

AMAG PHARMACEUTICALS INC.

Form 10-Q

November 08, 2011

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2011

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 001-10865

**AMAG PHARMACEUTICALS, INC.**

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(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**04-2742593**  
(IRS Employer  
Identification No.)

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

**02421**  
(Zip Code)

**(617) 498-3300**

(Registrant's Telephone Number, Including Area Code)

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

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  No

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

Accelerated filer

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

Smaller reporting company

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

As of November 2, 2011 there were 21,202,959 shares of the registrant's Common Stock, par value \$0.01 per share, outstanding.

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AMAG PHARMACEUTICALS, INC.

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Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements.****AMAG PHARMACEUTICALS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)****(Unaudited)**

	September 30, 2011	December 31, 2010
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 75,777	\$ 112,646
Short-term investments	153,560	147,619
Accounts receivable, net	7,069	5,785
Inventories	15,577	16,344
Receivable from collaboration	192	441
Prepaid and other current assets	5,786	7,949
Total current assets	257,961	290,784
Property, plant and equipment, net	9,684	11,235
Long-term investments	21,631	33,597
Restricted cash	460	460
Total assets	\$ 289,736	\$ 336,076
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,601	\$ 4,553
Accrued expenses	32,528	25,555
Deferred revenues	6,346	6,603
Total current liabilities	43,475	36,711
Long-term liabilities:		
Deferred revenues	46,720	51,292
Other long-term liabilities	2,527	2,787
Total liabilities	92,722	90,790
Commitments and contingencies (Notes I & J)		
Stockholders' equity:		
Preferred stock, par value \$0.01 per share, 2,000,000 shares authorized; none issued		
Common stock, par value \$0.01 per share, 58,750,000 shares authorized; 21,202,959 and 21,137,428 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively	212	211
Additional paid-in capital	623,635	614,942
Accumulated other comprehensive loss	(5,506)	(7,028)
Accumulated deficit	(421,327)	(362,839)
Total stockholders' equity	197,014	245,286
Total liabilities and stockholders' equity	\$ 289,736	\$ 336,076

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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 SHARE AND PER SHARE DATA)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
<b>Revenues:</b>				
Product sales, net	\$ 15,802	\$ 15,173	\$ 39,905	\$ 44,694
License fee and other collaboration revenues	1,707	1,684	6,322	4,213
Royalties	46	35	115	118
Total revenues	17,555	16,892	46,342	49,025
<b>Costs and expenses:</b>				
Cost of product sales	2,669	2,274	7,792	5,168
Research and development expenses	14,894	14,031	45,155	41,183
Selling, general and administrative expenses	17,230	17,986	53,690	65,446
Total costs and expenses	34,793	34,291	106,637	111,797
<b>Other income (expense):</b>				
Interest and dividend income, net	378	448	1,390	1,323
Gains (losses) on investments, net	14	(396)	(194)	402
Fair value adjustment of settlement rights				(788)
Total other income (expense)	392	52	1,196	937
Net loss before income taxes	(16,846)	(17,347)	(59,099)	(61,835)
Income tax benefit	215	351	611	462
Net loss	\$ (16,631)	\$ (16,996)	\$ (58,488)	\$ (61,373)
<b>Net loss per share:</b>				
Basic and diluted	\$ (0.78)	\$ (0.81)	\$ (2.76)	\$ (2.96)
<b>Weighted average shares outstanding used to compute net loss per share:</b>				
Basic and diluted	21,194	21,085	21,169	20,700

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 September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net loss	\$ (16,631)	\$ (16,996)	\$ (58,488)	\$ (61,373)
Other comprehensive income (loss):				
Unrealized gains (losses) on securities:				
Holding gains (losses) arising during period, net of tax	45	335	1,314	751
Reclassification adjustment for (gains) losses included in net loss	(2)	400	208	400
Net unrealized gains (losses) on securities	43	735	1,522	1,151
Total comprehensive loss	\$ (16,588)	\$ (16,261)	\$ (56,966)	\$ (60,222)

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)

	Nine Months Ended September 30,	
	2011	2010
Cash flows from operating activities:		
Net loss	\$ (58,488)	\$ (61,373)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation	1,966	1,781
Non-cash equity-based compensation expense	8,798	10,736
Non-cash income tax benefit	(611)	(462)
Amortization of premium/discount on purchased securities	2,778	904
Fair value adjustment of settlement rights		788
Losses (gains) on investments, net	194	(402)
Changes in operating assets and liabilities:		
Accounts receivable, net	(1,284)	19,702
Inventories	2,094	(7,157)
Receivable from collaboration	249	(564)
Prepaid and other current assets	2,163	(2,221)
Accounts payable and accrued expenses	5,083	380
Deferred revenues	(4,829)	49,702
Other long-term liabilities	(260)	(219)
Total adjustments	16,341	72,968
Net cash (used in) provided by operating activities	(42,147)	11,595
Cash flows from investing activities:		
Proceeds from sales or maturities of available-for-sale investments	99,096	110,285
Purchases of available-for-sale investments	(93,707)	(234,045)
Capital expenditures	(415)	(1,100)
Net cash provided by (used in) investing activities	4,974	(124,860)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	10	1,322
Proceeds from the issuance of common stock, net of underwriting discounts and other expenses		165,559
Proceeds from the issuance of common stock under ESPP	294	642
Net cash provided by financing activities	304	167,523
Net (decrease) increase in cash and cash equivalents	(36,869)	54,258
Cash and cash equivalents at beginning of the period	112,646	50,126
Cash and cash equivalents at end of the period	\$ 75,777	\$ 104,384

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

SEPTEMBER 30, 2011

(Unaudited)

**A. Description of Business**

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a biopharmaceutical company focused on the development and commercialization of a therapeutic iron compound to treat iron deficiency anemia, or IDA. Our principal source of revenue is from the sale of *Feraheme*® (ferumoxytol) Injection for Intravenous, or IV, use, which was approved for marketing in the U.S. in June 2009 by the U.S. Food and Drug Administration, or the FDA, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with chronic kidney disease, or CKD. We market and sell *Feraheme* in the U.S. through our own commercial organization and began shipping *Feraheme* to our customers in July 2009. 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*, our potential inability to become profitable in the future, the potential development of significant safety or drug interaction problems with respect to *Feraheme*, competition in our industry, uncertainties regarding market acceptance of *Feraheme*, uncertainties related to patient insurance coverage, coding and third-party reimbursement for *Feraheme*, uncertainties related to the impact of current and future healthcare initiatives and legislation, 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 facilities in compliance with current good manufacturing practices, our potential inability to obtain raw or other materials and manufacture sufficient quantities of *Feraheme*, 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 obtain additional financing, if necessary, on acceptable terms, 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 broader *Feraheme* indication, for any indications outside of the U.S. or for potential alternative manufacturing facilities and processes, uncertainty of the results of our clinical trials, our dependence on key personnel, uncertainties related to the protection of proprietary technology, any adverse results from our recent corporate restructuring, potential product liability, potential legislative and regulatory changes, and potential costs and liabilities associated with pending or future litigation.

In July 2011, we entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, with Alamo Acquisition Sub, Inc., a Delaware corporation and our wholly-owned subsidiary, or Merger Sub, and Allos Therapeutics, Inc., or Allos, which was amended in August 2011. In October 2011, pursuant to the terms of the Merger Agreement, we terminated the Merger Agreement and paid Allos an expense reimbursement amount equal to \$2.0 million in connection with such termination, which will be recorded as an expense in our condensed consolidated statement of operations in the fourth quarter of 2011.

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As a result of the termination of the Merger Agreement, certain voting agreements, dated as of July 19, 2011, by and between us and each of the then directors, other than Timothy P. Lynch, and certain executive officers of Allos, and Warburg Pincus Private Equity VIII, L.P., or Warburg Pincus, automatically terminated pursuant to their respective terms; and a stockholders agreement, dated as of July 19, 2011, by and between us and Warburg Pincus, also automatically terminated pursuant to its terms.

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

**B. Basis of Presentation and Summary of Significant Accounting Policies**

*Basis of Presentation*

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

In accordance with accounting principles generally accepted in the United States of America for interim financial reports and the instructions for Form 10-Q and the rules of the Securities and Exchange Commission, certain information and footnote disclosures normally included in annual financial statements have been condensed or omitted. Our accounting policies are described in the Notes to the Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2010. 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, 2010.

*Use of Estimates and Assumptions*

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

*Principles of Consolidation*

The accompanying condensed consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiaries, Alamo Acquisition Sub, Inc., AMAG Europe Limited, and AMAG Securities Corporation. Alamo Acquisition Sub, Inc. was incorporated in Delaware in July 2011. AMAG Europe Limited was incorporated in October 2009 in London, England. AMAG Securities Corporation is a Massachusetts corporation which was incorporated in August 2007. All intercompany account balances and transactions between the companies have been eliminated.

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

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

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

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

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

We hold certain assets that are required to be measured at fair value on a recurring basis, including our cash equivalents and short- and long-term investments. The following tables represent the fair value hierarchy as of September 30, 2011 and December 31, 2010 for those assets that we measure at fair value on a recurring basis (in thousands):

	Total	Fair Value Measurements at September 30, 2011 Using:		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	\$ 62,709	\$ 62,709	\$	\$
Corporate debt securities	92,757		92,757	
U.S. treasury and government agency securities	44,310		44,310	
Commercial paper	12,993		12,993	
Auction rate securities	25,131			25,131
	\$ 237,900	\$ 62,709	\$ 150,060	\$ 25,131

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	Fair Value Measurements at December 31, 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	\$ 110,238	\$ 110,238	\$	\$
Corporate debt securities	83,768		83,768	
U.S. treasury and government agency securities	50,925		50,925	
Foreign government securities	2,431		2,431	
Commercial paper	10,495		10,495	
Auction rate securities	33,597			33,597
	\$ 291,454	\$ 110,238	\$ 147,619	\$ 33,597

With the exception of our auction rate securities, or ARS, which are valued using Level 3 inputs, as discussed below, the fair value of our investments other than money market funds is primarily determined from independent pricing services which use Level 2 inputs to determine fair value. Independent pricing services normally derive security prices from recently reported trades for identical or similar securities, making adjustments based upon other significant observable market transactions. At the end of each reporting period, we perform quantitative and qualitative analyses of prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analyses, we did not adjust or override any fair value measurements provided by our pricing services as of either September 30, 2011 or December 31, 2010. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the nine months ended September 30, 2011.

We also analyze when the volume and level of activity for an asset or liability have significantly decreased and when circumstances indicate that a transaction may not be considered orderly. In order to determine whether the volume and level of activity for an asset or liability have significantly decreased, we assess current activity as compared to normal market activity for the asset or liability. We rely on many factors such as trading volume, trading frequency, the levels at which market participants indicate their willingness to buy and sell our securities, as reported by market participants, and current market conditions. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if there has been a significant decrease in the volume and level of activity for an asset, group of similar assets, or liabilities. Similarly, in order to identify transactions that are not orderly, we take into consideration the activity in the market which can influence the determination and occurrence of an orderly transaction. Also, we inquire as to whether there may have been restrictions on the marketing of the security to a single or limited number of participants. Where possible, we assess the financial condition of the seller to determine whether observed transactions may have been forced. If there is a significant disparity between the trading price for a security held by us as compared to the trading prices of similar recent transactions, we consider whether this disparity is an indicator of a disorderly trade. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if the evidence suggests that a transaction or group of similar transactions is not orderly. Based upon these procedures, we determined that market activity for our non-ARS assets appeared normal and that transactions did not appear disorderly as of September 30, 2011.

The following table provides a rollforward of our assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the nine months ended September 30, 2011 (in thousands):

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Balance at beginning of period	\$	33,597
Total gains (losses) (realized or unrealized):		
Included in other comprehensive income (loss)		2,694
Purchases		
Sales		

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

*Revenue Recognition*

*Net Product Sales*

We recognize net product sales in accordance with current accounting guidance related to the recognition, presentation and disclosure of revenue in financial statements, which outlines the basic criteria that must be met to recognize revenue and provides guidance for disclosure of revenue in financial statements. We 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 whether additional allowances or accruals are required based on inventory in our sales channel. An analysis of our product sales allowances and accruals for the three and nine months ended September 30, 2011 and 2010 is as follows (in thousands):



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	<b>Three Months Ended September 30,</b>	
	<b>2011</b>	<b>2010</b>
Product sales allowances and accruals		
Discounts and chargebacks	\$ 3,601	\$ 1,218
Government and other rebates	2,120	4,383
Medicaid rebate reserve adjustment	(3,026)	
Returns	354	359
Total product sales allowances and accruals	\$ 3,049	\$ 5,960
Total gross product sales	\$ 18,851	\$ 21,133
Total product sales allowances and accruals as a percent of total gross product sales	16%	28%

	<b>Nine Months Ended September 30,</b>	
	<b>2011</b>	<b>2010</b>
Product sales allowances and accruals		
Discounts and chargebacks	\$ 9,400	\$ 3,035
Government and other rebates	6,897	11,917
Medicaid rebate reserve adjustment	(2,532)	
Returns	1,022	936
Total product sales allowances and accruals	\$ 14,787	\$ 15,888
Total gross product sales	\$ 54,692	\$ 60,582
Total product sales allowances and accruals as a percent of total gross product sales	27%	26%

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

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legislation, changes to rebate contracts, changes in the level of discounts, and changes in product sales trends. Although allowances and accruals are recorded at the time of product sale, certain rebates are typically paid out, on average, up to six months or longer after the sale.

As part of our sales allowances and accruals, we reserve for Medicaid rebates associated with instances where Medicaid will act as the insurer and for which we are required to pay a statutory rebate to Medicaid. During the three months ended September 30, 2011, we revised our estimated Medicaid utilization based on actual rebate claims received since the launch of *Feraheme* in July 2009, our expectations of state level activities, and estimated rebate claims not yet submitted, which resulted in a \$3.0 million reduction of our estimated Medicaid rebate reserve related to *Feraheme* sales from 2009, 2010 and the first half of 2011. This change in estimate is reflected as an increase in our net product sales for the three months ended September 30, 2011 and resulted in a significant decline in our gross to net percentage for the three months ended September 30, 2011 as compared to the same period in 2010. The reduction of our estimated Medicaid rebate reserve had an impact of \$0.14 per basic and diluted share for each of the three and nine months ended September 30, 2011.

If we determine in future periods that our actual rebate experience is not indicative of expected claims or if other factors affect estimated claims rates, we may be required to adjust our current Medicaid accumulated reserve estimate, which would affect our earnings in the period of the adjustment and could be significant.

*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, payment 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 this model, revenue is generally recognized in an amount equal to the lesser of the amount due under the agreements or an 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. In cases where we are reimbursed for certain research and development costs associated with our collaboration agreements and where we are acting as the principal in carrying out these services, any reimbursement payments are recorded in license fee and other collaboration revenues in our condensed consolidated statement of operations to match the costs that we incur during the period in which we perform those services. 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. This guidance provides that for unmodified agreements entered into prior to January 1, 2011, 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



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recognized as revenue as a single unit of accounting 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 is 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 agreements may entitle us to additional payments upon the achievement of performance-based milestones. If a milestone involves substantive effort on our part and its achievement is not considered probable at the inception of the collaboration, we recognize the milestone consideration as revenue in the period in which the milestone is achieved only if it meets the following additional criteria: (1) the milestone 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 consideration is reasonable relative to all deliverables and payment terms in the arrangement. For milestones that do not meet the above criteria and are therefore not considered substantive milestones, we recognize that portion of the milestone payment equal to the percentage of the performance period completed at the time the milestone is achieved and the above conditions are met. 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*

Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash, cash equivalents, investments, and accounts receivable. As of September 30, 2011, our cash, cash equivalents and investments amounted to approximately \$251.0 million. We currently invest our excess cash primarily in U.S. government and agency money market funds, and investments in corporate debt securities, U.S. treasury and government agency securities, commercial paper and ARS. As of September 30, 2011, we had approximately \$62.7 million of our total \$75.8 million cash and cash equivalents balance invested in institutional money market funds of which \$48.2 million was invested in a single fund, which is collateralized solely by U.S. treasury and government agency securities.

Our operations are located solely within the U.S. We are focused principally on developing, manufacturing and commercializing *Feraheme*. We perform ongoing credit evaluations of our customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our total revenues for the nine months ended September 30, 2011 and 2010:

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	<b>Nine Months Ended September 30,</b>	
	<b>2011</b>	<b>2010</b>
AmerisourceBergen Drug Corporation	42%	36%
McKesson Corporation	20%	<10%
Takeda Pharmaceutical Company Limited	13%	<10%
Cardinal Health, Inc.	12%	<10%
Metro Medical Supply, Inc.	<10%	21%

Revenues from customers outside of the U.S. amounted to approximately 15% and less than 10% of our total revenues for the nine months ended September 30, 2011 and 2010, respectively, and were principally related to collaboration revenue recognized in connection with our collaboration agreement with Takeda Pharmaceutical Company Limited, or Takeda, which is based in Japan.

**C. Investments**

As of September 30, 2011 and December 31, 2010, the combined total of our short- and long-term investments equaled \$175.2 million and \$181.2 million, respectively, and consisted of securities classified as available-for-sale in accordance with accounting standards which provide guidance related to accounting and classification of certain investments in debt and equity securities.

The following is a summary of our short- and long-term investments as of September 30, 2011 and December 31, 2010 (in thousands):

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	September 30, 2011			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	\$ 68,122	\$ 68	\$ (91)	\$ 68,099
Due in one to three years	24,619	105	(66)	24,658
U.S. treasury and government agency securities				
Due in one year or less	21,291	66		21,357
Due in one to three years	22,682	271		22,953
Commercial paper				
Due in one year or less	12,999		(6)	12,993
Auction rate securities				
Due after five years	3,500			3,500
Total short-term investments	\$ 153,213	\$ 510	\$ (163)	\$ 153,560
Long-term investments:				
Auction rate securities				
Due after five years	\$ 25,100	\$	\$ (3,469)	\$ 21,631
Total long-term investments	\$ 25,100	\$	\$ (3,469)	\$ 21,631
Total short and long-term investments	\$ 178,313	\$ 510	\$ (3,632)	\$ 175,191

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	December 31, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	\$ 37,660	\$ 65	\$ (12)	\$ 37,713
Due in one to three years	45,883	197	(25)	46,055
U.S. treasury and government agency securities				
Due in one year or less	22,554	39	(1)	22,592
Due in one to three years	28,103	235	(5)	28,333
Foreign government securities				
Due in one year or less	2,431			2,431
Commercial paper				
Due in one year or less	10,493	2		10,495
Total short-term investments	\$ 147,124	\$ 538	\$ (43)	\$ 147,619
Long-term investments:				
Auction rate securities				
Due after five years	\$ 39,550	\$	\$ (5,953)	\$ 33,597
Total long-term investments	\$ 39,550	\$	\$ (5,953)	\$ 33,597
Total short and long-term investments	\$ 186,674	\$ 538	\$ (5,996)	\$ 181,216

*Auction Rate Securities*

As of September 30, 2011, we held a total of \$25.1 million in fair market value of ARS, reflecting a reduction of approximately \$3.5 million from the par value of these securities of approximately \$28.6 million. As of September 30, 2011, 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 September 30, 2011 by at least one of the major securities rating agencies and was primarily collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program. As of September 30, 2011, all of our ARS continue to pay interest according to their stated terms.

In October 2011, one of our ARS investments with a par value of \$3.5 million was redeemed by the issuer. In accordance with the terms of the offer, the issuer purchased the security from us at par value, which was paid to us in October 2011. As a result of this October 2011 ARS redemption, we have reclassified this security to short-term investments in our condensed consolidated balance sheet as of September 30, 2011.

In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions since that time. As a result of the lack of significant observable ARS market activity since February 2008, we use a discounted cash flow methodology to value these securities as opposed to valuing them at their par value. Our valuation analysis considers, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the

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security, the creditworthiness of the issuer and any associated guarantees, credit ratings of the security by the major securities rating agencies, the ability or inability to sell the investment in an active market or to the issuer, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when call features may be exercised by the issuer. In addition, for all available-for-sale debt securities with unrealized losses, management performs an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. In the event that we intend to sell a security, or may be required to do so, the decline in fair value of the security would be deemed to be other-than-temporary and the full amount of the unrealized loss would be recorded in our condensed consolidated statement of operations as an impairment loss. Regardless of our intent to sell a security, we perform additional analyses on all securities with unrealized losses to evaluate whether there could be a credit loss associated with the security. Based on the methodology and the analysis above, we have estimated the fair value of our ARS to be \$25.1 million and have recorded the \$3.5 million decline in value as an unrealized loss to accumulated other comprehensive loss as of September 30, 2011.

Due to our belief that the market for ARS will likely take in excess of twelve months to fully recover, with the exception of the security which we tendered for repurchase as described above, we have classified our portfolio of ARS as long-term investments in our condensed consolidated balance sheet as of September 30, 2011. We believe that the impairment related to our ARS is primarily attributable to the lack of liquidity of these investments, coupled with the ongoing uncertainty in the credit and capital markets, and we have no reason to believe that any of the underlying issuers of our ARS are presently at risk of default. 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 25 to 35 years in the future. We believe we will ultimately be able to liquidate our investments in ARS without significant loss prior to their maturity dates primarily due to the collateral securing most of our ARS. However, it could take until final maturity of the ARS to realize our investments par value. As a result, we believe the decline in value of our ARS is a temporary impairment and similarly, any future fluctuation in fair value related to our ARS that we deem to be temporary, including any recoveries of previous write-downs, would be recorded to accumulated other comprehensive loss. If we determine that any future unrealized loss is other-than-temporary, we will record a charge to our condensed consolidated statement of operations. In the event that we need to access our investments in these securities, we will not be able to do so until a future auction is successful, the issuer calls the security pursuant to a mandatory tender or redemption prior to maturity, a buyer is found outside the auction process, or the securities mature. In addition, as part of our determination of the fair value of our investments, we consider credit ratings provided by independent investment rating agencies as of the valuation date. These ratings are subject to change, and we may be required to adjust our future valuation of these ARS which may adversely affect the value of these investments. Based upon the various analyses described above, we did not recognize any unrealized credit losses related to our securities during the three and nine months ended September 30, 2011.

*Impairments and Unrealized Gains and Losses on Investments*

The following is a summary of the fair value of our investments with unrealized losses that are deemed to be temporarily impaired and their respective gross unrealized losses aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position as of September 30, 2011 and December 31, 2010 (in thousands):



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	Less than 12 Months		September 30, 2011 12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	\$ 45,400	\$ (156)	\$ 1,540	\$ (1)	\$ 46,940	\$ (157)
Commercial paper	12,993	(6)			12,993	(6)
Auction rate securities			25,131	(3,469)	25,131	(3,469)
	\$ 58,393	\$ (162)	\$ 26,671	\$ (3,470)	\$ 85,064	\$ (3,632)

	Less than 12 Months		December 31, 2010 12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	\$ 31,005	\$ (37)	\$	\$	\$ 31,005	\$ (37)
U.S. treasury and government agency securities	13,447	(6)			13,447	(6)
Auction rate securities			33,597	(5,953)	33,597	(5,953)
	\$ 44,452	\$ (43)	\$ 33,597	\$ (5,953)	\$ 78,049	\$ (5,996)

We did not recognize any impairment losses in our condensed consolidated statements of operations related to our securities during either of the three or nine months ended September 30, 2011 or 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 entire amortized cost basis of a security and which may necessitate the recording of future realized losses on securities in our portfolio. Significant losses in the estimated fair values of our investments could have a material adverse effect on our earnings in future periods.

*Realized Gains and Losses on Investments*

Gains and losses are determined on the specific identification method. During the nine months ended September 30, 2011, we recorded net realized losses of approximately \$0.2 million to our condensed consolidated statement of operations. These net realized losses were primarily attributable to our participation in a June 2011 purchase offer from an issuer of one of our ARS holdings with a par value of \$5.0 million which resulted in our receipt of proceeds of approximately \$4.8 million and our recognition of a \$0.2 million realized loss.

**D. Accounts Receivable**

Our accounts receivable were \$7.1 million and \$5.8 million as of September 30, 2011 and December 31, 2010, respectively, and primarily represented amounts due from wholesalers and distributors to whom we sell *Feraheme* directly. Accounts receivable are recorded net of reserves for estimated chargeback obligations, prompt payment discounts and any allowance for doubtful accounts. Reserves for other sales-related allowances such as rebates, distribution and other fees, and product returns are included in accrued expenses in our condensed consolidated balance sheets.

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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 September 30, 2011 or December 31, 2010. If the financial condition of any of our significant customers was to

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deteriorate and result in an impairment of its ability to make payments owed to us, an allowance for doubtful accounts may be required which could have a material effect on earnings in the period of any such adjustment.

Customers which represented greater than 10% of our accounts receivable balances as of September 30, 2011 and December 31, 2010 were as follows:

	September 30, 2011	December 31, 2010
AmerisourceBergen Drug Corporation	53%	65%
McKesson Corporation	18%	10%
Cardinal Health, Inc.	14%	14%
Metro Medical Supply, Inc.	<10%	18%

**E. Inventories**

Our major classes of inventories were as follows as of September 30, 2011 and December 31, 2010 (in thousands):

	September 30, 2011	December 31, 2010
Raw materials	\$ 1,645	\$ 2,332
Work in process	3,146	55
Finished goods	10,786	13,957
Total inventories	\$ 15,577	\$ 16,344

Included in work in process and finished goods inventories as of September 30, 2011 was approximately \$2.5 million of *Feraheme* produced in third-party manufacturing facilities and using processes for which we have not yet received regulatory approval. We believe future regulatory approval of these facilities and processes is probable and that this inventory is realizable.

Equity-based compensation of approximately \$0.1 million and \$0.6 million was capitalized into inventory for the nine months ended September 30, 2011 and 2010, respectively.

**F. Income Taxes**

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

For the nine months ended September 30, 2011 and 2010, we recognized a current federal income tax benefit of \$0.6 million and \$0.5 million, respectively, 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 respective periods. The corresponding income tax expense was recorded in other comprehensive income. Due to the uncertainty surrounding the realization of favorable tax attributes in future tax returns, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets.

Table of Contents**G. Net Loss per Share**

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

	As of September 30,	
	2011	2010
Options to purchase shares of common stock	2,013	2,631
Shares of common stock issuable upon the vesting of restricted stock units	629	206
<b>Total</b>	<b>2,642</b>	<b>2,837</b>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net loss	\$ (16,631)	\$ (16,996)	\$ (58,488)	\$ (61,373)
Weighted average common shares outstanding	21,194	21,085	21,169	20,700
Net loss per share:				
Basic and diluted	\$ (0.78)	\$ (0.81)	\$ (2.76)	\$ (2.96)

**H. Equity-Based Compensation**

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

*Second Amended and Restated 2007 Equity Incentive Plan*

As of September 30, 2011, we have granted options and restricted stock units covering 3,762,425 shares of common stock under our 2007 Plan, of which 1,238,485 stock options and 191,173 restricted stock units have expired or terminated, and of which 35,338 options have been exercised and 99,326 shares of common stock have been issued pursuant to restricted stock units that became fully vested. The number of options and restricted stock units outstanding under this plan as of September 30, 2011 was 1,568,821 and 629,282, respectively. The remaining number of shares available for future grants as of September 30, 2011 was 1,278,105, not including shares subject to outstanding awards under the 2000 Plan, which will be added to the total number of shares available for issuance under the 2007 Plan to the extent that such awards expire or terminate for any reason prior to exercise. All outstanding stock options granted under our 2007 Plan have an exercise price equal to the closing price of a share of our common stock on the grant date and a ten-year term.

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In January 2011, we granted restricted stock units to certain members of our senior management covering a total of 380,000 shares of common stock, of which 320,000 were outstanding as of

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September 30, 2011. Of the 320,000 grants outstanding as of September 30, 2011, 147,000 are subject to a performance condition tied to the price of our common stock. These performance based restricted stock units vest in a single installment on the earlier of (1) the fourth anniversary of the date of grant and (2) immediately prior to a change of control of our company, provided that, in either case the closing price of a share of our common stock is at least \$30.00 per share. The total fair value of the outstanding performance based restricted stock units is \$1.5 million, which we recognize to expense over a period of four years from the date of grant, subject to any forfeitures.

*Amended and Restated 2000 Stock Plan*

As of September 30, 2011, the number of shares underlying outstanding options which were issued pursuant to our 2000 Plan was 444,181. There were no restricted stock units outstanding as of September 30, 2011. In November 2007, the 2000 Plan was succeeded by the 2007 Plan and, accordingly, no further grants may be made under this plan. Any shares that remained available for issuance under the 2000 Plan as of the date of adoption of the 2007 Plan are included in the number of shares that may be issued under the 2007 Plan. Any shares subject to outstanding awards granted under the 2000 Plan that expire or terminate for any reason prior to exercise will be added to the total number of shares available for issuance under the 2007 Plan.

*Equity-based compensation expense*

Equity-based compensation expense, excluding amounts that have been capitalized into inventory, for the three and nine months ended September 30, 2011 and 2010 consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Cost of product sales	\$ 131	\$ 100	\$ 483	\$ 300
Research and development	84	158	1,365	2,696
Selling, general and administrative	1,487	1,242	6,950	7,740
Total equity-based compensation expense	\$ 1,702	\$ 1,500	\$ 8,798	\$ 10,736

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

Equity-based compensation expense of \$0.1 million was capitalized into inventory for the nine months ended September 30, 2011. There was no equity-based compensation expense capitalized into inventory for the three months ended September 30, 2011. Capitalized equity-based compensation expense is recognized into cost of product sales when the related product is sold.

**I. Commitments and Contingencies**

*Legal Proceedings related to Allos*

Between July 21, 2011 and August 15, 2011, nine putative class action lawsuits were filed against us, Allos, members of the Allos board of directors and our Board, and Merger Sub, arising out of the



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then proposed merger between us and Allos. Two lawsuits were filed in the United States District Court for the District of Colorado entitled *Radmore/Salem v. Allos Therapeutics, Inc.* and *Everage v. Allos Therapeutics, Inc.*, or the Colorado Federal Court Actions. Four lawsuits were filed in the Court of Chancery of the State of Delaware, one of which (entitled *Everage v. Berns*) was voluntarily dismissed on July 27, 2011, and two of which (entitled *Lam v. Allos Therapeutics, Inc.* and *Mulligan v. Allos Therapeutics, Inc.*) were consolidated, or the Delaware Action. The fourth action in Delaware is *Gaines v. Narachi*, or the Gaines Action. Three lawsuits, entitled *Nunn v. Berns*, *Stevens v. Hoffman*, and *Hannon v. Allos Therapeutics, Inc.*, were filed in Jefferson County District Court for the State of Colorado and subsequently consolidated, or the Colorado State Court Action. With the exception of The Gaines Action, which is described below, these lawsuits name members of the Allos board of directors, as well as Allos, us, and Merger Sub as defendants, and generally allege that the Allos directors breached their fiduciary duties to Allos stockholders in connection with the Merger Agreement by agreeing to an unfair price, conducting a flawed sales process, enacting preclusive deal protection devices, engaging in self-dealing, and failing to disclose material information (relating to Allos and our financial projections, the fairness opinions of J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC, and the background of the then proposed transaction) in the joint proxy statement filed by us and Allos. These lawsuits further claim that we, Allos and Merger Sub aided and abetted those alleged breaches of fiduciary duty. In general, these lawsuits seek damages and injunctive relief, including an award of attorneys fees and costs, in addition to other relief.

On October 21, 2011, our shareholders voted against consummation of the then proposed transaction. That same day, plaintiffs in The Colorado Federal Actions voluntarily dismissed their cases without prejudice. On October 25, 2011, plaintiffs in The Colorado State Court Action voluntarily dismissed their case without prejudice. Therefore, as of November 4, 2011, the only cases still pending are The Delaware Action and The Gaines Action, both of which are described in more detail below.

**The Delaware Action.** On August 1, 2011, the Delaware Court of Chancery consolidated the *Lam* and *Mulligan* cases into *In re Allos Therapeutics, Inc. Shareholders Litigation*, Consolidated C.A. No. 6714. In early September 2011, the parties to this action stipulated to a briefing schedule on plaintiffs anticipated motion for preliminary injunction. Thereafter, plaintiffs filed a motion for preliminary injunction, defendants opposed, and a preliminary injunction hearing was scheduled for October 17, 2011. On October 13, 2011, the parties to The Delaware Action agreed in principle to settle the litigation by executing a memorandum of understanding, or MOU. Under the terms of the MOU, plaintiff, on behalf of Allos shareholders, agreed to release all claims against defendants, and Allos agreed to make certain supplemental disclosures in a Current Report on Form 8-K, which was filed with the U.S. Securities and Exchange Commission on October 14, 2011. The settlement contemplated by the MOU was subject to approval by the Delaware Court of Chancery and contingent on consummation of the merger, which our shareholders did not approve on October 21, 2011. On October 31, 2011 and November 1, 2011, defendants moved to dismiss plaintiffs consolidated complaint.

**The Gaines Action.** On September 20, 2011, plaintiff in the *Gaines v. Narachi* matter filed an amended complaint which generally alleges that the members of our board of directors breached their fiduciary duties in connection with the then proposed merger with Allos by: (i) failing to maximize shareholder value; (ii) ignoring procedural safeguards in negotiating the then proposed merger; (iii) negotiating an acquisition in which our stockholders will suffer dilution; (iv) rejecting an allegedly superior buy-out proposal from MSMB Capital Management LLC; and (v) disseminating a supposedly false and misleading proxy statement. This action seeks damages and injunctive relief, including an award of attorneys fees and costs, in addition to other relief. In late September 2011, plaintiff Gaines filed a motion for expedited proceedings and a motion for preliminary injunction, which defendants opposed. On September 27, 2011, the Court heard the motion and subsequently denied plaintiff s

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request for expedited proceedings. Thereafter, plaintiff filed a motion for reconsideration of the September 30, 2011 order to consider the sole issue as to whether the free cash flow projections used by Morgan Stanley & Co. LLC in its discounted cash flow analysis should be disclosed. Defendants opposed the reconsideration motion, but the court granted it and scheduled a preliminary injunction hearing for October 17, 2011 on this one issue. On October 14, 2011, we voluntarily disclosed the requested free cash flow projections in a Current Report on Form 8-K. As a result, plaintiff's preliminary injunction motion, and request for relief thereunder, is now moot. On November 1, 2011, we moved to dismiss plaintiff's amended complaint.

We believe that the allegations in the above-referenced actions lack merit. We have and will continue to contest them vigorously. We do not expect any liability to result from either the Delaware Action or the Gaines Action other than potential immaterial attorneys fees.

*Other Legal Proceedings*

A purported class action complaint was originally filed on March 18, 2010 in the United States District Court for the District of Massachusetts, entitled Silverstrand Investments et. al. v. AMAG Pharm., Inc., et. al., Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Executive Vice President and Chief Financial Officer, our Board of Directors, and certain underwriters in our January 2010 offering of common stock violated certain federal securities laws, specifically Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, and that our former President and Chief Executive Officer and former Executive Vice President and Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff sought unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. On August 11, 2011, the Court issued an Opinion and Order dismissing the SAC in its entirety for failure to state a claim upon which relief could be granted. A separate Order of Dismissal was filed on August 15, 2011. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the United States Court of Appeals for the First Circuit, or the Court of Appeals. By Order issued by the Court of Appeals dated October 26, 2011, plaintiffs brief is due on December 5, 2011, with responding briefs due on January 4, 2012. Plaintiffs reply brief is due on January 18, 2012. We have not recorded an estimated liability associated with this legal proceeding as we do not believe that such a liability is probable nor do we believe that a range of loss is currently estimable.

During 2010 we received correspondence from a supplier with whom we have an agreement related to the supply of a certain material used in the production of certain of our products. This correspondence suggests that we are in violation of the terms of the agreement. We believe we have valid arguments against such allegations, and we intend to vigorously defend against any such allegations. We are currently unable to predict the outcome or reasonably estimate the range of potential loss associated with this potential claim, if any, and have therefore not recorded any estimated liability as we do not believe that such a liability is probable nor do we believe that a range of loss is currently estimable.

We may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which we are focused. Other than the above actions, we are not aware of any material claims against us as of September 30, 2011. We expense legal costs as they are incurred.

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*Contractual Obligations*

Under the terms of the Merger Agreement, we are required to pay Allos a termination fee of \$14.0 million (less the \$2.0 million expense reimbursement fee we paid Allos in October 2011) if a definitive agreement for an acquisition transaction, as defined in the Merger Agreement, is entered into on or before October 21, 2012 or such a transaction is consummated on or before such date.

**J. Collaborative Agreements**

Our commercial strategy includes the formation of alliances with other pharmaceutical companies to facilitate the sale and distribution of our products outside of the U.S. As of September 30, 2011, we were a party to the following collaborations:

*Takeda*

In March 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda, under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey, or collectively, the Licensed Territory.

Under the Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme* and, accordingly, are responsible for supply of *Feraheme* to Takeda. We are also responsible for conducting, and bearing the costs related to, certain pre-defined clinical studies with the costs of future modifications or additional studies to be allocated between the parties according to an agreed upon cost-sharing mechanism, which provides for a cap on such costs. In connection with the execution of the Takeda Agreement, we received a \$60.0 million upfront payment from Takeda in April 2010. We may also receive a combination of regulatory approval and performance-based milestone payments, reimbursement of certain out-of-pocket regulatory and clinical supply costs, defined payments for supply of *Feraheme*, and tiered double-digit royalties on net product sales in the Licensed Territory under the Takeda Agreement. The milestone payments we may be entitled to receive under the agreement could over time equal approximately \$220.0 million, including up to an aggregate of \$33.0 million upon the regulatory approval and commercial launch of *Feraheme* in the European Union and Canada. 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 in effect when we signed the Takeda Agreement, and which governed revenue recognition on multiple element arrangements, we evaluated the four deliverables under the Takeda Agreement and determined that our obligation to provide manufacturing supply of product meets the criteria for separation and is therefore treated as a single unit of accounting, which we refer to as the supply unit of accounting. Further, we concluded that the license is not separable from the undelivered future know-how and technological improvements or the undelivered regulatory and clinical research 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.



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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 the current patent life of *Feraheme* and our best estimate of the period over which we will substantively perform our obligations. The potential milestone payments that may be received in the future will be recognized into revenue on a cumulative catch up basis when they become due and payable.

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

Revenues related to the combined unit of accounting and any reimbursement revenues are recorded in license fee and other collaboration revenues in our condensed consolidated statement of operations. During the three and nine months ended September 30, 2011, we recorded approximately \$1.5 million and \$4.6 million in revenues, respectively, associated with the upfront payment. In addition, we recorded \$0.1 million and \$1.7 million associated with other reimbursement revenues for the three and nine months ended September 30, 2011, respectively. Payments to be received for supply of the drug product and royalties will be recorded in product sales and royalties in our condensed consolidated statement of operations.

*3SBio*

In 2008, we entered into a Collaboration and Exclusive License Agreement, or the 3SBio License Agreement, and a Supply Agreement, or the 3SBio Supply Agreement, with 3SBio Inc., or 3SBio, for the development and commercialization of *Feraheme* as an IV iron replacement therapeutic agent in China. The 3SBio License Agreement grants 3SBio an exclusive license for an initial term of thirteen years to develop and commercialize *Feraheme* as a therapeutic agent in China for an initial indication for the treatment of IDA in patients with CKD, and an option to expand into additional therapeutic indications. In consideration of the grant of the license, we received an upfront payment of \$1.0 million, the recognition of which has been deferred and is being recognized under the proportional performance methodology as we supply *Feraheme* to 3SBio over the thirteen year initial term of the agreement. We are eligible to receive certain other specified milestone payments upon regulatory approval of *Feraheme* in China for CKD and other indications. We are also entitled to receive tiered royalties of up to 25% based on net sales of *Feraheme* by 3SBio in China. We retained all manufacturing rights for *Feraheme* under these agreements. In addition, pursuant to the 3SBio Supply Agreement, 3SBio has agreed to purchase from us, and we have agreed to supply to 3SBio, *Feraheme* at a predetermined supply price for clinical and commercial use in connection with 3SBio's development and commercialization obligations described above for so long as the 3SBio License Agreement is in effect. To date we have not provided 3SBio with any product under this agreement.

Table of Contents**K. October 2010 Restructuring**

In October 2010, in order to reduce our operating expenses, we initiated a corporate restructuring plan, including a workforce reduction, pursuant to which we would reduce our workforce by greater than 60 positions. During the fourth quarter of 2010, we recorded \$2.2 million of restructuring related costs as operating expenses, primarily related to employee severance, benefits and related costs. The majority of the workforce reduction was completed during 2010. Expenses associated with this restructuring plan are expected to be substantially paid by the end of 2011.

The following table outlines the components of our restructuring expenses related to our October 2010 restructuring, which were recorded in operating expenses and current liabilities for the three and nine months ended September 30, 2011 (in thousands):

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30, 2011</b>		<b>September 30, 2011</b>	
Accrued restructuring, beginning of period	\$	224	\$	1,324
Employee severance, benefits and related costs		11		188
Payments		(108)		(1,263)
Other adjustments		(10)		(132)
Accrued restructuring, end of period	\$	117	\$	117

**L. Recently Issued and Proposed Accounting Pronouncements**

In June 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2011-05, Presentation of Comprehensive Income, or ASU 2011-05. ASU 2011-05 updates existing guidance to amend the presentation of comprehensive income. Under ASU 2011-05, entities are required to present items of net income and other comprehensive income either in one continuous statement referred to as the statement of comprehensive income or in two separate, but consecutive, statements of net income and other comprehensive income. Under both alternatives, companies will be required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. In the single continuous statement approach, the guidance requires the entity to present the components of net income and total net income, the components of other comprehensive income and a total for other comprehensive income, along with the total of comprehensive income in that statement. In the two-statement approach, the income statement will be followed immediately by the statement of other comprehensive income, which will include the amount for total comprehensive income. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We do not expect the adoption of this ASU to have an impact on our condensed consolidated financial statements.

In May 2011, the FASB issued ASU No. 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs, or ASU 2011-04. This ASU updates existing guidance to amend fair value measurements and related disclosures. ASU 2011-04 relates to a major convergence project of the FASB and the International Accounting Standards Board to improve International Financial Reporting Standards, or IFRS, and U.S. generally accepted accounting principles, or GAAP. ASU 2011-04



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results in a consistent definition of fair value and common requirements for measurement of and disclosure about fair value between IFRS and U.S. GAAP. The ASU also changes some fair value measurement principles and enhances disclosure requirements related to activities in Level 3 of the fair value hierarchy. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We do not expect the adoption of this ASU to have an 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, Fair Value Measurements and Disclosure. 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 rollforward of activity in Level 3 fair value measurements. Those disclosures are effective for fiscal years beginning after December 31, 2010, which for us is fiscal 2011. We have adopted all provisions of this pronouncement, and such adoption did not 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 Accounting Standards Codification 605-25 (previously included within Emerging Issues Task Force, or EITF, No. 00-21, Revenue Arrangements with Multiple Deliverables, or EITF 00-21). ASU 2009-13 provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and how the consideration should be 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 became effective prospectively for revenue arrangements entered into or materially modified beginning on January 1, 2011. The initial adoption of this guidance did not have any impact on our condensed consolidated financial statements; however, it will likely impact us if we enter into any future transactions involving multiple deliverables or if we enter into any material modifications to any of our existing collaborations.

**M. Subsequent Events**

On November 4, 2011, we announced a corporate restructuring, including a workforce reduction plan, which includes an approximate 25% reduction in positions. We communicated our decision to our employees on November 4, 2011. In addition, we also announced that the employment of each of Brian J.G. Pereira, M.D., President and Chief Executive Officer, and Gary Zieziula, Executive Vice President and Chief Commercial Officer, has terminated, effective as of November 4, 2011. Dr. Pereira has also resigned from our Board of Directors effective as of November 4, 2011. As a result of this reduction in our workforce, we currently estimate that we will record restructuring charges of approximately \$3.2 million, which are expected to be recorded primarily in the fourth quarter of 2011. These estimated restructuring charges relate primarily to employee severance and benefits. We expect the majority of the workforce reduction to be



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completed by the end of 2011 and the majority of our restructuring charges to be paid during the twelve months following this restructuring. Our estimated restructuring charges are based on a number of assumptions. Actual results may differ materially from our expectations and additional charges not currently expected may be incurred in connection with, or as a result of, these reductions.

As a result of the restructuring, we reduced our 2011 annual employee bonus accrual and revised our estimated equity incentive compensation forfeiture rate. As a result, we recorded a \$0.8 million reduction in expense for the three months ended September 30, 2011.

In connection with Dr. Pereira's departure, we entered into a Separation and Consulting Agreement, or the Separation Agreement. Pursuant to the Separation Agreement, and consistent with the terms of his prior employment agreement with us, Dr. Pereira will receive two times his current base salary, payable over a period of two years in equal monthly installments. In addition, Dr. Pereira will be eligible for consideration for a 2011 performance bonus based on the Board of Directors' final scoring of our 2011 performance goals after the year end.

Dr. Pereira has also agreed to provide certain consulting services until June 30, 2012, which may be extended in the event we enter into a definitive agreement with respect to a transaction that would constitute a change in control, as defined in the Separation Agreement, during the consulting period. In consideration for such services, Dr. Pereira will receive compensation equal to his current base salary rate of \$52,500 per month. Dr. Pereira's outstanding equity awards will continue to vest under their current vesting schedules through his provision of consulting services to us.

Under the Separation Agreement, if a change in control occurs while Dr. Pereira is providing consulting services to us, all of Dr. Pereira's outstanding unvested equity awards will become automatically vested in full, provided that any performance related conditions in such equity awards will remain in effect and unmodified. Additionally, upon such an event, Dr. Pereira will be entitled to a bonus equal to two times his 2011 target performance bonus amount, or approximately \$0.95 million in total.

Pursuant to the terms of Mr. Zieziula's existing employment agreement with us, in connection with Mr. Zieziula's departure, he will receive severance pay equal to his current base salary, payable over one year in equal monthly installments.

**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, 2010.*

*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*



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*Report on Form 10-Q, words such as may, will, expect, intend, and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.*

*Examples of forward-looking statements contained in this report include statements regarding the following: the design and expected timing of completion of our global studies of Feraheme for the treatment of iron deficiency anemia in a broad range of patients, the design of our two pediatric studies to be conducted to meet our Pediatric Research Equity Act requirement, our expectations of the timing of a decision by the European Medicines Agency on our Marketing Authorization Application submission, our intention to conduct two additional pediatric studies included in our Pediatric Investigation Plan, our plan to conduct 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 and the design of such trial, our expectation of the timing of a decision by Health Canada on our submission in response to the Notice of Non-Compliance, our expectation of the timing of a decision from Swissmedic on our Marketing Authorization Application, our statement that our partner in China, 3SBio Inc., or 3SBio, plans to conduct a Feraheme clinical study in China, our expectation that sales of GastroMARK® will not materially increase, our expectation of revenue sources to fund our future operations, our expectations regarding the success of our collaboration with Takeda Pharmaceutical Company Limited, or Takeda, including any potential milestone payments we may receive, our expectations regarding our future revenues, including expected Feraheme revenues under our Takeda and 3SBio collaborations, our expectation that dialysis sales for the remainder of 2011 and beyond will not be significant, our expectation that our reserves as a percentage of gross sales will increase during the remainder of 2011, our expectations regarding future license fee revenues from 3SBio, our expectation that our costs of product sales as a percentage of net product sales will remain relatively consistent or increase slightly for the remainder of 2011, our expectation that our research and development expenses will increase during the remainder of 2011, our expectations regarding the amount of external expenses and the timing of our planned research and development projects, our expectation that selling, general and administrative expenses, will increase during the remainder of 2011, 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 estimates and timing of payment of the restructuring charges relating to our workforce reduction and our expectations that the majority of our workforce reduction will be completed by the end of 2011, our belief regarding the potential impact of the adoption of newly issued and future accounting guidance on our financial statements, and information with respect to any other plans and strategies for our business. Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements.*

*Any forward-looking statement should be considered in light of the factors discussed in this Quarterly Report on Form 10-Q. We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the United States Securities and Exchange Commission to publicly update or revise any such statements to reflect any change in company expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in these forward-looking statements.*

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*Overview*

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a biopharmaceutical company focused on the development and commercialization of a therapeutic iron compound to treat iron deficiency anemia, or IDA. Our principal source of revenue is from the sale of *Feraheme*® (ferumoxytol) Injection for Intravenous, or IV, use which was approved for marketing in the U.S. in June 2009 by the U.S. Food and Drug Administration, or the FDA, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with chronic kidney disease, or CKD. We are currently pursuing marketing applications in the European Union, or EU, Canada and Switzerland for *Feraheme* for the treatment of IDA in CKD patients. We market and sell *Feraheme* in the U.S. through our own commercial organization, including a specialized sales force. We began commercial sale of *Feraheme* in July 2009 and sell *Feraheme* primarily to authorized wholesalers and specialty distributors.

*Feraheme* is approved in the U.S. for use in the treatment of IDA in both dialysis and non-dialysis dependent adult CKD patients. During 2010, a new prospective payment system for the reimbursement of dialysis services was adopted and became effective on January 1, 2011, which made it less likely that dialysis providers would choose to use *Feraheme* and caused our sales in the dialysis market to decline. Our commercial strategy is primarily focused on growing the utilization of *Feraheme* in non-dialysis dependent adult CKD patients with IDA in the U.S., specifically in hematology, oncology, nephrology, and hospital sites of care, where a large number of CKD patients are treated.

On November 4, 2011, we announced a corporate restructuring, including a workforce reduction plan, which includes an approximate 25% reduction in positions. In addition, we also announced that the employment of each of Brian J.G. Pereira, M.D., President and Chief Executive Officer, and Gary Zieziula, Executive Vice President and Chief Commercial Officer, has terminated, effective as of November 4, 2011. Dr. Pereira has also resigned from our Board of Directors effective as of November 4, 2011. As a result of the reduction in our workforce, we currently estimate that we will record restructuring charges of approximately \$3.2 million, which are expected to be recorded primarily in the fourth quarter of 2011. These estimated restructuring charges relate primarily to employee severance and benefits. We expect that the majority of such amounts will be paid during the next twelve months following this restructuring. Our estimated restructuring charges are based on a number of assumptions. Actual results may differ materially from our expectations and additional charges not currently expected may be incurred in connection with, or as a result of, these reductions. We expect the majority of the workforce reduction to be complete by the end of 2011.

As a result of the restructuring, we reduced our 2011 annual employee bonus accrual and revised our estimated equity incentive compensation forfeiture rate. As a result, we recorded a \$0.8 million reduction in expense for the three months ended September 30, 2011.

In connection with Dr. Pereira's departure, we entered into a Separation and Consulting Agreement, or the Separation Agreement. Pursuant to the Separation Agreement, and consistent with the terms of his prior employment agreement with us, Dr. Pereira will receive two times his current base salary, payable over a period of two years in equal monthly installments. In addition, Dr. Pereira will be eligible for consideration for a 2011 performance bonus based on the Board of Directors' final scoring of our 2011 performance goals after the year end.

Dr. Pereira has also agreed to provide certain consulting services until June 30, 2012, which may be extended in the event we enter into a definitive agreement with respect to a transaction that would constitute a change in control, as defined in the Separation Agreement, during the consulting period. In consideration for such services, Dr. Pereira will receive compensation equal to his current base salary



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rate of \$52,500 per month. Dr. Pereira's outstanding equity awards will continue to vest under their current vesting schedules through his provision of consulting services to us.

Under the Separation Agreement, if a change in control occurs while Dr. Pereira is providing consulting services to us, all of Dr. Pereira's outstanding unvested equity awards will become automatically vested in full, provided that any performance related conditions in such equity awards will remain in effect and unmodified. Additionally, upon such an event, Dr. Pereira will be entitled to a bonus equal to two times his 2011 target performance bonus amount, or approximately \$0.9 million in total.

Pursuant to the terms of Mr. Zieziula's existing employment agreement with us, in connection with Mr. Zieziula's departure, he will receive severance pay equal to his current base salary, payable over one year in equal monthly installments.

On November 4, 2011, our Board of Directors appointed Frank E. Thomas, currently our Executive Vice President and Chief Financial Officer, to serve as our Chief Operating Officer and interim President and Chief Executive Officer until we have appointed a permanent successor.

*Business Development Activities*

In July 2011, we entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, with Alamo Acquisition Sub, Inc., a Delaware corporation and our wholly-owned subsidiary, or Merger Sub, and Allos Therapeutics, Inc., or Allos, which was amended in August 2011. In October 2011, pursuant to the terms of the Merger Agreement, we terminated the Merger Agreement and paid Allos an expense reimbursement amount equal to \$2.0 million in connection with such termination, which will be recorded as an expense in our condensed consolidated statement of operations in the fourth quarter of 2011.

As a result of the termination of the Merger Agreement, certain voting agreements, dated as of July 19, 2011, by and between us and each of the then directors, other than Timothy P. Lynch, and certain executive officers of Allos, and Warburg Pincus Private Equity VIII, L.P., or Warburg Pincus, automatically terminated pursuant to their respective terms; and a stockholders agreement, dated as of July 19, 2011, by and between us and Warburg Pincus, also automatically terminated pursuant to its terms.

*Takeda Collaboration*

In March 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda Pharmaceutical Company Limited, or Takeda, under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey. Under the Takeda Agreement we were 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. We have since transferred the *Feraheme* regulatory applications in Canada and Switzerland to Takeda. Under the Takeda Agreement we may be entitled to receive milestone payments over time equaling approximately \$220.0 million, including up to an aggregate of \$33.0 million upon the regulatory approval and commercial launch of *Feraheme* in the EU and Canada.



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*Clinical Development and Regulatory Status of Feraheme*

We continue to advance our *Feraheme* clinical development program in adults by conducting a global registrational program consisting of two Phase III multi-center clinical trials to assess *Feraheme* for the treatment of IDA in a broad range of patients for whom treatment with oral iron is unsatisfactory, including women with abnormal uterine bleeding, patients with cancer or gastrointestinal diseases and postpartum women.

In June 2010, we initiated a double blind, placebo-controlled Phase III 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. During 2011 we implemented certain patient enrollment initiatives with respect to this study in an effort to complete enrollment in this study by the end of 2011. However, notwithstanding these initiatives, it is likely that enrollment in this study will not be complete until early 2012.

We have completed enrollment in an open label, active-controlled Phase III 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, an open label extension study is currently 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.

We have initiated two randomized, active-controlled pediatric studies of *Feraheme* for the treatment of IDA in pediatric CKD patients to meet our FDA post-approval Pediatric Research Equity Act requirement to support pediatric labeling of *Feraheme*. One study is in dialysis-dependent CKD patients, and the other is in CKD patients not on dialysis. Both studies are currently open for enrollment. Each study will assess the safety and efficacy of *Feraheme* treatment as compared to oral iron in approximately 144 pediatric patients.

In June 2010 we submitted our Marketing Authorization Application, or MAA, for *Feraheme* for the treatment of IDA in CKD patients with the European Medicines Agency, or EMA. We expect a decision by the EMA on our MAA submission in the first quarter of 2012.

To support our MAA, we have completed enrollment in a global, randomized, multi-center, active-controlled post-approval trial with 162 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, our Pediatric Investigation Plan, which was approved by the EMA in December 2009, includes the two pediatric studies needed to meet the requirements of the Pediatric Research Equity Act in the U.S. described above and two additional pediatric studies requested by the EMA, including a rollover study and a study in pediatric patients with IDA.

As part of our obligations under the Takeda Agreement, we are also required to initiate a multi-center post-approval clinical trial to assess the safety and efficacy of repeat, episodic *Feraheme* administration for the treatment of persistent or recurrent IDA over a 12 month period. In this study, subjects would receive an initial course of two doses of 510 milligrams each of *Feraheme* and subsequent courses of two doses of 510 milligrams each of *Feraheme* whenever they meet treatment criteria. The study is expected to enroll a total of approximately 300 CKD patients



with IDA including hemodialysis and peritoneal dialysis patients and those not on dialysis, including post-kidney

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transplant recipients, however, final decisions regarding this study are pending further discussions with Takeda.

In January 2011, we received a Notice of Non-Compliance from the Therapeutic Products Directorate of Health Canada, or Health Canada, regarding our New Drug Submission for *Feraheme* for the treatment of IDA in adult CKD patients. The Notice of Non-Compliance outlined Health Canada's concerns, which focused mainly on chemistry, manufacturing and control and preclinical toxicology issues. In May 2011, we submitted our response to the Notice of Non-Compliance. This resubmission has been accepted for review by Health Canada, and we expect a decision by the end of 2011.

In August 2010, Takeda filed an MAA with Swissmedic, the Swiss Agency for Therapeutic Products, for *Feraheme* for the treatment of IDA in CKD patients. We expect a decision from Swissmedic during the second quarter of 2012.

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.

*Other information*

GastroMARK®, our oral contrast agent used for delineating the bowel in magnetic resonance imaging, or 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 approximately their current levels for many years, and we do not expect sales of *GastroMARK* to materially increase.

Prior to 2009, we devoted substantially all of our resources to our research and development programs. Since the FDA approval and commercial launch of *Feraheme* in mid-2009, we have incurred substantial costs related to the commercialization and development of *Feraheme*. We expect to continue to incur significant expenses to manufacture, market and sell *Feraheme* as an IV iron replacement therapeutic for use in CKD patients in the U.S., to further develop *Feraheme* for the treatment of IDA in a broad range of patients, and to obtain regulatory approval to market *Feraheme* in countries outside of the U.S. Prior to the commercial launch of *Feraheme*, we financed our operations primarily from the sale of our equity securities, cash generated by our investing activities, and payments from our strategic partners. Since 2009, our revenues have been primarily attributable to product sales of *Feraheme*. We currently expect to fund our future operations from revenue from sales of *Feraheme* in addition to payments from our strategic partners, cash generated by our investing activities, revenue from sales of additional products that we may acquire or in-license, and the sale of our equity securities, if necessary. As of September 30, 2011, we had an accumulated deficit of approximately \$421.3 million and a cash, cash equivalents and investments balance of approximately \$251.0 million.

Table of Contents**Results of Operations***Three and nine months ended September 30, 2011 and 2010**Revenues*

Our revenues for the three and nine months ended September 30, 2011 and 2010 consisted of the following (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2011	2010	\$ Change	% Change	2011	2010	\$ Change	% Change
Product sales, net	\$ 15,802	\$ 15,173	\$ 629	4%	\$ 39,905	\$ 44,694	\$ (4,789)	-11%
License fee and other collaboration revenues	1,707	1,684	23	1%	6,322	4,213	2,109	50%
Royalties	46	35	11	31%	115	118	(3)	-3%
Total	\$ 17,555	\$ 16,892	\$ 663	4%	\$ 46,342	\$ 49,025	\$ (2,683)	-5%

The \$0.7 million increase in our total revenues during the three months ended September 30, 2011 as compared to the three months ended September 30, 2010 was primarily attributable to a \$0.6 million increase in net product sales. Included in our net product sales for the three months ended September 30, 2011 is a \$3.0 million reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales, as discussed in more detail below.

The \$2.7 million decrease in our total revenues during the nine months ended September 30, 2011 as compared to the same period in 2010 was primarily attributable to a \$4.8 million decrease in net product sales, partially offset by a \$2.1 million increase in our license fee and other collaboration revenues. Included in our net product sales for the nine months ended September 30, 2011 is a \$2.5 million reduction of our estimated Medicaid rebate reserve related to *Feraheme* sales during 2009 and 2010, as discussed in more detail below. The increase in license fee and other collaboration revenues during the nine months ended September 30, 2011 as compared to the same periods in 2010 was due to revenues associated with the Takeda Agreement.

The following table sets forth customers who represented 10% or more of our total revenues for the three and nine months ended September 30, 2011 and 2010.

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
AmerisourceBergen Drug Corporation	45%	45%	42%	36%
McKesson Corporation	21%	<10%	20%	<10%
Cardinal Health, Inc.	11%	<10%	12%	<10%
Takeda Pharmaceutical Company Limited	<10%	10%	13%	<10%
Metro Medical Supply, Inc.	<10%	12%	<10%	21%

*Net Product Sales*

Net product sales for the three and nine months ended September 30, 2011 and 2010 consisted of the following (in thousands):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2011	2010	\$ Change	% Change	2011	2010	\$ Change	% Change
<i>Feraheme</i>	\$ 15,560	\$ 15,091	\$ 469	3%	\$ 39,267	\$ 44,161	\$ (4,894)	-11%
<i>GastroMARK</i>	242	82	160	>100%	638	533	105	20%
Total	\$ 15,802	\$ 15,173	\$ 629	4%	\$ 39,905	\$ 44,694	\$ (4,789)	-11%

Our total net product sales increased by \$0.6 million during the three months ended September 30, 2011 as compared to the same period in 2010. This \$0.6 million increase primarily reflects a \$3.0 million reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales, partially offset by a \$2.3 million decrease in our gross product sales. During the three months ended September 30, 2011, we revised our estimated Medicaid utilization based on actual rebate claims received since the launch of *Feraheme* in 2009, our expectations of state level activity, and estimated rebate claims not yet submitted, which resulted in a \$3.0 million reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales. The \$2.3 million decrease in our gross product sales during the three months ended September 30, 2011 as compared to the same period in 2010, is due primarily to decreased revenues of \$2.2 million related to our Launch Incentive Program for our dialysis customers, which was in place in 2010 but not in 2011. Our *Feraheme* sales to dialysis customers in 2011 has been de minimus relative to our dialysis sales during 2010 principally as a result of the January 2011 implementation of the Medicare prospective payment system, which made it less likely that dialysis providers would choose to use *Feraheme*. The decreases in our dialysis sales were partially offset by increased sales from certain non-dialysis settings, such as hematology and oncology clinics and hospitals.

Our total net product sales decreased by \$4.8 million during the nine months ended September 30, 2011 as compared to the same period in 2010. The \$4.8 million decrease reflects a \$5.9 million decrease in our gross product sales, primarily as the result of decreased sales to dialysis providers during 2011 as compared to 2010, including a decrease of \$6.8 million in revenues related to our Launch Incentive Program, partially offset by a \$2.5 million reduction of our estimated Medicaid rebate reserve related to *Feraheme* sales in 2009 and 2010. In addition, during the nine months ended September 30, 2011, we offered higher average customer discounts, chargebacks and rebates to our end-users as compared to the same period in 2010. During the nine months ended September 30, 2011, we reduced our gross product sales by recording allowances of \$17.3 million, which was partially offset by the \$2.5 Medicaid rebate reserve reduction, as compared to allowances of \$15.9 million recorded during the nine months ended September 30, 2010.

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

- Wholesaler demand forecasts and buying decisions, as well as end-user demand, which can create uneven purchasing patterns by our customers;
- Changes or adjustments to our reserves or changes in the timing or availability of government or customer discounts, rebates and incentives;
- Changes in the actual or perceived safety profile of *Feraheme* or products that compete with *Feraheme*, which could cause customers to reduce, discontinue or increase their use of *Feraheme*;
- The introduction of new products into the market that compete with *Feraheme*, such as Nulecit™;
- Changes in our contracting strategies and discounts; and
- The expansion or contraction of the overall IV iron market.

Our net product sales may also fluctuate from period to period due to the enactment of or changes in legislation that impact third-party reimbursement coverage and pricing. For example, in January 2011, a new prospective payment system for dialysis services provided to Medicare beneficiaries who have end stage renal disease became effective, which has significantly diminished the utilization of *Feraheme* in the dialysis market and has consequently adversely affected our *Feraheme* sales in the dialysis setting. As a result of the implementation of the prospective payment system, we expect our dialysis sales for the remainder of 2011 and beyond will not be significant.

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 whether additional allowances or accruals are required based on inventory in our sales channel. 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, 2010.

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An analysis of our product sales allowances and accruals for the three and nine months ended September 30, 2011 and 2010 is as follows (in thousands):

	<b>Three Months Ended September 30,</b>	
	<b>2011</b>	<b>2010</b>
Product sales allowances and accruals		
Discounts and chargebacks	\$ 3,601	\$ 1,218
Government and other rebates	2,120	4,383
Medicaid rebate reserve adjustment	(3,026)	
Returns	354	359
Total product sales allowances and accruals	\$ 3,049	\$ 5,960
Total gross product sales	\$ 18,851	\$ 21,133
Total product sales allowances and accruals as a percent of total gross product sales	16%	28%

	<b>Nine Months Ended September 30,</b>	
	<b>2011</b>	<b>2010</b>
Product sales allowances and accruals		
Discounts and chargebacks	\$ 9,400	\$ 3,035
Government and other rebates	6,897	11,917
Medicaid rebate reserve adjustment	(2,532)	
Returns	1,022	936
Total product sales allowances and accruals	\$ 14,787	\$ 15,888
Total gross product sales	\$ 54,692	\$ 60,582
Total product sales allowances and accruals as a percent of total gross product sales	27%	26%

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 product directly from us. Indirect fees, discounts and rebates are contractual price adjustments payable to healthcare providers and organizations, such as certain physicians, clinics, hospitals, GPOs, and dialysis organizations that typically do not purchase products directly from us but rather from wholesalers and specialty distributors. In accordance with guidance related to accounting for fees and consideration given by a vendor to a customer (including a reseller of a vendor's products), these fees, discounts and rebates are presumed to be a reduction of the selling price of *Feraheme*. Product sales allowances and accruals are based on definitive contractual agreements or legal requirements related to the purchase and/or utilization of the product by these entities.

Product sales allowances and accruals are recorded in the same period that the related revenue is recognized and are estimated using either historical, actual and/or other data, including estimated patient

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usage, applicable contractual rebate rates, contract performance by the benefit providers, other current contractual and statutory requirements, historical market data based upon experience of *Feraheme* and other products similar to *Feraheme*, specific known market events and trends such as competitive pricing and new product introductions and current and forecasted customer buying patterns and inventory levels, and the shelf life of *Feraheme*. As part of this evaluation, we also review changes to federal and other legislation, changes to rebate contracts, changes in the level of discounts, and changes in product sales trends. Reserve estimates are evaluated quarterly and may require adjustments to better align our estimates with actual results. Although allowances and accruals are recorded at the time of product sale, certain rebates are typically paid out, on average, up to six months or longer after the sale.

We are subject to reimbursement arrangements with state Medicaid programs for which we estimate and record rebate reserves. Our estimates of these reserves are based on actual *Feraheme* sales and Medicaid reimbursement data, market research data related to utilization rates by various end-users, and forecasted customer buying patterns blended with historical experience of products similar to *Feraheme* sold by others. During the three months ended September 30, 2011, we revised our estimated Medicaid utilization based on actual rebate claims received since the 2009 launch of *Feraheme*, our expectations of state level activity, and estimated rebate claims not yet submitted, which resulted in a \$3.0 million reduction of our estimated Medicaid rebate reserve related to *Feraheme* sales from 2009, 2010 and the first half of 2011. This change in estimate is reflected as an increase in our net product sales for the three and nine months ended September 30, 2011 and resulted in a significant decline in our gross to net percentage to 16% for the three months ended September 30, 2011 as compared to 28% during the same period in 2010. We expect our reserves as a percentage of gross sales will increase to approximately its prior period levels in future quarters. If we determine in future periods that our actual rebate experience is not indicative of expected claims or if other factors affect estimated claims rates, we may be required to adjust our current Medicaid accumulated reserve estimate, and that adjustment could be significant and would affect our earnings in the period of the adjustment.

An analysis of the amount of, and changes in, our product allowances and accruals reserves for the nine months ended September 30, 2011 and 2010 is as follows (in thousands):

	Discounts	Rebates and Fees	Returns	Total
Balance at January 1, 2011	\$ 1,148	\$ 8,218	\$ 1,797	\$ 11,163
Current provisions relating to sales in current year	9,623	6,958	1,022	17,603
Other provisions relating to deferred revenue		(18)		(18)
Adjustments relating to sales in prior years	(223)	(2,593)		(2,816)
Payments/returns relating to sales in current year	(8,139)	(3,903)	(51)	(12,093)
Payments/returns relating to sales in prior years	(926)	(4,914)	(100)	(5,940)
Balance at September 30, 2011	\$ 1,483	\$ 3,748	\$ 2,668	\$ 7,899

	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	3,035	12,200	1,007	16,242
Other provisions relating to deferred revenue		(968)		(968)
Adjustments relating to sales in prior year		(283)	(71)	(354)
Payments/returns relating to sales in current year	(2,439)	(6,196)		(8,635)
Payments/returns relating to sales in prior year	(499)	(2,105)		(2,604)
Balance at September 30, 2010	\$ 596	\$ 7,842	\$ 1,399	\$ 9,837



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During the nine months ended September 30, 2011 and 2010, we decreased our product sales allowances and accruals by approximately \$2.8 million and \$0.4 million, respectively, for changes in estimates relating to sales in prior years. These adjustments were primarily caused by differences between actual Medicaid utilization and claims experience to date as compared to our initial estimates as described above. During the three months ended September 30, 2011, we revised our estimated Medicaid utilization based on actual rebate claims received since the launch of *Feraheme* in 2009, our expectations of state level activity, and estimated rebate claims not yet submitted, which resulted in a \$2.5 million reduction of our estimated Medicaid rebate reserve related to *Feraheme* sales during 2009 and 2010.

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

- Variations in, and the success of pricing, fee, rebate and discount structures implemented in our efforts to increase adoption of *Feraheme*;
- Variations in our customer mix;
- Changes in legislation, such as the Health Care and Education Affordability Reconciliation Act, or the Health Care Reform Act, or any future healthcare legislation; and
- Adjustments and refinements to our prior estimates and assumptions.

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

- The magnitude and timing of adoption of *Feraheme* by physicians, hospitals and other healthcare payors and providers;
- The effect of federal and other legislation such as the Health Care Reform Act;
- The inventory levels maintained by *Feraheme* wholesalers, distributors and other customers;
- The frequency of re-orders by existing customers;

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

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

*License Fee and Other Collaboration Revenues*

License fee and other collaboration revenues for the three and nine months ended September 30, 2011 and 2010 consisted of the following (in thousands):

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	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2011	2010	\$ Change	% Change	2011	2010	\$ Change	% Change
Deferred license fee revenues recognized in connection with the Takeda Agreement	\$ 1,524	\$ 1,548	\$ (24)	-2%	\$ 4,572	\$ 3,048	\$ 1,524	50%
Reimbursement revenues recognized primarily in connection with the Takeda Agreement	183	136	47	35%	1,750	1,165	585	50%
Total	\$ 1,707	\$ 1,684	\$ 23	1%	\$ 6,322	\$ 4,213	\$ 2,109	50%

Most of our license fee and other collaboration revenues for the three and nine months ended September 30, 2011 and 2010 related to revenue recognized under the Takeda Agreement, which we entered into in March 2010. During each of the three months ended September 30, 2011 and 2010, we recorded \$1.5 million of revenues associated with the amortization of \$61.0 million of deferred revenues recorded in connection with the Takeda Agreement. During the nine months ended September 30, 2011 and 2010 we recorded \$4.6 million and \$3.0 million, respectively, associated with the amortization of \$61.0 million of deferred revenues recorded in connection with the Takeda Agreement. The \$1.5 million increase for the nine months ended September 30, 2011 as compared to the same period in 2010 was the result of recognizing nine months of the upfront payment during 2011 as compared to six months during 2010. The \$61.0 million of deferred revenues was comprised of a \$60.0 million upfront payment which we received from Takeda in April 2010, as well as approximately \$1.0 million reimbursed to us during 2010 for certain expenses incurred prior to entering the agreement, which we considered an additional upfront payment. As of September 30, 2011, we had approximately \$51.8 million remaining in deferred revenues related to the \$61.0 million upfront payments received from Takeda.

In addition, under the terms of the Takeda Agreement, Takeda is responsible for reimbursing us for certain out-of-pocket regulatory and clinical trial supply costs we incur in the conduct of certain regulatory and clinical research services we perform under the agreement. Because we are acting as the principal in carrying out these activities, any reimbursement payments received from Takeda is recorded in license fee and other collaboration revenues in our condensed consolidated statement of operations and offsets the costs that we incur during the period in which we perform those services. During each of the three months ended September 30, 2011 and 2010, we recorded \$0.1 million of revenues associated with the reimbursement of certain out-of-pocket regulatory and clinical supply costs. During the nine months ended September 30, 2011 and 2010, we recorded \$1.7 million and \$1.2 million, respectively, of revenues associated with the reimbursement of out-of-pocket regulatory and clinical supply costs in connection with the Takeda Agreement.

In May 2008, we entered into a Collaboration and Exclusive License Agreement with 3SBio for 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 and nine months ended September 30, 2011 or 2010, and we do not expect license fee revenues under this agreement to be significant during the remainder of 2011.

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Cost of product sales for the three and nine months ended September 30, 2011 and 2010 consisted of the following (in thousands):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2011	2010	\$ Change	% Change	2011	2010	\$ Change	% Change
Cost of Product Sales	\$ 2,669	\$ 2,274	\$ 395	17%	\$ 7,792	\$ 5,168	\$ 2,624	51%
Percentage of Net Product Sales	17%	15%			20%	12%		

Our cost of product sales are primarily comprised of manufacturing costs associated with *Feraheme*. Our cost of product sales increased by \$0.4 million and \$2.6 million during the three and nine months ended September 30, 2011, respectively, as compared to the same periods in 2010, primarily due to higher idle capacity costs at our Cambridge, Massachusetts manufacturing facility as well as higher production costs.

We expect our cost of product sales as a percentage of net product sales to remain relatively consistent or increase slightly for the remainder of 2011.

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

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Research and development expenses for the three and nine months ended September 30, 2011 and 2010 consisted of the following (in thousands):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2011	2010	\$ Change	% Change	2011	2010	\$ Change	% Change
<b>External Research and Development Expenses</b>								
<i>Feraheme</i> to treat IDA regardless of the underlying cause	\$ 7,780	\$ 5,550	\$ 2,230	40%	\$ 21,195	\$ 11,889	\$ 9,306	78%
<i>Feraheme</i> to treat IDA in CKD patients	2,512	2,444	68	3%	7,153	7,727	(574)	-7%
<i>Feraheme</i> as a therapeutic agent, general	138	169	(31)	-18%	756	629	127	20%
<i>Feraheme</i> manufacturing process development and materials	412	893	(481)	-54%	2,356	2,876	(520)	-18%
<i>Feraheme</i> as an imaging agent		742	(742)	-100%		2,128	(2,128)	-100%
Other external costs	54	199	(145)	-73%	127	725	(598)	-82%
<b>Total</b>	<b>\$ 10,896</b>	<b>\$ 9,997</b>	<b>\$ 899</b>	<b>9%</b>	<b>\$ 31,587</b>	<b>\$ 25,974</b>	<b>\$ 5,613</b>	<b>22%</b>
<b>Internal Research and Development Expenses</b>								
Compensation, payroll taxes, benefits and other expenses	3,914	3,876	38	1%	12,203	12,513	(310)	-2%
Equity-based compensation expense	84	158	(74)	-47%	1,365	2,696	(1,331)	-49%
<b>Total</b>	<b>\$ 3,998</b>	<b>\$ 4,034</b>	<b>\$ (36)</b>	<b>-1%</b>	<b>\$ 13,568</b>	<b>\$ 15,209</b>	<b>\$ (1,641)</b>	<b>-11%</b>
<b>Total Research and Development Expenses</b>	<b>\$ 14,894</b>	<b>\$ 14,031</b>	<b>\$ 863</b>	<b>6%</b>	<b>\$ 45,155</b>	<b>\$ 41,183</b>	<b>\$ 3,972</b>	<b>10%</b>

Total research and development expenses incurred in the three and nine months ended September 30, 2011 increased by \$0.9 million, or 6%, and \$4.0 million, or 10%, respectively, as compared to the three and nine months ended September 30, 2010. The \$0.9 million and \$4.0 million increases were primarily due to greater external research and development expenses resulting from increased clinical trial activity during 2011, partially offset by decreases in internal research and development expenses.

Our external research and development expenses increased by \$0.9 million, or 9%, and \$5.6 million, or 22%, for the three and nine months ended September 30, 2011, respectively, as compared to the same periods in 2010. The increases in our external expenses were 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, and costs incurred to prepare for certain of our pediatric studies. These increases were partially offset by a reduction in costs associated with our global clinical program to support our MAA in Europe for the treatment of IDA in CKD patients, as well as certain costs incurred during the three and nine months ended September 30, 2010 in connection with a clinical trial for *Feraheme* as a diagnostic agent for vascular-enhanced MRI, which was discontinued in mid-2010.

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Our internal research and development expenses remained relatively unchanged for the three months ended September 30, 2011 as compared to the same period in 2010 and decreased by \$1.6 million, or 11%, for the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010. The decrease in internal costs for the three and nine months ended September 30, 2011 was primarily attributable to the reduction of equity-based and other compensation-related costs, principally due to our October 2010 restructuring plan, as well as a reduction in estimated accrued compensation costs related to the expected impact of our 2011 corporate restructuring.

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*Research and Development Activities*

We expect research and development expenses to continue to increase for the remainder of 2011 primarily due to the continued advancement of our clinical development programs, including studies and activities required under the Takeda Agreement, costs associated with our recently announced corporate restructuring, as well as other miscellaneous research and development related activities in support of our *Feraheme* development programs. Factors which will impact 2011 research and development expenses include the design, timing and pace of enrollment of our clinical trials for *Feraheme*, including our development program for *Feraheme* in a broad range of patients with IDA and 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 evaluating *Feraheme* treatment compared to treatment with placebo; (2) a Phase III clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron; and (3) an extension study.
- *Feraheme* to treat IDA in CKD patients. This project currently includes: (1) a post-approval clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron to support our MAA submission; (2) two ongoing pediatric studies that are being conducted as part of our post-approval Pediatric Research Equity Act requirement to support pediatric CKD labeling of *Feraheme*; (3) two additional pediatric studies to be conducted in accordance with our approved Pediatric Investigation Plan to support our MAA submission; and (4) a multi-center 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 September 30, 2011, we have incurred aggregate external research and development expenses of approximately \$39.1 million related to our current program for the development of *Feraheme* to treat IDA regardless of the underlying cause. We currently estimate that the total remaining external costs associated with the efforts needed to complete this development project will be in the range of approximately \$20.0 to \$30.0 million, the majority of which will be incurred by the end of 2012. This represents a decrease of \$9.0 million from our expected range at June 30, 2011 and primarily reflects actual expenses incurred during the three months ended September 30, 2011.

Through September 30, 2011, we have incurred aggregate external research and development expenses of approximately \$18.4 million related to our current program for the development of *Feraheme* to treat IDA in CKD patients. We currently estimate that the total remaining external costs associated with this development project will be in the range of approximately \$30.0 to \$40.0 million over the next several years. This represents a decrease of \$6.0 million from our expected range at June 30, 2011 and primarily reflects actual expenses incurred during the three months ended September 30, 2011 as well as reductions in future spending on certain of our clinical trial activities as a result of our November 2011 corporate restructuring.





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We are also planning to conduct a post-marketing registry study in order to better understand the frequency and timing of adverse events following *Feraheme* administration in the CKD setting. However, until we complete our discussions with the FDA regarding the potential objectives and design of the proposed registry study, we cannot estimate the cost associated with this study.

Conducting clinical trials involves a number of uncertainties, many of which are out of our control. Our estimates of external costs associated with our research and development projects could therefore vary from our current estimates for a variety of reasons including but not limited to the following: delays in our clinical trials due to slow enrollment, unexpected results from our clinical sites that affect our ability to complete the studies in a timely manner, unanticipated adverse reactions to *Feraheme* either in commercial use or in a clinical trial setting, inadequate performance or errors by third-party service providers, any deficiencies in the design or oversight of these studies by us, the need to conduct additional clinical trials, any adverse regulatory action or a delay in the submission of any applicable regulatory filing. As a result, we are unable to reasonably estimate the specific timing of any expected net cash inflows resulting from these projects, provided, however, we expect regulatory decisions on our marketing applications for *Feraheme* in the CKD indication from Health Canada in 2011 and the EMA and Swissmedic in early 2012. If one or more of these regulatory applications is approved, we expect that *Feraheme* will be launched commercially in the approved territory or territories shortly thereafter, at which point we will receive certain milestone payments and we will begin receiving royalty payments in accordance with the Takeda Agreement.

*Selling, General and Administrative Expenses*

Our selling, general and administrative expenses include costs related to our commercial personnel, including our specialized sales force, medical education professionals, 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 activities.

Selling, general and administrative expenses for the three and nine months ended September 30, 2011 and 2010 consisted of the following (in thousands):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2011	2010	\$ Change	% Change	2011	2010	\$ Change	% Change
Compensation, payroll taxes and benefits	\$ 7,193	\$ 7,927	\$ (734)	-9%	\$ 23,483	\$ 27,888	\$ (4,405)	-16%
Professional and consulting fees and other expenses	8,550	8,817	(267)	-3%	23,257	29,818	(6,561)	-22%
Equity-based compensation expense	1,487	1,242	245	20%	6,950	7,740	(790)	-10%
Total	\$ 17,230	\$ 17,986	\$ (756)	-4%	\$ 53,690	\$ 65,446	\$ (11,756)	-18%

Total selling, general and administrative expenses incurred in the three months ended September 30, 2011 decreased by \$0.8 million, or 4%, as compared to the three months ended September 30, 2010. Compensation, payroll taxes and benefits decreased by \$0.7 million during the three months ended September 30, 2011 as compared to the three months ended September 30, 2010 primarily as a result of reduced headcount resulting from our October 2010 restructuring and the reduction of certain accrued compensation costs as a result of our November 2011 restructuring. At September 30, 2011, we had 145 employees in our selling, general and administrative departments as compared to 193 employees at September 30, 2010, a 25% decrease. In addition, professional and consulting fees and other expenses were lower during the three months ended September 30, 2011 as compared to the same period in 2010 due to reduced costs related to field-based contract nurses, advertising and marketing materials, and certain other general marketing costs, partially offset by \$1.9 million of costs



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incurred in connection with our then proposed merger with Allos. The \$0.2 million increase in equity-based compensation expense during the three months ended September 30, 2011 as compared to the same period in 2010 was due primarily to a \$2.1 million reduction to our equity-based compensation expense during the three months ended September 30, 2010 related to the impact on our equity compensation forfeitures resulting from our October 2010 corporate workforce reduction, partially offset by the expected impact on our equity compensation forfeitures resulting from our November 2011 corporate workforce reduction.

Total selling, general and administrative expenses incurred in the nine months ended September 30, 2011 decreased by \$11.8 million, or 18%, as compared to the nine months ended September 30, 2010. Compensation, payroll taxes and benefits decreased by \$4.4 million during the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010 primarily as a result of reduced headcount resulting from our October 2010 restructuring and the reduction of certain accrued compensation costs as a result of our November 2011 restructuring. In addition, professional and consulting fees and other expenses decreased by \$6.6 million during the nine months ended September 30, 2011 as compared to the same period in 2010 due to reduced costs related to field-based contract nurses, advertising and marketing materials, and certain other general marketing costs, partially offset by \$2.7 million of costs incurred in connection with our then proposed merger with Allos. The \$0.8 million decrease in equity-based compensation expense during the nine months ended September 30, 2011 as compared to the same period in 2010 was due primarily to a \$2.1 million reduction to our equity-based compensation expense during the nine months ended September 30, 2010 related to the impact on our equity compensation forfeitures resulting from our October 2010 corporate workforce reduction, the reduction of expense associated with the resignation of our former Chief Financial Officer in June 2011, and the expected impact on our equity compensation forfeitures resulting from our November 2011 corporate workforce reduction, partially offset by the expense associated with equity awards to new employees and additional equity awards to existing employees, including senior management and members of our Board of Directors.

We expect total selling, general and administrative expenses to increase for the remainder of 2011 as the result of costs related to our then proposed merger with Allos, including the \$2.0 million expense reimbursement fee we paid to Allos in October 2011 in connection with the termination of the Merger Agreement, and estimated costs resulting from our November 2011 corporate restructuring, partially offset by cost savings expected to be realized by our 2011 corporate restructuring.

*Other Income (Expense)*

Other income (expense) for the three and nine months ended September 30, 2011 and 2010 consisted of the following (in thousands):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2011	2010	\$ Change	% Change	2011	2010	\$ Change	% Change
Interest and dividend income, net	\$ 378	\$ 448	\$ (70)	-16%	\$ 1,390	\$ 1,323	\$ 67	5%
Gains (losses) on investments, net	14	(396)	410	<(100)%	(194)	402	(596)	<(100)%
Fair value adjustment of settlement rights				N/A		(788)	788	-100%
Total	\$ 392	\$ 52	\$ 340	>100%	\$ 1,196	\$ 937	\$ 259	28%

Other income for the three months ended September 30, 2011 was \$0.4 million as compared to less than \$0.1 million for the three months ended September 30, 2010 primarily due to a \$0.4 million



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other-than-temporary impairment related to the redemption of one of our auction rate securities, or ARS, investments in a tender offer from the issuer in October 2010.

Other income for the nine months ended September 30, 2011 was \$1.2 million as compared to \$0.9 million for the nine months ended September 30, 2010. During the nine months ended September 30, 2011, we recorded net realized losses of approximately \$0.2 million primarily attributable to our participation in a June 2011 purchase offer from the issuer of one of our ARS investments. During the nine months ended September 30, 2010, we recorded a \$0.4 million other-than-temporary impairment related to the redemption of one of our ARS investments in a tender offer from the issuer in October 2010. In addition, during the nine months ended September 30, 2010, we recognized both a realized gain of \$0.8 million related to the redemption of certain of our 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 decrease slightly from current levels for the remainder of 2011 as a result of lower expected average cash balances due to our continued use of cash in operations.

*Net Loss*

For the reasons stated above, we incurred a net loss of \$16.6 million and \$58.5 million, or \$0.78 and \$2.76 per basic and diluted share, for the three and nine months ended September 30, 2011 as compared to a net loss of \$17.0 million and \$61.4 million, or \$0.81 and \$2.96 per basic and diluted share, for the three and nine months ended September 30, 2010.

**Liquidity and Capital Resources**

*General*

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

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

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

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- The magnitude of *Feraheme* 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;

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- Costs associated with our development of *Feraheme* for the treatment of IDA in a broad range of patients in the U.S.;
- Costs associated with our pursuit of approval for *Feraheme* outside of the U.S.;
- Costs associated with commercial-scale manufacturing of *Feraheme*, including costs of raw or other materials, and costs associated with maintaining commercial inventory and qualifying additional manufacturing capacities and alternative suppliers;
- The outcome of any material litigation to which we are or may become a party;
- Our ability to liquidate our investments in ARS in a timely manner and without significant loss;
- 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 September 30, 2011, our investments consisted primarily of corporate debt securities, U.S. treasury and government agency securities, commercial paper and ARS. We place our cash and investments in instruments that meet high credit quality and diversification standards, as specified in our investment policy. Our investment policy also limits the amount of our credit exposure to any one issue or issuer, excluding U.S. government entities, and seeks to manage these assets to achieve our goals of preserving principal, maintaining adequate liquidity at all times, and maximizing returns.

Cash, cash equivalents and investments as of September 30, 2011 and December 31, 2010 consisted of the following (in thousands):

	September 30, 2011	December 31, 2010	\$ Change	% Change
Cash and cash equivalents	\$ 75,777	\$ 112,646	\$ (36,869)	-33%
Short-term investments	153,560	147,619	5,941	4%
Long-term investments	21,631	33,597	(11,966)	-36%
Total	\$ 250,968	\$ 293,862	\$ (42,894)	-15%

The \$42.9 million decrease in cash, cash equivalents and investments as of September 30, 2011 from December 31, 2010 was primarily due to cash used in operations partially offset by cash received from *Feraheme* sales and interest income.

We expect that during the remainder of 2011 our cash balance will decline as we continue to invest in the development and commercialization of *Feraheme*. We believe that our cash, cash equivalents, and short-term investments as of September 30, 2011 and the cash we currently expect to receive from sales of *Feraheme*, earnings on our investments, and potential milestones from the Takeda Agreement, including up to an aggregate of \$33.0 million upon the regulatory approval and commercial launch of *Feraheme* in the EU and Canada, will be sufficient to satisfy our cash flow needs for at least the next twelve months, including projected operating expenses related to our ongoing development and commercialization programs for *Feraheme*.



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In November 2011, we announced a corporate restructuring, including a workforce reduction plan, which includes an approximate 25% reduction in positions. As a result of this reduction in our workforce, we currently estimate that we will record restructuring charges of approximately \$3.2 million, which are expected to be recorded primarily in the fourth quarter of 2011. These estimated restructuring charges relate primarily to employee severance and benefits. We expect the majority of the workforce reduction to be completed by the end of 2011 and the majority of our restructuring charges to be paid during the twelve months following this restructuring. Our estimated restructuring charges are based on a number of assumptions. Actual results may differ materially from our expectations and additional charges not currently expected may be incurred in connection with, or as a result of, these reductions.

In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions since that time. As a result of the lack of significant observable ARS market activity since February 2008, we use a discounted cash flow methodology to value these securities as opposed to valuing them at their par value. Our valuation analysis considers, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, credit ratings of the security by the major securities rating agencies, the ability or inability to sell the investment in an active market or to the issuer, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when call features may be exercised by the issuer. We believe we will ultimately be able to liquidate our investments in ARS without significant loss prior to their maturity dates primarily due to the collateral securing most of our ARS. Our ARS balance has declined from a par value of \$105.4 million at December 31, 2007 to a par value of \$28.6 million without the recognition of a material loss. However, it could take until final maturity of the ARS to realize the par value of our remaining ARS investments. In the event that we need to access our investments in these securities, we will not be able to do so until a future auction is successful, the issuer calls the security pursuant to a mandatory tender or redemption prior to maturity, a buyer is found outside the auction process, or the securities mature.

As of September 30, 2011, we held a total of \$25.1 million in fair market value of ARS, reflecting a reduction in value of approximately \$3.5 million from the par value of these securities of approximately \$28.6 million. As of September 30, 2011, 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 September 30, 2011 by at least one of the major securities rating agencies and was primarily collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program. As of September 30, 2011, all of our ARS continue to pay interest according to their stated terms.

In October 2011, one of our ARS investments with a par value of \$3.5 million was redeemed by the issuer. In accordance with the terms of the offer, the issuer purchased the security from us at par value, which was paid to us in October 2011.

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

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*Cash flows from operating activities*

During the nine months ended September 30, 2011, our use of \$42.1 million of cash in operations was attributable principally to our net loss of approximately \$58.5 million, adjusted for the following:

- Non-cash operating items of \$13.1 million, including equity-based compensation expense, depreciation, amortization, and other non-cash items;
  
- A decrease of \$4.3 million in prepaid assets and inventories;
  
- An increase of \$5.1 million in accounts payable and accrued expenses; and
  
- A decrease in deferred revenues and other operating assets and liabilities of \$6.1 million, which reflect timing differences between the receipt and payment of cash associated with certain transactions and the recognition of such amounts in our results of operations.

Our net loss of \$58.5 million for the nine months ended September 30, 2011 was primarily the result of commercialization expenses, including marketing 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 sales and collaboration revenues.

*Cash flows from investing activities*

Cash provided by investing activities was \$5.0 million during the nine months ended September 30, 2011 and was primarily attributable to proceeds from the sales and maturities of our investments partially offset by purchases of investments.

*Business Development Activities*

In July 2011, we entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, with Alamo Acquisition Sub, Inc., a Delaware corporation and our wholly-owned subsidiary, or Merger Sub, and Allos Therapeutics, Inc., or Allos, which was amended in August 2011. In October, 2011, pursuant to the terms of the Merger Agreement, we terminated the Merger Agreement and paid Allos an expense reimbursement amount equal to \$2.0 million in connection with such termination, which will be recorded as an expense in our condensed consolidated statement of operations in the fourth quarter of 2011.

*Contractual Obligations*

Under the terms of the Merger Agreement, we are required to pay Allos a termination fee of \$14.0 million (less the \$2.0 million expense reimbursement fee we paid Allos in October 2011) in the event that we enter into certain acquisition transactions on or prior to October 21, 2012 or such a transaction is consummated on or before such date. Other than this termination fee, there have been no material changes to our contractual obligations from those described in our Annual Report on Form 10-K for the year ended December 31, 2010.

**Off-Balance Sheet Arrangements**

As of September 30, 2011, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

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**Critical Accounting Policies**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make certain estimates and assumptions that affect the reported amount of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The most significant estimates and assumptions are used in, but are not limited to, revenue recognition related to product sales and collaboration agreements, product sales allowances and accruals, assessing investments for potential other-than-temporary impairment and determining values of investments, reserves for doubtful accounts, accrued expenses, reserves for legal matters, income taxes and equity-based compensation expense. Actual results could differ materially from those estimates. 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, 2010. There have been no changes to these critical accounting policies and estimates since December 31, 2010 that materially impacted our financial statements.

**Impact of Recently Issued and Proposed Accounting Pronouncements**

In June 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2011-05, Presentation of Comprehensive Income, or ASU 2011-05. ASU 2011-05 updates existing guidance to amend the presentation of comprehensive income. Under ASU 2011-05, entities are required to present items of net income and other comprehensive income either in one continuous statement referred to as the statement of comprehensive income or in two separate, but consecutive, statements of net income and other comprehensive income. Under both alternatives, companies will be required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. In the single continuous statement approach, the guidance requires the entity to present the components of net income and total net income, the components of other comprehensive income and a total for other comprehensive income, along with the total of comprehensive income in that statement. In the two-statement approach, the income statement will be followed immediately by the statement of other comprehensive income, which will include the amount for total comprehensive income. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We do not expect the adoption of this ASU to have an impact on our condensed consolidated financial statements.

In May 2011, the FASB issued ASU No. 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs, or ASU 2011-04. This ASU updates existing guidance to amend fair value measurements and related disclosures. ASU 2011-04 relates to a major convergence project of the FASB and the International Accounting Standards Board to improve International Financial Reporting Standards, or IFRS, and U.S. generally accepted accounting principles, or GAAP. ASU 2011-04 results in a consistent definition of fair value and common requirements for measurement of and disclosure about fair value between IFRS and U.S. GAAP. The ASU also changes some fair value measurement principles and enhances disclosure requirements related to activities in Level 3 of the fair value hierarchy. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We do not expect the adoption of this ASU to have an impact on our condensed consolidated financial statements.

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In January 2010, the FASB issued ASU No. 2010-06, Improving Disclosures About Fair Value Measurements, or ASU 2010-06, which amends ASC 820, Fair Value Measurements and Disclosure. 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 rollforward of activity in Level 3 fair value measurements. Those disclosures are effective for fiscal years beginning after December 31, 2010 which for us is fiscal 2011. We have adopted all provisions of this pronouncement, and such adoption did not 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 Accounting Standards Codification 605-25 (previously included within Emerging Issues Task Force, or EITF, No. 00-21, Revenue Arrangements with Multiple Deliverables, or EITF 00-21). ASU 2009-13 provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and how the consideration should be 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 became effective prospectively for revenue arrangements entered into or materially modified beginning on January 1, 2011. The initial adoption of this guidance did not have any impact on our condensed consolidated financial statements; however, it will likely impact us if we enter into any future transactions involving multiple deliverables 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 September 30, 2011, our short- and long-term investments equaled \$175.2 million and were invested primarily 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 September 30, 2011, this would have resulted in a hypothetical decline in fair value of our investments, excluding ARS, which are described below, of approximately \$0.6 million.

At September 30, 2011, we held a total of \$25.1 million in fair market value of ARS, reflecting an unrealized loss of approximately \$3.5 million compared to the par value of these securities of approximately \$28.6 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

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participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, credit ratings of the security by the major securities rating agencies, the ability or inability to sell the investment in an active market or to the issuer, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when call features may be exercised by the issuer. Based upon this methodology, we have estimated the fair value of our ARS that we do not intend to sell prior to recovery to be \$21.6 million at September 30, 2011 and have recorded the \$3.5 million decline in value as an unrealized loss related to our ARS to accumulated other comprehensive loss as of September 30, 2011.

In October 2011, one of our ARS investments with a par value of \$3.5 million was redeemed by the issuer. In accordance with the terms of the offer, the issuer purchased the security from us at par value, which was paid to us in October 2011.

We believe there are several significant assumptions that are utilized in our ARS valuation analysis, the two most critical of which are the discount rate and the average expected term. Holding all other factors constant, if we were to increase the discount rate utilized in our ARS valuation analysis by 50 basis points, or one-half of a percentage point, this change would have the effect of reducing the fair value of our ARS by approximately \$0.4 million as of September 30, 2011. Similarly, holding all other factors constant, if we were to increase the average expected term utilized in our fair value calculation by one year, this change would have the effect of reducing the fair value of our ARS by approximately \$0.7 million as of September 30, 2011.

**Item 4. Controls and Procedures.**

**Managements Evaluation of our Disclosure Controls and Procedures**

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in the Exchange Act Rule 13a-15(e), or Rule 15d-15(e)), with the participation of our management, have each concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective and were designed to ensure that information we are required to disclose in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms. It should be noted that any system of controls is designed to provide reasonable, but not absolute, assurances that the system will achieve its stated goals under all reasonably foreseeable circumstances. Our principal executive officer and principal financial officer have each concluded that our disclosure controls and procedures as of the end of the period covered by this report are effective at a level that provides such reasonable assurances.

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2011 that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.



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**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

*Legal Proceedings related to Allos*

Between July 21, 2011 and August 15, 2011, nine putative class action lawsuits were filed against us, Allos, members of the Allos board of directors and our Board, and Alamo Acquisition Sub., Inc., or Merger Sub, arising out of the then proposed merger between us and Allos. Two lawsuits were filed in the United States District Court for the District of Colorado entitled *Radmore/Salem v. Allos Therapeutics, Inc.* and *Everage v. Allos Therapeutics, Inc.*, or the Colorado Federal Court Actions. Four lawsuits were filed in the Court of Chancery of the State of Delaware, one of which (entitled *Everage v. Berns*) was voluntarily dismissed on July 27, 2011, and two of which (entitled *Lam v. Allos Therapeutics, Inc.* and *Mulligan v. Allos Therapeutics, Inc.*) were consolidated, or the Delaware Action. The fourth action in Delaware is *Gaines v. Narachi*, or the Gaines Action. Three lawsuits, entitled *Nunn v. Berns*, *Stevens v. Hoffman*, and *Hannon v. Allos Therapeutics, Inc.*, were filed in Jefferson County District Court for the State of Colorado and subsequently consolidated, or the Colorado State Court Action. With the exception of The Gaines Action, which is described below, these lawsuits name members of the Allos board of directors, as well as Allos, us, and Merger Sub as defendants, and generally allege that the Allos directors breached their fiduciary duties to Allos stockholders in connection with the Merger Agreement by agreeing to an unfair price, conducting a flawed sales process, enacting preclusive deal protection devices, engaging in self-dealing, and failing to disclose material information (relating to Allos and our financial projections, the fairness opinions of J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC, and the background of the then proposed transaction) in the joint proxy statement filed by us and Allos. These lawsuits further claim that we, Allos and Merger Sub aided and abetted those alleged breaches of fiduciary duty. In general, these lawsuits seek damages and injunctive relief, including an award of attorneys' fees and costs, in addition to other relief.

On October 21, 2011, our shareholders voted against consummation of the then proposed transaction. That same day, plaintiffs in The Colorado Federal Actions voluntarily dismissed their cases without prejudice. On October 25, 2011, plaintiffs in The Colorado State Court Action voluntarily dismissed their case without prejudice. Therefore, as of November 4, 2011, the only cases still pending are The Delaware Action and The Gaines Action, both of which are described in more detail below.

**The Delaware Action.** On August 1, 2011, the Delaware Court of Chancery consolidated the *Lam* and *Mulligan* cases into *In re Allos Therapeutics, Inc. Shareholders Litigation*, Consolidated C.A. No. 6714. In early September 2011, the parties to this action stipulated to a briefing schedule on plaintiffs' anticipated motion for preliminary injunction. Thereafter, plaintiffs filed a motion for preliminary injunction, defendants opposed, and a preliminary injunction hearing was scheduled for October 17, 2011. On October 13, 2011, the parties to The Delaware Action agreed in principle to settle the litigation by executing a memorandum of understanding, or MOU. Under the terms of the MOU, plaintiff, on behalf of Allos shareholders, agreed to release all claims against defendants, and Allos agreed to make certain supplemental disclosures in a Current Report on Form 8-K, which was filed with the U.S. Securities and Exchange Commission on October 14, 2011. The settlement contemplated by the MOU was subject to approval by the Delaware Court of Chancery and contingent on consummation of the merger, which our shareholders did not approve on October 21, 2011. On October 31, 2011 and November 1, 2011, defendants moved to dismiss plaintiffs' consolidated complaint.

**The Gaines Action.** On September 20, 2011, plaintiff in the *Gaines v. Narachi* matter filed an amended complaint which generally alleges that the members of our board of directors breached their fiduciary duties in connection with the then proposed merger with Allos by: (i) failing to maximize shareholder value; (ii) ignoring procedural safeguards in negotiating the then proposed merger; (iii)





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negotiating an acquisition in which our stockholders will suffer dilution; (iv) rejecting an allegedly superior buy-out proposal from MSMB Capital Management LLC; and (v) disseminating a supposedly false and misleading proxy statement. This action seeks damages and injunctive relief, including an award of attorneys' fees and costs, in addition to other relief. In late September 2011, plaintiff Gaines filed a motion for expedited proceedings and a motion for preliminary injunction, which defendants opposed. On September 27, 2011, the Court heard the motion and subsequently denied plaintiff's request for expedited proceedings. Thereafter, plaintiff filed a motion for reconsideration of the September 30, 2011 order to consider the sole issue as to whether the free cash flow projections used by Morgan Stanley & Co. LLC in its discounted cash flow analysis should be disclosed. Defendants opposed the reconsideration motion, but the court granted it and scheduled a preliminary injunction hearing for October 17, 2011 on this one issue. On October 14, 2011, we voluntarily disclosed the requested free cash flow projections in a Current Report on Form 8-K. As a result, plaintiff's preliminary injunction motion, and request for relief thereunder, is now moot. On November 1, 2011, we moved to dismiss plaintiff's amended complaint.

We believe that the allegations in the above-referenced actions lack merit. We have and will continue to contest them vigorously.

*Other Legal Proceedings*

On October 29, 2010, the United States Attorney's Office for the District of Massachusetts issued a Civil Investigative Demand, or CID, pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, examining allegations that we caused the submission of false claims to Federal health care programs. The CID required the delivery of documents and the testimony of two current and one former employee of ours. We fully cooperated with the Department of Justice. On February 17, 2011, we were informed by the Department of Justice that it had closed its investigation and that we did not need to further respond to the CID. As the government's investigation was conducted in connection with a sealed qui tam complaint filed in the District Court of Massachusetts, the United States filed a declination of intervention as well as a request that the plaintiff-relator's qui tam complaint be unsealed, which the Court granted on February 22, 2011. The qui tam complaint, which lists us and Liberty Dialysis, LLC as defendants, alleges that we violated the False Claims Act and similar statutes in 28 states through improperly marketing *Feraheme* for off-label use. On July 18, 2011 the plaintiff-relator filed a Notice of Voluntary Dismissal with prejudice and on July 19, 2011 the United States filed a Notice of Consent to Relator's Voluntary Dismissal of Relator's Complaint without prejudice. On July 22, 2011, the District Court of Massachusetts terminated the case.

A purported class action complaint was originally filed on March 18, 2010 in the United States District Court for the District of Massachusetts, entitled *Silverstrand Investments et. al. v. AMAG Pharm., Inc., et. al.*, Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Executive Vice President and Chief Financial Officer, our Board of Directors, and certain underwriters in our January 2010 offering of common stock violated certain federal securities laws, specifically Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, and that our former President and Chief Executive Officer and former Executive Vice President and Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff sought unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. On August 11, 2011, the Court issued an Opinion and Order dismissing the SAC in its entirety for failure to state a claim upon which relief could be granted. A separate Order of Dismissal was filed on August 15, 2011. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the United States Court of Appeals for the First Circuit, or the Court of Appeals. By Order issued by the Court of Appeals dated

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October 26, 2011, plaintiffs brief is due on December 5, 2011, with responding briefs due on January 4, 2012. Plaintiffs reply brief is due on January 18, 2012.

In February 2010, we submitted to FINRA Dispute Resolution, Inc. an arbitration claim against our broker-dealer, Jefferies & Company, Inc., or Jefferies, and two former Jefferies employees, Anthony J. Russo, and Robert A. D. Addario, who managed our cash account with Jefferies. We allege that Jefferies, Russo and D. Addario wrongfully marketed and sold a balance of \$54.1 million in unsuitable ARS to us from September 2007 through January 2008. We further allege that Jefferies, Russo and D. Addario misrepresented or omitted material facts concerning the nature and risks of ARS, which were inconsistent with our investment objectives to maintain liquidity and flexibility in our portfolio. We primarily seek damages from Jefferies, Russo and D. Addario in an amount equal to the total adjusted par value of the ARS that Jefferies, Russo and D. Addario wrongfully marketed and sold to us, plus interest.

In addition, during 2010 we received correspondence from a supplier with whom we have an agreement related to the supply of a certain material used in the production of certain of our products. This correspondence suggests that we are in violation of the terms of the agreement. We believe we have valid arguments against such allegations, and we intend to vigorously defend against any such allegations.

**Item 1A. Risk Factors**

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

***We are solely dependent on the success of Feraheme.***

We currently derive and expect to continue to derive substantially all of our revenue from sales of *Feraheme* and, therefore, our ability to become profitable 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 approximately their current levels for many 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 continue to dedicate significant resources to our *Feraheme* development efforts; however, we may not be successful in our efforts to expand the *Feraheme* package insert to include additional indications or obtain marketing approval for *Feraheme* in additional geographies. Although we have commenced additional clinical trials for *Feraheme* in indications other than chronic kidney disease, or CKD, we are not currently conducting or sponsoring research to expand our product development pipeline beyond *Feraheme* and therefore our revenues and operations will not be as diversified as some of our competitors which have multiple products or product candidates. Any failure by us to gain approval for *Feraheme* in additional indications, gain approval for *Feraheme* in new geographies, or acquire, develop and commercialize additional products and product candidates, could limit long-term shareholder value and adversely affect the future prospects of our business.



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

We have a history of significant operating losses, and we may not be profitable in the future, and if we do attain profitability, such profitability may not be sustainable. In the past, we have financed our operations primarily from the sale of our equity securities, cash generated by our investing activities, and payments from our strategic partners. As of September 30, 2011, we had an accumulated deficit of approximately \$421.3 million. Our losses were primarily the result of costs incurred in research and development, including costs associated with our *Feraheme* and other development programs, costs associated with 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 intravenous, or IV, iron replacement therapeutic for use in CKD patients in the U.S., to further develop *Feraheme* for the treatment of iron deficiency anemia, or IDA, in a broad range of patients and to obtain regulatory approval for *Feraheme* in 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 use in CKD patients in the U.S. We have never independently marketed or sold any products prior to *Feraheme*, 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.

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

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

The data submitted to the FDA as part of our New Drug Application, or 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 or by patients 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, among other things, provide additional warnings and/or restrictions on the *Feraheme* package insert, including a boxed

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warning, directly alert healthcare providers of new safety information, narrow our approved indications, alter or terminate current or planned trials for additional uses of *Feraheme*, or even remove *Feraheme* from the market, any of which could have a significant adverse impact on potential sales of *Feraheme* or require us to expend significant additional funds.

For example, in November 2010, following discussions with the FDA, we revised the *Feraheme* package insert to include bolded warnings and precautions that describe events that have been reported after *Feraheme* administration in the post-marketing environment, including life-threatening hypersensitivity reactions and clinically significant hypotension. We also directly alerted healthcare providers of the changes to the *Feraheme* package insert. During June 2011, we made further changes to the *Feraheme* package insert based on additional post-marketing data. These or any future changes to the *Feraheme* package insert could adversely impact our ability to successfully compete in the IV iron market and potential sales of *Feraheme* and our future business prospects. In addition, as more data become available and an increased number of patients are treated with *Feraheme*, we may be required to make further changes to the *Feraheme* package insert, including the inclusion of a boxed warning, directly alert healthcare providers of new safety information, narrow our approved indications, alter or terminate current or planned trials for additional uses of *Feraheme*, or even remove *Feraheme* from the market.

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

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

- Our ability to demonstrate to the medical community, particularly hematologists, oncologists, hospitals, nephrologists, and others who may purchase or prescribe *Feraheme*, the clinical efficacy and safety of *Feraheme* as an alternative to current treatments for IDA in CKD patients;
- The actual or perceived safety profile of *Feraheme* compared to alternative iron replacement therapeutic agents, particularly if unanticipated adverse reactions to *Feraheme* result in further changes to or restrictions in the *Feraheme* package insert and/or otherwise create safety concerns among potential prescribers;
- The ability of physicians and other providers to be adequately reimbursed for *Feraheme* from payors, including government payors, such as Medicare and Medicaid, and private payors, particularly in light of the recently enacted prospective payment system for dialysis patients with end stage renal disease, or ESRD;
- 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; and

- The effectiveness of our sales and marketing organization and our distribution network.

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We are approved to market and sell *Feraheme* for use in both dialysis and non-dialysis adult CKD patients. However, sales in the dialysis market have recently declined significantly due, in large part, to implementation of the prospective payment system for ESRD drugs like *Feraheme*. Accordingly, we expect sales of *Feraheme* in the dialysis market to represent a very small portion of our total sales going forward. As a result, unless we capture a significant share of the non-dialysis CKD market, potential *Feraheme* sales, our potential profitability and our future business prospects will be materially adversely impacted.

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

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

In the U.S., our ability to successfully commercialize *Feraheme* is dependent, in significant part, on the availability and extent of reimbursement to end-users from third-party payors for the use of *Feraheme*, including U.S. governmental payors, managed care organizations, private health insurers and other third-party payors. Reimbursement by a third-party payor depends on a number of factors, including the third-party's determination that the product is competitively priced, safe and effective, appropriate for the specific patient, and cost-effective. Third-party payors are increasingly challenging the prices charged for pharmaceutical products and have instituted and continue to institute cost containment measures to control or significantly influence the purchase of pharmaceutical products. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the Health Care Reform Act, was enacted in March 2010 and includes certain cost containment measures including an increase to the minimum rebates for products covered by Medicaid programs and the extension of such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations as well as the expansion of the 340(B) Public Health Services drug discount program. These and any future changes in government regulations or private third-party payors' reimbursement policies may reduce the extent of reimbursement for *Feraheme* and adversely affect our future operating results.



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The phase-in of the ESRD expanded prospective payment system began on January 1, 2011, and must be completed by January 1, 2014. This bundled approach to reimbursement has and will likely continue to alter the utilization of physician-administered drugs in the ESRD market as well as put downward pressure on the prices pharmaceutical companies can charge ESRD facilities for such drugs, particularly where alternative products are available. *Feraheme* is sold at a price that is substantially higher than alternative IV iron products in the dialysis setting, and as a result, the demand for *Feraheme* in the dialysis setting has significantly declined. While the prospective payment system provisions apply only to Medicare, Medicare is the predominant payor in the ESRD market, and Medicare payment policy, in time, can also influence pricing and reimbursement in the non-Medicare markets, as private third-party payors and state Medicaid plans frequently adopt Medicare principles in setting reimbursement methodologies, particularly in the ESRD setting. Changes in the Medicare reimbursement rate may, therefore, result in changes to payment rates from non-Medicare payors as well, further limiting our ability to successfully market and sell *Feraheme* in the dialysis setting.

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

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

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

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

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***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* competes with several other IV iron replacement therapies in the U.S., including Venofer®, which is marketed in the U.S. by Fresenius Medical Care North America and American Regent Laboratories, Inc., or American Regent, a subsidiary of Luitpold Pharmaceuticals, Inc., or Luitpold, Ferrlecit®, which is marketed by Sanofi-Aventis U.S. LLC, Nulecit®, a generic version of Ferrlecit®, which is marketed by Watson Pharmaceuticals, Inc., or Watson, INFED®, an iron dextran product marketed by Watson, and Dexferrum®, an iron dextran product marketed by American Regent. *Feraheme* may not receive the same level of market acceptance as these competing iron replacement therapy products, especially since most of 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 payers to switch from using the other IV iron therapeutic products to *Feraheme*. The iron replacement therapy market is highly sensitive to several factors including, but not limited to, the actual and perceived safety profile of the available products, the ability to obtain appropriate insurance coverage, coding and reimbursement, price competitiveness, and product characteristics such as convenience of administration and dosing regimens. To date, we have not completed any head-to-head clinical studies comparing *Feraheme* to other IV iron replacement products.

The market opportunity for *Feraheme* could also be negatively affected by approved generic IV iron replacement therapy products that achieve commercial success. For example, in 2011, Watson launched a generic version of Ferrlecit® known as Nulecit® (sodium ferric gluconate complex in sucrose injection). Nulecit® is approved for the treatment of IDA in adult patients and in pediatric patients age six years and older undergoing chronic hemodialysis who are receiving supplemental epoetin therapy. Companies that manufacture generic products typically invest far less resources in research and development than the manufacturers of branded products and can therefore price their products significantly lower than those already on the market. It remains unclear what effect Nulecit® or any future generic IV iron replacement therapy product will have on our business or results of operations.

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 is currently approved in 22 European countries for the treatment of IDA, Injectafer®, which is known as Ferinject® in Europe and is approved for marketing in 35 countries worldwide, including 30 countries in Europe. In October 2011, Luitpold submitted a NDA to the FDA for Injectafer® for the treatment of IDA. If either of these product candidates are approved for marketing and sale in the U.S., our efforts to market and sell *Feraheme* in the U.S. and our ability to generate additional revenues and achieve profitability could be adversely affected.

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***We have limited experience independently commercializing a pharmaceutical product, and any failure on our part to effectively execute our Feraheme commercial plans, particularly in light of our recent restructuring, 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 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. In November 2011, we reduced our workforce by approximately 25% of our positions as part of an overall corporate restructuring, including certain positions within our sales and marketing functions. In November 2011, we also announced the departure of our chief executive officer and our chief commercial officer. This workforce reduction, together with the departure of our chief executive officer and our chief commercial officer, or any future reductions or departures, could harm our ability to attract and retain qualified personnel, which could prevent us from successfully commercializing *Feraheme*, impair our ability to maintain sales levels and/or impair our ability to support potential sales growth and sales of *Feraheme* for any additional indications we may commercialize in the future. Any failure by us to successfully execute our commercialization plans for *Feraheme* could have a material adverse impact on our ability to generate revenues, our ability to achieve profitability, and the future prospects for our business.

***Our recent corporate restructuring may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business, all of which could have a material adverse effect on our business.***

As a result of the November 2011 reduction in our workforce, we currently estimate that we will record restructuring charges of approximately \$3.2 million, which are expected to be recorded primarily in the fourth quarter of 2011. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to achieve the anticipated benefits, savings or improvements in our cost structure in the expected time frame or other unforeseen events occur, our business and results of operations may be adversely affected.

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

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

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*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, a significant amount 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 could be significantly impaired. The loss of any of our third-party providers, together with a delay or inability to secure an alternate distribution source for end-users in a timely manner, could cause the distribution of *Feraheme* to be delayed or interrupted, which would have an adverse effect on our business, financial condition and results of operations.

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

Our Cambridge, Massachusetts manufacturing facility and our recently approved third-party contract manufacturing facilities are subject to current good manufacturing practices, or cGMP, regulations enforced by the FDA through periodic inspections to confirm such compliance. We and our contract manufacturers must continually expend time, money and effort in production, record-keeping and quality assurance and control to ensure that these manufacturing facilities meet 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, among other things, 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 *Feraheme* inventory, suspension of the FDA's review of any future supplemental New Drug Applications, enforcement actions, injunctions or criminal prosecution. A government-mandated recall or a voluntary recall could divert managerial and financial resources, could be difficult and costly to correct, could result in the suspension of sales of *Feraheme*, and could have a severe adverse impact on our potential profitability and the future prospects of our business. In addition, if the FDA inspects any of these manufacturing facilities and determines that they are not in compliance with cGMP regulations or we or our contract manufacturers otherwise determine that we or they are not in compliance with these regulations, we could experience an inability to manufacture or have manufactured sufficient quantities of *Feraheme*.

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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.

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

We currently manufacture *Feraheme* for commercial use and for use in human clinical trials in our Cambridge, Massachusetts manufacturing facility. In April 2011, the FDA also approved certain of our third-party contract manufacturers to begin production of *Feraheme* drug substance and drug product. Our ability to manufacture *Feraheme* or have *Feraheme* manufactured in sufficient quantities and at acceptable costs to meet our commercial demand and clinical development needs is dependent on the uninterrupted and efficient operation of these manufacturing facilities. 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.

In addition, the transition of the manufacturing processes to third-party contract manufacturers and the oversight of such third-parties could take a significant amount of time and may increase the risk of certain problems, including cost overruns, process reproducibility, stability issues, the inability to deliver required quantities of product that conform to specifications in a timely manner, or the inability to manufacture *Feraheme* in accordance with cGMP. If we are unable to consistently manufacture *Feraheme* or have *Feraheme* manufactured on a timely basis because of these or other factors, we may not be able to meet commercial demand or our clinical development needs for *Feraheme*. 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 and other materials used in the manufacture of Feraheme could adversely impact our ability to manufacture sufficient quantities of Feraheme, which would have an adverse impact on our business.***

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

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

- Regulatory requirements or action;
- Adverse financial developments at or affecting the supplier; or
- Import or export problems.

If any of our third-party suppliers cease to supply certain raw or other materials to us for any reason we could be unable to manufacture *Feraheme* in sufficient quantities or on a timely basis until we are

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

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

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

***Our ability to grow revenues from sales of Feraheme will be limited if we do not obtain approval, or if we experience significant delays in our efforts to obtain approval in the U.S. to market Feraheme for the treatment of IDA in a broad range of patients.***

We are currently conducting clinical trials to support our global registrational program to assess *Feraheme* for the treatment of IDA in a broad range of patients. Before obtaining regulatory approval in the U.S. for the commercial marketing and sale of *Feraheme* for the broad IDA indication, we must demonstrate through extensive human clinical trials that *Feraheme* is safe and efficacious for use in this broader patient population. Conducting clinical trials is a complex, time-consuming and expensive process that requires adherence to a wide range of regulatory requirements. The FDA has substantial discretion in the approval process and may decide that the results of our clinical trials are insufficient for approval or that *Feraheme* is not effective or safe in indications other than CKD. Clinical and other data is often susceptible to varying interpretations, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products. There is no guarantee that we will be successful in completing any clinical trials for the treatment of IDA in a broad range of patients in a timely manner or that, if completed, the results of such clinical trials will demonstrate *Feraheme* to be safe and effective in such patient population.

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





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experience significant delays or prevent us from obtaining regulatory approval for *Feraheme* for the IDA indication. 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.

Our ability to complete our global registrational program for the broad IDA indication 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;
- The ability of our clinical research organizations to perform their oversight responsibilities and meet expected deadlines;
- Any adverse impact of our recently announced corporate restructuring on our ability to execute our ongoing or planned clinical trials effectively and prepare and file the necessary sNDA for *Feraheme* for the broad IDA indication in a timely manner;
- Any adverse regulatory action which would preclude our ability to continue to conduct or complete our clinical trials, such as a clinical hold on our clinical trials or any further changes to the *Feraheme* package insert; and
- The discovery of previously unknown safety or drug interaction problems with respect to *Feraheme*.

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

***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 Pharmaceutical Company Limited, or Takeda, 3SBio Inc., or us to market and sell *Feraheme* in any country outside of the U.S. for any indication, it will be necessary to obtain regulatory approval from the appropriate regulatory authorities, which approval must include approval of our proposed manufacturing processes and facilities. The requirements and timing for regulatory approval vary widely from country to country and may in some cases be different than or more rigorous than requirements in the U.S. For example, in January 2011, we

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received a Notice of Non-Compliance from the Therapeutic Products Directorate of Health Canada, or Health Canada, which contained concerns focused mainly on chemistry, manufacturing, and control and preclinical toxicology issues. Health Canada requested, among other things, additional information on polyglucose sorbitol carboxymethylether, or PSC, a material used in the manufacture of *Feraheme*, including information related to pre-clinical safety of PSC and the manufacturing processes and controls related to the incorporation of PSC. We may not be able to adequately address all of the concerns raised in Notice of Non-Compliance in a timely manner, which could delay or prevent approval of *Feraheme* in Canada. In addition, our June 2010 Marketing Authorization Application submitted to the European Medicines Agency, or EMA, for the approval of *Feraheme* for the treatment of IDA in CKD patients, is largely supported by data from the clinical trials we conducted to support our U.S. NDA filing for the approval of *Feraheme* for the treatment of IDA in CKD patients. The EMA may require us to perform additional

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studies or provide additional data in order to obtain regulatory approval for any indication in the European Union, or EU. In addition, any adverse regulatory action taken by the FDA with respect to *Feraheme* in the U.S. may affect the regulatory requirements or decisions made by certain foreign regulatory bodies with regard to the regulatory approval of *Feraheme* outside of the U.S.

Any failure 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 business, including our clinical trials, and if they fail to fulfill their obligations, our commercialization and development plans may be adversely affected.***

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

In addition, we have and we plan to continue to contract with certain third-parties to provide certain services, including site selection, enrollment, monitoring and data management services, in connection with the conduct of our clinical trials. 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. Further, in order to increase the number of patients available for enrollment in our clinical trials and to support foreign regulatory approval of *Feraheme*, we are conducting trials in geographies outside the U.S. We have no experience conducting clinical trials outside the U.S., and, therefore, we are largely relying on third-parties such as clinical research organizations to manage, monitor and carry out these clinical trials outside of the U.S.

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

In March 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda, under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey, or collectively, the Licensed Territory. 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



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U.S. If Takeda fails to perform its obligations under the Takeda Agreement or is ineffective in its commercialization of *Feraheme* in the Licensed Territory or if we fail to effectively manage our relationship with Takeda, our ability to and the extent to which we 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 clinical development 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 Takeda Agreement under certain conditions. If Takeda terminates the agreement, we would be required to either enter into alternative arrangements with third parties to commercialize *Feraheme* in the Licensed Territory, which we may be unable to do, or to increase our internal infrastructure, both of which would likely result in significant additional expense and delay or termination of our *Feraheme* clinical development programs outside of the U.S.

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

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

- The magnitude of *Feraheme* sales;
  
- 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;
  
- Any adverse impact on our financial results stemming from our recent corporate restructuring;
  
- The timing and magnitude of costs associated with our ongoing and planned clinical studies of *Feraheme* in connection with our pursuit of additional indications and our development of *Feraheme* in countries outside of the U.S.;
  
- The timing and magnitude of milestone payments we may receive under the Takeda Agreement;

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- The timing and magnitude of costs associated with commercial-scale manufacturing of *Feraheme*, including costs of raw and other materials and costs associated with maintaining commercial inventory and qualifying additional manufacturing capacities and alternative suppliers;
- The magnitude of costs incurred in connection with business development activities;
- Changes in laws and regulations affecting *Feraheme* from federal and state legislative and regulatory authorities, government health administration authorities, private health insurers and other third-party payors;
- The initiation or outcome of any material litigation to which we are a party; and
- Implementation of new or revised accounting or tax rules or policies.

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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 *Feraheme*, sales of *Feraheme* could be adversely affected. For example, in advance of an anticipated price increase or a reduction in expected rebates or discounts, customers may order *Feraheme* in larger than normal quantities which could cause sales of *Feraheme* to be lower in subsequent quarters than they would have been otherwise. Further, any changes in purchasing patterns, inventory levels, increases in returns of *Feraheme*, delays in purchasing products or delays in payment for products by one of our distributors could also have a negative impact on our revenue and results of operations.

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

Our condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us, and the related disclosure of contingent assets and liabilities. On an ongoing basis, our management evaluates our critical and other significant estimates and judgments, including among others, those associated with revenue recognition related to collaboration agreements and product sales, product sales allowances and accruals, our assessment of investments for potential other-than-temporary impairment and our determination of the value of our investments, reserves for doubtful accounts, accrued expenses, reserves for legal matters, income taxes and equity-based compensation expense. We base our estimates on market data, our observance of trends in our industry, and various other assumptions that we believe to be reasonable under the circumstances. If actual results differ from these estimates, there could be a material adverse effect on our financial results and the performance of our stock. In addition, we may fail to realize our publicly disclosed financial guidance or other expectations about our business, which could cause our stock to decline in value.

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.

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

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

The market price of our common stock has been, and may continue to be, volatile, and your investment in our stock could decline in value or fluctuate significantly. Our stock price has ranged between \$12.65 and \$19.48 in the fifty-two week period through November 2, 2011. The stock market has from time to time experienced extreme price and volume fluctuations, particularly in the biotechnology and pharmaceuticals sectors, which have often been unrelated to the operating performance of particular companies. Various factors and events, many of which are beyond our control, may have a significant impact on the market price of our common stock. Factors which may affect the market price of our common stock include, among others:

- Our ability to successfully commercialize *Feraheme* in the U.S.;
- The timing and magnitude of *Feraheme* revenue and actual or anticipated fluctuations in our operating results;
- Changes in or our failure to meet financial estimates published by securities analysts or our own publicly disclosed financial guidance;
- The availability of reimbursement coverage for *Feraheme* or changes in the reimbursement policies of governmental or private payors;
- Public announcements of U.S. or foreign regulatory actions with respect to *Feraheme* or products or product candidates of our competitors;
- Actual or perceived safety concerns related to *Feraheme* or products or product candidates of our competitors, including any actions taken by regulatory authorities in connection with such concerns;
- The status or results of clinical trials for *Feraheme* or products or product candidates of our competitors;



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- The acquisition or development of technologies, product candidates or products by us or our competitors;
- Developments in patents or other proprietary rights by us or our competitors;
- The initiation or outcome of any material litigation to which we are a party;
- Significant collaboration, acquisition, joint venture or similar agreements by us or our competitors;
- General market conditions; and

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- Sales of large blocks of our common stock.

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

***If securities analysts downgrade our stock, cease coverage of us, or if our operating results do not meet our own publicly disclosed financial guidance or analysts' forecasts and expectations, our stock price could decline.***

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us and our business. Currently, ten financial analysts publish reports about us and our business. We do not control these or any other analysts. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. In addition, our future operating results are subject to substantial uncertainty, and our stock price could decline significantly if we fail to meet or exceed our own publicly disclosed financial guidance or analysts' forecasts and expectations. If any of the analysts who cover us downgrade our stock or issue commentary or observations that are perceived by the market to be adverse to us or our stock, our stock price would likely decline rapidly. If these analysts cease coverage of our company, we could lose visibility in the market, which in turn could also cause our stock price to decline.

***We may need additional capital to achieve our business objectives.***

We have expended and will continue to expend substantial funds to successfully commercialize and develop *Feraheme*. Our long-term capital requirements will depend on many factors, including, but not limited to:

- The magnitude of *Feraheme* sales;
- Our ability to obtain regulatory approval for the broad IDA indication in the U.S. and our ability to obtain regulatory approval for *Feraheme* outside the U.S.;
- 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, costs associated with executing our promotional and marketing strategy for *Feraheme*, and costs associated with conducting post-marketing clinical studies;

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- Costs associated with our development of the broad IDA indication for *Feraheme* in the U.S.;
- Costs associated with our pursuit of approval for *Feraheme* outside of the U.S.;
- The outcome of any material litigation to which we are or may become a party;
- Our ability to liquidate our investments in auction rate securities, or ARS, in a timely manner and without significant loss;

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- 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 as of September 30, 2011, 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 and our results of operations, liquidity and financial condition.***

As of September 30, 2011, we had \$75.8 million in cash and cash equivalents, \$153.6 million in short-term investments, and \$21.6 million in long-term investments. These investments are subject to general credit, liquidity, market and interest rate risks, which have been and may continue to be exacerbated by the U.S. and global financial crisis which has been occurring over the past several years. The ongoing disruptions in the credit and financial markets have negatively affected many industries, including those in which we invest, and we may realize losses in the fair value of certain of our investments or a complete loss of these investments, which would have an adverse effect on our results of operations, liquidity and financial condition.

As of September 30, 2011, we held a total of \$25.1 million in fair market value of ARS reflecting a reduction in value of approximately \$3.5 million from the par value of these securities of approximately \$28.6 million. In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions. Since that time, the continued uncertainty in the credit markets has caused almost all additional auctions with respect to our ARS to fail and prevented us from liquidating certain of our holdings of ARS because the amount of these securities submitted for sale has exceeded the amount of purchase orders for these securities. These auctions may continue to fail indefinitely, and there could be a further decline in value of these securities or any other securities, which may ultimately be deemed to be other-than-temporary. In the future, should we determine that these declines in value of ARS are other-than-temporary, we will recognize the credit-related portion of the loss to our condensed consolidated statement of operations, which could be material. In addition, failed auctions will adversely impact the liquidity of our investments.

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

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

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

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

***Our ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income may be limited as a result of 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 January 2010 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.

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***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 pay penalties, sanctions and fines which could have a material adverse effect on our business, financial condition and results of operations.***

As a condition of reimbursement by various federal and state healthcare programs for *Feraheme*, we are required to calculate and report certain pricing information to Federal and state healthcare agencies. For example, we are required to provide average selling price information to the Centers for Medicare and Medicaid Services on a quarterly basis in order to compute Medicare payment rates. Price reporting and payment obligations are highly complex and vary among products and programs. Our processes for estimating amounts due under these governmental pricing programs involve subjective decisions, and as a result, our price reporting calculations remain subject to the risk of errors and our methodologies for calculating these prices could be challenged under the Federal False Claims Act or other laws. In addition, the Health Care Reform Act modified the rules related to certain price reports and expanded the scope of pharmaceutical product sales to which Medicaid rebates apply, among other things. Presently, uncertainty exists as many of the specific determinations necessary to implement this new legislation have yet to be decided and communicated to industry participants. This uncertainty in the interpretation of the legislation increases the chances of an error in price reporting, which could in turn lead to a legal challenge or investigation. If we become subject to investigations or other inquiries concerning our compliance with price reporting laws and regulations, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

- Warning Letters;
- Civil or criminal penalties;
- Suspension or withdrawal of regulatory approvals;
- Temporary or permanent closing of our manufacturing facilities;

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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*;
- Changes to our package insert;
- Implementation of an FDA-mandated REMS;



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- 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.

For example, in October 2010, we received a Warning Letter from the Division of Drug Marketing, Advertising, and Communications, or DDMAC, alleging violations of certain FDA regulations with respect to the *GastroMARK* and *Feraheme* pages of our corporate web site. In addition, in February 2011 we received an Untitled Letter from DDMAC alleging that one of our marketing pieces misbranded the drug in violation of certain FDA regulations. Although we have addressed the concerns raised in the Warning Letter and the Untitled Letter, there is no guarantee that we will not receive additional warning or untitled letters in the future. Any of the above sanctions could have a material adverse impact on our ability to generate revenues and to achieve profitability and cause us to incur significant additional expenses.

***If we 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 additional Federal, state and foreign healthcare regulation, which includes but is not limited to, the Federal False Claims Act, the Federal Anti-Kickback Statute and the Foreign Corrupt Practices Act. 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 operations.

In recent years, several states have enacted legislation requiring pharmaceutical companies to establish marketing and promotional compliance programs or codes of conduct and/or to file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered by additional states and by Congress. In addition, as part of the Health Care Reform Act, the federal government has enacted the Physician Sunshine provisions. Beginning in 2013, manufacturers of drugs will be required to publicly report gifts and payments made to physicians and teaching hospitals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Compliance with these laws is difficult, time consuming and costly, and if we are found to not be in full compliance with these laws, we may face enforcement actions, fines and other penalties, and we could receive adverse publicity which could have an adverse effect on our business, financial condition and results of operations.

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

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

Because of the specialized nature of our business, our success depends to a significant extent on the continued service of our executive officers and on our ability to continue to attract, retain and motivate qualified sales, manufacturing, managerial, scientific, and medical 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. There is intense competition for qualified personnel in the areas of our activities, and we may not be able to continue to attract and retain the qualified personnel necessary for the development of our business. In addition, in November 2011, we announced a corporate restructuring, including a workforce reduction plan, which includes an approximate 25% reduction in positions. In addition, in November 2011, we also announced the departure of our chief executive officer and our chief commercial officer. This workforce reduction and executive departures, any future reduction or departures, could harm our ability to attract and retain qualified key personnel. If we are unable to attract such personnel, or we lose the services of our key personnel for any reason, our *Feraheme* development and commercialization efforts could be adversely impacted. 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 *Feraheme* patents are currently scheduled to expire in 2020. These and any other patents issued to us may be contested or invalidated. For example, in July 2010, Sandoz GmbH, or Sandoz, filed an opposition to one of our patents which covers *Feraheme* in the EU with the European Patent Office, or EPO. Although we believe that the subject patent is valid, there is a possibility that the EPO could invalidate or require us to narrow the claims contained in our patent. We believe the Sandoz patent opposition is without merit and intend to defend against the opposition vigorously, however, this or future patent interference proceedings involving our patents may result in substantial costs to us, distract our management, prevent us 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



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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 for *Feraheme*, we may be unable to prevent others from developing or selling similar products. In addition, in jurisdictions outside the U.S. where we have patent rights, we may be unable to prevent unlicensed parties from selling or importing products or technologies derived elsewhere using our proprietary technology.

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

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

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

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

If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements, which could lead to a decline in our stock price. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, the NASDAQ Global Select Market or other regulatory authorities.



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*An adverse determination in any future lawsuits in which we are a defendant, could have a material adverse affect on us.*

A purported class action complaint was originally filed on March 18, 2010 in the United States District Court for the District of Massachusetts, entitled Silverstrand Investments et. al.v. AMAG Pharm., Inc., et. al., Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Executive Vice President and Chief Financial Officer, our Board of Directors, and certain underwriters in our January 2010 offering of common stock violated certain federal securities laws by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff sought unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. On August 11, 2011, the Court issued an Opinion and Order dismissing the SAC in its entirety for failure to state a claim upon which relief could be granted. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the United States Court of Appeals for the First Circuit. Whether or not the plaintiff's appeal is successful, this type of litigation is often expensive and diverts management's attention and resources, which could adversely affect the operation of our business. If we are ultimately required to pay significant defense costs, damages or settlement amounts, such payments could adversely affect our operations.

We may also be the target of similar litigation in the future. Any future litigation could result in substantial costs and divert our management's attention and resources, which could cause serious harm to our business, operating results and financial condition. We maintain liability insurance, however, if any costs or expenses associated with this or any other litigation exceed our insurance coverage, we may be forced to bear some or all of these costs and expenses directly, which could be substantial.

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

The administration of our products to humans, whether in clinical trials or after approved commercial use, may expose us to liability claims, whether or not our products are actually at fault for causing an injury. As *Feraheme* is used over longer periods of time by a wider group of patients taking numerous other medicines or by patients with additional underlying health problems, the likelihood of adverse drug reactions or unintended side effects, including death, may increase. Although we maintain product liability insurance coverage for claims arising from the use of our products in clinical trials and commercial use, coverage is expensive, and we may not be able to maintain sufficient insurance at a reasonable cost, if at all. Product liability claims, whether or not they have merit, could also decrease demand for *Feraheme*, subject us to product recalls or harm our reputation, cause us to incur substantial costs, and divert management's time and attention.

*Our shareholder rights plan, certain provisions in our charter and by-laws, certain contractual relationships and certain Delaware law provisions could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current members of our Board 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 stockholders (other than the potential hostile acquiror) to purchase significant amounts of additional shares of our common stock at dilutive prices. The rights issued pursuant to our shareholder rights plan become exercisable generally upon the earlier of 10 days after a person or group acquires 20% or 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



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via tender offer or similar transaction. The shareholder rights plan could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices.

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

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

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

As a result of the termination of our merger agreement with Allos Therapeutics, Inc. or Allos, we may be required to pay Allos an additional \$12.0 million if a definitive agreement for an acquisition transaction, as defined in the Agreement and Plan of Merger and Reorganization, is entered into on or before October 21, 2012 or such a transaction is consummated on or before such date. Such potential payment could delay or discourage transactions involving an actual or potential change in control of our company.

In addition to the above factors, an acquisition of our company could be made more difficult by employment agreements we have in place with our executive officers, as well as a company-wide change of control policy which provide for severance benefits as well as the full acceleration of vesting of any outstanding options or restricted stock units in the event of a change of control and subsequent termination of employment.



Further, our Second Amended and Restated 2007 Equity Incentive Plan generally permits our Board to provide for the acceleration of vesting of options granted under that plan in the event of certain transactions that result in a change of control.

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***MSMB Capital's unsolicited, non-binding acquisition proposal and preliminary consent solicitation may distract our management and employees and create uncertainty that may adversely affect our business and results.***

On August 2, 2011, MSMB Capital Management LLC, or MSMB Capital, sent a letter to our Board of Directors offering to purchase us for \$18.00 per share in cash. MSMB Capital has not provided any evidence of its ability to finance its offer. Additionally, MSMB Capital filed a preliminary consent solicitation statement with the SEC in order to remove and replace all of our current directors with MSMB Capital's nominees to pursue MSMB Capital's unsolicited, non-binding acquisition proposal. The review, consideration, and response to MSMB Capital's efforts to gain control of us requires the expenditure of significant time and resources by us and may be a significant distraction for our management and employees. MSMB Capital's acquisition efforts may also create uncertainty for our employees, and this uncertainty may adversely affect our ability to retain key employees and to attract new employees. The impact of MSMB Capital's acquisition efforts due to these or other factors may undermine our business and have a material adverse effect on our results of operations.

***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 September 30, 2011.

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**Item 6. Exhibits.**

**(a) List of Exhibits**

<b>Exhibit Number</b>	<b>Description</b>
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.
32.1 ++	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 September 30, 2011, 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.

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+ 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/ Frank E. Thomas  
Frank E. Thomas,  
Chief Operating Officer and  
Interim President and Chief Executive Officer  
(principal financial and accounting officer and  
principal executive officer)

Date: November 8, 2011

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**EXHIBIT INDEX**

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