1,672	2,737
Returns	(292)	369
Total provision for product sales allowances and accruals	$ 8,226	$ 6,685
Total gross product sales	$ 22,646	$ 19,766
Total provision for product sales allowances and accruals as a percent of total gross product sales	36%	34%

	Six Months Ended June 30,	
	2012	2011
Product sales allowances and accruals		
Discounts and chargebacks	$ 12,738	$ 5,799
Government and other rebates	3,132	5,271
Returns	(558)	668
Total provision for product sales allowances and accruals	$ 15,312	$ 11,738
Total gross product sales	$ 43,440	$ 35,841
Total provision for product sales allowances and accruals as a percent of total gross product sales	35%	33%

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

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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 half of 2012, we reduced our reserve for product returns by approximately $1.1 million due to the lapse of the product return period on certain manufactured *Feraheme* lots that carried a two year expiration. As a result, the product returns reserve applied to gross sales for the six months ended June 30, 2012 was ($0.6) million as compared to $0.7 million in the six months ended June 30, 2011.

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 June 30, 2012, our cash, cash equivalents and investments amounted to approximately $207.2 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, and commercial paper. As of June 30, 2012 we had approximately $27.4 million of our total $30.7 million cash and cash equivalents balance invested in institutional money market funds, of which $13.0 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 six months ended June 30, 2012 and 2011.

	Six Months Ended June 30,	
	2012	**2011**
Takeda Pharmaceuticals Company Limited	40%	16%
AmerisourceBergen Drug Corporation	30%	40%
McKesson Corporation	14%	19%
Cardinal Health, Inc.	10%	12%

In addition, approximately 32% of our end-user demand during the six months ended June 30, 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 40% and 17% of our total revenues for the six months ended June 30, 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 June 30, 2012 and December 31, 2011, the combined total of our short- and long-term investments equaled $176.6 million and $166.2 million, respectively, and consisted of securities classified

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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 June 30, 2012 and December 31, 2011 (in thousands):

	June 30, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	$ 57,598	$ 86	$ (37)	$ 57,647
Due in one to three years	52,577	64	(70)	52,571
U.S. treasury and government agency securities				
Due in one year or less	17,972	95		18,067
Due in one to three years	40,709	104	(4)	40,809
Commercial paper				
Due in one year or less	7,487		(10)	7,477
Total investments	$ 176,343	$ 349	$ (121)	$ 176,571

	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

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Auction Rate Securities

In June 2012, we sold our remaining ARS portfolio, with a par value of $19.8 million, for proceeds of $18.3 million and recognized a loss of approximately $1.5 million in other income (expense) in our condensed consolidated statements of income for the three and six months ended June 30, 2012. All of the ARS we held consisted of municipal bonds with an auction reset feature and were classified as available-for-sale.

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 June 30, 2012 and December 31, 2011 (in thousands):

	June 30, 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	$ 58,433	$ (92)	$ 937	$ (15)	$ 59,370	$ (107)
U.S. treasury and government agency securities	8,391	(4)			8,391	(4)
Commercial paper	7,477	(10)			7,477	(10)
	$ 74,301	$ (106)	$ 937	$ (15)	$ 75,238	$ (121)

	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 of the three or six months ended June 30, 2012. 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. During both the three and six months ended June 30, 2012 we recorded realized losses of $1.5 million to our condensed consolidated statements of operations related to the sale of our remaining ARS portfolio, as discussed above.

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D. Accounts Receivable

Our accounts receivable were $5.8 million and $5.9 million as of June 30, 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 June 30, 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 June 30, 2012 and December 31, 2011 were as follows:

	June 30, 2012	December 31, 2011
AmerisourceBergen Drug Corporation	48%	44%
McKesson Corporation	25%	33%
Cardinal Health, Inc.	20%	15%

E. Inventories

Our major classes of inventories were as follows as of June 30, 2012 and December 31, 2011 (in thousands):

	June 30, 2012	December 31, 2011
Raw materials	$ 1,803	$ 1,892
Work in process	2,171	3,696
Finished goods	9,606	9,618
Total inventories	$ 13,580	$ 15,206

During the first half of 2012, we wrote-off $0.6 million of inventory which was produced to validate the manufacturing process at third-party suppliers and which we no longer believed was suitable for sale. In addition, included in our total inventory at June 30, 2012 is $0.6 million of additional inventory reserves recognized as a restructuring cost in the three and six months ended June 30, 2012 related to our planned divestiture of our Cambridge, Massachusetts manufacturing facility.

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* finished goods inventory. If actual market conditions are less

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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 six months ended June 30, 2012, we recognized a $0.5 million current federal income tax benefit, which was primarily the result of a decrease in unrealized losses associated with the sale of our remaining ARS portfolio in the second quarter of 2012. For the six months ended June 30, 2011, we recognized a $0.4 million current federal income tax benefit, which was the result of our recognition of corresponding income tax expense associated with the increase in the value of certain securities that we carried at fair market value during the period. The corresponding income tax expense was recorded in other comprehensive income (loss). 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 Income (Loss) Per Share

We compute basic net income (loss) per share by dividing net income (loss) by the weighted average number of common shares outstanding during the relevant period. The components of basic and diluted net income (loss) per share were as follows (in thousands, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Net income (loss)	$ 3,319	$ (19,562)	$ (9,097)	$ (41,857)
Weighted average common shares outstanding	21,370	21,167	21,359	21,156
Effect of dilutive securities:				
Stock options and restricted stock units	279			
Shares used in calculating dilutive net income (loss) per share	21,649	21,167	21,359	21,156
Net income (loss) per share:				
Basic	$ 0.16	$ (0.92)	$ (0.43)	$ (1.98)
Diluted	$ 0.15	$ (0.92)	$ (0.43)	$ (1.98)

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), that were excluded from our computation of diluted net income (loss) per share because such options and restricted stock units were anti-dilutive due to a net loss or because the exercise price exceeded the current stock price

for options in the relevant periods (in thousands):

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Options to purchase shares of common stock	3,044	2,127	2,873	2,127
Shares of common stock issuable upon the vesting of restricted stock units	142	649	484	649
Total	3,186	2,776	3,357	2,776

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 June 30, 2012, we have granted options and restricted stock units covering 5,161,025 shares of common stock under our 2007 Plan, of which 1,723,324 stock options and 584,880 restricted stock units have expired or terminated, and of which 35,338 options have been exercised and 247,725 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 June 30, 2012 was 2,186,032 and 383,726, respectively. The remaining number of shares available for future grants as of June 30, 2012 was 847,505, 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 have either a seven or ten-year term.

Amended and Restated 2000 Stock Plan

As of June 30, 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 June 30, 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.

Other Equity Compensation Grants

In addition, in May 2012, in connection with his entry into an employment agreement as our President and Chief Executive Officer, our Board of Directors granted William Heiden an option to purchase 300,000 shares of our common stock at an exercise price equal to the then fair market value of a share of our common stock. The option will be exercisable in four equal annual installments beginning on the first anniversary of the grant date. Mr. Heiden was also granted 100,000 restricted stock units, which will vest in four equal annual installments beginning on the first

anniversary of the grant date. The foregoing grants were made pursuant to an inducement grant exception under the NASDAQ rules and therefore were granted outside of our 2007 Plan. We assessed the terms of these awards to Mr. Heiden and determined there was no possibility that we would have to settle these awards in cash and therefore, equity accounting was applied.

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Equity-based compensation expense

Equity-based compensation expense, excluding amounts that have been capitalized into inventory, for the three and six months ended June 30, 2012 and 2011 consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Cost of product sales	$ 68	$ 157	$ 146	$ 352
Research and development	525	639	947	1,281
Selling, general and administrative	984	1,825	2,169	5,463
Total equity-based compensation expense	$ 1,577	$ 2,621	$ 3,262	$ 7,096

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. After briefing was completed by all parties, the Court of Appeals heard oral argument on May 11, 2012, and took the matter under advisement. 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.

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 June 30, 2012. We expense legal costs as they are incurred.

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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.

In November 2011, we entered into an agreement with our financial advisor, Jefferies & Company, Inc., or Jefferies, or the Jefferies Agreement, with respect to conducting a strategic review of our company. In connection with the conclusion of our strategic review, which we announced in May 2012, we terminated the Jefferies Agreement in July 2012. Pursuant to the terms of the Jefferies Agreement, we are required to pay Jefferies a transaction fee in the event that we enter into certain sale or acquisition transactions above a certain threshold on or prior to April 3, 2013 or such a transaction is consummated on or before such date. The fee would be determined based on the transaction value of the respective transaction but in no event be less than $1.5 million, depending on the nature of the transaction.

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 June 30, 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/Rienso* 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. In June 2012, we entered into an amendment to the Takeda Agreement, or the Amended Takeda Agreement, which removed the Commonwealth of Independent States from the territories under which Takeda has the exclusive rights to develop and commercialize *Feraheme/Rienso,* or the Amended Licensed Territory. In addition, the Amended Takeda Agreement modified the timing and pricing arrangements for a supply agreement to be entered into between us and Takeda in the future, the terms related to primary and secondary manufacturing for drug substance and drug product, certain patent related provisions, and the allocation of certain of the agreed upon milestone payments. We analyzed the Amended Takeda Agreement and determined that the amended terms do not result in a material modification of the original Takeda Agreement.

Under the Amended Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme/Rienso* and, accordingly, are responsible for supply of *Feraheme/Rienso* 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 original 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 additional regulatory approval and performance-based milestone payments, reimbursement of certain out-of-pocket regulatory and clinical supply costs, defined payments for supply of *Feraheme/Rienso,* and tiered double-digit royalties on net product sales in the

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Amended Licensed Territory under the Amended Takeda Agreement. The remaining milestone payments we may be entitled to receive under the agreement could over time equal approximately $205.0 million, including up to an aggregate of $18.0 million upon the commercial launch of *Feraheme/Rienso* in Canada and the EU. We have determined that any milestone 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 achieved.

In June 2012, we earned a $15.0 million milestone payment from Takeda based on the European Commission marketing authorization for ferumoxytol, which is recorded as a receivable from collaboration in our condensed consolidated balance sheet. We have deemed this milestone payment to be a substantive milestone based on our analysis that the milestone consideration received was commensurate with our performance to achieve the milestone, was solely related to past performance, and was reasonable relative to all of the deliverables and payment terms, including other milestones, within the arrangement. Therefore, we recognized the $15.0 million milestone payment as revenue in the three and six months ended June 30, 2012 in our condensed consolidated statements of operations. Any future non-substantive milestone payments will be accounted for in accordance with our revenue attribution method for the upfront payment as described below.

We have determined that our obligations under the Amended Takeda Agreement have not changed and include the following four deliverables: the license, access to future know-how and improvements to the *Feraheme/Rienso* technology, regulatory and clinical research activities, and the manufacturing and supply of product. Pursuant to the accounting guidance in effect when we signed the original Takeda Agreement in March 2010, and which governed revenue recognition on multiple element arrangements, we evaluated the four deliverables under the original 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 Amended 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 originally entered the Takeda Agreement, which represented the then current patent life of *Feraheme/Rienso* 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 Amended 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.

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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 and six months ended June 30, 2012, we recorded $1.5 million and $3.0 million in revenues, respectively, associated with the upfront payment. In addition, we recorded $0.1 million and $0.3 million associated with other reimbursement revenues in our condensed consolidated statement of operations for the three and six months ended June 30, 2012, respectively.

Payments to be received for supply of the drug product and royalties are recorded in product sales and royalties in our condensed consolidated statement of operations. During the three and six months ended June 30, 2012, we recorded $0.2 million in net product revenues related to the supply of drug product to Takeda in preparation for the planned launch of the product in Canada.

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 *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 June 2012, we initiated a corporate restructuring, including a workforce reduction plan. The majority of the workforce reduction plan is associated with our manufacturing and development infrastructure. As a result of the restructuring, we expect to record total charges of approximately $1.6 million. Of the $1.6 million, approximately $1.0 million is related to employee severance and benefits. We recognized $0.5 million of the $1.0 million during the second quarter of 2012 and additional charges will likely occur in future quarters. In addition, in connection with our decision to divest our Cambridge, Massachusetts manufacturing facility, we have recorded $0.6 million in restructuring charges related to the write-down of primarily raw material inventory that will no longer be usable upon the closure of the facility. We expect that the majority of our restructuring charges will be paid by the end of 2012.

In November 2011, we initiated a corporate restructuring, including a workforce reduction plan, which included a 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.

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The following table outlines the components of our restructuring expenses which were recorded in operating expenses and current liabilities for the three and six months ended June 30, 2012 (in thousands):

	Three Months Ended June 30, 2012	Six Months Ended June 30, 2012
Accrued restructuring, beginning of period	$ 1,763	$ 2,366
Employee severance, benefits and related costs	493	578
Payments	(518)	(1,127)
Reclassifiction to inventory reserve	(575)	(575)
Other adjustments	565	486
Accrued restructuring, end of period	$ 1,728	$ 1,728

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 Takeda Pharmaceutical Company Limited, or Takeda, will launch Feraheme/Rienso in Canada and the European Union, or EU, 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 the fourth quarter of 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, including our plan to conduct an iron sucrose treatment arm and a magnetic resonance imaging study to evaluate the potential for iron deposits in the body following treatment with IV iron, our statement that Takeda expects to initiate a Phase IIIb study to examine the efficacy and safety of Feraheme as compared to an active comparator, our expectation that Feraheme will be sold in the EU 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, our expectation that we plan to divest our manufacturing facility, our expectation that we will manufacture Feraheme drug substance and drug product for use in the EU at our third-party manufacturers, our expectation that the majority of our November 2011 and June 2012 restructuring charges will be paid by the end of 2012, our expectations regarding our future revenues, including expected Feraheme/Rienso revenues under our Takeda and 3SBio collaborations, our expectation that our reserves as a percentage of gross product sales will increase slightly during the remainder of 2012, our expectation that the average net selling price of Feraheme will begin to increase in future periods, our expectations 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 increase slightly 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 regarding the potential impact of the adoption of newly issued and future accounting guidance on our financial statements, our expectations that our cash and cash equivalents will remain relatively consistent at the

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end of 2012 as compared to at the end of 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 specialty pharmaceutical company focused on the development and commercialization of Feraheme® (ferumoxytol) Injection for Intravenous, or IV, use to treat iron deficiency anemia, or IDA. Our principal source of revenue is from the sale of *Feraheme*, 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, ferumoxytol was granted marketing approval in Canada, under the trade name *Feraheme*, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. In June 2012, the European Commission granted marketing authorization for ferumoxytol, under the trade name Rienso® 30mg/ml solution for Injection, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. The marketing authorization is valid in the current European Union, or EU, Member States as well as in Iceland and Norway, and is based on data obtained from an extensive clinical development program. Under an agreement with Takeda Pharmaceutical Company Limited, or Takeda, Takeda has an exclusive license to market and sell ferumoxytol in Canada and in the EU. The EU marketing authorization triggered a $15.0 million milestone payment to us from Takeda, which we received in July 2012. We expect Takeda to launch *Feraheme/Rienso* in Canada and the EU in the second half of 2012. In addition, we are currently pursuing a marketing application with Takeda for ferumoxytol in Switzerland, under the trade name *Rienso*, for the treatment of IDA in CKD patients.

In June 2012, we initiated a corporate restructuring, including a workforce reduction plan. The majority of the workforce reduction plan is expected to be associated with our manufacturing and development infrastructure. As a result of the restructuring, we expect to record charges of approximately $1.6 million. Of the $1.6 million, approximately $1.0 million is related to employee severance and benefits, of which $0.5 million was recognized during the second quarter of 2012 and the remaining $0.5 million will be recognized in the second half of 2012. In addition, in connection with our decision to divest our Cambridge, Massachusetts manufacturing facility, we have recorded $0.6 million in restructuring charges related to the write-down of primarily raw material inventory that will no longer be usable upon the closure of the facility. We expect that the majority of our restructuring charges will be paid by the end of 2012.

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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 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 continue 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 milestone payments and 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/Rienso* in Canada and the EU, royalties we may receive with respect to sales of *Feraheme/Rienso* in Canada and the EU, cash generated by our investing activities, and the sale of our equity securities, if necessary. As of June 30, 2012, we had an accumulated deficit of approximately $449.0 million and a cash, cash equivalents and investments balance of approximately $207.2 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/Rienso* 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. In June 2012, we entered into an amendment to the Takeda Agreement, or the Amended Takeda Agreement, which removed the Commonwealth of Independent States from the territories under which Takeda has the exclusive rights to develop and commercialize *Feraheme/Rienso.* In addition, the Amended Takeda Agreement modified the timing and pricing arrangements for a supply agreement to be entered into between us and Takeda in the future, the terms related to primary and secondary manufacturing for drug substance and drug product, certain patent related provisions, and the allocation of certain of the agreed upon milestone payments. In June 2012, we earned a $15.0 million milestone payment based on the European Commission marketing authorization for *Rienso,* which we received in July 2012. Under the Amended Takeda Agreement, we may also be entitled to receive additional milestone payments over time equaling approximately $205.0 million, including up to an aggregate of $18.0 million upon the commercial launch of *Feraheme/Rienso* in Canada and the EU, which we expect to receive in 2012.

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

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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 for the EU regulatory authorities was the mean change in hemoglobin from the date of determination of each patient s baseline hemoglobin level, or baseline, to the fifth week following administration of the study drug, or week five. The primary efficacy endpoint of the study for the FDA was the proportion of patients who achieved a greater than or equal to 2.0 gram per deciliter increase in hemoglobin at any time from base line to week five.

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 AEs 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.

In July 2012, we reported preliminary results from the second of the two Phase III studies in our global IDA registrational program. This study was a double-blind, placebo-controlled trial that compared treatment with *Feraheme* to placebo and enrolled 808 patients at 136 sites in the U.S., Canada, India, Latvia, Hungary, and Poland. The patients enrolled in this study had a history of unsatisfactory response to, or could otherwise not tolerate, 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 placebo and was designed to demonstrate superiority on efficacy of *Feraheme* as compared to placebo. Of the 808 patients enrolled in this study, 608 patients were randomly assigned to receive *Feraheme* and 200 were randomly assigned to receive placebo. The demographics and all baseline parameters of patients who participated in

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this study were well balanced between the two treatment groups. The primary efficacy endpoint of the study for the FDA was the proportion of subjects who achieved a greater than 2.0 grams per deciliter increase in hemoglobin at any time from baseline to week five. The primary efficacy endpoint of the study for the EU regulatory authorities was the mean change in hemoglobin from baseline to week five. Patients enrolled in this study were eligible to enter an ongoing open-label extension study to evaluate repeat dosing with *Feraheme*. We have completed enrollment in this extension study with 634 patients. These patients 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.

In our second of two Phase III studies, *Feraheme* demonstrated superiority on all primary efficacy endpoints evaluated and the efficacy and safety of *Feraheme* demonstrated in this study were comparable to that reported earlier this year in the first of our two Phase III trials in our global IDA registrational program, which compared *Feraheme* to iron sucrose. Patients treated with *Feraheme* in the second of our two Phase III trials achieved a statistically significant mean increase in hemoglobin at week five of 2.7 grams per deciliter, compared to a mean increase of only 0.1 grams per deciliter in patients who received placebo. These data are consistent with the 2.7 grams per deciliter increase in hemoglobin reported in the first of our two Phase III studies. In addition, a greater than 2.0 grams per deciliter increase in hemoglobin at any time from baseline to week five was achieved in a statistically significantly greater proportion, 81.1%, of patients treated with *Feraheme* in this study, compared with only 5.5% of patients who received placebo. These data are also consistent with the data from the first of our two Phase III trials, in which 84.0% of *Feraheme*-treated patients achieved a greater than 2.0 grams per deciliter increase in hemoglobin. Further, a statistically significant improvement in fatigue, as assessed by patient reported outcome measures, was demonstrated at week five in *Feraheme*-treated patients.

No new safety signals were observed with *Feraheme* in the second of our two Phase III trials and the types of reported AEs were consistent with those seen in both our previously reported IDA phase III study, our CKD phase III studies, and those contained in the approved U.S. package insert for *Feraheme*. Overall, AEs were reported in 49.2% of *Feraheme*-treated patients as compared to 43.0% of patients who received placebo. Patients in both groups experienced protocol-defined AEs of special interest, including mild to severe hypotension or hypersensitivity reactions ranging from fever alone to an anaphylactoid reaction. Of the *Feraheme*-treated patients, 3.6% experienced AEs of special interest compared to 1.0% of patients who received placebo. Cardiovascular AEs were reported in 0.8% of *Feraheme*-treated patients, all of which were considered unrelated to study drug by the investigators, and none were reported in the placebo group. SAEs were reported at a comparable frequency in both treatment groups, with SAEs reported in 2.6% of *Feraheme*-treated patients and 3.0% of patients who received placebo. Four of the SAEs in *Feraheme*-treated patients, or 0.7%, were reported as related to study drug by investigators. The percent of *Feraheme*-treated patients that experienced an SAE in this study, or 2.6%, was lower than that previously reported in the first of our two Phase III trials, or 4.2%, and was comparable to the rate of SAEs in iron sucrose-treated patients, or 2.5% in that study.

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 fourth quarter of 2012. In addition, we expect that in 2013 Takeda will file a Type II Variation, which is the equivalent of a sNDA in the U.S., with the European Medicines Agency, or EMA, seeking marketing approval for *Feraheme/Rienso* for the treatment of anemia in all adult patients with IDA with a history of unsatisfactory oral iron therapy.

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

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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 Marketing Authorization Application, or 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.

As part of our obligations under the Amended Takeda Agreement, we are also required to initiate a multi-center clinical trial to determine the safety and efficacy of repeat doses of ferumoxytol for the treatment of IDA in patients with hemodialysis dependent CKD. As part of the post-approval commitment we made to the EMA as a condition of the approval of our MAA for ferumoxytol in the EU, this study will be modified to include a treatment arm with iron sucrose as well as a magnetic resonance imaging, or MRI, study which will 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. 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, Takeda expects to initiate a Phase IIIb open-label, head-to-head, non-inferiority study to examine the efficacy and safety of two doses of 510 milligrams each of ferumoxytol compared with a one gram dose of an active comparator for the treatment of IDA in approximately 275 patients with non-dialysis dependent CKD. The cost of this trial will be allocated between us and Takeda according to the Amended Takeda Agreement. 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 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 half 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.

Other information

GastroMARK®, which has been 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. In the second quarter of 2012, we terminated our commercial license agreements for *GastroMARK*. Following the completion of our obligations under these agreements, we no longer intend to commercially manufacture or sell *GastroMARK*. Pursuant to the terms of the respective termination

agreements, during the three months ended June 30, 2012, we paid our licensees termination fees of $1.6 million, which we recorded in selling, general and administrative expenses in our condensed consolidated statement of operations.

In November 2011, we entered into an agreement with our financial advisor, Jefferies & Company, Inc., or Jefferies, or the Jefferies Agreement with respect to conducting a strategic review of our company. In connection with the conclusion of our strategic review, which we announced in May 2012, we terminated the Jefferies Agreement in July 2012. Pursuant to the terms of the Jefferies Agreement, we are required to pay Jefferies a transaction fee in the event that we enter into certain sale or acquisition transactions above a certain threshold on or prior to April 3, 2013 or such a transaction is consummated on or before such date. The fee would be determined based on the transaction value of the respective transaction but in no event be less than $1.5 million, depending on the nature of the transaction.

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Results of Operations

Three and six months ended June 30, 2012 and 2011

Revenues

Our total revenues for the three and six months ended June 30, 2012 and 2011 consisted of the following (in thousands):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2012	2011	$ Change	% Change	2012	2011	$ Change	% Change
Product sales, net	$ 14,420	$ 13,081	$ 1,339	10%	$ 28,128	$ 24,103	$ 4,025	17%
License fee and other collaboration revenues	16,592	2,288	14,304	>100%	$ 18,345	4,615	13,730	>100%
Royalties		33	(33)	-100%	$ 19	69	(50)	-72%
Total	$ 31,012	$ 15,402	$ 15,610	>100%	$ 46,492	$ 28,787	$ 17,705	62%

The $15.6 million increase in our total revenues during the three months ended June 30, 2012 as compared to the three months ended June 30, 2011 was primarily attributable to a $15.0 million milestone payment earned by us upon marketing approval by the European Commission in June 2012 and a $1.3 million increase in our net product sales, partially offset by a $0.7 million decrease in our other license fee and other collaboration revenues as compared to the three months ended June 30, 2011, as discussed in greater detail below.

The $17.7 million increase in our total revenues during the six months ended June 30, 2012 as compared to the same period in 2011 was primarily attributable to a $15.0 million milestone payment earned by us upon marketing approval by the European Commission in June 2012 and a $4.0 million increase in our net product sales, offset by a $1.3 million decrease in our other license fee and other collaboration revenues as compared to the six months ended June 30, 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 and six months ended June 30, 2012 and 2011.

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Takeda Pharmaceuticals Company Limited	54%	15%	40%	16%
AmerisourceBergen Drug Corporation	23%	41%	30%	40%
McKesson Corporation	11%	20%	14%	19%
Cardinal Health, Inc.	< 10%	12%	10%	12%

Net Product Sales

Net product sales for the three and six months ended June 30, 2012 and 2011 consisted of the following (in thousands):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2012	2011	$ Change	% Change	2012	2011	$ Change	% Change
Feraheme	$ 14,262	$ 12,846	$ 1,416	11%	$ 27,888	$ 23,707	$ 4,181	18%
GastroMARK	158	235	(77)	-33%	240	396	(156)	-39%
Total	$ 14,420	$ 13,081	$ 1,339	10%	$ 28,128	$ 24,103	$ 4,025	17%

Our total net product sales increased by $1.3 million and $4.0 million during the three and six months ended June 30, 2012, respectively, as compared to the same periods in 2011, primarily as the result of an increase in *Feraheme* provider demand in the three and six months ended June 30, 2012 and to a lesser extent, the impact of our May 2012 *Feraheme* price increase. In addition, during the three and six months ended June 30, 2012, we reduced our reserve for product returns by approximately $0.6 million and $1.1 million, respectively, due to the lapse of the return period as compared to no reductions of our reserve for product returns during 2011. Our gross product sales increased by $2.9 million and $7.6 million during the three and six months ended June 30, 2012, respectively, as compared to the same periods in 2011. However, we offered higher average customer discounts, chargebacks and rebates to our end-users during the three and six months ended June 30, 2012 as compared to the same periods in 2011, which partially offset the increase in gross product sales for the respective periods. During the three and six months ended June 30, 2012, we reduced our gross product sales by recording allowances of $8.2 million and $15.3 million, respectively, as compared to allowances of $6.7 million and $11.7 million recorded during the three and six months ended June 30, 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 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;

- The impact of any pricing strategies we may implement related to *Feraheme;*

- 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*;

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- 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 and six months ended June 30, 2012 and 2011 is as follows (in thousands):

	Three Months Ended June 30,	
	2012	2011
Product sales allowances and accruals		
Discounts and chargebacks	$ 6,846	$ 3,579
Government and other rebates	1,672	2,737
Returns	(292)	369
Total provision for product sales allowances and accruals	$ 8,226	$ 6,685
Total gross product sales	$ 22,646	$ 19,766
Total provision for product sales allowances and accruals as a percent of total gross product sales	36%	34%

	Six Months Ended June 30,	
	2012	2011
Product sales allowances and accruals		
Discounts and chargebacks	$ 12,738	$ 5,799
Government and other rebates	3,132	5,271
Returns	(558)	668
Total provision for product sales allowances and accruals	$ 15,312	$ 11,738
Total gross product sales	$ 43,440	$ 35,841
Total provision for product sales allowances and accruals as a percent of total gross product sales	35%	33%

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, group purchasing organizations, and dialysis organizations that typically do not purchase products directly from us but rather

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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.

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. Actual claims to date have been limited, and if we determine in future periods that such experience is indicative of expected claims, we may be required to reduce our current Medicaid accumulated reserve estimate, and that adjustment could be significant. Any such adjustments would be reflected as a reduction to our sales allowances and, accordingly, an increase to net product sales in that period. If actual future results vary from any of our estimates, we may need to adjust our previous estimates, which would also affect our earnings in the period of the adjustment.

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 half of 2012, we reduced our reserve for product returns by approximately $1.1 million due to the lapse of the product return period on certain manufactured *Feraheme* lots that carried a two year expiration. As a result, the product returns reserve applied to gross product sales for the three and six months ended June 30, 2012 was ($0.3) million and ($0.6) million, respectively, as compared to $0.4 million and $0.7 million for the three and six months ended June 30, 2011. Actual returns to date have been limited, and if we determine in future periods that such experience is indicative of expected returns, we may be required to reduce our accumulated product returns reserve estimate, and that adjustment could be significant. This adjustment would be reflected as a reduction to our sales allowances and, accordingly, an increase to net product sales in that period. If actual future results vary from any of our estimates, we may need to adjust our previous estimates, which would also affect our earnings in the period of the adjustment.

An analysis of the amount of, and change in, reserves for the six months ended June 30, 2012 and 2011 is as follows (in thousands):

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	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	12,738	3,226	531	16,495
Adjustments relating to sales in prior years		(94)	(1,089)	(1,183)
Payments/returns relating to sales in current year	(10,644)	(1,574)		(12,218)
Payments/returns relating to sales in prior years	(1,859)	(1,584)	(290)	(3,733)
Balance at June 30, 2012	$ 2,057	$ 3,075	$ 1,994	$ 7,126

	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	6,022	5,406	668	12,096
Other provisions relating to deferred revenue		(18)		(18)
Adjustments relating to sales in prior years	(223)	(135)		(358)
Payments/returns relating to sales in current year	(4,533)	(1,576)	(11)	(6,120)
Payments/returns relating to sales in prior years	(925)	(4,909)		(5,834)
Balance at June 30, 2011	$ 1,489	$ 6,986	$ 2,454	$ 10,929

During the six months ended June 30, 2012 and 2011, we decreased our product sales allowances and accruals by approximately $1.2 million and $0.4 million, respectively, for changes in estimates relating to sales in prior years. The $1.2 million adjustments in the first half of 2012 were primarily due to the reduction of our reserve for product returns of $1.1 million due to the lapse of the return period on certain manufactured *Feraheme* lots that carried a two year expiration. The $0.4 million adjustments in the first half of 2011 were primarily due to 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 continue to expire throughout the third quarter of 2012, and it is possible there will be additional reductions in our reserve for products returns 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 slightly 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. During the second quarter of 2012, we implemented the first gross price increase for *Feraheme* since its launch. We anticipate that the effect of the price increase will offset the impact of the widening gross to net adjustment and that the average net selling price of *Feraheme* will begin to increase in future periods.

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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;

- 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 and six months ended June 30, 2012 and 2011 consisted of the following (in thousands):

	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change

	2012	2011	$ Change	% Change	2012	2011	$ Change	% Change
Milestone revenues recognized from Takeda	$ 15,000	$	$ 15,000	N/A	$ 15,000	$	$ 15,000	N/A
Deferred license fee revenues recognized from Takeda	1,524	1,524			3,048	3,048		
Reimbursement revenues primarily from Takeda	68	764	(696)	-91%	297	1,567	(1,270)	-81%
Total	$ 16,592	$ 2,288	$ 14,304	>100%	$ 18,345	$ 4,615	$ 13,730	>100%

Most of our license fee and other collaboration revenues for the three and six months ended June 30, 2012 and 2011 related to revenue recognized under the Amended Takeda Agreement. In June 2012, we recorded $15.0 million of revenue associated with the milestone payment earned upon the marketing authorization granted for ferumoxytol by the European Commission. In addition, during each of the three and six months ended June 30, 2012 and 2011, we recorded $1.5 million and $3.0 million of revenues, respectively, associated with the amortization of $61.0 million of deferred revenues recorded in connection with the original 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 June 30, 2012, we had

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approximately $47.2 million remaining in deferred revenues related to the $61.0 million upfront payments received from Takeda.

In addition, under the terms of the Amended 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 offset the costs that we incur during the period in which we perform those services. During the three months ended June 30, 2012 and 2011, we recorded $0.1 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 Amended Takeda Agreement. During the six months ended June 30, 2012 and 2011, we recorded $0.3 million and $1.6 million, respectively, of revenues associated with the reimbursement of out-of pocket regulatory and clinical supply costs in connection with the Amended Takeda Agreement.

We anticipate that our license fee and other collaboration revenues will decrease for the remainder of 2012 due to our recording of $15.0 million in the first half of 2012 as a substantive milestone. In the second half of 2012 we expect to receive an additional $18.0 million in milestone payments from Takeda upon the commercial launch of *Feraheme/Rienso* in Canada and the EU. The $18.0 million non-substantive milestone payments will be recorded and amortized using the proportional performance method extended over the life of the Amended Takeda Agreement.

Costs and Expenses

Cost of Product Sales

Cost of product sales for the three and six months ended June 30, 2012 and 2011 consisted of the following (in thousands):

Cost of Product Sales	$ 3,224	$ 2,082	$ 1,142	55%	$ 5,870	$ 5,123	$ 747	15%		

Our cost of product sales are primarily comprised of manufacturing costs associated with *Feraheme*. Our cost of product sales increased by $1.1 million, or 55%, and $0.7 million, or 15%, respectively, during the three and six months ended June 30, 2012 as compared to the same periods in 2011. The $1.1 million and $0.7 million increases were primarily due to higher idle capacity charges during 2012 as compared to 2011, partially offset by a lower average production cost of certain vials sold in the first half of 2012 as compared to vials sold in the first half of 2011 due to the sale of certain inventory in the first half of 2012 that had lower associated carrying value because it was produced prior to regulatory approval. In addition, our cost of product sales for the three and six months ended June 30, 2012 includes $0.3 million in accelerated depreciation associated with our planned divestiture of our Cambridge, Massachusetts manufacturing facility. As of June 30, 2012, we determined that our manufacturing facility was not impaired and we classified the facility as held for use due to the fact that we were still manufacturing product. This charge, and additional charges expected to be incurred in the third quarter of 2012, reflect a change in the estimated useful life of the related assets in order to reduce the carrying value to what we believe is the best estimate of the net realizable value of the assets upon divestiture.

We expect our cost of product sales as a percentage of net product sales to increase slightly for the remainder of 2012.

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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.

Research and development expenses for the three and six months ended June 30, 2012 and 2011 consisted of the following (in thousands):

External Research and Development Expenses								
Feraheme to treat IDA in CKD patients	1,265	2,142	(877)	-41%	1,995	4,641	(2,646)	-57%
Feraheme manufacturing process development and materials	335	1,522	(1,187)	-78%	1,218	1,944	(726)	-37%
Total	$ 3,947	$ 11,939	$ (7,992)	-67%	$ 12,485	$ 20,691	$ (8,206)	-40%
Internal Research and Development Expenses								
Equity-based compensation expense	525	639	(114)	-18%	947	1,281	(334)	-26%

Total research and development expenses incurred in the three and six months ended June 30, 2012 decreased by $9.0 million, or 54%, and $10.1 million or 33%, respectively, as compared to the three and six months ended June 30, 2011. The $9.0 million and $10.1 million decreases were primarily due to reduced external costs related to our Phase III clinical development program for *Feraheme* to treat IDA regardless of the underlying cause, decreased clinical trial activity in our CKD related trials, and decreased costs associated with the establishment of alternative source manufacturing facilities and processes. In addition, the $9.0 million and $10.1 million decreases in total research and development expenses were 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 $8.0 million, or 67%, and $8.2 million, or 40%, for the three and six months ended June 30, 2012, respectively, as compared to the three and six months ended June 30, 2011. The decreases in our external expenses were due primarily to decreased costs incurred in connection with our Phase III clinical development program for *Feraheme* to treat IDA

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regardless of the underlying cause, 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.* In addition, our *Feraheme* manufacturing process development and materials costs decreased by $1.2 million and $0.7 million in the first three and six months of 2012 as compared to the same periods in 2011 due to decreased costs associated with alternative source manufacturing facilities and processes, partially offset by the 2012 write-off of inventory which was produced to validate the manufacturing process at a third-party supplier and which we no longer believed was suitable for sale.

Our internal research and development expenses decreased by $1.0 million, or 22%, and $1.9 million, or 20%, for the three and six months ended June 30, 2012, respectively, as compared to the same periods in 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.

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/Rienso* 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/Rienso* MAA by the EMA, such as the MRI trial discussed above, and as part of our obligations under the Amended Takeda Agreement, such as the head-to-head study 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, including a treatment arm with iron sucrose as well as a MRI study to evaluate the potential for iron to deposit in the body

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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; and (5) a Phase IIIb open-label, head-to-head, non-inferiority study to examine the efficacy and safety of treatment with ferumoxytol compared with treatment of an active comparator for the treatment of IDA in patients with non-dialysis dependent CKD.

Through June 30, 2012, we have incurred aggregate external research and development expenses of approximately $54.3 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 $7.0 to $12.0 million, the majority of which will be incurred by the end of 2012.

Through June 30, 2012, we have incurred aggregate external research and development expenses of approximately $22.8 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 $25.0 to $35.0 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 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/Rienso* in the CKD indication from the European Commission and HealthCanada, we have earned $15.0 million in milestone payments and expect that *Feraheme* will be launched commercially in Canada and the EU during 2012, at which point we will receive an aggregate of $18.0 million of additional milestone payments and we will begin receiving royalty payments in accordance with the Amended Takeda Agreement.

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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 and six months ended June 30, 2012 and 2011 consisted of the following (in thousands):

Compensation, payroll taxes and benefits	$ 6,151	$ 7,882	$ (1,731)	-22%	$ 12,958	$ 16,290	$ (3,332)	-20%
General and adminitsrtative consulting, professional fees, and other expenses	4,472	2,975	1,497	50%	7,129	5,899	1,230	21%
Total	$ 15,101	$ 16,826	$ (1,725)	-10%	$ 28,282	$ 36,460	$ (8,178)	-22%

Total selling, general and administrative expenses incurred in the three and six months ended June 30, 2012 decreased by $1.7 million, or 10%, and $8.2 million, or 22%, respectively, as compared to the same periods in 2011. Compensation, payroll taxes and benefits decreased by $1.7 million and $3.3 million, respectively, during the three and six months ended June 30, 2012 as compared to the same periods 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 $0.7 million and $2.8 million, respectively, during the three and six months ended June 30, 2012 as compared to the same periods in 2011 primarily due to reduced costs related to advertising and marketing materials, and certain other general marketing costs. Our general and administrative consulting, professional fees and other expenses increased by $1.5 million and $1.2 million, respectively, during the three and six months ended June 30, 2012 as compared to the same periods in 2011 primarily due to termination fee payments made to our *GastroMARK* licensees in connection with the termination of our commercial license agreements with them. The $0.8 million and $3.3 million decreases in equity-based compensation expenses for the three and six months ended June 30, 2012 were due primarily to a $0.8 million and $2.8 million, respectively, 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, the 2012 departure of our former General Counsel, and the impact of our November 2011 and June 2012 corporate workforce reductions, 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.

Restructuring Expense

In June 2012, we initiated a corporate restructuring, including a workforce reduction plan. The majority of the workforce reduction plan is expected to be associated with our manufacturing and development infrastructure. As a result of the restructuring, we expect to record charges of approximately $1.6 million. Of the $1.6 million, approximately $1.0 million is related to employee severance and benefits, of which $0.5 million was recognized during the second quarter of 2012 and the remaining $0.5

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million will be recognized in the second half of 2012. In addition, in connection with our decision to divest our Cambridge, Massachusetts manufacturing facility, we have recorded $0.6 million in restructuring charges related to the write-down of primarily raw material inventory that will no longer be usable upon the closure of the facility. We expect that the majority of our restructuring charges will be paid by the end of 2012.

In November 2011, we initiated a corporate restructuring, including a workforce reduction plan, which included a 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.

Other Income (Expense)

Other income (expense) for the three and six months ended June 30, 2012 and 2011 consisted of the following (in thousands):

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2012	2011	$ Change	% Change	2012	2011	$ Change	% Change
Interest and dividend income, net	$ 338	$ 452	$ (114)	-25%	$ 731	$ 1,012	$ (281)	-28%
Losses on investments, net	(1,471)	(209)	(1,262)	>100%	(1,471)	(208)	(1,263)	>100%
Total	$ (1,133)	$ 243	$ (1,376)	<(100)%	$ (740)	$ 804	$ (1,544)	<(100)%

Other income (expense) for the three and six months ended June 30, 2012 decreased by $1.4 million and $1.5 million, respectively, as compared to the three and six months ended June 30, 2011. These decreases were primarily attributable to the loss realized on the sale of our remaining $19.8 million par value ARS portfolio in June 2012 for proceeds of $18.3 million. In addition, there was a slight decrease in our interest and dividend income as the result of lower average cash balances in the first half of 2012 as compared to the same period in 2011.

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

Net Income (Loss)

For the reasons stated above, we earned net income of $3.3 million, or $0.16 per basic share and $0.15 per diluted share, for the three months ended June 30, 2012 and incurred a net loss of $9.1 million, or $0.43 per basic and diluted share, for the six months ended June 30, 2012 as compared to a net loss of $19.6 million and $41.9 million, or $0.92 and $1.98 per basic and diluted share, for the three and six months ended June 30, 2011.

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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 in and 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/Rienso* in its licensed territories outside of the U.S.;

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

- Our ability to obtain U.S. and EU regulatory approval for ferumoxytol to treat IDA regardless of the underlying cause;

- Our ability to achieve the various milestones and receive the associated payments under the Amended 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 qualifying additional manufacturing capacities and alternative suppliers;

- 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;

- The success, costs and structure of any business or corporate development initiatives to bring additional products into our portfolio;

- 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 June 30, 2012, our investments consisted of corporate debt securities, U.S. treasury and government agency securities, and commercial paper. We place our cash and investments in instruments

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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 June 30, 2012 and December 31, 2011 consisted of the following (in thousands):

	June 30, 2012	December 31, 2011	$ Change	% Change
Cash and cash equivalents	$ 30,678	$ 63,474	$ (32,796)	-52%
Short-term investments	176,571	148,703	27,868	19%
Long-term investments		17,527	(17,527)	-100%
Total	$ 207,249	$ 229,704	$ (22,455)	-10%

The $22.5 million decrease in cash, cash equivalents and investments as of June 30, 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 and June 2012 corporate restructurings, and reflects the receipt of a $15.0 million milestone payment from Takeda in July 2012 and the expected receipt of an additional aggregate of $18.0 million in milestone payments from Takeda during the remainder of 2012. We believe that our cash, cash equivalents, and short-term investments as of June 30, 2012 and the cash we currently expect to receive from sales of *Feraheme*, earnings on our investments, the $15.0 million milestone payment we received from Takeda in July 2012 and potential additional 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 June 2012, we initiated a corporate restructuring, including a workforce reduction plan. The majority of the workforce reduction plan is expected to be associated with our manufacturing and development infrastructure. As a result of the restructuring, we expect to record charges of approximately $1.6 million. Of the $1.6 million, approximately $1.0 million is related to employee severance and benefits, of which $0.5 million was recognized during the second quarter of 2012 and the remaining $0.5 million will be recognized in the second half of 2012. In addition, in connection with our decision to divest our Cambridge, Massachusetts manufacturing facility, we have recorded $0.6 million in restructuring charges related to the write-down of primarily raw material inventory that will no longer be usable upon the closure of the facility. We expect that the majority of our restructuring charges will be paid by the end of 2012.

In addition, in November 2011, we initiated a corporate restructuring, including a workforce reduction plan, which included a 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.

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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 six months ended June 30, 2012, our use of $22.0 million of cash in operations was attributable principally to our net loss of approximately $9.1 million, adjusted for the following:

- Non-cash operating items of $7.1 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 $3.3 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 increase of $10.2 million in accounts receivable, prepaid assets and inventories; and

- A decrease of $6.5 million in accounts payable and accrued expenses.

Our net loss of $9.1 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 $11.0 million during the six months ended June 30, 2012 and was primarily attributable to the purchases of investments partially offset by proceeds from the sales and maturities of our investments, including the recent sale of our remaining ARS portfolio.

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.

In November 2011, we entered into the Jefferies Agreement with our financial advisor Jefferies with respect to conducting a strategic review of our company. In connection with the conclusion of our strategic review, which we announced in May 2012, we terminated the Jefferies Agreement in July 2012. Pursuant to the terms of the Jefferies Agreement, we are required to pay Jefferies a transaction fee in the

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event that we enter into certain sale or acquisition transactions above a certain threshold on or prior to April 3, 2013 or such a transaction is consummated on or before such date. The fee would be determined based on the transaction value of the respective transaction but in no event be less than $1.5 million, depending on the nature of the transaction.

Off-Balance Sheet Arrangements

As of June 30, 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 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 June 30, 2012, our investments equaled $176.6 million and were invested in corporate debt securities, U.S. treasury and government agency securities, and commercial paper. These investments are subject to interest rate risk and will fall in value if market interest rates increase. However, even if market

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interest rates for comparable investments were to increase immediately and uniformly by 50 basis points, or one-half of a percentage point, from levels at June 30, 2012, this would have resulted in a hypothetical decline in fair value of our investments of approximately $1.0 million.

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 June 30, 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 Appeals for the First Circuit, or the Court of Appeals. After briefing was completed by all parties, the Court of Appeals heard oral argument on May 11, 2012, and took the matter under advisement.

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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/Rienso* 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/Rienso.* Accordingly, if we are unable to generate sufficient revenues from sales of *Feraheme/Rienso,* milestone payments and royalties we expect to receive related to *Feraheme/Rienso*, 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.

In addition, we have recently announced our intention to acquire or in-license other products as part of our strategy to expand our product portfolio and achieve profitability. There can be no assurance that once we identify an appropriate acquisition candidate, we will be able to successfully negotiate any such acquisition on favorable terms, if at all, or successfully integrate such an acquired product into our existing business. In addition, the in-licensing and acquisition of products is a competitive area, and many well-established companies are also pursuing strategies to in-license or acquire products that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. If we are unable to successfully obtain rights to suitable products or if any acquisition or in-license arrangement we make is not successful, our business, financial condition and prospects for growth could suffer.

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 June 30, 2012, we had an accumulated deficit of approximately $449.0 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

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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/Rienso* in Canada and the European Union, or EU, and royalties we may receive with respect to sales of *Feraheme/Rienso* in Canada and the EU under our License, Development and Commercialization Agreement, as amended in June 2012, or the Amended Takeda Agreement, which we originally 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/Rienso*. If we or Takeda are not successful in marketing and selling *Feraheme/Rienso*, 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 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.

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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/Rienso* 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/Rienso* 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/Rienso* 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/Rienso* may not be viewed as attractive as the pricing and/or reimbursement of alternative IV iron products. The degree of market acceptance of *Feraheme/Rienso* 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/Rienso*, the clinical efficacy and safety of *Feraheme/Rienso* 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/Rienso* 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/Rienso* compared to alternative iron replacement therapeutic agents, particularly if unanticipated adverse reactions to *Feraheme/Rienso* result in further changes to or restrictions in the *Feraheme/Rienso* package insert and/or otherwise create safety concerns among potential prescribers;

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

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- 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/Rienso* as compared to alternative iron replacement therapeutic agents;

- The actual or perceived convenience and ease of administration of *Feraheme/Rienso* 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.

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/Rienso* 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/Rienso*, 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

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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/Rienso* 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 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/Rienso* to be profitable in those countries. Any such limitations on the reimbursement for *Feraheme/Rienso* in countries outside of the U.S. would have an adverse impact on Takeda s ability to generate product sales of

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Feraheme/Rienso 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/Rienso, the commercial opportunity for Feraheme/Rienso 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/Rienso* commercial opportunity will be reduced or eliminated if our competitors develop, commercialize, 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/Rienso*.

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 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/Rienso 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

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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 40 countries worldwide, 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/Rienso* 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/Rienso,* 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/Rienso* to be approved only for use in CKD patients, which could put *Feraheme/Rienso* 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 September 2011, Luitpold submitted an NDA to the FDA seeking marketing approval for Injectafer® for the treatment of IDA. On July 26, 2012, Luitpold received a Complete Response letter from the FDA withholding approval of Injectafer due to issues related to Luitpold s U.S. manufacturing facility. 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/Rienso* 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/Rienso*, 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/Rienso* 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 anemia in a broader group of patients than *Feraheme/Rienso*. 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/Rienso*. If we or Takeda are not able to differentiate *Feraheme/Rienso*

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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.

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 restructurings, 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, as well as additional positions associated with our June 2012 restructuring. These workforce reductions 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.

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 a 25% reduction in positions and the departure of our then chief executive officer and our chief commercial officer. In addition, in June 2012, we announced our plan to reduce our workforce by the end of 2012. We hired William Heiden as our Chief Executive Officer in May 2012, however, the uncertainty regarding our November 2011 and June 2012 workforce reductions, other 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/Rienso 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/Rienso in the licensed territories, or if our collaboration is terminated, our plans to commercialize Feraheme/Rienso outside of the U.S. may be adversely affected.

In March 2010 and as amended in June 2012,we entered into the Amended Takeda Agreement with Takeda, under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme/Rienso* as a therapeutic agent in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey, or collectively, the Amended Licensed Territory. We are highly

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dependent on Takeda for certain regulatory filings outside of the U.S. with respect to *Feraheme/Rienso* and the commercialization of *Feraheme/Rienso* outside of the U.S., including in Canada and the EU. If Takeda fails to perform its obligations under the Amended Takeda Agreement, delays the commercial launch of *Feraheme/Rienso* in the Amended Licensed Territory, or is ineffective in its commercialization of *Feraheme/Rienso* in the Amended 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/Rienso* and our *Feraheme/Rienso* 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 Amended Takeda Agreement. Further, if we fail to fulfill certain of our obligations under the Amended Takeda Agreement, Takeda has the right to assume the responsibility of clinical development of *Feraheme/Rienso* in the Amended Licensed Territory, which would increase the cost of and delay the *Feraheme/Rienso* development program outside of the U.S.

Takeda has the unilateral right to terminate the Amended 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/Rienso* in the Amended 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 Amended Takeda Agreement.

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

Our recent restructuring plans 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,

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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 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. For example, in May 2012, the FDA conducted an on-site inspection of our Cambridge, Massachusetts facility. Following the inspection we received a Form 483 which included the inspector s observations concerning certain of our quality, manufacturing and facilities and equipment systems, none of these observations were considered critical observations. Although we do not believe that these observations rise to the level of additional regulatory action, we cannot be assured that the FDA will be satisfied with our corrective actions. 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

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

We expect to manufacture *Feraheme* drug substance and drug product for use in the EU market at certain of our third-party contract manufacturers. We currently manufacture *Feraheme* drug substance and drug product for use in the Canadian market at our Cambridge facility. In June 2012, we announced our plans to move to an outsourced manufacturing model and sell our Cambridge, Massachusetts manufacturing facility. Although we are working to establish and qualify additional alternative source manufacturing facilities for the production of *Feraheme* for Canada, we will not have such alternative source manufacturing facilities available upon initial commercial launch of *Feraheme/Rienso* in this geography.

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 Amended 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

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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.

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 our 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 both March and July 2012 we announced results from each 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

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our clinical trials, including the recently announced results from both 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 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, in June 2012 the European Commission granted marketing authorization for ferumoxytol for the treatment of IDA in CKD patients. As a condition of approval, we are required to perform certain studies for the CKD indication in the EU that were not required for the U.S. approval of ferumoxytol for the treatment of IDA in CKD patients.

In addition, in both March and July 2012 we announced results from each 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 of 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 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.

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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 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 have implemented or 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;

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

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

- 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;

- 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;

- 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. Three customers accounted for 84% of our total revenues during the six months ended June 30, 2012 and three customers accounted for 93% of our accounts receivable balance at June 30, 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 32% of our end-user demand in the first half 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

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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.

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 $12.43 and $19.62 in the fifty-two week period through July 30, 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

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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;

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

- 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, product or business acquisition, joint venture or similar agreements by us or our competitors;

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

- 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, eight 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. 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 Amended Takeda Agreement on *Feraheme* sales outside of the U.S.;

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

- Our ability to achieve the various milestones and receive the associated payments under the Amended 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;

- The timing and magnitude of costs associated with qualifying additional manufacturing capacities and alternative suppliers;

- 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;

- The success, costs and structure of any business or corporate development initiatives to bring additional products into our portfolio;

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- 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 June 30, 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 June 30, 2012, we had $30.7 million in cash and cash equivalents and $176.6 million in short-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.

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. 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

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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 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.

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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 third-party contract 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 or our third-party contract manufacturers. 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.

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/Rienso 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

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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.

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. For example, 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 efforts by activist shareholders may require the expenditure of significant time and resources by us and may be a significant distraction for our management and employees. The impact of activist shareholders efforts due to these or other factors may undermine our business and have a material adverse effect on our results of operations.

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; and

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- 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*.

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

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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 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. After briefing was completed by all parties, the Court of Appeals heard oral argument on May 11, 2012, and took the matter under advisement. 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.

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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, which was amended in May 2012, 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 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 25% with respect to a particular shareholder) 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% (or 25% with respect to a particular shareholder) 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;

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- 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 Therapeutics, Inc., or 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.

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 June 30, 2012.

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Item 6. Exhibits

(a) List of Exhibits

Exhibit Number		Description
4.1		Amendment to Rights Agreement, dated May 10, 2012, by and between the Company and American Stock Transfer & Trust Company LLC (incorporated herein by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K filed May 10, 2012).
10.1		Employment Agreement, dated May 6, 2012, by and between the Company and William K. Heiden (incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed May 10, 2012).
10.2		Form of Non-Plan Restricted Stock Unit Agreement, by and between the Company and William K. Heiden (incorporated herein by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K filed May 10, 2012).
10.3		Form of Non-Plan Stock Option Agreement, by and between the Company and William K. Heiden (incorporated herein by reference to Exhibit 10.3 to the Company s Current Report on Form 8-K filed May 10, 2012).
10.4		Letter Agreement, dated May 9, 2012, by and between the Company and Frank Thomas (incorporated herein by reference to Exhibit 10.4 to the Company s Current Report on Form 8-K filed May 10, 2012).
10.5		Stockholder Agreement, May 9, 2012, by and between the Company and Adage Capital Management, L.P. (incorporated herein by reference to Exhibit 10.5 to the Company s Current Report on Form 8-K filed May 10, 2012).
10.6		Amendment to the License, Development and Commercialization Agreement, dated June 25, 2012, by and between the Company and Takeda Pharmaceutical Company Limited (incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed June 29, 2012) (Portions of this exhibit have been omitted pursuant to a request for confidential treatment filed with the Securities and Exchange Commission).
10.7		Option Agreement under the Company s Second Amended and Restated 2007 Equity Incentive Plan between the Company and Lee F. Allen, dated as of June 25, 2012 (incorporated herein by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K filed June 29, 2012).
10.8		Option Agreement under the Company s Second Amended and Restated 2007 Equity Incentive Plan between the Company and Christopher G. White, dated as of June 25, 2012 (incorporated herein by reference to Exhibit 10.3 to the Company s Current Report on Form 8-K filed June 29, 2012).
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 June 30, 2012, formatted in XBRL (Extensible Business Reporting Language), (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.

+ 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/ William K. Heiden
William K. Heiden
President and Chief Executive Officer

Date: August 7, 2012

AMAG PHARMACEUTICALS, INC.

By: /s/ Scott A. Holmes
Scott A. Holmes
Chief Accounting Officer,

Vice President and Controller

Date: August 7, 2012

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