AMAG PHARMACEUTICALS INC.
Form 10-Q
August 05, 2010
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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, 2010

OR

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

For the transition period from to

Commission File Number 0-14732

AMAG PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

(617) 498-3300

(Registrant s Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). **Yes** 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 the definitions of large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

Yes o **No** x

As of August 2, 2010 there were 21,050,459 shares of the registrant s Common Stock, par value $.01 per share, outstanding.

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AMAG PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

AMAG PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

(Unaudited)

	June 30, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 135,793	$ 50,126
Short-term investments	153,337	29,578
Settlement rights		788
Accounts receivable, net	14,230	27,350
Inventories	15,431	9,415
Receivable from collaboration	1,029	
Prepaid and other current assets	4,930	5,472
Total current assets	324,750	122,729
Property, plant and equipment, net	11,886	12,417
Long-term investments	38,876	49,013
Restricted cash	460	460
Total assets	$ 375,972	$ 184,619
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,855	$ 5,432
Accrued expenses	27,548	21,931
Deferred revenues	12,367	10,198
Total current liabilities	43,770	37,561
Long-term liabilities:		
Deferred revenues	53,500	1,000
Other long-term liabilities	2,936	3,081
Total liabilities	100,206	41,642
Commitments and contingencies (Note K & L)		
Stockholders equity:		
Preferred stock, par value $0.01 per share, 2,000,000 shares authorized; none issued		
Common stock, par value $0.01 per share, 58,750,000 shares authorized; 21,044,872 and 17,362,710 shares issued and outstanding at June 30, 2010 and December 31, 2009, respectively	210	174
Additional paid-in capital	609,128	432,414
Accumulated other comprehensive loss	(7,509)	(7,925)
Accumulated deficit	(326,063)	(281,686)
Total stockholders equity	275,766	142,977
Total liabilities and stockholders equity	$ 375,972	$ 184,619

The accompanying notes are an integral part of the 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,	
	2010	2009	2010	2009
Revenues:				
Product sales, net	$ 16,226	$	$ 29,521	$ 393
License fee and other collaboration revenues	2,529		2,529	516
Royalties	72	55	83	102
Total revenues	18,827	55	32,133	1,011
Costs and expenses:				
Cost of product sales	1,884		2,894	61
Research and development expenses	14,784	10,114	27,152	21,186
Selling, general and administrative expenses	24,004	17,268	47,460	35,018
Total costs and expenses	40,672	27,382	77,506	56,265
Other income (expense):				
Interest and dividend income, net	404	783	875	2,039
Gains on investments, net	794	275	798	1,267
Fair value adjustment of settlement rights	(788)	(185)	(788)	(1,108)
Total other income (expense)	410	873	885	2,198
Net loss before income taxes	(21,435)	(26,454)	(44,488)	(53,056)
Income tax benefit	111		111	179
Net loss	$ (21,324)	$ (26,454)	$ (44,377)	$ (52,877)
Net loss per share:				
Basic and diluted	$ (1.01)	$ (1.55)	$ (2.16)	$ (3.10)
Weighted average shares outstanding used to compute net loss per share:				
Basic and diluted	21,017	17,038	20,504	17,030

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

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AMAG PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(IN THOUSANDS)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Net loss	$ (21,324)	$ (26,454)	$ (44,377)	$ (52,877)
Other comprehensive income (loss):				
Unrealized gains (losses) on securities:				
Holding (losses) gains arising during period, net of tax	552	1,512	416	3,713
Reclassification adjustment for losses and gains, net, included in net loss		1		5
Net unrealized (losses) gains	552	1,513	416	3,718
Total comprehensive loss	$ (20,772)	$ (24,941)	$ (43,961)	$ (49,159)

The accompanying notes are an integral part of the 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,	
	2010	**2009**
Net loss	$ (44,377)	$ (52,877)
Cash flows from operating activities:		
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	1,174	883
Non-cash equity-based compensation expense	9,236	7,625
Non-cash income tax benefit	(111)	
Amortization of premium/discount on purchased securities	258	357
Fair value adjustment of settlement rights	788	1,108
Gains on investments, net	(798)	(1,267)
Changes in operating assets and liabilities:		
Accounts receivable	13,120	408
Inventories	(5,787)	34
Receivable from collaboration	(1,029)	
Prepaid and other current assets	542	1,644
Accounts payable and accrued expenses	3,929	(215)
Deferred revenues	54,669	(516)
Other long-term liabilities	(145)	52
Total adjustments	75,846	10,113
Net cash provided by (used in) operating activities	31,469	(42,764)
Cash flows from investing activities:		
Proceeds from sales or maturities of available-for-sale investments	67,475	49,105
Purchase of available-for-sale investments	(179,919)	(310)
Capital expenditures	(643)	(852)
Change in restricted cash		61
Net cash (used in) provided by investing activities	(113,087)	48,004
Cash flows from financing activities:		
Proceeds from the exercise of stock options	1,084	225
Proceeds from the issuance of common stock, net of underwriting discount and other expenses	165,559	
Proceeds from the issuance of common stock under ESPP	642	579
Net cash provided by financing activities	167,285	804
Net increase in cash and cash equivalents	85,667	6,044
Cash and cash equivalents at beginning of the period	50,126	64,182
Cash and cash equivalents at end of the period	$ 135,793	$ 70,226

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

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AMAG PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2010

(Unaudited)

A. Description of Business

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a biopharmaceutical company that utilizes our proprietary technology for the development and commercialization of a therapeutic iron compound to treat iron deficiency anemia, or IDA, and novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. We currently manufacture and sell two approved products, Feraheme® (ferumoxytol) Injection for intravenous, or IV, use and GastroMARK®.

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

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

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

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

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B. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

These condensed consolidated financial statements are unaudited and, in the opinion of management, include all adjustments necessary for a fair statement of the financial position and results of operations of the Company for the interim periods presented. Such adjustments consisted only of normal recurring items. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America.

In accordance with accounting principles generally accepted in the United States of America for interim financial reports and the instructions for Form 10-Q and the rules of the Securities and Exchange Commission, certain information and footnote disclosures normally included in annual financial statements have been condensed or omitted. Our accounting policies are described in the Notes to the Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2009. Interim results are not necessarily indicative of the results of operations for the full year. These interim financial statements should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2009.

Use of Estimates and Assumptions

The preparation of condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The most significant estimates and assumptions are used in, but are not limited to, revenue recognition related to collaboration agreements and product sales, product sales allowances and accruals, assessing investments for potential other-than-temporary impairment and determining values of investments, reserves for doubtful accounts, accrued expenses, income taxes and equity-based compensation expense. Actual results could differ materially from those estimates.

Principles of Consolidation

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

Fair Value of Financial Instruments

Under current accounting standards, fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

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

Current accounting guidance establishes a hierarchy used to categorize how fair value is measured and which is based on three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

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

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

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

We hold, or held during the period, certain assets that are required to be measured at fair value on a recurring basis, including our cash equivalents, short- and long-term investments and our Settlement Rights, as defined below. The following tables present the fair value hierarchy for those assets that we measure at fair value on a recurring basis as of June 30, 2010 and December 31, 2009 (in thousands):

	Fair Value Measurements at June 30, 2010 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 124,980	$ 124,980	$	$
Corporate debt securities	55,617		55,617	
U.S. treasury and government agency securities	57,316		57,316	
Commercial paper	40,404		40,404	
Auction rate securities	38,876			38,876
	$ 317,193	$ 124,980	$ 153,337	$ 38,876

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	Total	Fair Value Measurements at December 31, 2009 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	$ 46,451	$ 46,451	$	$
Corporate debt securities	9,804		9,804	
U.S. treasury and government agency securities	11,247		11,247	
Auction rate securities	57,540			57,540
Settlement rights	788			788
	$ 125,830	$ 46,451	$ 21,051	$ 58,328

With the exception of our auction rate securities, or ARS, and Settlement Rights, which are valued using Level 3 inputs, as discussed below, the fair value of our non-money market fund investments is primarily determined from independent pricing services which use Level 2 inputs 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 fair value. At the end of each reporting period, we perform quantitative and qualitative analyses on prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analyses, we did not adjust or override any fair value measurements provided by our pricing services as of June 30, 2010 or December 31, 2009. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the six months ended June 30, 2010.

We also analyze when the volume and level of activity for an asset or liability have significantly decreased and when circumstances indicate that a transaction may not be considered orderly. In order to determine whether the volume and level of activity for an asset or liability have significantly decreased, we assess current activity with normal market activity for the asset or liability. We rely on many factors such as trading volume, trading frequency, the levels at which market participants indicate their willingness to buy and sell our securities as reported by market participants, and current market conditions. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if there has been a significant decrease in the volume and level of activity for an asset or group of similar assets. Similarly, in order to identify transactions that are not orderly, we take into consideration the activity in the market which can influence the determination and occurrence of an orderly transaction. Also, we inquire as to whether there may have been restrictions on the marketing of the security to a single or limited number of participants. Where possible, we assess the financial condition of the seller to determine whether observed transactions may have been forced. If there is a significant disparity between the trading price for a security held by us as compared to the trading prices of similar recent transactions, we consider whether this disparity is an indicator of a disorderly trade. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if the evidence suggests that a transaction or group of similar transactions is not orderly. Based upon these procedures, we determined that market activity for our non-ARS assets appeared normal and that transactions did not appear disorderly as of June 30, 2010.

In November 2008, we elected to participate in a rights offering by UBS AG, or UBS, one of our securities brokers, which provided us with rights to sell to UBS $9.3 million in par value of our ARS portfolio, at par value, at any time during a two-year sale period beginning June 30, 2010, or the Settlement Rights. In November 2008, we elected the fair value option with respect to our Settlement Rights in accordance with accounting guidance related to the fair value option for financial assets and

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financial liabilities. Under this guidance we were required to periodically assess the fair value of both the Settlement Rights and our ARS subject to Settlement Rights and record changes until the date when the Settlement Rights were exercised and our ARS subject to Settlement Rights were redeemed. In accordance with the terms of the Settlement Rights, during the three months ended June 30, 2010 UBS redeemed all of our ARS subject to Settlement Rights at their par value. As a result, during the three months ended June 30, 2010 we recognized both a realized gain of $0.8 million related to the redemption of our UBS ARS subject to Settlement Rights and a corresponding realized loss of $0.8 million related to the exercise of the Settlement Rights.

The following table presents assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) as of June 30, 2010 (in thousands):

		Six Months Ended June 30, 2010
Balance at beginning of period	$	58,328
Transfers to Level 3		
Total gains (losses) (realized or unrealized):		
Included in earnings		10
Included in other comprehensive income (loss)		713
Purchases (settlements), net		(20,175)
Balance at end of period	$	38,876
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	$	10

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

Revenue Recognition

Net Product Sales

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

- persuasive evidence of an arrangement exists;

- delivery of product has occurred or services have been rendered;

- the sales price charged is fixed or determinable; and

- collection is reasonably assured.

Because we only recently launched *Feraheme* in the U.S., there are a number of factors that make it difficult to predict the magnitude of future *Feraheme* sales, including but not limited to, the magnitude and timing of adoption of *Feraheme* by physicians, dialysis clinics, hospitals and other healthcare payors and providers, the effect of federal and other legislation such as the recent healthcare legislation and final

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Centers for Medicare & Medicaid Services rule regarding the prospective payment system, the inventory levels maintained by *Feraheme* wholesalers, distributors and other customers, the frequency of re-orders by existing customers, the timing and magnitude of revenues recognized under our Launch Incentive Program, 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*.

We record product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and other rebates, distributor, wholesaler and group purchasing organization, or GPO, fees, and product returns as a reduction of revenue in our condensed consolidated statement of operations at the time the product sales are recorded. Calculating these gross-to-net sales adjustments involves estimates and judgments based primarily on actual *Feraheme* sales data, forecasted customer buying patterns blended with historical experience of products similar to *Feraheme* sold by others, and other market research. In addition, we also monitor our distribution channel to determine the level of additional allowances or accruals required based on inventory in our sales channel. There were no product sales allowances or accruals for the three and six months ended June 30, 2009. An analysis of our product sales allowances and accruals for the three and six months ended June 30, 2010 is as follows (in thousands):

	Three Months Ended June 30, 2010	Six Months Ended June 30, 2010
Product sales allowances and accruals:		
Discounts and chargebacks	$ 1,075	$ 1,817
Government and other rebates	4,533	7,534
Returns	333	577
Total product sales allowances and accruals	$ 5,941	$ 9,928
Total net product sales	$ 16,226	$ 29,521
Total gross product sales	$ 22,167	$ 39,449
Total product sales allowances and accruals as a percent of total gross product sales	27%	25%

Product sales allowances and accruals are primarily comprised of both direct and indirect fees, discounts and rebates and provisions for estimated product returns. Direct fees, discounts and rebates are contractual fees and price adjustments payable to wholesalers, specialty distributors and other customers that purchase products directly from us. Indirect fees, discounts and rebates are contractual price adjustments payable to healthcare providers and organizations, such as certain dialysis organizations, physicians, clinics, hospitals, and GPOs that typically do not purchase products directly from us but rather from wholesalers and specialty distributors. In accordance with guidance related to accounting for fees and consideration given by a vendor to a customer (including a reseller of a vendor s products), these fees, discounts and rebates are presumed to be a reduction of the selling price of *Feraheme*. Product sales allowances and accruals are based on definitive contractual agreements or legal requirements (such as Medicaid laws and regulations) related to the purchase and/or utilization of the product by these entities. These allowances and accruals are generally recorded in the same period that the related revenue is recognized and are estimated using either historical, actual and/or other data, including estimated patient usage, applicable contractual rebate rates, contract performance by the benefit providers, other current contractual and statutory requirements, historical market data based upon experience of other 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, including the shelf life of *Feraheme*. As part of this evaluation, we also review changes to federal and other

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legislation, changes to rebate contracts, changes in the level of discounts, and changes in product sales trends. Reserve estimates are evaluated quarterly and may require adjustments to better align our estimates with actual results.

During the six months ended June 30, 2010, our product sales allowances and accruals reflected an increase in statutory minimum rebate rates related to Medicaid allowances from 15.1% to 23.1% pursuant to healthcare legislation enacted in March 2010. In addition, we reduced our product sales allowances and accruals by $0.4 million for changes in estimates relating to sales in the prior year. These adjustments were primarily caused by a reduction during the three months ended March 31, 2010 in our estimates of Medicaid utilization across *Feraheme* customer classes based on additional data, including information regarding Medicaid claims experience for comparable products. Although allowances and accruals are recorded at the time of product sale, certain rebates are typically paid out, on average, up to six months or longer after the sale. If actual future results vary from our estimates, we may need to adjust our previous estimates, which would affect our earnings in the period of the adjustment.

Deferred Revenue - Launch Incentive Program

During the third quarter of 2009, certain dialysis organizations purchased *Feraheme* from us under our Launch Incentive Program. These purchases were made under agreements which provided these customers with an opportunity to purchase *Feraheme* through September 30, 2009 at discounted pricing and further provided for extended payment terms and expanded rights of return. As a result, in accordance with current accounting guidance which requires that we defer recognition of revenues until we can reasonably estimate returns related to those purchases, we have deferred the recognition of revenues associated with these purchases until our customers report to us that such inventory has been utilized in their operations. Any purchases returned to us will not be recorded as revenue. As of June 30, 2010, we have a remaining balance of $5.9 million in deferred revenues associated with *Feraheme* purchased under the Launch Incentive Program and which remained held by the dialysis organizations at June 30, 2010, net of any applicable discounts and estimated rebates, which are included in our commercial rebate accruals as of June 30, 2010.

During the three months ended June 30, 2010, we agreed to extend the payment terms of the outstanding balance due from one of our customers who participated in the Launch Incentive Program. This customer has informed us that its rate of *Feraheme* utilization has been less than originally anticipated and that it will return to us any unused inventory by year end. As of June 30, 2010, this customer held *Feraheme* inventory representing approximately $3.5 million of net *Feraheme* revenues, which is currently recorded as deferred revenues in our condensed consolidated balance sheet.

We are unable to reasonably estimate the amount of inventory that may be returned under this program, as well as the timing of any such returns. Therefore, we cannot provide any assurance that any amounts currently reported as deferred revenue will be utilized by our customers and thereby recorded as product revenues in our future condensed consolidated statements of operations.

License Fee and Other Collaboration Revenues

The terms of product development agreements entered into between us and our collaborative partners may include non-refundable license fees, payments based on the achievement of certain milestones and performance goals, reimbursement of certain out-of-pocket costs, payments for manufacturing services, and royalties on product sales. We recognize license fee and research and development revenue under collaborative

arrangements over the term of the applicable agreements using a proportional performance model, if practical, otherwise, we recognize such revenue on a straight-line basis. Under

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this model, revenue is generally recognized in an amount equal to the lesser of the amount due under the agreements or the amount based on the proportional performance to date. In cases where project costs or other performance metrics are not estimable but there is an established contract period, revenues are recognized on a straight-line basis over the term of the relevant agreement. Nonrefundable payments and fees are recorded as deferred revenue upon receipt and may require deferral of revenue recognition to future periods.

Multiple Element Arrangements and Milestone Payments

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

When multiple deliverables are combined and accounted for as a single unit of accounting, we base our revenue recognition pattern on the last to be delivered element. Revenue will be recognized using either a proportional performance or straight-line method, depending on whether we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and whether such performance obligations are provided on a best-efforts basis. To the extent we cannot reasonably estimate our performance obligations, we recognize revenue on a straight-line basis over the period we expect to complete our performance obligations.

Our collaboration arrangements may entitle us to additional payments upon the achievement of performance-based milestones. Milestones that involve substantive effort on our part and the achievement of which are not considered probable at the inception of the collaboration are considered substantive milestones. We recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets the following criteria: (1) the consideration received is commensurate with either the level of effort required to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone; (2) the milestone is related solely to past performance; and (3) the milestone is reasonable relative to all deliverables and payment terms in the arrangement. For milestones that are not considered substantive milestones at the onset of the agreement, we recognize the milestone when the conditions are met by recognizing immediately the portion of the milestone payment equal to the percentage of the performance period completed when the milestone is achieved. The remaining portion of the milestone will be recognized over the remaining performance period using a proportional performance or straight-line method.

Concentrations and Significant Customer Information

As of June 30, 2010 we had approximately $69.6 million and $44.5 million of our total $135.8 million cash and cash equivalents balance invested in two institutional money market funds, both of which are collateralized solely by U.S. Treasury and U.S. government agency securities.

Our operations are located solely within the U.S. We are focused principally on developing, manufacturing and commercializing an IV iron replacement therapeutic agent and novel imaging agents. We perform ongoing credit evaluations of our customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our revenues for the six months ended June 30, 2010 and

2009.

	Six Months Ended June 30,	
	2010	2009
AmerisourceBergen Drug Corporation	30%	
Metro Medical Supply, Inc.	26%	
Guerbet S.A.	<10%	31%
Covidien Public Limited Company	<10%	17%
Bayer Healthcare Pharmaceuticals	<10%	52%

Revenues from customers outside of the U.S. amounted to approximately 9.0% and 31.0% of our total revenues for the six months ended June 30, 2010 and 2009, respectively.

Subsequent Events

We did not have any material recognizable subsequent events.

C. Investments

At June 30, 2010 and December 31, 2009, the combined total of our short- and long-term investments was $192.2 million and $78.6 million, respectively, and consisted of securities classified as trading and

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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 at June 30, 2010 and December 31, 2009 (in thousands):

	June 30, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	$ 17,534	$ 26	$ (45)	$ 17,515
Due in one to three years	38,104	61	(63)	38,102
U.S. treasury and government agency securities				
Due in one year or less	27,318	79		27,397
Due in one to three years	29,707	212		29,919
Commercial paper				
Due in one year or less	40,448		(44)	40,404
Due in one to three years				
Total short-term investments	$ 153,111	$ 378	$ (152)	$ 153,337
Long-term investments:				
Auction rate securities - available for sale				
Due in one year or less	$	$	$	$
Due after five years	45,300		(6,424)	38,876
Total long-term investments	$ 45,300	$	$ (6,424)	$ 38,876
Total short and long-term investments	$ 198,411	$ 378	$ (6,576)	$ 192,213

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

Auction Rate Securities and UBS Settlement Rights

At June 30, 2010, we held a total of $38.9 million in fair market value of ARS, reflecting a decline in value of approximately $6.4 million compared to the par value of these securities of $45.3 million. The $6.4 million difference was considered a temporary impairment and was reported as an unrealized loss in accumulated other comprehensive loss at June 30, 2010. At June 30, 2010, all of our ARS were municipal bonds with an auction reset feature and were classified as available-for-sale. The majority of our ARS portfolio was rated AAA as of June 30, 2010 by at least one of the major securities rating agencies and was primarily collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program. In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions. As a result of the lack of observable ARS market activity since that time, we use a discounted cash flow analysis to value these securities as opposed to valuing them at par value. Our valuation analysis considers, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, credit ratings of the security by the major securities rating agencies, the ability or inability to sell the investment in an active market, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when call features may be exercised by the issuer. Based upon this methodology, we have estimated the fair value of our ARS to be $38.9 million at June 30, 2010, and have recorded a $6.4 million unrealized loss to accumulated other comprehensive loss as of June 30, 2010. As discussed in greater detail below, for all available-for-sale debt securities with unrealized losses, management performs an analysis to assess whether we intend to sell or whether we would more likely than not be

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required to sell the security before the expected recovery of the amortized cost basis. In the event that we intend to sell a security, or may be required to do so, the decline in fair value of the security would be deemed to be other-than-temporary and the full amount of the unrealized loss would be recorded in our condensed consolidated statement of operations as an impairment loss. Regardless of our intent to sell a security, we perform additional analyses on all securities with unrealized losses to evaluate whether there could be a credit loss associated with the security. We did not recognize any credit losses related to our securities during the three and six months ended June 30, 2010. As of June 30, 2010, all of our ARS continue to pay interest according to their stated terms.

In November 2008, we elected to participate in a rights offering by UBS which provided us with rights to sell to UBS $9.3 million in par value of our ARS portfolio, at par value, at any time during a two-year sale period beginning June 30, 2010. In accordance with the terms of the Settlement Rights, during the three months ended June 30, 2010 UBS redeemed all of our ARS subject to Settlement Rights at their par value. As a result, during the three months ended June 30, 2010, we recognized both a realized gain of $0.8 million related to the redemption of our UBS ARS subject to Settlement Rights and a corresponding realized loss of $0.8 million related to the exercise of the Settlement Rights.

Due to our belief that the market for ARS may take in excess of twelve months to fully recover, we have classified our portfolio of ARS as long-term investments in our condensed consolidated balance sheet at June 30, 2010. As discussed in greater detail below, we believe that the temporary impairment related to our ARS is primarily attributable to the lack of liquidity of these investments, coupled with the ongoing turmoil in the credit and capital markets, and we have no reason to believe that any of the underlying issuers of our ARS are presently at risk of default. Any future fluctuation in fair value related to our ARS that we deem to be temporary, including any recoveries of previous write-downs, would be recorded to accumulated other comprehensive loss. If we determine that any future unrealized loss is other-than-temporary, we will record a charge to our condensed consolidated statement of operations. In the event that we need to access our investments in these securities, we will not be able to do so until a future auction is successful, the issuer calls the security pursuant to a mandatory tender or redemption prior to maturity, a buyer is found outside the auction process, or the securities mature. For example, during the three months ended June 30, 2010, in addition to UBS calling $9.3 million of our ARS at par value, as noted above, two separate issuers of our ARS not subject to Settlement Rights repurchased from us an aggregate of $10.0 million of our ARS at par value. For all of our ARS, the underlying maturity date is in excess of one year, and the majority have final maturity dates which occur approximately 30 to 40 years in the future. We believe we will ultimately be able to liquidate our investments without significant loss prior to their maturity dates primarily due to the collateral securing most of our ARS. However, it could take until final maturity of the ARS to realize our investments par value. In addition, as part of our determination of the fair value of our investments, we consider credit ratings provided by independent investment rating agencies as of the valuation date. These ratings are subject to change, and we may be required to adjust our future valuation of these ARS which may adversely affect the value of these investments.

Impairments and Unrealized Gains and Losses on Investments

The following is a summary of the fair value of our investments with unrealized losses that are deemed to be temporarily impaired and their respective gross unrealized losses aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position at June 30, 2010 and December 31, 2009 (in thousands):

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	June 30, 2010					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	$ 30,898	$ (108)	$	$	$ 30,898	$ (108)
Commercial paper	40,404	(44)			40,404	(44)
Auction rate securities			38,876	(6,424)	38,876	(6,424)
	$ 71,302	$ (152)	$ 38,876	$ (6,424)	$ 110,178	$ (6,576)

	December 31, 2009					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Auction rate securities	$	$	$ 49,013	$ (7,137)	$ 49,013	$ (7,137)
	$	$	$ 49,013	$ (7,137)	$ 49,013	$ (7,137)

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

Based upon our evaluation, we did not consider the unrealized losses on our available-for-sale investments at June 30, 2010 and December 31, 2009 to be other-than-temporary impairments. We did not recognize any impairment losses in our condensed consolidated statement of operations related to available-for-sale securities during the three or six months ended June 30, 2010.

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

Realized Gains and Losses

Gains and losses are determined on the specific identification method. As noted above, because UBS called all of our ARS subject to Settlement Rights at their par value, during the three months ended June 30, 2010 we recognized both a realized gain of $0.8 million related to the redemption of our ARS subject to Settlement Rights and a corresponding realized loss of $0.8 million related to the exercise of the Settlement Rights. As a result of these transactions, we recorded net realized gains of approximately $6,000 and $10,000 to our condensed consolidated statements of operations during the three and six months ended June 30, 2010, respectively.

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D. Accounts Receivable

Our accounts receivable were $14.2 million and $27.4 million at June 30, 2010 and December 31, 2009, respectively, and primarily represented amounts due from wholesalers and distributors to whom we sell *Feraheme* directly and customers who participated in the Launch Incentive Program. Accounts receivable are recorded net of reserves for estimated chargeback obligations, prompt payment discounts and any allowance for doubtful accounts. Reserves for other sales related allowances such as rebates, distribution and other fees, and product returns are included in accrued expenses in our condensed consolidated balance sheets.

Included within our accounts receivable balance at June 30, 2010 were $2.1 million in receivables from one of our customers to whom we shipped *Feraheme* under the 2009 Launch Incentive Program. This shipment was made under an agreement with this customer which provided it with an opportunity to purchase *Feraheme* in September 2009 at discounted pricing and further provided for extended payment terms and expanded rights of return. In June 2010, we further extended the payment terms for the receivable outstanding from this customer to December 31, 2010. As of June 30, 2010, we have a remaining balance of $5.9 million in deferred revenues associated with *Feraheme* purchased under the Launch Incentive Program and which remained held by the dialysis organizations which participated in the program, including this customer, at June 30, 2010, net of any applicable discounts and estimated rebates.

As part of our credit management policy, we perform ongoing credit evaluations of our customers and we have not required collateral from any customer. To date, we have not experienced significant bad debts. Accordingly, we have not established an allowance for doubtful accounts at either June 30, 2010 or December 31, 2009. If the financial condition of any of our significant customers was to deteriorate and result in an impairment of their ability to make payments owed to us, an allowance for doubtful accounts may be required which could have a material effect on earnings in the period of any such adjustment. Customers which represented greater than 10% of our accounts receivable balance at June 30, 2010 and December 31, 2009 were as follows:

	June 30, 2010	December 31, 2009
AmerisourceBergen Drug Corporation	44%	29%
Metro Medical Supply, Inc.	21%	20%
Dialysis Clinics, Inc.	14%	15%
Cardinal Health, Inc.	10%	
Liberty Dialysis, LLC		10%
Satellite Healthcare, Inc.*		10%

* During 2009, our Chief Executive Officer was a member of the Board of Directors of Satellite Healthcare, Inc. but resigned from that position during the three months ended March 31, 2010. At December 31, 2009, we had a receivable of approximately $2.8 million from this customer. In addition, during the three months ended March 31, 2010, we recognized approximately $1.0 million in revenues from this customer.

E. Inventories

Our major classes of inventories were as follows at June 30, 2010 and December 31, 2009 (in thousands):

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	June 30, 2010	December 31, 2009
Raw materials	$ 2,380	$ 1,584
Work in process	1,618	1,169
Finished goods	11,285	6,326
Finished goods held by others	148	336
Total inventories	$ 15,431	$ 9,415

Finished goods inventory held by others primarily relates to inventories held by dialysis organizations to which we shipped *Feraheme* under the Launch Incentive Program. Agreements entered into under this program provided certain customers with extended payment terms and expanded rights of return. As a result, in accordance with current accounting and reporting standards related to revenue recognition, we have deferred both the recognition of revenues and the costs of the inventory sold under this program and presented inventories held by others as a separate component of our overall inventory as of June 30, 2010 and December 31, 2009.

Equity-based compensation of $0.4 million was capitalized into inventory for the six months ended June 30, 2010. There was no equity-based compensation capitalized into inventory for the six months ended June 30, 2009.

F. Property, Plant and Equipment

Property, plant and equipment consisted of the following at June 30, 2010 and December 31, 2009 (in thousands):

	June 30, 2010	December 31, 2009
Land	$ 360	$ 360
Buildings and improvements	10,902	10,356
Laboratory and production equipment	7,195	6,839
Furniture and fixtures	4,497	4,345
Construction in process	757	1,294
Total property, plant and equipment	23,711	23,194
Less - accumulated depreciation	(11,825)	(10,777)
Property, plant and equipment, net	$ 11,886	$ 12,417

G. Income Taxes

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

For the six months ended June 30, 2010 we recognized a $0.1 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 same period. This income tax expense was recorded in other comprehensive income. For the six months ended June 30,

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2009, we recognized a current federal income tax benefit of $0.2 million associated with U.S. research and development tax credits against which we had previously provided a full valuation allowance, but which became refundable as a result of legislation passed in February 2009. Due to the uncertainty surrounding realization of favorable tax attributes in future tax returns, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets.

H. Net Loss per Share

We compute basic net loss per share by dividing net loss by the weighted average number of common shares outstanding during the relevant period. The following table sets forth the potential common shares issuable upon the exercise of outstanding options and the vesting of restricted stock units (prior to consideration of the treasury stock method), the total of which was excluded from our computation of diluted net loss per share because such options and restricted stock units were anti-dilutive due to a net loss in the relevant periods (in thousands):

	As of June 30,	
	2010	**2009**
Options to purchase shares of common stock	2,801	2,704
Shares of common stock issuable upon the vesting of restricted stock units	264	225
Total	3,065	2,929

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	**2009**	**2010**	**2009**
Net loss	$ (21,324)	$ (26,454)	$ (44,377)	$ (52,877)
Weighted average common shares outstanding	21,017	17,038	20,504	17,030
Net loss per share:				
Basic and diluted	$ (1.01)	$ (1.55)	$ (2.16)	$ (3.10)

I. 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, or the 2010 ESPP.

Second Amended and Restated 2007 Equity Incentive Plan

Our 2007 Plan was originally approved by our stockholders in November 2007. In each of May 2009 and May 2010, our stockholders approved proposals to amend and restate our 2007 Plan to, among other things, increase the number of shares authorized for issuance thereunder by 600,000 and 800,000 shares, respectively.

As of June 30, 2010, we have granted options and restricted stock units covering 2,898,275 shares of common stock under our 2007 Plan, of which 447,820 stock options and 34,166 restricted stock units have expired or terminated, and of which 28,876 options have been exercised and 5,000 shares of

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common stock have been issued pursuant to restricted stock units that became fully vested. The number of stock options and restricted stock units outstanding under this plan as of June 30, 2010 was 2,122,598 and 259,815, respectively. The remaining number of shares available for future grants as of June 30, 2010 was 1,210,063, 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 our common stock on the grant date and a ten-year term.

In May 2010, our Board of Directors, or Board, approved a revised Non-Employee Director Compensation Policy, which establishes compensation to be paid to non-employee directors. Pursuant to this revised policy, in May 2010 the Board granted the Chairman of our Board stock options to purchase 10,000 shares of our common stock and restricted stock units covering 5,000 shares of our common stock under the 2007 Plan. In addition, each of the non-employee members of the Board other than the Chairman were granted stock options to purchase 5,000 shares of our common stock and restricted stock units covering 2,500 shares of our common stock under the 2007 Plan; provided that the foregoing awards were pro-rated for those non-employee directors who had served on the Board for less than one year prior to the date of grant. Each of the foregoing grants vests monthly in twelve equal installments beginning on June 1, 2010; provided that delivery of the shares of common stock underlying the foregoing restricted stock unit grants is deferred until the earlier of the third anniversary of the grant date and the date of the director s separation from service from the Board. Each stock option granted to the non-employee members of the Board has an exercise price per share equal to the fair market value of a share of our common stock on the grant date and has a ten-year term.

Amended and Restated 2000 Stock Plan

As of June 30, 2010, we have granted stock options and restricted stock units covering 2,182,700 shares of common stock under the 2000 Plan, of which 453,959 stock options and 1,500 restricted stock units have expired or terminated, and of which 1,006,018 stock options have been exercised and 38,250 shares of common stock have been issued pursuant to restricted stock units that became fully vested. The remaining number of shares underlying outstanding stock options and restricted stock units pursuant to the 2000 Plan as of June 30, 2010 was 678,723 and 4,250, respectively. All outstanding stock options granted under the 2000 Plan have an exercise price equal to the closing price of our common stock on the grant date. In November 2007, the 2000 Plan was succeeded by our 2007 Plan and, accordingly, no further grants may be made under this plan. Any shares that remained available for issuance under the 2000 Plan as of the date of adoption of the 2007 Plan are included in the number of shares that may be issued under the 2007 Plan. Any shares subject to outstanding awards granted under the 2000 Plan that expire or terminate for any reason prior to exercise will be added to the total number of shares available for issuance under the 2007 Plan.

2010 Employee Stock Purchase Plan

In May 2010, our stockholders approved our 2010 ESPP as the successor to and continuation of our 2006 Employee Stock Purchase Plan. The 2010 ESPP authorizes the issuance of up to 100,000 shares of our common stock to eligible employees. Currently, eligible employees may purchase shares (subject to certain plan and/or income tax limitations) in semi-annual offerings through payroll deductions of up to an annual maximum of 10% of the employee s total compensation, as defined by the Board. The purchase price per share is the lesser of 85% of the fair market value of our common stock on the first or last day of the plan period. As of June 30, 2010, no shares have been issued under our 2010 ESPP.

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Equity-based compensation expense

Equity-based compensation expense, net of amounts capitalized into inventory, as of the three and six months ended June 30, 2010 and 2009 consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Cost of product sales	$ 125	$	$ 200	$
Research and development	1,333	1,241	2,538	2,336
Selling, general and administrative	3,477	2,882	6,498	5,289
Total equity-based compensation expense	$ 4,935	$ 4,123	$ 9,236	$ 7,625

Equity-based compensation of $0.2 million and $0.4 million was capitalized into inventory for the three and six months ended June 30, 2010, respectively. Capitalized equity-based compensation is recognized into cost of product sales when the related product is sold.

J. Common Stock Transactions

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

K. Commitments and Contingencies

Legal Proceedings

A purported class action complaint was filed on March 18, 2010 in the United States District Court for the District of Massachusetts against us and our President and Chief Executive Officer, and Executive Vice President and Chief Financial Officer, entitled *Silverstrand Investments v. AMAG Pharm., Inc., et. al.*, Civil Action No. 1:10-CV-10470-NMG. The complaint alleges that the defendants violated the federal securities laws, specifically Section 11 of the Securities Act of 1933, as amended, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff seeks unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. No trial date has been scheduled. We believe that the allegations contained in the complaint are without merit and intend to defend the case vigorously. We have not recorded an estimated liability associated with this legal proceeding as we do not believe that such a liability is probable or estimable.

We may periodically become subject to legal proceedings and claims arising in connection with on-going business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which we are focused. Other than the complaint described above, we are not aware of any material claims against us at June 30, 2010.

L. Collaborative Agreements

On March 31, 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda Pharmaceutical Company Limited, or Takeda. Under the Takeda

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Agreement, we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey, or collectively, the Licensed Territory.

As provided under the Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme* and, accordingly, are responsible for supply of *Feraheme* to Takeda. We are also responsible for conducting, and bearing the costs related to, certain predefined clinical studies with the costs of future modifications or additional studies to be allocated between the parties according to an agreed upon cost-sharing mechanism, which provides for a cap on such costs. In April 2010 we received a $60.0 million upfront payment from Takeda, which we recorded as deferred revenue. In addition, we may receive a combination of regulatory approval and performance-based milestone payments, reimbursement of certain out-of-pocket regulatory and clinical supply costs, as well as defined payments for supply of *Feraheme,* and tiered double-digit royalties on net product sales by Takeda in the Licensed Territory. The milestone payments may over time total up to approximately $220.0 million. Of the $220.0 million in potential milestone payments, we have determined that any payments which may become due upon approval by certain regulatory agencies will be deemed substantive milestones and, therefore, will be accounted for as revenue in the period in which they are achieved. All remaining milestone payments will be accounted for in accordance with our revenue attribution method for the upfront payment as defined below.

We have determined that the Takeda Agreement includes four deliverables: the license, access to future know-how and improvements to the *Feraheme* technology, regulatory and clinical research services, and the manufacturing and supply of product. Pursuant to the accounting guidance under Accounting Standards Codification 605-25, or ASC 605-25, which governs revenue recognition on multiple element arrangements, we have evaluated the four deliverables under the Takeda Agreement and determined that our obligation to provide manufacturing supply of product meets the criteria for separation and is therefore treated as a single unit of accounting, which we refer to as the supply unit of accounting. Further, under ASC 605-25, we have concluded that the license is not separable from the undelivered future know-how and technological improvements or the undelivered regulatory and clinical research services. 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.

When multiple deliverables are combined and accounted for as a single unit of accounting, we base our revenue recognition pattern on the last to be delivered element. With respect to the combined unit of accounting, our obligation to provide access to our future know-how and technological improvements is the final deliverable and is an obligation which exists throughout the term of the Takeda Agreement. Because we cannot reasonably estimate the total level of effort required to complete the obligations under the combined deliverable, we are recognizing the entire $60.0 million upfront payment 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, which represents

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the current patent life of *Feraheme* and our best estimate of the period over which we will substantively perform these 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 terms of the Takeda Agreement, Takeda is responsible for reimbursing us for certain out-of-pocket regulatory and clinical trial supply costs associated with carrying out our regulatory and clinical research services under the collaboration agreement. Because we are acting as the principal in carrying out these activities, 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 activities.

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. We recorded $1.5 million associated with the upfront payment and $1.0 million associated with other reimbursement revenues in our condensed consolidated statements of operations during the three and six months ended June 30, 2010. The $1.0 million in reimbursement revenues remains outstanding at June 30, 2010. Payments to be received for supply of the drug product and royalties will be recorded in product sales and royalties in our condensed consolidated statement of operations. We did not record any revenue for this accounting unit in our condensed consolidated statement of operations during either the three or six months ended June 30, 2010.

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 Inc., or 3SBio, with respect to the development and commercialization of *Feraheme* as an IV iron replacement therapeutic agent in China. The 3SBio License Agreement grants 3SBio an exclusive license for an initial term of thirteen years to develop and commercialize *Feraheme* as a therapeutic agent in China for an initial indication for the treatment of IDA in patients with CKD, and an option to expand into additional therapeutic indications. In consideration of the grant of the license, we received an upfront payment of $1.0 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 sales of *Feraheme* by 3SBio in China. We retained all manufacturing rights for *Feraheme*. In addition, pursuant to the 3SBio Supply Agreement, 3SBio has agreed to purchase from us, and we have agreed to supply to 3SBio, *Feraheme* at a predetermined supply price for clinical and commercial use in connection with 3SBio s development and commercialization obligations described above for so long as the 3SBio License Agreement is in effect. To date we have not provided 3SBio with any significant product under the 3SBio Supply Agreement.

M. Recently Issued and Proposed Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2010-17, Revenue Recognition Milestone Method, or ASU 2010-17. ASU 2010-17 provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. An entity can recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. The following criteria must be met for a milestone to be considered substantive. The consideration earned by achieving the milestone should (1) be commensurate with either the level of effort required to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the entity s performance to

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achieve the milestone; (2) be related solely to past performance; and (3) be reasonable relative to all deliverables and payment terms in the arrangement. No bifurcation of an individual milestone is allowed and there can be more than one milestone in an arrangement. Accordingly, an arrangement may contain both substantive and nonsubstantive milestones. ASU 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The adoption of this guidance did not have a significant impact on our condensed consolidated financial statements.

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

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

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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, 2009.

Except for the historical information contained herein, the matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q, words such as may, will, expect, intend, and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Examples of forward-looking statements contained in this report include statements regarding the following: our expectations regarding our intended development and commercialization of Feraheme® (ferumoxytol) Injection, our expectations regarding the success of our collaboration with Takeda Pharmaceutical Company Limited, our plan to conduct four pediatric studies and the expected timing and design of these studies, our plan to conduct and the intended timing and design of our global studies of Feraheme for the treatment of iron deficiency anemia in a broad range of patients, the design of our post-approval trial to assess the safety and efficacy of Feraheme compared to an IV iron sucrose product in chronic kidney disease patients, our plan to conduct and the design of a post-approval trial to assess the safety and efficacy of repeat, episodic Feraheme administration for the treatment of persistent or recurrent iron deficiency anemia, our plan to complete our Phase II study of Feraheme in vascular-enhanced magnetic resonance imaging later in 2010, our statement that our partner in China, 3SBio Inc., plans to conduct a Feraheme clinical study in China, our expectation that sales of GastroMARK will not change materially, our expectation regarding our future revenues, including expected Feraheme, Takeda collaboration and 3SBio collaboration revenues and our expectation to partly fund our future operations with Feraheme revenues, our expectation that our reserves as a percentage of gross sales will increase during the remainder of 2010, our expectation that during 2010 and into the future our net sales as a percentage of gross sales will be negatively affected as a result of recently enacted healthcare legislation, the potential impact on our net product sales of the recently enacted CMS prospective payment system rule, our expectation regarding milestone payments we may receive from Takeda Pharmaceutical Company Limited, our expectation that our costs of product sales will increase, our expectation regarding our research and development expenses for the remainder of 2010, our expectations regarding the amount of external expenses and the timing of our planned research and development projects, our expectation regarding our selling, general and administrative expenses for the remainder of 2010, our expectation regarding our dividend and interest income, our expectations regarding our short- and long-term liquidity and capital requirements and our ability to finance our operations, our expectations regarding our future cash flows, our belief that the decline in the value of our auction rate securities is temporary and that we will ultimately be able to liquidate these investments without significant loss, our belief that the allegations asserted against us in the class action lawsuit are without merit, and information with respect to any other plans and strategies for our business. Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements. Any forward-looking statement should be considered in light of the factors discussed in this Quarterly Report on Form 10-Q. We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the United States Securities and Exchange Commission to publicly update or revise any such statements to reflect any change in company expectations or in events, conditions or circumstances on which any such statements

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may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a biopharmaceutical company that utilizes our proprietary technology for the development and commercialization of a therapeutic iron compound to treat iron deficiency anemia, or IDA, and novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. We currently manufacture and sell two approved products, Feraheme® (ferumoxytol) Injection for intravenous, or IV, use and GastroMARK®.

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

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

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

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

In connection with our responsibilities under the Takeda Agreement, in June 2010 we submitted our Marketing Authorization Application, or MAA, for *Feraheme* for the treatment of IDA in CKD patients

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with the European Medicines Agency, or EMA, and have since been notified that the submission was deemed valid by the EMA and is currently under review. Our Pediatric Investigation Plan, which was approved by the EMA in December 2009, includes the two pediatric studies needed to meet our Pediatric Research Equity Act requirement and two additional pediatric studies requested by the EMA. To further support our MAA, we have initiated a global, randomized, multi-center, active controlled post-approval trial with approximately 150 adult CKD patients with IDA, both on dialysis and not on dialysis. This study will assess the safety and efficacy of two doses of 510 milligrams each of *Feraheme* compared to a total dose of 1,000 milligrams of an IV iron sucrose product.

In addition, as part of our obligations under the Takeda Agreement, we are planning to advance our *Feraheme* clinical development program in adult patients with CKD by initiating a multi-center post-approval clinical trial. This study will assess the safety and efficacy of repeat, episodic *Feraheme* administration for the treatment of persistent or recurrent IDA over a 12 month period. Subjects will receive an initial course of two doses of 510 milligrams each of *Feraheme*, and will receive subsequent courses of two doses of 510 milligrams of *Feraheme* whenever they meet treatment criteria. The study is expected to enroll a total of approximately 300 CKD patients with IDA including patients on dialysis (hemodialysis or peritoneal dialysis) and those not on dialysis, including post-kidney transplant recipients.

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

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

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

In the past, we have devoted substantially all of our resources to our research and development programs and, more recently, we have also incurred substantial costs related to the commercialization of *Feraheme*. Prior to the commercial launch of *Feraheme*, we financed our operations primarily from the sale of our equity securities, cash generated by our investing activities, and payments from our strategic partners. At June 30, 2010, our accumulated deficit was approximately $326.1 million. We expect to continue to incur significant expenses to manufacture, market and sell *Feraheme* as an iron replacement therapeutic in CKD patients in the U.S. and to further develop *Feraheme* for additional indications and in additional countries outside of the U.S. In the second half of 2009, we began to derive revenues from product sales of *Feraheme*. We currently expect to fund our future operations in part from the sale of

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Feraheme in addition to cash generated by our investing activities, payments from our strategic partners, and the sale of our equity securities, if necessary.

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

Results of Operations for the Three Months Ended June 30, 2010 as Compared to the Three Months Ended June 30, 2009

Revenues

Total revenues were $18.8 million and $55,000 for the three months ended June 30, 2010 and 2009, respectively, representing an increase of approximately $18.8 million. The increase in revenues was primarily due to product sales of *Feraheme* following its commercial launch in July 2009.

The following table sets forth customers who represented 10% or more of our revenues for the three months ended June 30, 2010 and 2009:

	Three Months Ended June 30,	
	2010	2009
AmerisourceBergen Drug Corporation	32%	
Metro Medical Supply, Inc.	20%	
Takeda Pharmaceutical Company Limited	13%	
Cardinal Health, Inc.	10%	
Covidien Public Limited Company	<10%	74%
Bayer Healthcare Pharmaceuticals		26%

Our revenues for the three months ended June 30, 2010 and 2009 consisted of the following (in thousands):

	Three Months Ended June 30,			
	2010	2009	$ Change	% Change
Product sales, net	$ 16,226	$	$ 16,226	N/A
License fee and other collaboration revenues	2,529		2,529	N/A
Royalties	72	55	17	31%
Total	$ 18,827	$ 55	$ 18,772	>100%

Net Product Sales

Net product sales for the three months ended June 30, 2010 and 2009 consisted of the following (in thousands):

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	Three Months Ended June 30, 2010	2009	$ Change	% Change
Feraheme	$ 16,014	$	$ 16,014	N/A
GastroMARK	212		212	N/A
Total	$ 16,226	$	$ 16,226	N/A

The $16.2 million increase in net product sales was primarily due to the FDA approval and subsequent U.S. commercial launch of *Feraheme* in mid-2009. Included in *Feraheme* product sales is $2.4 million of net product sales related to previously deferred revenues recorded under our Launch Incentive Program.

Our net product sales may fluctuate from period to period as a result of factors such as wholesaler demand forecasts and buying decisions as well as end user demand, which can create uneven purchasing patterns by our customers. Our net product sales may also fluctuate due to changes or adjustments to our reserves or changes in government or customer discounts, rebates and incentives. For example, in addition to our customary discounts and rebates, during June 2010 we provided additional rebates to providers for *Feraheme* purchases above a certain minimum threshold during a limited period ended June 30, 2010. This additional volume rebate was designed to respond to competitive pricing and reimbursement pressures which arose in the last few weeks of June and to retain and/or increase *Feraheme* market share as well as to continue encouraging adoption of *Feraheme* by new users.

Our net product sales may also fluctuate from period to period due to the enactment of or changes in legislation which impact third-party reimbursement coverage and pricing. For example, in July 2010, the Centers for Medicare & Medicaid Services, or CMS, published a final rule establishing the new prospective payment system for dialysis services provided to Medicare beneficiaries who have end stage renal disease, which may lower utilization of *Feraheme* in this patient population and consequently adversely affect our *Feraheme* sales in the dialysis setting. Separately, in March 2010, U.S. healthcare reform legislation was enacted which contained several provisions which impact our business. Although many provisions of the new legislation do not take effect immediately, several provisions became effective in the first quarter of 2010, including the following:

- an increase in the minimum statutory Medicaid rebate to states participating in the Medicaid program from 15.1% to 23.1%;

- an extension of the Medicaid rebate to drugs dispensed to Medicaid beneficiaries enrolled with managed care organizations; and

- an expansion of the 340(B) Public Health Services drug pricing program, which provides drugs at reduced rates, to include additional hospitals, clinics, and healthcare centers in an outpatient setting.

Under this new healthcare legislation, beginning in 2011, we may incur our share of a new fee assessed on all branded prescription drug manufacturers and importers. This fee will be calculated based upon *Feraheme s* percentage share of total branded prescription drug sales to U.S. government programs (such as Medicare, Medicaid and other related government agencies) made during the previous year. The aggregated industry wide fee is expected to range from $2.5 billion to $4.1 billion annually. Presently, uncertainty exists as many of the specific determinations necessary to implement this new legislation have yet to be decided and communicated to industry participants. For example, determinations as to how the

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annual fee on branded prescription drugs will be calculated and allocated remain to be clarified, though, as noted above, this provision will not be effective until 2011.

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

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

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

We record product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and other rebates, distributor, wholesaler and group purchasing organization, or GPO, fees, and product returns as a reduction of revenue in our condensed consolidated statement of operations at the time product sales are recorded. Calculating these gross-to-net sales adjustments involves estimates and judgments based primarily on actual *Feraheme* sales data, forecasted customer buying patterns blended with historical experience of products similar to *Feraheme* sold by others, and other market research. In addition, we also monitor our distribution channel to determine the level of additional allowances or accruals required based on inventory in our sales channel. There were no product sales allowances or accruals for the three months ended June 30, 2009. For further details related to our revenue recognition and related sales allowances policy, refer to our critical accounting policies included in Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations of our Annual Report on Form 10-K for the year ended December 31, 2009.

An analysis of our product sales allowances and accruals for the three months ended June 30, 2010 is as follows (in thousands):

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	Three Months Ended June 30, 2010
Product sales allowances and accruals:	
Discounts and chargebacks	$ 1,075
Government and other rebates	4,533
Returns	333
Total product sales allowances and accruals	$ 5,941
Total net product sales	$ 16,226
Total gross product sales	$ 22,167
Total product sales allowances and accruals as a percent of total gross product sales	27%

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

An analysis of the amount of, and change in, reserves for the six months ended June 30, 2010 is as follows (in thousands):

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	Discounts	Rebates and Fees	Returns	Total
Balance at January 1, 2010	$ 499	$ 5,194	$ 463	$ 6,156
Current provisions relating to sales in current year	1,817	7,817	648	10,282
Other provisions relating to deferred revenue		(612)		(612)
Adjustments relating to sales in prior year		(283)	(71)	(354)
Payments/returns relating to sales in current year	(1,150)	(2,458)		(3,608)
Payments/returns relating to sales in prior year	(499)	(2,105)		(2,604)
Balance at June 30, 2010	$ 667	$ 7,553	$ 1,040	$ 9,260

During the six months ended June 30, 2010, our product sales allowances and accruals reflected an increase in statutory minimum rebate rates related to Medicaid allowances from 15.1% to 23.1% pursuant to healthcare legislation described above. In addition, we reduced our product sales allowances and accruals by $0.4 million for changes in estimates relating to sales in the prior year. These adjustments were primarily caused by a reduction, during the three months ended March 31, 2010, in our estimates of Medicaid utilization across *Feraheme* customer classes based on additional data, including information regarding Medicaid claims experience for comparable products. Although allowances and accruals are recorded at the time of product sale, certain rebates are typically paid out, on average, up to six months or longer after the sale. If actual future results vary from our estimates, we may need to adjust our previous estimates, which would affect our earnings in the period of the adjustment.

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

- variations in, and the success of, fee, rebate and discount structures implemented in our efforts to increase adoption of *Feraheme*;

- variations in our future customer mix;

- changes in legislation, such as the recent healthcare legislation and final CMS rule regarding the prospective payment system discussed above;

- the percentage of total revenues in each period which are the result of utilization by customers who purchased *Feraheme* directly from us at the discounted pricing under our Launch Incentive Program; and

- adjustments and refinements to our prior estimates and assumptions.

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

product sales.

Because we only recently launched *Feraheme* in the U.S., there are a number of factors that make it difficult to predict the magnitude of future *Feraheme* sales, including but not limited to, the magnitude and timing of adoption of *Feraheme* by physicians, dialysis clinics, hospitals and other healthcare payors and providers, the effect of changes in federal and other legislation such as the recent healthcare

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legislation and final CMS rule regarding the prospective payment system, the inventory levels maintained by *Feraheme* wholesalers, distributors and other customers, the frequency of re-orders by existing customers, the timing and magnitude of revenues recognized under our Launch Incentive Program, 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 previous quarters may not be indicative of future *Feraheme* net product revenues.

Deferred Revenue - Launch Incentive Program

During the third quarter of 2009, certain dialysis organizations purchased *Feraheme* from us under our Launch Incentive Program. These purchases were made under agreements which provided these customers with an opportunity to purchase *Feraheme* through September 30, 2009 at discounted pricing and further provided for extended payment terms and expanded rights of return. As a result, in accordance with current accounting guidance which requires that we defer recognition of revenues until we can reasonably estimate returns related to those purchases, we have deferred the recognition of revenues associated with these purchases until our customers report to us that such inventory has been utilized in their operations. Any purchases returned to us will not be recorded as revenue, and, if necessary, we will issue a refund to the customer. As of June 30, 2010, we have a remaining balance of $5.9 million in deferred revenues associated with *Feraheme* purchased under the Launch Incentive Program and which remained held by the dialysis organizations at June 30, 2010, net of any applicable discounts and estimated rebates.

During the three months ended June 30, 2010, we agreed to extend the payment terms of the outstanding balance due from one of our customers who participated in the Launch Incentive Program. This customer has informed us that its rate of *Feraheme* utilization has been less than originally anticipated and that it will return to us any unused inventory by year end. As of June 30, 2010, this customer held *Feraheme* inventory representing approximately $3.5 million of net *Feraheme* revenues, which is currently recorded as deferred revenues in our condensed consolidated balance sheet. Because certain customers who participated in the Launch Incentive Program have fully utilized the *Feraheme* purchased under the program, we expect that total revenues recognized under the Launch Incentive Program will decrease in the future. In addition, because we are unable to reasonably estimate the amount of inventory that may be returned under this program, as well as the timing of any such returns, although we believe that revenues recognized under this program will be at reduced levels going forward, we cannot provide any assurance that any amounts currently reported as deferred revenue will be utilized by our customers and thereby recorded as product revenues in our future condensed consolidated statements of operations.

License Fee and Other Collaboration Revenues

License fee and other collaboration revenues for the three months ended June 30, 2010 and 2009 consisted of the following (in thousands):

	Three Months Ended June 30,			
	2010	2009	$ Change	% Change
Deferred license fee revenues recognized in connection with the Takeda Agreement	$ 1,500	$	$ 1,500	N/A
Reimbursement revenues recognized in connection with the Takeda Agreement	1,029		1,029	N/A
Total	$ 2,529	$	$ 2,529	N/A

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All of our license fee and other collaboration revenues for the three months ended June 30, 2010 related to revenue recognized under the Takeda Agreement, which we entered into in March 2010. Under the Takeda Agreement, we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey. During the three months ended June 30, 2010, we recorded $1.5 million of revenues associated with a $60.0 million upfront payment from Takeda, which we received in April 2010 and which we recorded as deferred revenue. In addition to the upfront payment, we may receive a combination of regulatory approval and performance-based milestone payments, reimbursement of certain out-of pocket regulatory and clinical supply costs, as well as defined payments for supply of *Feraheme* and tiered double-digit royalties on net product sales by Takeda in the Licensed Territory. The milestone payments may over time total up to approximately $220.0 million. We are recognizing the entire $60.0 million upfront payment and will also recognize that portion of the $220.0 million of potential milestone payments that are achieved and which are not deemed to be substantive milestones into revenues on a straight-line basis over a period of ten years, which represents the current patent life of *Feraheme* and our best estimate of the period over which we will substantively perform these 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. Of the $220.0 million in potential milestone payments, we have determined that any payments which may become due upon approval by certain regulatory agencies will be deemed substantive milestones and, therefore, will be accounted for as revenue in the period in which they are achieved. All remaining milestone payments will be accounted for in accordance with our revenue attribution method for the upfront payment as defined above.

In addition, under the terms of the Takeda Agreement, Takeda is responsible for reimbursing us for certain out-of-pocket regulatory and clinical trial supply costs associated with carrying out our regulatory and clinical research services under the collaboration agreement. Because we are acting as the principal in carrying out these activities, 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 activities. During the three months ended June 30, 2010, we recorded $1.0 million of revenues associated with reimbursement of certain out-of pocket regulatory and clinical supply costs. Because we filed the MAA in June 2010 and do not expect the costs associated with that filing to recur, we anticipate that the reimbursable activities and costs and related reimbursement revenues for the remainder of 2010 will be lower on a quarterly basis than the levels experienced during the three months ended June 30, 2010.

In May 2008, we entered into a Collaboration and Exclusive License Agreement with 3SBio with respect to the development and commercialization of *Feraheme* as an IV iron replacement therapeutic agent in China. In consideration of the grant of the license, we received an upfront payment of $1.0 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 did not record any revenues associated with our agreement with 3SBio during the three months ended June 30, 2010 and do not expect license revenues under this agreement to be significant for the remainder of 2010.

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Costs and Expenses

Cost of Product Sales

We incurred costs of $1.9 million, or 11.6%, of net product sales during the three months ended June 30, 2010, which was comprised primarily of manufacturing costs associated with *Feraheme*. We did not incur any costs of product sales during the three months ended June 30, 2009. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the costs of *Feraheme* sold during the three months ended June 30, 2010 were expensed prior to the June 2009 FDA approval of *Feraheme*, and therefore are not included in the cost of product sales during this period. We continue to hold *Feraheme* inventory that has been previously expensed, and once such inventory has been fully depleted, we expect our cost of product sales as a percentage of net product sales will increase, reflecting the full manufacturing cost of our inventory. We cannot predict when such previously expensed materials will be exhausted, as this will be dependent on the timing and magnitude of *Feraheme* sales in the U.S. In addition, we expect our cost of product sales as a percentage of net product sales to increase as a result of reduced net product sales price and general increases in manufacturing costs.

Research and Development Expenses

Research and development expenses include external expenses, such as costs of clinical trials, contract research and development expenses, certain manufacturing research and development costs, consulting and professional fees and expenses, and internal expenses, such as compensation of employees engaged in research and development activities, the manufacture of product needed to support research and development efforts, related costs of facilities, and other general costs related to research and development. As discussed below, where possible, we track our external costs by major project. To the extent that external costs are not attributable to a specific project or activity, they are included in other external costs. Prior to the June 2009 regulatory approval of *Feraheme*, costs associated with manufacturing process development and the manufacture of the drug product were recorded as research and development expenses. Subsequent to FDA approval, costs associated with the manufacture of *Feraheme* to be made commercially available in the U.S. are capitalized and recorded as cost of sales when sold.

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Research and development expenses for the three months ended June 30, 2010 and 2009 consisted of the following (in thousands):

	Three Months Ended June 30, 2010	2009	$ Change	% Change
External Research and Development Expenses				
Feraheme to treat IDA regardless of the underlying cause	$ 4,445	$	$ 4,445	N/A
Feraheme to treat IDA in CKD patients	3,294		3,294	N/A
Feraheme as a therapeutic agent, general	167	1,704	(1,537)	-90%
Feraheme as an imaging agent in PAD patients	804	499	305	61%
Feraheme manufacturing and materials	346	859	(513)	-60%
Other external costs	199	126	73	58%
Total	$ 9,255	$ 3,188	$ 6,067	>100%
Internal Research and Development Expenses				
Compensation, payroll taxes, benefits and other expenses	4,196	5,685	(1,489)	-26%
Equity-based compensation expense	1,333	1,241	92	7%
Total	$ 5,529	$ 6,926	$ (1,397)	-20%
Total Research and Development Expenses	$ 14,784	$ 10,114	$ 4,670	46%

Total research and development expenses incurred in the three months ended June 30, 2010 amounted to $14.8 million, an increase of $4.7 million, or 46%, from the three months ended June 30, 2009. The $4.7 million increase primarily reflects an increase in costs as we prepared and initiated new clinical trials and increased spending on ongoing clinical trials. In addition, our research and development expenses during the three months ended June 30, 2009 included costs we did not incur during the three months ended June 30, 2010, such as costs associated with pre-approval activities required to ready our manufacturing capabilities at our Cambridge, Massachusetts manufacturing facility and costs associated with the manufacture of *Feraheme* prior to FDA approval for commercial sale.

Our external research and development expenses increased by $6.1 million, or greater than 100%, for the three months ended June 30, 2010 as compared to the three months ended June 30, 2009. The increase in our external expenses was due primarily to costs incurred in connection with our Phase III clinical development program for *Feraheme* to treat IDA regardless of the underlying cause, which was initiated in June 2010, costs associated with our global clinical study to support our MAA in Europe for the treatment of IDA in CKD patients, costs incurred to begin preparations for certain of our planned pediatric studies, filing fees and costs associated with regulatory submissions, costs incurred as we completed enrollment of our Phase II study of *Feraheme* as a diagnostic agent for vascular-enhanced MRI for the assessment of PAD, and costs associated with research and development for new manufacturing processes. These increases were partially offset by certain costs incurred in the three months ended June 30, 2009, which were not incurred during 2010, including costs associated with our efforts to address the manufacturing observations noted by the FDA during a 2008 inspection of our Cambridge, Massachusetts manufacturing facility. Further, during the three months ended June 30, 2010, we capitalized to inventory the majority of external *Feraheme* manufacturing and materials costs, which, during the three months ended June 30, 2009, were expensed in advance of FDA approval.

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Our internal research and development expenses decreased by $1.4 million, or 20%, for the three months ended June 30, 2010 as compared to the three months ended June 30, 2009. The decrease in internal costs was due primarily to the allocation of internal manufacturing costs to inventory in the three months ended June 30, 2010, whereas such costs were expensed in the three months ended June 30, 2009 prior to FDA approval of *Feraheme*. At June 30, 2010, we had 60 full-time equivalents, or FTEs, in research and development as compared to 100 FTEs at June 30, 2009, a decrease of 40%, due primarily to the reallocation of manufacturing personnel out of research and development following FDA approval of *Feraheme* in June 2009.

We expect research and development expenses to continue to increase relative to current levels for the remainder of 2010 primarily as a result of our continued advancement of our clinical development programs, including studies and activities required under the Takeda Agreement, as well as other research and development related functions and activities in support of *Feraheme*. Factors which will impact 2010 research and development expenses include the design, timing and pace of enrollment of our clinical trials of *Feraheme,* including our development program for *Feraheme* in a broad range of patients with IDA, our trial to support our *Feraheme* MAA filing with the EMA, our safety and efficacy trial of repeat, episodic *Feraheme* administration for the treatment of persistent or recurrent IDA, and the timing of initiation and pace of enrollment of our pediatric studies of *Feraheme*.

We do not track our internal costs by project since our research and development personnel work on a number of projects concurrently and much of our fixed costs benefit multiple projects or our operations in general. We track our external costs on a major project by major project basis, in most cases through the 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 currently underway 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) an on-going post-approval clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron to support our MAA submission; (2) two pediatric studies to be 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; and (4) a multi-center post-approval clinical trial to be conducted to assess the safety and efficacy of repeat, episodic *Feraheme* administration for the treatment of persistent or recurrent IDA over a 12 month period.

Through June 30, 2010, we have incurred aggregate external research and development expenses of approximately $7.1 million related to our current program for the development of *Feraheme* to treat IDA regardless of the underlying cause. We currently estimate that the total external costs associated with the efforts needed to complete this development project will be in the range of approximately $50.0 to $60.0 million over the next several years. This represents a decrease of approximately $5.0 million from our expected range at March 31, 2010, which primarily reflects actual expenses incurred during the three months ended June 30, 2010 in connection with this project.

Through June 30, 2010, we incurred aggregate external research and development expenses of approximately $5.6 million related to our current program for the development of *Feraheme* to treat IDA

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in CKD patients. We currently estimate that the external costs associated with this development project will be in the range of approximately $45.0 to $55.0 million over the next several years. This is consistent with our expected range at March 31, 2010 and primarily reflects actual expenses incurred during the three months ended June 30, 2010 in connection with this project, slightly offset by increases in estimated trial costs.

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*, 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 delay in the submission of any applicable regulatory filing.

Selling, General and Administrative Expenses

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

Selling, general and administrative expenses for the three months ended June 30, 2010 and 2009 consisted of the following (in thousands):

	Three Months Ended June 30,			
	2010	2009	$ Change	% Change
Compensation, payroll taxes and benefits	$ 9,909	$ 8,074	$ 1,835	23%
Professional and consulting fees and other expenses	10,618	6,312	4,306	68%
Equity-based compensation expense	3,477	2,882	595	21%
Total	$ 24,004	$ 17,268	$ 6,736	39%

The $6.7 million, or 39%, increase in selling, general and administrative expenses for the three months ended June 30, 2010 as compared to the three months ended June 30, 2009 was due primarily to increased costs associated with the continued expansion of our commercial operations function and our general administrative infrastructure to support our growth as a commercial entity, including increased advertising and promotion costs associated with the U.S. commercial launch of *Feraheme* and compensation and benefits costs related to increased headcount. At June 30, 2010 we had 186 employees in our selling, general and administrative departments as compared to 174 employees at June 30, 2009, a 7% increase.

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

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Other Income (Expense)

Other income (expense) for the three months ended June 30, 2010 and 2009 consisted of the following (in thousands):

	Three Months Ended June 30,			
	2010	2009	$ Change	% Change
Interest and dividend income, net	$ 404	$ 783	$ (379)	-48%
Gains on investments, net	794	275	519	>100%
Fair value adjustment of settlement rights	(788)	(185)	(603)	>100%
Total	$ 410	$ 873	$ (463)	-53%

Other income (expense) for the three months ended June 30, 2010 decreased by $0.5 million, or 53%, as compared to the three months ended June 30, 2009. The $0.5 million decrease was primarily attributable to a $0.4 million decrease in interest and dividend income as the result of lower interest rates in the three months ended June 30, 2010 as compared to the three months ended June 30, 2009.

In November 2008, we elected to participate in a rights offering by UBS AG, or UBS, one of our securities brokers, which provided us with rights to sell to UBS $9.3 million in par value of our auction rate securities, or ARS, at par value, at any time during a two-year sale period beginning June 30, 2010, or the Settlement Rights. In accordance with the terms of the Settlement Rights, during the three months ended June 30, 2010 UBS redeemed all of our ARS subject to Settlement Rights at their par value. As a result, during the three months ended June 30, 2010, we recognized both a realized gain of $0.8 million related to the redemption of our UBS ARS subject to Settlement Rights and a corresponding realized loss of $0.8 million related to the exercise of the Settlement Rights.

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

Income Tax Benefit

We recognized an income tax benefit of $0.1 million during the three months ended June 30, 2010, 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 three months ended June 30, 2010. This income tax expense was recorded in other comprehensive income. There were no similar income tax benefits for the three months ended June 30, 2009.

Net Loss

For the reasons stated above, we incurred a net loss of $21.3 million, or $1.01 per basic and diluted share, for the three months ended June 30, 2010 as compared to a net loss of $26.5 million, or $1.55 per basic and diluted share, for the three months ended June 30, 2009.

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Results of Operations for the Six Months Ended June 30, 2010 as Compared to the Six Months Ended June 30, 2009

Revenues

Total revenues were $32.1 million and $1.0 million for the six months ended June 30, 2010 and 2009, respectively, representing an increase of approximately $31.1 million, or greater than 100%. The increase in revenues was primarily due to product sales of *Feraheme* following its commercial launch in July 2009.

The following table sets forth customers who represented 10% or more of our revenues for the six months ended June 30, 2010 and 2009.

	Six Months Ended June 30,	
	2010	**2009**
AmerisourceBergen Drug Corporation	30%	
Metro Medical Supply, Inc.	26%	
Guerbet S.A.	<10%	31%
Covidien Public Limited Company	<10%	17%
Bayer Healthcare Pharmaceuticals	<10%	52%

Our revenues for the six months ended June 30, 2010 and 2009 consisted of the following (in thousands):

	Six Months Ended June 30,			
	2010	**2009**	**$ Change**	**% Change**
Product sales, net	$ 29,521	$ 393	$ 29,128	>100%
License fee and other collaboration revenues	2,529	516	2,013	>100%
Royalties	83	102	(19)	-19%
Total	$ 32,133	$ 1,011	$ 31,122	>100%

Net Product Sales

Net product sales for the six months ended June 30, 2010 and 2009 consisted of the following (in thousands):

	Six Months Ended June 30,			
	2010	**2009**	**$ Change**	**% Change**
Feraheme	$ 29,070	$	$ 29,070	N/A
GastroMARK	451	393	58	15%
Total	$ 29,521	$ 393	$ 29,128	>100%

The $29.1 million, or greater than 100%, increase in net product sales was primarily due to the FDA approval and subsequent U.S. commercial launch of *Feraheme* in mid-2009. Included in *Feraheme* product sales is $4.6 million of net product sales related to previously deferred revenues recorded under our Launch Incentive Program.

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Our net product sales may fluctuate from period to period as a result of factors such as wholesaler demand forecasts and buying decisions as well as end user demand, which can create uneven purchasing patterns by our customers. Our net product sales may also fluctuate due to changes or adjustments to our reserves or changes in government or customer discounts, rebates and incentives.

As a result of the U.S. healthcare reform legislation enacted in March 2010, as discussed in more detail above, certain changes were made relative to Medicaid reimbursement for pharmaceutical products, including *Feraheme*. During the six months ended June 30, 2010, we recorded estimated Medicaid rebates due on *Feraheme* sales at 23.1% of our average manufacturing price as compared to 15.1% of our average manufacturing price recorded prior to the enactment of the legislation. As also noted above, we expect the impact of the increased rebates and other elements of this legislation to continue to negatively affect future sales.

We record product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and other rebates, distributor, wholesaler and GPO fees, and product returns as a reduction of revenue in our condensed consolidated statement of operations at the time product sales are recorded. There were no product sales allowances or accruals for the six months ended June 30, 2009. An analysis of our product sales allowances and accruals for the six months ended June 30, 2010 is as follows (in thousands):

	Six Months Ended June 30, 2010
Product sales allowances and accruals:	
Discounts and chargebacks	$ 1,817
Government and other rebates	7,534
Returns	577
Total product sales allowances and accruals	$ 9,928
Total net product sales	$ 29,521
Total gross product sales	$ 39,449
Total product sales allowances and accruals as a percent of total gross product sales	25%

License Fee and Other Collaboration Revenues

License fee and other collaboration revenues for the six months ended June 30, 2010 and 2009 consisted of the following (in thousands):

	Six Months Ended June 30, 2010	2009	$ Change	% Change
Deferred license fee revenues recognized in connection with the Takeda Agreement	$ 1,500	$	$ 1,500	N/A
Reimbursement revenues recognized in connection with the Takeda Agreement	1,029		1,029	N/A
Deferred license fee revenues recognized in connection with the Bayer Agreements		516	(516)	-100%
Total	$ 2,529	$ 516	$ 2,013	>100%

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All of our license fee and other collaboration revenues for the six months ended June 30, 2010 related to revenue recognized under the Takeda Agreement, which we entered into in March 2010. We recorded $1.5 million in revenues associated with a $60.0 million upfront payment received from Takeda in April 2010. We recorded the upfront payment as deferred revenue and are recognizing it into revenue on a straight-line basis over a period of ten years, which represents the current patent life of *Feraheme*. In addition, we recognized $1.0 million in revenues associated with reimbursement of certain out-of-pocket regulatory and clinical trial supply costs. Under the terms of the Takeda Agreement, Takeda is responsible for reimbursing us for certain out-of-pocket regulatory and clinical trial supply costs associated with carrying out our regulatory and clinical research services under the collaboration agreement. Our license fee revenues of $0.5 million for the six months ended June 30, 2009 consisted solely of deferred license fee revenues that were being amortized through the end of our performance obligations in connection with our agreements with Bayer Healthcare Pharmaceuticals, or Bayer, relating to a product we no longer sell and which were terminated in November 2008 as further described below.

In May 2008, we entered into a Collaboration and Exclusive License Agreement with 3SBio with respect to the development and commercialization of *Feraheme* as an IV iron replacement therapeutic agent in China. In consideration of the grant of the license, we received an upfront payment of $1.0 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 did not record any revenues associated with our agreement with 3SBio for the six months ended June 30, 2010.

In 1995, we entered into a License and Marketing Agreement and a Supply Agreement, or the Bayer Agreements, with Bayer, granting Bayer a product license and exclusive marketing rights to Feridex I.V.® in the U.S. and Canada. In connection with our decision to cease manufacturing *Feridex I.V.*, the Bayer Agreements were terminated in November 2008 by mutual agreement. Prior to the termination of the Bayer Agreements, we accounted for the revenues associated with the Bayer Agreements on a straight-line basis over their 15 year contract term. Pursuant to the termination agreement, Bayer could continue to sell any remaining *Feridex I.V.* inventory in its possession through April 1, 2009, and other than royalties owed by Bayer to us on such sales, no further obligation exists by either party. As a result of the termination of these agreements, we do not expect any additional license fee revenues from Bayer.

Costs and Expenses

Cost of Product Sales

We incurred costs of $2.9 million and $61,000 associated with product sales during the six months ended June 30, 2010 and 2009, respectively. Our cost of product sales for the six months ended June 30, 2010 was comprised primarily of manufacturing costs associated with *Feraheme*. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the costs of *Feraheme* sold during the six months ended June 30, 2010 were expensed prior to the June 2009 FDA approval, and therefore are not included in the cost of product sales during this period.

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Research and Development Expenses

Research and development expenses for the six months ended June 30, 2010 and 2009 consisted of the following (in thousands):

	Six Months Ended June 30,			
	2010	**2009**	**$ Change**	**% Change**
External Research and Development Expenses				
Feraheme to treat IDA regardless of the underlying cause	$ 6,339	$	$ 6,339	N/A
Feraheme to treat IDA in CKD patients	5,283		5,283	N/A
Feraheme as a therapeutic agent in AUB patients		1,131	(1,131)	-100%
Feraheme as a therapeutic agent, general	460	3,350	(2,890)	-86%
Feraheme as an imaging agent in PAD patients	1,386	822	564	69%
Feraheme manufacturing and materials	1,983	1,991	(8)	
Other external costs	526	324	202	62%
Total	$ 15,977	$ 7,618	$ 8,359	>100%
Internal Research and Development Expenses				
Compensation, payroll taxes, benefits and other expenses	8,637	11,232	(2,595)	-23%
Equity-based compensation expense	2,538	2,336	202	9%
Total	$ 11,175	$ 13,568	$ (2,393)	-18%
Total Research and Development Expenses	$ 27,152	$ 21,186	$ 5,966	28%

Total research and development expenses incurred in the six months ended June 30, 2010 amounted to $27.2 million, an increase of $6.0 million, or 28%, from the six months ended June 30, 2009. The $6.0 million increase reflects an increase in costs as we prepared and initiated new clinical trials and increased spending on ongoing clinical trials. In addition, during the six months ended June 30, 2009, we incurred costs which we did not incur during the six months ended June 30, 2010, including costs associated with our then planned AUB trial, costs to ready our manufacturing capabilities at our Cambridge, Massachusetts manufacturing facility, and costs associated with the manufacture of *Feraheme* prior to FDA approval for commercial sale.

Our external research and development expenses increased by $8.4 million, or greater than 100%, for the six months ended June 30, 2010 as compared to the six months ended June 30, 2009. The increase in our external expenses was due primarily to costs incurred as we commenced our Phase III clinical development program for *Feraheme* to treat IDA regardless of the underlying cause, which was initiated in June 2010, costs associated with our global clinical study to support our MAA in Europe for the treatment of IDA in CKD patients, costs incurred to begin preparations for certain of our planned pediatric studies, filing fees and costs associated with regulatory submissions, costs incurred as we completed enrollment of our Phase II study of *Feraheme* as a diagnostic agent for vascular-enhanced MRI for the assessment of PAD, and costs associated with research and development for new manufacturing processes. These increases were partially offset by certain costs incurred in the six months ended June 30, 2009, which were not incurred during 2010, including costs associated with our AUB trial, which was discontinued in 2009, and costs associated with our efforts to address the manufacturing observations noted by the FDA during a 2008 inspection of our Cambridge, Massachusetts manufacturing facility. Further, during the six months ended June 30, 2010, we capitalized to inventory certain external *Feraheme* manufacturing and materials costs, which, during the six months ended June 30, 2009, were expensed prior to FDA approval of *Feraheme*.

Our internal research and development expenses decreased by $2.4 million, or 18%, for the six months ended June 30, 2010 as compared to the six months ended June 30, 2009. The decrease in internal

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costs was due primarily to the allocation of internal manufacturing costs to inventory in the six months ended June 30, 2010, whereas such costs were expensed in the six months ended June 30, 2009 because *Feraheme* had not been approved for sale by the FDA. At June 30, 2010, we had 60 FTEs in research and development as compared to 100 FTEs at June 30, 2009, a decrease of 40%, due primarily to the reallocation of manufacturing personnel out of research and development following FDA approval of *Feraheme* in June 2009.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the six months ended June 30, 2010 and 2009 consisted of the following (in thousands):

	Six Months Ended June 30,			
	2010	2009	$ Change	% Change
Compensation, payroll taxes and benefits	$ 19,961	$ 16,494	$ 3,467	21%
Professional and consulting fees and other expenses	21,001	13,235	7,766	59%
Equity-based compensation expense	6,498	5,289	1,209	23%
Total	$ 47,460	$ 35,018	$ 12,442	36%

The $12.4 million, or 36%, increase in selling, general and administrative expenses for the six months ended June 30, 2010 as compared to the six months ended June 30, 2009 was due primarily to increased costs associated with the continued expansion of our commercial operations function and our general administrative infrastructure to support our growth as a commercial entity, including increased advertising and promotion costs associated with the July 2009 U.S. commercial launch of *Feraheme* and compensation and benefits costs related to increased headcount. In addition, during the six months ended June 30, 2010 we incurred legal and other consulting and professional fees in connection with our collaboration with Takeda. At June 30, 2010 we had 186 employees in our selling, general and administrative departments as compared to 174 employees at June 30, 2009, a 7% increase. The $1.2 million increase in equity-based compensation expense was due primarily to increased equity awards to both new and existing employees.

Other Income (Expense)

Other income (expense) for the six months ended June 30, 2010 and 2009 consisted of the following (in thousands):

	Six Months Ended June 30,			
	2010	2009	$ Change	% Change
Interest and dividend income, net	$ 875	$ 2,039	$ (1,164)	-57%
Gains on investments, net	798	1,267	(469)	-37%
Fair value adjustment of settlement rights	(788)	(1,108)	320	-29%
Total	$ 885	$ 2,198	$ (1,313)	-60%

Other income (expense) for the six months ended June 30, 2010 decreased by $1.3 million, or 60%, as compared to the six months ended June 30, 2009. The $1.3 million decrease was primarily attributable to a $1.2 million decrease in interest and dividend income as the result of lower interest rates in the six months ended June 30, 2010 as compared to the six months ended June 30, 2009.

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

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period beginning June 30, 2010. In accordance with the terms of the Settlement Rights, during the six months ended June 2010 UBS redeemed all of our ARS subject to Settlement Rights at their par value. As a result, during the six months ended June 30, 2010, we recognized both a realized gain of $0.8 million related to the redemption of our UBS ARS subject to Settlement Rights and a corresponding realized loss of $0.8 million related to the exercise of the Settlement Rights.

Income Tax Benefit

We recognized an income tax benefit of $0.1 million during the six months ended June 30, 2010, 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 six months ended June 30, 2010. This income tax expense was recorded in other comprehensive income. During the six months ended June 30, 2009, we recognized $0.2 million in income tax benefit associated with U.S. research and development tax credits against which we had previously provided a full valuation allowance, but which became refundable as a result of legislation passed in 2009.

Net Loss

For the reasons stated above, we incurred a net loss of $44.4 million, or $2.16 per basic and diluted share, for the six months ended June 30, 2010 as compared to a net loss of $52.9 million, or $3.10 per basic and diluted share, for the six months ended June 30, 2009.

Liquidity and Capital Resources

General

We finance our operations primarily from the sale of *Feraheme*, the sale of our common stock, cash generated from our investing activities, and payments from our strategic partners. Our long-term capital requirements will depend on many factors, including, but not limited to, the following:

- Our ability to successfully commercialize *Feraheme* in the U.S. as an IV iron replacement therapeutic agent;
- The magnitude of *Feraheme* sales and the timing of the receipt of cash from such sales;
- Our ability to achieve the various milestones and receive the associated payments under the Takeda Agreement;

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

- Costs associated with our development of additional indications for *Feraheme* in the U.S.;

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

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

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- Costs associated with potential business development and in-licensing activities;

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

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

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

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

As of June 30, 2010, our investments consisted of corporate debt securities, U.S. treasury and government agency securities, and ARS. We place our cash and investments in instruments that meet high credit quality standards, as specified in our investment policy. Our investment policy also limits the amount of our non U.S. government credit exposure to any one issue or issuer and seeks to manage these assets to achieve our goals of preserving principal, maintaining adequate liquidity at all times, and maximizing returns.

Cash and cash equivalents and investments at June 30, 2010 and December 31, 2009 consisted of the following (in thousands):

	June 30, 2010	December 31, 2009	$ Change	% Change
Cash and cash equivalents	$ 135,793	$ 50,126	$ 85,667	>100%
Short-term investments	153,337	29,578	123,759	>100%
Long-term investments	38,876	49,013	(10,137)	-21%
Total cash, cash equivalents and investments	$ 328,006	$ 128,717	$ 199,289	>100%

The increase in cash and cash equivalents and investments as of June 30, 2010 as compared to December 31, 2009 is primarily the result of net proceeds of $165.6 million from our January 2010 public offering, the $60.0 million upfront payment we received under the Takeda Agreement, cash received from *Feraheme* sales, and interest income, partially offset by cash used in operations.

As of June 30, 2010, we believe that our cash, cash equivalents, and short-term investments and the cash we currently expect to receive from sales of *Feraheme* and earnings on our investments, will be sufficient to satisfy our future cash flow needs for at least the next twelve months, including projected operating expenses related to our ongoing development and commercialization programs for *Feraheme*.

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

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Cash flows from operating activities

During the six months ended June 30, 2010, our $31.5 million of cash provided by operations was due principally to the receipt of a $60.0 million upfront payment from Takeda in April 2010 as well as approximately $10.0 million received in connection with sales deferred under our Launch Incentive Program, adjusted for the following:

- Our net loss of $44.4 million, which was primarily the result of commercialization expenses, including advertising and promotion costs, compensation and other expenses, research and development costs, including costs associated with clinical trials, and general and administrative costs, partially offset by net product and collaboration revenues;

- Additional costs of $5.8 million capitalized to inventory as of June 30, 2010;

- A decrease of $3.1 million in accounts receivable, excluding sales deferred under our Launch Incentive Program;

- An increase of $3.9 million in accounts payable and accrued expenses, including an increase of $2.2 million of reserves for commercial discounts and rebates;

- Non-cash operating items of $10.5 million, including equity-based compensation expense, depreciation and amortization, income tax benefit, and other non-cash items; and

- Changes in other operating assets and liabilities of $5.8 million, which reflect timing differences between the receipt and payment of cash associated with certain transactions and when such transactions are recognized in our results of operations.

Cash flows from investing activities

Cash used by investing activities was $113.1 million during the six months ended June 30, 2010 and was primarily attributable to the purchase of investments with the proceeds received from our January 2010 financing.

Cash flows from financing activities

Cash provided by financing activities was $167.3 million during the six months ended June 30, 2010. In January 2010, we sold 3.6 million shares of our common stock at a public offering price of $48.25 per share, which resulted in net proceeds to us of approximately $165.6 million.

Contractual Obligations

Our contractual obligations primarily consist of our obligations under non-cancellable operating leases and other purchase obligations as described in our Annual Report on Form 10-K for the year ended December 31, 2009. Other than as described below, there have been no significant changes in our contractual obligations since December 31, 2009.

On March 31, 2010, we entered into the Takeda Agreement. Under the Takeda Agreement, we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey. As provided under the Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme* and, accordingly, are responsible for supply of *Feraheme* to Takeda. We are also responsible for conducting, and bearing the costs related to,

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certain predefined clinical studies with the costs of future modifications or additional studies to be allocated between the parties according to an agreed upon cost-sharing mechanism, which provides for a cap on such costs. We have received an upfront payment and may receive a combination of regulatory approval and performance-based milestone payments, as well as defined payments for supply of the drug product and royalties on net product sales by Takeda in the Licensed Territory.

Legal Proceedings

A purported class action complaint was filed on March 18, 2010 in the United States District Court for the District of Massachusetts against us and our President and Chief Executive Officer, and Executive Vice President and Chief Financial Officer, entitled *Silverstrand Investments v. AMAG Pharm., Inc., et. al.*, Civil Action No. 1:10-CV-10470-NMG. The complaint alleges that the defendants violated the federal securities laws, specifically Section 11 of the Securities Act of 1933, as amended, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff seeks unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. No trial date has been scheduled. We believe that the allegations contained in the complaint are without merit and intend to defend the case vigorously. We have not recorded an estimated liability in connection with this legal proceeding as we do not believe that such a liability is probable or estimable.

On July 21, 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 the patent. We believe the Sandoz patent opposition is without merit and intend to defend against the opposition vigorously.

Off-Balance Sheet Arrangements

As of June 30, 2010, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

Critical Accounting Policies

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect the reported amount of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The most significant estimates and assumptions are used in, but are not limited to, revenue recognition related to collaboration agreements and product sales, product sales allowances and accruals, assessing investments for potential other-than-temporary impairment and determining values of investments, reserves for doubtful accounts, accrued expenses, income taxes and equity-based compensation expense. Actual results could differ materially from those estimates. In making these estimates and assumptions, management employs critical accounting policies. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the year ended December 31, 2009. As a result of our collaboration agreement with Takeda in March 2010, our critical accounting policies have changed to include revenue recognition of multiple element arrangements, as described below. There have otherwise been no significant changes to these critical accounting policies and estimates since December 31, 2009.

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Multiple Element Arrangements

From time to time, we may enter into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of our products or product candidates. The terms of the agreements may include non-refundable license fees, payments based upon the achievement of certain milestones and performance goals, reimbursement of certain out-of-pocket costs, payments for manufacturing services and royalties on product sales.

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

When multiple deliverables are combined and accounted for as a single unit of accounting, we base our revenue recognition pattern on the last to be delivered element. Revenue will be recognized using either a proportional performance or straight-line method, depending on whether we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and whether such performance obligations are provided on a best-efforts basis. To the extent we cannot reasonably estimate our performance obligations, we recognize revenue on a straight-line basis over the period we expect to complete our performance obligations. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement. We may have to revise our estimates based on changes in the expected level of effort or the period we expect to complete our performance obligations.

Our collaboration arrangements may entitle us to additional payments upon the achievement of performance-based milestones. Milestones that involve substantive effort on our part and the achievement of which are not considered probable at the inception of the collaboration are considered substantive milestones. We recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets the following criteria: (1) the consideration received is commensurate with either the level of effort required to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone; (2) the milestone is related solely to past performance; and (3) the milestone is reasonable relative to all deliverables and payment terms in the arrangement. There is significant judgment involved in determining whether a milestone meets all of these criteria. For milestones that are not considered substantive milestones at the onset of the agreement, we recognize the milestone when the conditions are met by recognizing immediately the portion of the milestone payment equal to the percentage of the performance period completed when the milestone is achieved. The remaining portion of the milestone will be recognized over the remaining performance period using a proportional performance or straight-line method.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in our condensed consolidated balance sheets. Amounts not expected to be recognized within the next 12 months are classified as long-term deferred revenue.

Takeda Agreement

On March 31, 2010, we entered into the Takeda Agreement. As provided under the Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme* and, accordingly, are responsible for supply of *Feraheme* to Takeda. We are also responsible for conducting, and bearing the costs related to, certain predefined clinical studies with the costs of future modifications or additional studies to be allocated between the parties according to an agreed upon cost-sharing mechanism, which provides for a cap on such costs. In April 2010 we received a $60.0 million upfront payment from Takeda, which we recorded as deferred revenue. In addition, we may receive a combination of regulatory approval and performance-based milestone payments, reimbursement of certain out-of-pocket regulatory and clinical supply costs, as well as defined payments for supply of *Feraheme,* and tiered double-digit royalties on net product sales by Takeda in the Licensed Territory. The milestone payments may over time total up to approximately $220.0 million.

We have determined that the Takeda Agreement includes four deliverables: the license, access to future know-how and improvements to the *Feraheme* technology, regulatory and clinical research services, and the manufacturing and supply of product. Pursuant to the accounting guidance under Accounting Standards Codification 605-25, or ASC 605-25, which governs revenue recognition on multiple element arrangements, we have evaluated the four deliverables under the Takeda Agreement and determined that our obligation to provide manufacturing supply of product meets the criteria for separation and is therefore treated as a single unit of accounting, which we refer to as the supply unit of accounting. Further, under ASC 605-25, we have concluded that the license is not separable from the undelivered future know-how and technological improvements or the undelivered regulatory and clinical research services. 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.

We have allocated the consideration to be received under the Takeda Agreement based upon a residual value approach for the combined unit of accounting determined at the date we entered into the Takeda Agreement. There is significant judgment involved in assessing whether the consideration being received for the supply of *Feraheme* is fair value. In assessing the consideration to be allocated to the supply unit of accounting, we determined that the amount of the consideration allocated to this unit should be based upon the estimated fair value of manufacturing profit to be earned over the expected term of the performance obligation. Based upon an analysis of our estimated costs to supply *Feraheme* as well as profit earned by third-party contract pharmaceutical manufacturers, we have determined that the consideration to be received for product supply in addition to the royalties to be received related to those sales represents fair value in return for our supply of product. Therefore, no other consideration under the contract is being allocated to the supply unit of accounting. Of the $220.0 million in potential milestone payments, we have determined that any payments which may become due upon approval by certain regulatory agencies will be deemed substantive milestones and, therefore, will be accounted for as revenue in the period in which they are achieved. All remaining milestone payments will be accounted for in accordance with our revenue attribution method for the upfront payment as defined below.

With respect to the combined unit of accounting, our obligation to provide access to our future know-how and technological improvements is

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the final deliverable and is an obligation which exists throughout the term of the Takeda Agreement. Because we cannot reasonably estimate the total level of effort required to complete the obligations under the combined deliverable, we are recognizing the entire $60.0 million upfront payment 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, which represents the current patent life of *Feraheme* and our best estimate of the period over which we will substantively perform these 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.

Impact of Recently Issued and Proposed Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2010-17, Revenue Recognition Milestone Method, or ASU 2010-17. ASU 2010-17 provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. An entity can recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. The following criteria must be met for a milestone to be considered substantive. The consideration earned by achieving the milestone should (1) be commensurate with either the level of effort required to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the entity s performance to achieve the milestone; (2) be related solely to past performance; and (3) be reasonable relative to all deliverables and payment terms in the arrangement. No bifurcation of an individual milestone is allowed and there can be more than one milestone in an arrangement. Accordingly, an arrangement may contain both substantive and nonsubstantive milestones. ASU 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The adoption of this guidance did not have a significant impact on our condensed consolidated financial statements.

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

In October 2009, the FASB issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13. ASU 2009-13 amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB ASC Subtopic 605-25 (previously included within Emerging Issues Task Force, or EITF, No. 00-21, Revenue Arrangements with Multiple Deliverables, or EITF 00-21). The consensus to EITF Issue No. 08-1, Revenue Arrangements with Multiple Deliverables, or EITF 08-1,

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provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management s estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. EITF 00-21 previously required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under EITF 00-21, if the fair value of all of the elements in the arrangement was not determinable, then revenue was generally deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011 will require us to apply this guidance retrospectively to January 1, 2010 and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. We do not currently expect this guidance to have a significant impact on our condensed consolidated financial statements, however, it could potentially impact us if we adopt the guidance early in the future, complete any future transactions or if we enter into any material modifications to any of our existing collaborations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As of June 30, 2010, our short- and long-term investments totaled $192.2 million and were invested in corporate debt securities, U.S. treasury and government agency securities, commercial paper, and ARS. These investments are subject to interest rate risk and will fall in value if market interest rates increase. However, even if market interest rates for comparable investments were to increase immediately and uniformly by 50 basis points, or one-half of a percentage point, from levels at June 30, 2010, this would have resulted in a hypothetical decline in fair value of our investments, excluding ARS, which are described below, of less than $0.8 million.

At June 30, 2010, we held a total of $38.9 million in fair market value of ARS, reflecting a decline in value of approximately $6.4 million from the par value of these securities of $45.3 million. In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions. As a result of the lack of observable ARS market activity since that time, we use a discounted cash flow analysis to value these securities as opposed to valuing them at par value. Our valuation analysis considers, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, credit ratings of the security by the major securities rating agencies, the ability or inability to sell the investment in an active market, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when call features may be exercised by the issuer. Based upon this methodology, we have recorded a $6.4 million unrealized loss related to our ARS to accumulated other comprehensive loss as of June 30, 2010.

We believe there are several significant assumptions that are utilized in our valuation analysis, the two most critical of which are the discount rate and the average expected term. Holding all other factors constant, if we were to increase the discount rate utilized in our valuation analysis by 50 basis points, or one-half of a percentage point, this change would have the effect of reducing the fair value of our ARS by approximately $0.7 million as of June 30, 2010. Similarly, holding all other factors constant, if we were to increase the average expected term utilized in our fair value calculation by one year, this change would have the effect of reducing the fair value of our ARS by approximately $1.2 million as of June 30, 2010.

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

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended June 30, 2010 that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

On July 21, 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 the patent. We believe the Sandoz patent opposition is without merit and intend to defend against the opposition vigorously.

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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.

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

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

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

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

Feraheme primarily competes with two other IV iron replacement therapies, including Venofer®, which is marketed in the U.S. by Fresenius Medical Care North America, or Fresenius, and American Regent Laboratories, Inc., a subsidiary of Luitpold Pharmaceuticals, Inc., or Luitpold, and Ferrlecit®, which is marketed by Sanofi-Aventis U.S. LLC. *Feraheme* may not receive the same level of market acceptance as these competing iron replacement therapy products, especially since these products have been on the market longer and are currently widely used by physicians. We may not be able to convince physicians and other healthcare providers or payors to switch from using the other marketed IV iron therapeutic products to *Feraheme*. The iron replacement therapy market is highly sensitive to several factors including, but not limited to, the

actual and perceived safety profile of the available products, the ability to obtain appropriate insurance coverage, coding and reimbursement, price competitiveness, and product characteristics such as

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convenience of administration and dosing regimens. To date, we have not completed any head-to-head clinical studies comparing *Feraheme* to other IV iron replacement products.

In addition to the foregoing currently marketed products, there are several iron replacement therapy products in various stages of clinical and commercial development in the U.S. and abroad, including Monofer® (iron isomaltoside 1000), an injectable iron preparation which in December 2009 received a positive recommendation in 22 European countries and a final marketing authorization in 16 countries for the treatment of IDA, Injectafer®, which is known as Ferinject® in Europe and is approved for marketing in 23 European countries, Switzerland and South Korea, and soluble ferric pyrophosphate, a form of iron given as part of the hemodialysis procedure.

In addition to competition from other marketed products and products known by us to be currently under development, the market opportunity for *Feraheme* could be negatively affected if generic IV iron replacement therapy products were to be approved and achieve commercial success. For example, in July 2009, Watson Pharmaceuticals, Inc. announced that it entered into a license agreement with GeneraMedix, Inc. for the exclusive U.S. marketing rights to a generic version of Ferrlecit®, which is indicated for the treatment of IDA in hemodialysis patients receiving supplemental erythropoiesis stimulating agent therapy. GeneraMedix, Inc. has filed an Abbreviated New Drug Application, or NDA, with the U.S. Food and Drug Administration, or FDA, which is under expedited review. Companies that manufacture generic products typically invest far less resources in research and development than the manufacturer of a branded product and can therefore price their products significantly lower than those already on the market. It remains unclear if and when a generic product will enter this market.

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

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

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

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

- The ability of physicians and other providers to be adequately reimbursed for *Feraheme* in a timely manner from payors, including government payors, such as Medicare and Medicaid, and private payors, particularly in light of the expected bundling of costs of providing care to dialysis patients;

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

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

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

- The actual or perceived safety profile of *Feraheme* compared to alternative iron replacement therapeutic agents, particularly if unanticipated adverse reactions to *Feraheme* result in safety concerns among prescribers.

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

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

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

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

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

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

In the U.S., both federal and state agencies continue to promote efforts to reduce healthcare costs. For example, among other things, recently enacted federal healthcare legislation requires pharmaceutical manufacturers to be responsible for higher minimum Medicaid rebates owed to state Medicaid agencies, extends the rebate provisions to Medicaid managed care organizations, and expands the 340(b) Public Health Services drug pricing program. As a result of these and other reimbursement and legislative proposals, and the trend toward managed health care in the U.S., third-party payors, including government and private payors, are also increasingly attempting to contain health care costs by limiting the coverage and the level of reimbursement of new drugs. These cost-containment methods may include, but are not limited to, using formularies, which are lists of approved or preferred drugs, requiring prior authorization or step therapy, which is a program to encourage using lower cost alternative treatments, basing payment amounts on the least costly alternative treatment, or refusing to provide coverage of approved products for medical indications other than those for which the FDA has granted marketing approval. Cost control initiatives could adversely affect the commercial opportunity or decrease the price of *Feraheme* and may impede the ability of potential *Feraheme* users to obtain reimbursement, any of which could have a material adverse effect on our potential profitability and future business prospects.

Medicare currently reimburses for physician-administered drugs in the hospital outpatient, dialysis center and physician clinic settings at a rate of 106% of the drug s average selling price, or ASP. If the Centers for Medicare & Medicaid Services, or CMS, or one of its local contractors, believe that *Feraheme* s ASP is too high, it may attempt to initiate one or more of the cost-containment methods discussed above at either the national or local level. In addition, in July 2008, Congress enacted the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, which created a Medicare-expanded bundled payment system for the treatment of end stage renal disease, or ESRD, to be implemented by January 1, 2011. MIPPA requires CMS to move from a system in which it pays separately for physician-administered drugs for dialysis patients to a system in which all costs of providing care to dialysis patients are bundled together into a single capitated payment. The ESRD expanded bundle is to be phased in beginning on January 1, 2011, and the phase-in must be completed by January 1, 2014. In July 2010, CMS published a final rule establishing the new prospective payment system for dialysis services provided to Medicare beneficiaries who have ESRD. This bundled approach to reimbursement may lower utilization of physician-administered drugs in the ESRD market. In addition, the bundled approach to reimbursement in the dialysis setting may lower the amount of reimbursement available for *Feraheme* and consequently put downward pressure on the price we can charge for *Feraheme*. Therefore, we may be limited in our ability to successfully market and sell *Feraheme* in the dialysis setting. While the MIPPA ESRD provisions apply only to Medicare, Medicare payment policy can also influence pricing and reimbursement in the non-Medicare markets, as private third-party payors and state Medicaid plans frequently adopt Medicare principles in setting reimbursement methodologies, particularly in the ESRD setting. Changes in the Medicare reimbursement rate may,

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therefore, result in changes to payment rates from non-Medicare payors as well, further limiting our ability to successfully market and sell *Feraheme*.

To the extent we sell our products internationally, market acceptance may also depend, in part, upon the availability of reimbursement within existing healthcare payment systems. Generally, in Europe and other countries outside of the U.S., the government sponsored healthcare system is the primary payor of healthcare costs of patients and therefore enjoys significant market power. Some foreign countries also set prices for pharmaceutical products as part of the regulatory process, and we cannot guarantee that the prices set by such governments will be sufficient to generate substantial revenues in those countries.

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

Discovery of previously unknown problems with an approved product may result in recalls, restrictions on the product s permissible uses, or withdrawal of the product from the market. The data submitted to the FDA as part of our NDA was obtained in controlled clinical trials of limited duration. New safety or drug interaction issues may arise as *Feraheme* is used over longer periods of time by a wider group of patients taking numerous other medicines and with additional underlying health problems. In addition, as we conduct other clinical trials for *Feraheme*, new safety problems may be identified which could negatively impact both our ability to successfully complete these studies and the use and/or regulatory status of *Feraheme* for the treatment of IDA in patients with CKD. New safety or drug interaction issues may require us to provide additional warnings on the *Feraheme* label, directly alert healthcare providers of new safety information, narrow our approved indications, or alter or terminate current or planned trials for additional uses of *Feraheme*, any of which could reduce the market acceptance of *Feraheme*. In addition, if significant safety or drug interaction issues arise, FDA approval for *Feraheme* could be withdrawn, and the FDA could require the recall of all existing *Feraheme* in the marketplace. The FDA also has the authority to require the recall of our products if there is contamination or other problems with manufacturing, transport or storage of the product. A government-mandated recall or a voluntary recall could divert managerial and financial resources, could be difficult and costly to correct, could result in the suspension of sales of *Feraheme*, and could have a severe adverse impact on our potential profitability and the future prospects of our business.

We may also be required to conduct certain post-approval clinical studies to assess known or suspected significant risks associated with *Feraheme*. The Food and Drug Administration Amendments Act of 2007 expanded the FDA s authority. Under the Food and Drug Administration Amendments Act of 2007, the FDA may: (i) require manufacturers to conduct post-approval clinical studies to assess known risks or signals of serious risks, or to identify unexpected serious risks; (ii) mandate labeling changes to a product based on new safety information; or (iii) require sponsors to implement a Risk Evaluation Management Strategy, or REMS, where necessary to assure safe use of the drug. If we are required to conduct post-approval clinical studies or implement a REMS, or if the FDA changes the label for *Feraheme* to include additional discussion of potential safety issues, such requirements or restrictions could have a material adverse impact on our ability to generate revenues from sales of *Feraheme*, or require us to expend significant additional funds on clinical studies.

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

Prior to our commercialization of *Feraheme*, we had never independently marketed or sold a drug product as we had relied on our corporate partners to market and sell our previously approved products. We

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have an internal sales and marketing infrastructure to market and sell *Feraheme* in the U.S., and if we are unsuccessful in maintaining an effective sales and marketing function or experience a high level of turnover, then the commercialization of *Feraheme* could be severely impaired. Any failure by us to successfully execute our commercialization plans for *Feraheme* could have a material adverse impact on our ability to generate revenues, our ability to achieve profitability, and the future prospects for our business.

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

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

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

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

Our Cambridge, Massachusetts manufacturing facility is subject to current good manufacturing practices, or cGMP, regulations enforced by the FDA through periodic inspections to confirm such compliance. We must continually expend time, money and effort in production, record-keeping and quality assurance and control to ensure that our manufacturing facility meets the FDA s regulatory requirements. Failure to maintain ongoing compliance with cGMP regulations and other applicable manufacturing requirements of various regulatory agencies could result in the FDA s issuance of Warning Letters, fines, the withdrawal or recall of *Feraheme* from the marketplace, total or partial suspension of *Feraheme* production, the loss of our *Feraheme* inventory, suspension of the FDA s review of any future supplemental NDAs, enforcement actions, injunctions or criminal prosecution. If the FDA inspects our manufacturing facility and determines that we are not in compliance with cGMP regulations or we

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otherwise determine that we are not in compliance with these regulations, we could experience an inability to manufacture sufficient quantities of *Feraheme* to meet demand or incur unanticipated compliance expenditures, either of which could have an adverse impact on *Feraheme* sales, our potential profitability and the future prospects of our business.

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

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

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

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

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

We currently purchase certain raw materials used to manufacture *Feraheme* from third-party suppliers. We do not have any long-term supply contracts with these third parties. Some of these raw materials are procured from a single source with no qualified alternative supplier. We are in the process of identifying and

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qualifying additional third-party suppliers for these raw materials used to manufacture *Feraheme*. Third-party suppliers may cease to produce the raw materials used in *Feraheme* or otherwise fail to supply these raw materials to us or fail to supply these raw materials to us in sufficient quantities for a number of reasons, including but not limited to the following:

- Unexpected demand for or shortage of raw materials;
- Labor disputes or shortages;
- Manufacturing difficulties;
- Regulatory requirements or action;
- Adverse financial developments at or affecting the supplier; or
- Import or export problems.

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

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

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

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

We have commenced or are pursuing additional clinical trials and plan to seek regulatory approval to market *Feraheme* in additional indications beyond CKD in the U.S. There is no guarantee that we will be successful in completing any clinical trials for additional indications in a timely manner or that, if completed, the results of such clinical trials will demonstrate *Feraheme* to be safe and effective in such uses and/or patient populations.

The FDA imposes substantial requirements on the development and production of all drug products. Before obtaining regulatory approval for the commercial marketing and sale of *Feraheme* for additional indications, we must demonstrate through extensive human clinical trials that *Feraheme* is safe and efficacious for these new uses and in these new patient populations. Conducting clinical trials is a complex,

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time-consuming and expensive process that requires adherence to a wide range of regulatory requirements. The FDA has substantial discretion in the approval process and may decide that the results of our clinical trials are insufficient for approval or that *Feraheme* is not effective or safe in indications other than CKD. Clinical and other data is often susceptible to varying interpretations, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products.

The FDA could also determine that our clinical trials and/or our manufacturing processes were not properly designed, were not conducted in accordance with federal laws and regulations, or were otherwise not properly managed. In addition, under the FDA s current good clinical practices regulations, or cGCP, we are responsible for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA may conduct inspections of clinical investigator sites which are involved in our clinical development programs to ensure their compliance with cGCP regulations. If the FDA determines that we, our contract research organizations or our study sites fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may disqualify certain data generated from those sites or require us to perform additional clinical trials before approving our marketing applications, which could adversely impact our ability to obtain approval for *Feraheme* in indications other than CKD. Any such deficiency in the design, implementation or oversight of our clinical development programs could cause us to incur significant additional costs, experience significant delays in our efforts to obtain regulatory approval for *Feraheme* in indications other than CKD, or even prevent us from obtaining regulatory approval for *Feraheme* for additional indications. This would, in turn, materially adversely impact our cash position, our ability to increase revenues, our ability to achieve profitability, and the future prospects of our business.

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

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

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

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

On March 31, 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda. Under the Takeda Agreement, we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in Europe,

Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey, or collectively, the Licensed Territory. We are highly dependent on Takeda for certain regulatory filings outside of the U.S. with respect to *Feraheme* and the commercialization of Feraheme outside of the U.S. If Takeda fails to perform its obligations under the Takeda Agreement or is ineffective in its

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commercialization of *Feraheme* in the Licensed Territory or if we fail to effectively manage our relationship with Takeda, our ability to and the extent to which we commercialize and obtain certain regulatory approvals of *Feraheme* outside of the U.S. would be significantly harmed. Further, if we fail to fulfill certain of our obligations under the Takeda Agreement, Takeda has the right to assume the responsibility of clinical development of *Feraheme* in the Licensed Territory, which would increase the cost of and delay the *Feraheme* development program outside of the U.S.

In addition, Takeda has the right to terminate the agreement under certain conditions. If Takeda terminates the Takeda Agreement, we would be required to either enter into alternative arrangements with third parties to commercialize *Feraheme* in the Licensed Territories, 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 outside of the U.S.

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

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

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

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

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

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

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

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

- The timing and magnitude of our recognition of revenues from sales of *Feraheme* associated with purchases made under our Launch Incentive Program, and the possibility that such purchases will be returned and never recognized as revenue by us;

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

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

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

- The timing and magnitude of milestone payments received under the Takeda Agreement;

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

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

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

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

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

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

Wholesaler and distributor buying patterns and other factors may cause our quarterly results to fluctuate, and these fluctuations may adversely affect our short-term results.

Our results of operations, including, in particular, product sales revenues, may vary from period to period due to a variety of factors, including the buying patterns of our wholesalers and distributors, which vary from quarter to quarter. In the event wholesalers and distributors with whom we do business determine to limit their purchases of our products, sales of our products could be adversely affected. For example, in advance of an anticipated price increase or a reduction in expected rebates or discounts,

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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 related to revenue recognition and related sales allowances, investments, reserves for doubtful accounts, equity-based compensation, accrued expenses and income taxes. We base our estimates on market data, our observance of trends in our industry, and on various other assumptions that we believe to be reasonable under the circumstances. If 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 negatively affect our financial position, results of operations and cash flows. In addition, to determine the required quantities of our products and the related manufacturing schedule, we also need to make significant judgments and estimates based on inventory levels, current market trends, anticipated sales, and other factors. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amount of product need. For example, the level of our access to wholesaler and distributor inventory levels and sales data, which varies based on the wholesaler or distributor, affects our ability to accurately estimate certain reserves included in our financial statements.

Any difference between our estimates and the actual amount of product demand could result in unmet demand or excess inventory, each of which would adversely impact our financial results and results of operation.

Our stock price has been and may continue to be volatile, and your investment in our stock could decline in value or fluctuate significantly.

The market price of our common stock has been, and may continue to be, volatile, and your investment in our stock could decline in value or fluctuate significantly. Our stock price has ranged between $29.58 and $52.49 in the fifty-two week period through August 2, 2010. The stock market has from time to time experienced extreme price and volume fluctuations, particularly in the biotechnology and pharmaceuticals sectors, which have often been unrelated to the operating performance of particular companies. Various factors and events, many of which are beyond our control, may have a significant impact on the market price of our common stock. Factors which may affect the market price of our common stock include, among others:

- Our ability to successfully commercialize *Feraheme* in the U.S.;

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- The timing and magnitude of *Feraheme* revenue and actual or anticipated fluctuations in our operating results;
- Changes in or our failure to meet financial estimates published by securities analysts;
- The availability of reimbursement coverage for *Feraheme* or changes in the reimbursement policies of governmental or private payors;
- Public announcements of regulatory actions with respect to *Feraheme* or products or product candidates of our competitors;
- Actual or perceived safety concerns related to *Feraheme* or products or product candidates of our competitors;
- General market conditions;
- Sales of large blocks of our common stock;
- The 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 outcome of any material litigation to which we are a party; and
- Significant collaboration, acquisition, joint venture or similar agreements by us or our competitors.

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

If securities analysts downgrade our stock, cease coverage of us, or if our operating results do not meet analysts forecasts and expectations, our stock price could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us and our business. Currently, eleven financial analysts publish reports about us and our business. We do not control these or any other analysts. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. In addition, our future operating results are subject to substantial uncertainty, and our stock price could decline significantly if we fail to meet or exceed analysts forecasts and expectations, especially with respect to the timing and magnitude of *Feraheme* revenues, including the recognition of net product revenues associated with purchases made under our Launch Incentive Program, which were initially deferred as of September 30, 2009. If any of the analysts who cover us downgrade our stock or issue commentary or observations that are perceived by the market to be adverse to us or our stock, our stock price would likely decline rapidly. If these analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

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

We have a history of significant operating losses, and we may not be profitable in the future or if we attain profitability, it may not be sustainable. In the past, we have financed our operations primarily from the sale of our equity securities, cash generated by our investing activities, and payments from our strategic partners. As of June 30, 2010, we had an accumulated deficit of approximately $326.1 million. Our losses are primarily the result of costs incurred in research and development, including costs associated with our *Feraheme* and other development programs, costs associated with establishing and maintaining our sales and marketing infrastructure, and other selling, general and administrative costs. We expect to continue to incur significant expenses to manufacture, market and sell *Feraheme* as an IV iron replacement therapeutic in CKD patients in the U.S. and to further develop *Feraheme* for additional indications and in additional countries outside of the U.S. As a result, we will need to generate sufficient revenues in future periods to achieve and maintain profitability. We anticipate that the vast majority of any revenue we generate in the near future will be from sales of *Feraheme* as an IV iron replacement therapeutic agent for CKD patients in the U.S. We have never independently marketed or sold any products, and we may not be successful in marketing or selling *Feraheme*. If we are not successful in marketing and selling *Feraheme*, if revenues grow more slowly than we anticipate or if our operating expenses exceed our expectations, our business, results of operations and financial condition could be materially adversely affected. In addition, if we are unable to achieve, maintain or increase profitability on a quarterly or annual basis, the market price of our common stock may decline.

We may need additional capital to achieve our business objectives.

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

- The magnitude of *Feraheme* sales and the timing of our receipt of cash from such sales;

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

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

- Costs associated with our development of additional indications for *Feraheme* in the U.S.;

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

- Costs associated with potential business development and in-licensing activities;

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

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

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

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

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

We estimate that our cash resources at June 30, 2010, combined with cash we currently expect to receive from sales of *Feraheme* and from earnings on our investments, will be sufficient to finance our currently planned operations for at least the next twelve months. Thereafter, we may require additional funds or need to establish additional alternative strategic arrangements to execute our business plans. We may seek needed funding through additional arrangements with collaborative partners or through public or private equity or debt financings. We may not be able to obtain financing or to secure alternative strategic arrangements on acceptable terms or within an acceptable timeframe, if at all.

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

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

At June 30, 2010, we had $135.8 million in cash and cash equivalents, $153.3 million in short-term investments, and $38.9 million in long-term investments. These investments are subject to general credit, liquidity, market and interest rate risks, which have been and may continue to be exacerbated by the U.S. and global financial crisis which has been occurring over the past several years. The ongoing disruptions in the credit and financial markets have negatively affected many industries, including those in which we invest, and we may realize losses in the fair value of certain of our investments or a complete loss of these investments, which would have an adverse effect on our results of operations, liquidity and financial condition.

At June 30, 2010, we held a total of $38.9 million in fair market value of auction rate securities, or ARS, reflecting a decline in value of approximately $6.4 million compared to the par value of these securities of $45.3 million. The $6.4 million difference was considered a temporary impairment and was reported as an unrealized loss in accumulated other comprehensive loss at June 30, 2010. In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions. Since that time, the continued uncertainty in the credit markets has caused almost all additional auctions with respect to our ARS to fail and prevented us from liquidating certain of our holdings

of ARS because the amount of these securities submitted for sale has exceeded the amount of purchase orders for these securities. These auctions may continue to fail indefinitely, and there could be a further decline in value of these securities or any other securities, which may ultimately be deemed to be other-than-temporary. In

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the future, should we determine that these declines in value of ARS are other-than-temporary, we will recognize the credit-related portion of the loss to our consolidated statement of operations, which could be material. In addition, failed auctions will adversely impact the liquidity of our investments. Based on our ability to access our cash and other short-term investments, our expected operating cash flows, and our other sources of cash, we do not anticipate that the current lack of liquidity with respect to these securities will materially affect our ability to operate our business in the ordinary course in the short term, however, we are uncertain when the current liquidity issues relating to ARS will improve, if at all.

The condition of the credit markets remains dynamic and unpredictable. As a result, we may experience a reduction in value or loss of liquidity with respect to our investments. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. Further, as part of our determination of the fair value of our investments, we consider credit ratings provided by independent investment rating agencies as of the valuation date. These ratings are subject to change. As the ratings of our ARS change we may be required to adjust our future valuation of our ARS which may adversely affect the value of these investments. These market risks associated with our investment portfolio may have an adverse effect on our results of operations, cash position, liquidity and overall financial condition.

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

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

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

Over the past several years, the U.S. and global economies have taken a dramatic downturn as a result of the volatility of the credit markets and related financial crisis, as well as a variety of other factors including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. The U.S. and certain foreign governments have taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If the actions taken by the U.S. and other governments are not successful, the continued economic decline may

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continue to negatively affect the liquidity of our investments, significantly impact our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all, and cause our investments to substantially decline in value. Any of these could have a material adverse effect on our liquidity, cash position and the potential future prospects of our business.

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

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

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

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

We are subject to ongoing regulatory requirements and review both in the U.S. and, in some cases, foreign jurisdictions, pertaining to *Feraheme s* manufacture, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. Failure to comply with such regulatory requirements or the later discovery of previously unknown problems with *Feraheme* or our manufacturing facility may result in restrictions on our ability to manufacture, market and sell *Feraheme*, including its withdrawal from the market. 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;

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- Requirements to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, or other issues involving *Feraheme;*

- Label changes;

- Implementation of an FDA-mandated REMS;

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

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

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

operation.

If we fail to comply with any federal, 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

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commercializing and marketing *Feraheme,* all of which could have a material adverse effect on our business, financial condition and results of operation.

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

As part of our business strategy, we intend to pursue collaboration and in-licensing opportunities, acquisitions of products or businesses, and/or strategic alliances that we believe would be complementary to our existing business. We have limited experience with respect to these business development activities. Any such strategic transactions by us could result in large and immediate write-offs or the incurrence of debt and contingent liabilities, any of which would adversely impact our operating results. Management of a license arrangement, collaboration, or other strategic arrangement and/or integration of an acquired asset or company may also disrupt our ongoing business, require management resources that otherwise would be available for ongoing development of our existing business and our U.S. commercialization of *Feraheme*. We may not identify or complete any such transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated financial benefits of any such transaction. In addition, to finance any such strategic transactions, we may choose to issue shares of our common or preferred stock as consideration, which would result in dilution to our stockholders. Alternatively, it may be necessary for us to raise additional funds through public or private financings, and such additional funds may not be available on terms that are favorable to us, if at all. In addition, proposing, negotiating and implementing collaborations, in-licensing arrangements or acquisition agreements may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for these arrangements, and we may not be able to enter into such arrangements on acceptable terms or at all.

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

We have experienced significant growth, which has placed and may continue to place a substantial strain on our management, employees, facilities and resources. In anticipation of the 2009 FDA approval and U.S. commercialization of *Feraheme*, we rapidly expanded our marketing, sales, manufacturing, regulatory, medical affairs, finance, development, and compliance capabilities. As our operations continue to expand, we will also need to manage additional relationships with various collaborative partners, suppliers and other third parties. In addition, we will need to continue to improve our operational and financial systems, train and manage our expanding workforce, and maintain close coordination among our various departments. We may not be able to accomplish these tasks, and our failure to accomplish any one of them could prevent us from successfully commercializing *Feraheme*, pursuing new business opportunities, or expanding our business, any one of which could adversely impact our future business prospects.

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

Because of the specialized nature of our business, our success depends to a significant extent on the continued service of our Chief Executive Officer and President, Brian J.G. Pereira, MD, our other executive officers and on our ability to continue to attract, retain and motivate qualified managerial, scientific, medical and sales personnel. We have entered into employment agreements with our senior executives but such agreements do not guarantee that these executives will remain employed by us for any significant period of time, or at all. If we are unable to retain these personnel, or we lose the services of our key personnel for any reason, our *Feraheme* development and commercialization efforts could be adversely impacted.

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Furthermore, our expansion into areas and activities requiring additional expertise, such as commercial-scale manufacturing, marketing and sales, and late-stage development has required the addition of new management personnel and the development of additional expertise by existing management personnel. There is intense competition for qualified personnel in the areas of our activities, and we may not be able to continue to attract and retain the qualified personnel necessary for the development of our business. Our failure to attract and retain such personnel or to develop such expertise could impose significant limits on our business operations and hinder our ability to successfully and efficiently commercialize *Feraheme* and complete our development projects.

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

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

Our U.S. *Feraheme* patents are currently scheduled to expire in 2020. These and any other patents issued to us may be contested or invalidated. For example, on July 21, 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 the patent. We believe the Sandoz patent opposition is without merit and intend to defend against the opposition vigorously. This or future patent interference proceedings involving our patents may result in substantial costs to us, distract our management, prevent us from marketing and selling *Feraheme*, limit our development and commercialization of *Feraheme* or otherwise harm 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*, limit our development and commercialization of *Feraheme*, or harm our competitive position and result in additional significant costs. In addition, any successful claim of infringement asserted against us could subject us to monetary damages or injunction, which could prevent us from making or selling *Feraheme*. We also may be required to obtain licenses to use the relevant technology. Such licenses may not be available on commercially reasonable terms, if at all.

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

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in

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part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants. These agreements, however, may be breached. We may not have adequate remedies for any such breaches, and our trade secrets might otherwise become known or might be independently discovered by our competitors. In addition, we cannot be certain that others will not independently develop substantially equivalent or superseding proprietary technology, or that an equivalent product will not be marketed in competition with *Feraheme*, thereby substantially reducing the value of our proprietary rights.

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

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

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

If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose 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 Securities and Exchange Commission, NASDAQ or other regulatory authorities.

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

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

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

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

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

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

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

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

- The ability of our Board of Directors to increase or decrease the size of the Board of Directors without stockholder approval;

- Advance notice requirements for the nomination of candidates for election to our Board of Directors and for proposals to be brought before our annual meeting of stockholders;

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- The authority of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval;

- Non-cumulative voting for directors; and

- Limitations on the ability of our stockholders to call special meetings of stockholders.

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

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

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

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.

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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, 2010.

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Item 6. Exhibits.

(a) List of Exhibits

Exhibit Number		Description
10.1		AMAG Pharmaceuticals, Inc. 2010 Employee Stock Purchase Plan (incorporated herein by reference to Appendix B to the Company s Definitive Proxy Statement on Schedule 14A, filed April 19, 2010, file No. 1-10865).
10.2	+	AMAG Pharmaceuticals, Inc. Non-Employee Director Compensation Policy.
10.3		AMAG Pharmaceuticals, Inc. Second Amended and Restated 2007 Equity Incentive Plan.(incorporated herein by reference to Appendix A to the Company s Definitive Proxy Statement on Schedule 14A, filed April 19, 2010, file No. 1-10865).
10.4	+	Form of Option Agreement (Nonqualified Option) for Annual Director Grants under the Second Amended and Restated 2007 Equity Incentive Plan.
10.5	+	Form of Restricted Stock Unit Agreement for Annual Director Grants under the Second Amended and Restated 2007 Equity Incentive Plan.
31.1	+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	++	The following materials from AMAG Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, 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, tagged as blocks of text.

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

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

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SIGNATURES

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

AMAG PHARMACEUTICALS, INC.

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

Date: August 5, 2010

AMAG PHARMACEUTICALS, INC.

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

Date: August 5, 2010

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