AMAG PHARMACEUTICALS INC.
Form 10-Q
November 06, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2013

OR

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

For the transition period from to

Commission file number 001-10865

AMAG Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-2742593**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1100 Winter Street Waltham, Massachusetts	**02451**
(Address of Principal Executive Offices)	(Zip Code)

(617) 498-3300

(Registrant s Telephone Number, Including Area Code)

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

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

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

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

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

As of October 31, 2013, there were 21,736,357 shares of the registrant s common stock, par value $0.01 per share, outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

AMAG PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

(Unaudited)

	September 30, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 30,946	$ 46,293
Investments	182,595	180,750
Accounts receivable, net	8,778	6,410
Inventories	14,694	12,451
Receivable from collaboration	250	263
Assets held for sale	1,934	2,000
Prepaid and other current assets	5,900	6,213
Restricted cash	460	
Total current assets	245,557	254,380
Property and equipment, net	1,741	3,297
Intangible assets, net	16,866	
Restricted cash	400	460
Total assets	$ 264,564	$ 258,137
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,001	$ 3,515
Accrued expenses	20,032	20,338
Deferred revenues	10,027	9,104
Total current liabilities	31,060	32,957
Long-term liabilities:		
Deferred revenues	44,428	50,350
Acquisition-related contingent consideration, net of current portion	13,097	
Other long-term liabilities	1,728	2,033
Total liabilities	90,313	85,340
Commitments and contingencies (Notes M & N)		
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; 21,735,707 and 21,506,754 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	217	215
Additional paid-in capital	640,176	632,487
Accumulated other comprehensive loss	(3,536)	(3,247)

Accumulated deficit		(462,606)		(456,658)
Total stockholders equity		174,251		172,797
Total liabilities and stockholders equity	$	264,564	$	258,137

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

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AMAG PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE DATA)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenues:				
U.S. *Feraheme* product sales, net	$ 19,347	$ 16,186	$ 52,381	$ 43,906
License fee and other collaboration revenues	1,998	1,566	6,056	19,911
Other product sales and royalties	271	(10)	708	417
Total revenues	21,616	17,742	59,145	64,234
Costs and expenses:				
Cost of product sales	2,547	4,323	8,634	10,193
Research and development expenses	4,530	5,260	13,983	25,393
Selling, general and administrative expenses	14,934	12,160	44,150	40,442
Restructuring expenses		562		1,620
Total costs and expenses	22,011	22,305	66,767	77,648
Other income (expense):				
Interest and dividend income, net	246	295	773	1,026
Gains on sale of assets			865	
Gains (losses) on investments, net	4	2	36	(1,469)
Total other income (expense)	250	297	1,674	(443)
Net loss before income taxes	(145)	(4,266)	(5,948)	(13,857)
Income tax benefit		299		793
Net loss	$ (145)	$ (3,967)	$ (5,948)	$ (13,064)
Net loss per share:				
Basic and diluted	$ (0.01)	$ (0.19)	$ (0.28)	$ (0.61)
Weighted average shares outstanding used to compute net loss per share:				
Basic and diluted	21,691	21,403	21,613	21,374

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

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AMAG PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(IN THOUSANDS)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net loss	$ (145)	$ (3,967)	$ (5,948)	$ (13,064)
Other comprehensive income (loss):				
Unrealized gains (losses) on securities:				
Holding gains (losses) arising during period, net of tax	399	176	(310)	222
Reclassification adjustment for (gains) losses included in net income (loss)		(2)	21	1,469
Net unrealized gains (losses) on securities	399	174	(289)	1,691
Total comprehensive income (loss)	$ 254	$ (3,793)	$ (6,237)	$ (11,373)

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

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AMAG PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

(Unaudited)

	Nine Months Ended September 30,	
	2013	**2012**
Cash flows from operating activities:		
Net loss	$ (5,948)	$ (13,064)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,935	2,742
Impairment loss on assets held for sale		800
Amortization of premium/discount on purchased securities	2,076	2,181
Write-off of inventory	502	598
Non-cash equity-based compensation expense	5,886	5,312
Non-cash income tax benefit		(793)
(Gains) losses on sale of assets	(865)	
(Gains) losses on investments, net	(36)	1,469
Change in fair value of contingent consideration	279	
Changes in operating assets and liabilities:		
Accounts receivable, net	(2,368)	(1,431)
Inventories	640	3,262
Receivable from collaboration	13	(349)
Prepaid and other current assets	313	(1,339)
Accounts payable and accrued expenses	(7,033)	(13,386)
Deferred revenues	(4,999)	(3,668)
Other long-term liabilities	(305)	(302)
Total adjustments	(2,962)	(4,904)
Net cash used in operating activities	(8,910)	(17,968)
Cash flows from investing activities:		
Proceeds from sales or maturities of investments	84,454	102,540
Purchase of investments	(88,629)	(105,305)
Acquisition of MuGard Rights and inventory	(3,434)	
Proceeds from sale of assets	977	
Change in restricted cash	(400)	
Capital expenditures	(1,206)	(47)
Net cash used in investing activities	(8,238)	(2,812)
Cash flows from financing activities:		
Payment of contingent consideration	(4)	
Proceeds from the exercise of stock options	1,629	56
Proceeds from the issuance of common stock under ESPP	176	150
Net cash provided by financing activities	1,801	206
Net decrease in cash and cash equivalents	(15,347)	(20,574)
Cash and cash equivalents at beginning of the period	46,293	63,474
Cash and cash equivalents at end of the period	$ 30,946	$ 42,900
Supplemental Data:		
Accrued fixed asset purchases	$ 193	$

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

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AMAG PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2013

(Unaudited)

A. Description of Business

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a specialty pharmaceutical company that markets Feraheme® (ferumoxytol) Injection for Intravenous, or IV, use to treat iron deficiency anemia, or IDA, and MuGard® Mucoadhesive Oral Wound Rinse for the management of oral mucositis.

Currently, our principal source of revenue is from the sale of *Feraheme*, which was approved for marketing in the U.S. in June 2009 by the U.S. Food and Drug Administration, 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 began selling *Feraheme* in the U.S. in July 2009 through our own commercial organization, including a specialty sales force. We sell *Feraheme* to authorized wholesalers and specialty distributors, who in turn, sell *Feraheme* to healthcare providers who administer *Feraheme* primarily within hospitals, hematology and oncology centers, and nephrology clinics.

Outside of the U.S., ferumoxytol has been granted marketing approval in Canada, Switzerland and the European Union, or EU, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. The European marketing authorization is valid in the current EU member states as well as in Iceland and Norway. Under our amended agreement with Takeda Pharmaceutical Company Limited, or Takeda, Takeda has an exclusive license to market and sell ferumoxytol in Canada, the EU and Switzerland, as well as certain other geographic territories. In Canada, Takeda promotes ferumoxytol under the trade name *Feraheme* and in the EU and Switzerland, Takeda promotes ferumoxytol under the trade name Rienso® 30mg/ml solution for Injection.

On June 6, 2013, or the Acquisition Date, we entered into a License Agreement with Access Pharmaceuticals, Inc., or Access, under which we acquired the U.S. commercial rights to *MuGard*, or the Access License Agreement. *MuGard* was launched by Access in 2010 after receiving 510(k) clearance from the FDA and is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces. Under the Access License Agreement, we obtained an exclusive, royalty-bearing license, with the right to grant sublicenses, to certain intellectual property rights, including know-how, patents and trademarks, to use, import, offer for sale, sell, manufacture and commercialize *MuGard* in the U.S. and its territories, or the U.S. Territory, for the management of all diseases or conditions of the oropharyngeal cavity, including mucositis, or the MuGard Rights. Additional details regarding the Access License Agreement and the MuGard Rights can be found in Note G.

We are subject to risks common to companies in the pharmaceutical industry including, but not limited to, our primary dependence on the success of *Feraheme/Rienso*, uncertainty of the regulatory approval process for the broader *Feraheme/Rienso* indication or for potential alternative manufacturing facilities and processes, the potential development of significant safety or drug interaction problems with respect to

Feraheme/Rienso, uncertainties related to the protection of our proprietary technology related to *Feraheme*, our dependence on third parties to manufacture *Feraheme/Rienso* and *MuGard*, uncertainties related to potential collaborations, in-licensing arrangements or acquisition agreements, competition in our industry, uncertainties regarding market acceptance of *Feraheme/Rienso* or *MuGard*, our reliance on a limited number of customers for *Feraheme*, uncertainties related to patient insurance

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coverage and third-party reimbursement rates and terms for *Feraheme/Rienso* or *MuGard*, our reliance on Takeda to commercialize *Feraheme/Rienso* in certain territories outside of the U.S., the potential inability of our or Access third-party manufacturers to operate their facilities in compliance with current good manufacturing practices and manufacture sufficient quantities of *Feraheme/Rienso* or *MuGard*, uncertainties related to the impact of current and future healthcare initiatives and legislation, our third-party manufacturers, or Access potential inability to obtain raw or other materials, our potential inadvertent failure to comply with reporting and payment obligations under government pricing programs, our potential inability to become profitable in the future, our limited experience commercializing and distributing a pharmaceutical product, our dependence on key personnel, 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, our potential inadvertent failure to comply with the regulations of the FDA or other federal, state or foreign government agencies, the volatility of our stock price, uncertainties related to the actions of activist stockholders, potential product liability, potential legislative and regulatory changes, and potential costs and liabilities associated with pending or future litigation or patent challenges.

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. As of the Acquisition Date, our financial statements include the assets, liabilities, operating results and cash flows related to the MuGard Rights.

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, 2012. 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, 2012.

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, the fair value of our assets held for sale,

contingent consideration, the impairment of long-lived assets, including intangible assets, accrued expenses, income taxes and equity-based compensation expense. Actual results could differ materially from those estimates.

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Principles of Consolidation

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

Fair Value Measurements

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 and liabilities that are required to be measured at fair value on a recurring basis, including our cash equivalents, investments, and contingent consideration. The following tables represent the fair value hierarchy as of September 30, 2013 and December 31, 2012 for those assets and liabilities that we measure at fair value on a recurring basis (in thousands):

		Fair Value Measurements at September 30, 2013 Using:		
	Total	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Assets:				

Money market funds	$ 22,736	$ 22,736	$	$
Corporate debt securities	129,664		129,664	
U.S. treasury and government agency securities	52,931		52,931	
Total Assets	$ 205,331	$ 22,736	$ 182,595	$
Liabilities:				
Acquisition-related contingent consideration	$ 13,975	$	$	$ 13,975
Total Liabilities	$ 13,975	$	$	$ 13,975

	Fair Value Measurements at December 31, 2012 Using:			
	Total	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Money market funds	$ 24,058	$ 24,058	$	$
Corporate debt securities	111,690		111,690	
U.S. treasury and government agency securities	59,569		59,569	
Commercial paper	9,491		9,491	
	$ 204,808	$ 24,058	$ 180,750	$

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With the exception of our money market funds and our acquisition-related contingent consideration, the fair value of our investments listed in the table above is primarily determined from independent pricing services. 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, 2013 or December 31, 2012. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the nine months ended September 30, 2013.

We are accounting for the acquisition of the MuGard Rights as a business combination under the acquisition method of accounting. Additional details regarding the Access License Agreement and the MuGard Rights can be found in Note G. The fair value measurements of contingent consideration obligations and the related intangible asset arising from business combinations are determined using unobservable, or Level 3, inputs. These inputs include (i) the estimated amount and timing of projected cash flows; (ii) the probability of the achievement of the factors on which the contingency is based; and (iii) the risk-adjusted discount rate used to present value the probability-weighted cash flows. Significant increases (decreases) in any of those inputs in isolation could result in a significantly lower or higher fair value measurement.

During the three months ended September 30, 2013, we completed the valuation for the acquisition of the MuGard Rights. Some of the amounts previously estimated have changed during the measurement period, including the amounts and timing of cash flows related to the royalties we expect to pay to Access under the Access License Agreement. The measurement period adjustments represent revisions to estimates in the interim period subsequent to the acquisition and initial accounting date. As a result of these changes, the fair value of the contingent consideration, which was originally assessed to be $14.0 million as of the Acquisition Date has been adjusted to $13.7 million as of the Acquisition Date. These measurement period adjustments have been retrospectively applied to our condensed consolidated balance sheet at June 30, 2013.

The following table presents a reconciliation of contingent consideration obligations related to our acquisition of the MuGard Rights measured on a recurring basis using Level 3 inputs as of September 30, 2013 (in thousands):

Balance as of June 6, 2013	$	
Acquisition date fair value of contingent consideration		13,700
Balance as of June 30, 2013	$	13,700
Payments made		(4)
Adjustments to fair value of contingent consideration		279
Balance as of September 30, 2013	$	13,975

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During the three and nine months ended September 30, 2013, we recorded $0.3 million in expense related to the increase in fair value of the contingent consideration liability. This expense represents the time value of money impact of the contingent consideration fair value assessment as of September 30, 2013 and is included in selling, general and administrative expenses in our condensed consolidated statements of operations. As of September 30, 2013, we estimate that the undiscounted royalty amounts we could pay under the Access License Agreement may range from $28.0 million to $34.0 million over a ten year period, which is our best estimate of the period over which we expect the majority of the asset s cash flows to be derived. This measure is based on significant Level 3 inputs not observable in the market. Key assumptions include a discount rate of approximately 15%. As of September 30, 2013, the assumptions used for determining fair value of the contingent consideration have not changed significantly from those used at the Acquisition Date.

In addition, in connection with the acquisition of the MuGard Rights, we acquired an intangible asset of $16.9 million, which was originally determined based on fair value measurements. These measures were based on significant Level 3 inputs not observable in the market. Key assumptions include a discount rate of 19%. We believe the estimated fair values of the MuGard Rights are based on reasonable assumptions, however, we cannot provide assurance that the underlying assumptions used to forecast the cash flows will materialize as we estimated and thus, our actual results may vary significantly from the estimated results.

Assets Held for Sale

During 2012, we determined that certain assets related to our Cambridge, Massachusetts manufacturing facility, including the related land, building and certain equipment, met the criteria established by current accounting guidance for classifying assets as held for sale. As a result, during 2012, we reclassified these assets from property and equipment to assets held for sale in our condensed consolidated balance sheet. In anticipation of a future sale, we valued these assets at the lower of their carrying amount or fair value less cost to sell to arrive at the estimated fair value of $2.0 million as of December 31, 2012. During the nine months ended September 30, 2013, we sold $0.5 million of equipment related to our Cambridge, Massachusetts manufacturing facility. In connection with these sales, we recorded a gain of $0.4 million during the nine months ended September 30, 2013 and reduced the carrying value of our assets held for sale by $0.1 million to $1.9 million at September 30, 2013. The fair values of the land, building, and equipment were estimated using Level 3 inputs, which included offers received from potential purchasers, real estate appraisals and other estimates from third-parties. On October 30, 2013, we sold our Cambridge, Massachusetts manufacturing facility, including the land, building and related personal property, to 61 Mooney Street LLC. Refer to Note P for additional information.

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Revenue Recognition and Related Sales Allowances and Accruals

An analysis of our product sales allowances and accruals for the three and nine months ended September 30, 2013 and 2012 is as follows (in thousands):

	Three Months Ended September 30,	
	2013	**2012**
Provision for U.S. *Feraheme* sales allowances and accruals		
Discounts and chargebacks	$ 10,205	$ 6,644
Government and other rebates	3,044	1,595
Medicaid rebate reserve adjustment	(625)	(861)
Returns	265	(1,122)
Total provision for U.S. *Feraheme* sales allowances and accruals	$ 12,889	$ 6,256
Total gross U.S. *Feraheme* sales	$ 32,236	$ 22,442
Total provision for U.S. *Feraheme* sales allowances and accruals as a percent of total gross U.S. *Feraheme* sales	40%	28%

	Nine Months Ended September 30,	
	2013	**2012**
Provision for U.S. *Feraheme* sales allowances and accruals		
Discounts and chargebacks	$ 26,925	$ 19,382
Government and other rebates	8,106	4,487
Medicaid rebate reserve adjustment	(568)	(621)
Returns	697	(1,680)
Total provision for U.S. *Feraheme* sales allowances and accruals	$ 35,160	$ 21,568
Total gross U.S. *Feraheme* sales	$ 87,541	$ 65,474
Total provision for U.S. *Feraheme* sales allowances and accruals as a percent of total gross U.S. *Feraheme* sales	40%	33%

We generally offer our wholesalers, specialty distributors and other customers a limited right to return *Feraheme* purchased directly from us, based on the product s expiration date which, once packaged, is currently five years in the U.S. Reserves for *Feraheme* returns for U.S. sales are recorded in the period the related revenue is recognized, resulting in a reduction to product sales. We evaluate our estimated product returns rate each period based on the historical return patterns and known or expected changes in the marketplace. We did not significantly adjust our reserve for product returns during the nine months ended September 30, 2013. During the nine months ended September 30, 2012, we reduced our reserve by approximately $2.1 million as a result of a lower expected rate of product returns based on our actual returns experience to date as well as the lapse of the product return period on certain manufactured *Feraheme* lots that carried a two-year expiration period. The product returns provision applied to gross product sales for the nine months ended September 30, 2013 was $0.7 million as compared to a credit of $1.7 million for the nine months ended September 30, 2012.

In addition, as part of our sales allowances and accruals, we reserve for estimated 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. We regularly assess our Medicaid reserve balance and the rate at which we accrue for claims against product sales. If we determine in future periods that our actual rebate experience is not indicative of expected claims, if our actual claims experience changes, or if other factors affect estimated claims rates, we may be required to adjust our

current Medicaid accumulated reserve estimate, which could significantly affect our earnings in the period of the adjustment. During each of the nine months ended September 30, 2013 and 2012, we revised our estimated Medicaid reserve rate based on actual product-specific rebate claims received since the July 2009 launch of *Feraheme*, our expectations of state level activities, and estimated rebate claims not yet submitted, which resulted in a $0.6 million

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reduction of our then estimated Medicaid rebate reserve related to prior period *Feraheme* sales. These changes in estimates are reflected as an increase in our net product sales for the nine months ended September 30, 2013 and 2012 and resulted in reductions to our gross to net percentage in the respective periods. The reduction of our estimated Medicaid rebate reserve had an impact of $0.03 per basic and diluted share for the each of the nine months ended September 30, 2013 and 2012.

Acquisitions

We account for acquired businesses using the acquisition method of accounting, which requires, with limited exceptions, that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date. Transaction costs are expensed as incurred. Any excess of the consideration transferred over the estimated fair values of the net assets acquired is recorded as goodwill.

Intangible Assets

Intangible assets with definite useful lives are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if certain events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Contingent Consideration

Contingent consideration arising from a business combination is included as part of the acquisition cost and is recognized at fair value as of the acquisition date. Any liability resulting from contingent consideration is remeasured to its fair value at each reporting date until the contingency is resolved. These changes in fair value are recognized in our condensed consolidated statements of operations.

Concentrations and Significant Customer Information

Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash, investments, and accounts receivable. As of September 30, 2013, our cash, cash equivalents and investments amounted to approximately $213.5 million. We currently invest our excess cash primarily in U.S. government and agency money market funds, and investments in corporate debt securities and U.S. treasury and government agency securities. As of September 30, 2013, we had approximately $22.7 million of our total $30.9 million cash and cash equivalents balance invested in institutional money market funds, of which $13.9 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/Rienso* and commercializing *MuGard*. 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,

2013 and 2012:

	Nine Months Ended September 30,	
	2013	2012
AmerisourceBergen Drug Corporation	43%	34%
McKesson Corporation	23%	17%
Cardinal Health, Inc.	16%	11%
Takeda Pharmaceuticals Company Limited	11%	31%

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In addition, approximately 32% and 33% of our end-user demand during the nine months ended September 30, 2013 and 2012, respectively, was generated by members of a single group purchasing organization with which we have contracted. Revenues from customers outside of the U.S. amounted to approximately 11% and 32% of our total revenues for the nine months ended September 30, 2013 and 2012, respectively, and were primarily related to collaboration revenue recognized in connection with our collaboration agreement with Takeda, which is headquartered in Japan.

We are currently solely dependent on a single supply chain for our *Feraheme/Rienso* drug substance and finished drug product. We are exposed to a significant loss of revenue from the sale of *Feraheme/Rienso* if our suppliers and/or manufacturers cannot fulfill demand for any reason.

C. Investments

As of September 30, 2013 and December 31, 2012, our investments equaled $182.6 million and $180.8 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 investments as of September 30, 2013 and December 31, 2012 (in thousands):

	September 30, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	$ 45,645	$ 67	$ (2)	$ 45,710
Due in one to three years	84,020	92	(158)	83,954
U.S. treasury and government agency securities				
Due in one year or less	22,551	25		22,576
Due in one to three years	30,321	53	(19)	30,355
Total investments	$ 182,537	$ 237	$ (179)	$ 182,595

	December 31, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	$ 52,332	$ 88	$ (6)	$ 52,414
Due in one to three years	59,176	137	(37)	59,276
U.S. treasury and government agency securities				
Due in one year or less	24,795	86		24,881
Due in one to three years	34,606	84	(2)	34,688
Commercial paper				
Due in one year or less	9,494	1	(4)	9,491
Total investments	$ 180,403	$ 396	$ (49)	$ 180,750

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Impairments and Unrealized Losses on Investments

We did not recognize any other-than-temporary impairment losses in our condensed consolidated statements of operations related to our securities during any of the three or nine month periods ended September 30, 2013 and 2012. We considered various factors, including the length of time that each security was in an unrealized loss position and our ability and intent to hold these securities until the recovery of their amortized cost basis occurs. Future events may occur, or additional information may become available, which may cause us to identify credit losses where we do not expect to receive cash flows sufficient to recover the entire amortized cost basis of a security and which may necessitate the recording of future realized losses on securities in our portfolio. Significant losses in the estimated fair values of our investments could have a material adverse effect on our earnings in future periods.

Realized Gains and Losses on Investments

Gains and losses are determined on the specific identification method. Realized gains were insignificant during both the three and nine months ended September 30, 2013. During the nine months ended September 30, 2012 we recorded realized losses of $1.5 million to our condensed consolidated statements of operations related to the sale of our then-remaining auction rate securities portfolio.

D. Accounts Receivable, Net

Our net accounts receivable were $8.8 million and $6.4 million as of September 30, 2013 and December 31, 2012, 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.

Customers which represented greater than 10% of our accounts receivable balances as of September 30, 2013 and December 31, 2012 were as follows:

	September 30, 2013	December 31, 2012
AmerisourceBergen Drug Corporation	48%	48%
Cardinal Health, Inc.	28%	18%
McKesson Corporation	19%	28%

E. Inventories

Our major classes of inventories were as follows as of September 30, 2013 and December 31, 2012 (in thousands):

	September 30, 2013	December 31, 2012
Raw materials	$ 5,151	$ 2,652
Work in process	5,835	2,524
Finished goods	3,708	7,275
Total inventories	$ 14,694	$ 12,451

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In May 2013, Takeda recalled one specific batch of *Rienso* from the Swiss market. The batch was only distributed to and sold in Switzerland and the recall was limited to the specific batch and specifically in Switzerland. We and Takeda have completed an investigation regarding the specific Swiss batch of *Rienso* and the reported adverse events and Takeda has filed a report with the Swiss Agency for Therapeutic Products, commonly known as SwissMedic. During the nine months ended September 30, 2013, we expensed $0.5 million of inventory related to this batch of *Rienso* which we no longer believed was suitable for sale and which was the subject of the voluntary recall by Takeda in the Swiss market.

F. Property and Equipment, Net

Property and equipment consisted of the following as of September 30, 2013 and December 31, 2012, respectively (in thousands):

	September 30, 2013	December 31, 2012
Buildings and improvements	$ 953	$ 5,373
Laboratory and production equipment	343	115
Furniture and fixtures	1,828	5,326
Construction in process	34	228
	3,158	11,042
Less - accumulated depreciation	(1,417)	(7,745)
Property and equipment, net	$ 1,741	$ 3,297

In September 2013, we relocated our corporate offices from Lexington, Massachusetts to Waltham, Massachusetts. In connection with our relocation, we recorded $1.4 million of new leasehold improvements and furniture and fixtures related to our new location. In addition, during the nine months ended September 30, 2013, we recorded $2.8 million of depreciation expense, including $1.9 million of accelerated depreciation expense related to fixed assets at our prior office facility.

G. Business Combination

As part of our strategy to expand our portfolio with additional commercial-stage specialty products, in June 2013, we entered into the Access License Agreement pursuant to which we obtained an exclusive, royalty-bearing license, with the right to grant sublicenses, to certain intellectual property rights, including know-how, patents and trademarks, to use, import, offer for sale, sell, manufacture and commercialize *MuGard* in the U.S. Territory for the management of all diseases or conditions of the oropharyngeal cavity, including mucositis.

MuGard was launched by Access in 2010 after receiving 510(k) clearance from the FDA and is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces.

Access will continue to manufacture *MuGard* and we have entered into or plan to enter into separate quality and supply agreements with Access under which we will purchase *MuGard* inventory from Access. Our inventory purchases will be at the price actually paid by Access to purchase it from a third-party plus a mark-up to cover administration, handling and overhead.

In consideration for the license, we paid Access an upfront payment of $3.3 million in June 2013. We will also pay Access royalties on future net sales of *MuGard* until the later of (i) the expiration of the

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licensed patents or (ii) the tenth anniversary of the first commercial sale of *MuGard* under the Access License Agreement in the U.S. Territory, or the Royalty Term. These tiered, double-digit royalty rates decrease for any part of the Royalty Term occurring after the expiration of the licensed patents and are subject to off-set against certain of our expenses. After the expiration of the Royalty Term, the license shall become a fully paid-up, royalty-free and perpetual license in the U.S. Territory. In addition to making an upfront payment of $3.3 million, we also acquired $0.2 million of existing *MuGard* inventory from Access, which was included in our condensed consolidated balance sheet as of the Acquisition Date.

We did not assume any pre-existing liabilities related to the *MuGard* business, contingent or otherwise, arising prior to the Acquisition Date. We are accounting for the acquisition of the MuGard Rights as a business combination under the acquisition method of accounting since we acquired the U.S. commercial rights for *MuGard* and inventory, and obtained access to certain related regulatory assets, employees and other assets, including certain patent and trademark rights, contracts, and related books and records, held by Access which are exclusively related to *MuGard* (inputs), including the infrastructure to sell, distribute and market *MuGard* (processes) and net sales of *MuGard* (outputs). In addition, during the term of the Access License Agreement, we will have control over sales, distribution and marketing of *MuGard* in the U.S. as Access has assigned to us all of its right, title and interest in *MuGard*-related internet and social media outlets and other sales, marketing and promotional materials currently owned or controlled by Access. Access will no longer commercialize, market, promote, sell or make public communications relating to *MuGard* in the U.S Territory, except as may be agreed to by us. Access has also agreed to not, directly or indirectly, research, develop, market, sell or commercialize any medical devices that directly compete with *MuGard* for the treatment of any diseases or conditions of the oropharyngeal cavity in the U.S. Territory.

We estimated the fair value of the acquired MuGard Rights using the income approach. The income approach uses valuation techniques to convert future amounts to a single present amount (discounted). This approach begins with a forecast of the net cash flows expected to be generated by the asset over its estimated useful life. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. Some of the more significant estimates and assumptions inherent in the income approach include the following:

- The amount and timing of projected future cash flows, adjusted for the probability of marketing success;
- The discount rate selected to measure the risks inherent in the future cash flows; and
- An assessment of the asset s life-cycle and the competitive trends impacting the asset.

The following table summarizes the total consideration for the MuGard Rights (in thousands):

Consideration:		
Cash	$	3,434
Acquisition-related contingent consideration		13,700
Total consideration	$	17,134

The $17.1 million total consideration includes the estimated fair value of the contingent consideration at the Acquisition Date. During the three months ended September 30, 2013, we completed the valuation for the acquisition of the MuGard Rights. Some of the amounts previously estimated have changed during

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the measurement period, including the amounts and timing of cash flows related to the royalties we expect to pay to Access under the Access License Agreement. As a result of these changes, the fair value of the contingent consideration, which was originally assessed to be $14.0 million as of the Acquisition Date, has been adjusted to $13.7 million as of the Acquisition Date, and the fair value of the intangible asset, which was originally assessed to be $17.2 million, was determined to be $16.9 million as of the Acquisition Date, both reflecting an adjustment of $0.3 million. The revised Acquisition Date fair value of the contingent consideration was determined based on various market factors, including an analysis of estimated sales using a discount rate of approximately 15%. As of September 30, 2013, we estimated that the undiscounted royalty amounts we could pay under the Access License Agreement may range from $28.0 million to $34.0 million over a ten year period, which is our best estimate of the period over which we expect the majority of the asset s cash flows to be derived. The $0.3 million adjustment to the fair value estimate was based on significant Level 3 inputs not observable in the market. The measurement period adjustments represent updates made to the preliminary valuation based on revisions to estimates in the interim period subsequent to the acquisition and initial accounting date. These measurement period adjustments have been retrospectively applied to our condensed consolidated balance sheet at June 30, 2013. There was no impact from this adjustment to our condensed consolidated statement of operations for the three months ended June 30, 2013.

We have classified $0.9 million of the contingent consideration as a short-term liability, which was included in accrued expenses in our condensed consolidated balance sheet as of September 30, 2013.

The following table summarizes the estimated fair values of the assets acquired related to the business combination as of the Acquisition Date (in thousands):

Assets Acquired:		
MuGard intangible asset	$	16,893
Inventory		241
Net identifiable assets acquired	$	17,134

The Acquisition Date fair value of the intangible asset was determined based on various market factors, including an analysis of estimated sales using a discount rate of 19%. This measure is based on significant Level 3 inputs not observable in the market. Such valuations require significant estimates and assumptions including but not limited to: estimating future cash flows from product sales and developing appropriate discount and probability rates. We believe the estimated fair values of the MuGard Rights are based on reasonable assumptions, however, we cannot provide assurance that the underlying assumptions used to forecast the cash flows will materialize as we estimated and thus, our actual results may vary significantly from the estimated results.

Commencing from the Acquisition Date, our condensed consolidated financial statements include the assets, liabilities, operating results and cash flows from the acquired product. As a result, our condensed consolidated financial statements for the nine months ended September 30, 2013 reflect less than four months of *MuGard* activity. Revenues related to *MuGard* sales for the nine months ended September 30, 2013 were not material.

Transaction costs are not included as a component of consideration transferred and are expensed as incurred. We incurred approximately $0.8 million of acquisition-related costs during the nine months ended September 30, 2013. These costs were primarily related to professional and legal fees and are included in selling, general and administrative expenses in our condensed consolidated statements of operations for the nine months ended September 30, 2013.

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Pro forma results of operations would not be materially different as a result of the acquisition of the MuGard Rights and therefore are not presented.

H. Intangible Assets, Net

In June 2013, we acquired the MuGard Rights from Access and recorded $16.9 million to finite-lived intangible assets based on the estimated fair value of the MuGard Rights as of the Acquisition Date.

We will amortize the MuGard Rights using an economic consumption model over ten years, which represents our best estimate of the period over which we expect the majority of the asset s cash flows to be derived. We believe this is the best approximation of the period over which we will derive the majority of value of the MuGard Rights. We recorded less than $0.1 million of amortization related to the MuGard Rights in cost of product sales in our condensed consolidated statements of operations for each of the three and nine months ended September 30, 2013 and as a result, our intangible asset related to the MuGard Rights remained at $16.9 million as of September 30, 2013.

Intangible assets are reviewed for impairment at least annually and whenever facts or circumstances suggest that the carrying value of these assets may not be recoverable. Our policy is to identify and record impairment losses, if necessary, on intangible assets when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets.

We expect future annual amortization expense related to our intangible asset to be as follows (in thousands):

Period		Estimated Amortization Expense
Year Ended December 31, 2013	$	41
Year Ended December 31, 2014		660
Year Ended December 31, 2015		915
Year Ended December 31, 2016		1,215
Year Ended December 31, 2017		1,616
Year Ended December 31, 2018		2,103
Thereafter		10,316
Total	$	16,866

I. Income Taxes

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

some or all of the deferred tax assets will not be realized.

For the three and nine months ended September 30, 2013, we did not recognize any tax expense or benefit due to our continued net operating loss position. For the three and nine months ended September 30, 2012, we recognized a $0.3 million and $0.8 million current federal income tax benefit, respectively, which was primarily the result of a decrease in unrealized losses associated with the sale of our then-remaining auction rate security portfolio in the second quarter of 2012. Due to the uncertainty

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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.

J. Accumulated Other Comprehensive Loss

In February 2013, the Financial Accounting Standards Board issued an amendment to the accounting guidance for the reporting of amounts reclassified out of accumulated other comprehensive loss, or AOCI. The amendment expands the existing disclosure by requiring entities to present information about significant items reclassified out of AOCI by component. In addition, an entity is required to provide information about the effects on net income of significant amounts reclassified out of each component of AOCI to net income either on the face of the income statement or as a separate disclosure in the notes of the financial statements. The amendment is effective for annual or interim reporting periods beginning after December 31, 2012. The adoption of this accounting pronouncement did not have a material impact on our financial statement disclosures.

The changes in AOCI, net of tax, for the three and nine months ended September 30, 2013 consisted of the following (in thousands):

	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2013
Beginning Balance	$ (3,935)	$ (3,247)
Other comprehensive income (loss) before reclassifications	399	(310)
Gain (loss) reclassified from other accumulated comprehensive loss		21
Ending Balance	$ (3,536)	$ (3,536)

The amounts reclassified from other comprehensive loss for the nine months ended September 30, 2013 primarily represented realized gains on investments, which are included in our condensed consolidated statement of operations under Gains (losses) on investments, net.

K. 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 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,	
	2013	2012	2013	2012
Net loss	$ (145)	$ (3,967)	$ (5,948)	$ (13,064)
Weighted average common shares outstanding	21,691	21,403	21,613	21,374
Net loss per share:				
Basic and diluted	$ (0.01)	$ (0.19)	$ (0.28)	$ (0.61)

The following table sets forth the potential common shares issuable upon the exercise of outstanding options and the vesting of restricted stock units (prior to consideration of the treasury stock method), that were excluded from our computation of diluted net loss per share because such options and restricted stock units were anti-dilutive (in thousands):

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	As of September 30,	
	2013	2012
Options to purchase shares of common stock	2,717	2,315
Shares of common stock issuable upon the vesting of restricted stock units	497	468
Total	3,214	2,783

L. Equity-Based Compensation

We currently maintain two equity compensation plans, including our Third Amended and Restated 2007 Equity Incentive Plan, or the 2007 Plan, and our Amended and Restated 2000 Stock Plan, or the 2000 Plan.

Third Amended and Restated 2007 Equity Incentive Plan

Our 2007 Plan was originally approved by our stockholders in November 2007. In each of May 2009, May 2010 and May 2013, our stockholders approved proposals to amend and restate our 2007 Plan to, among other things, increase the number of shares authorized for issuance thereunder by 600,000, 800,000 and 1,100,000 shares, respectively.

As of September 30, 2013, we have granted options and restricted stock units covering 6,220,350 shares of common stock under our 2007 Plan, of which 2,532,981 stock options and 626,122 restricted stock units have expired or terminated, and of which 137,865 options have been exercised and 423,997 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, 2013 was 2,157,148 and 342,237, respectively. The remaining number of shares available for future grants as of September 30, 2013 was 2,074,125, not including shares subject to outstanding awards under the 2000 Plan, which will be added to the total number of shares available for issuance under the 2007 Plan to the extent that such awards expire or terminate for any reason prior to exercise. All outstanding stock options granted under our 2007 Plan have an exercise price equal to the closing price of a share of our common stock on the grant date and have either a seven or ten-year term.

Amended and Restated 2000 Stock Plan

As of September 30, 2013, the number of shares underlying outstanding options which were issued pursuant to our 2000 Plan was 104,941. There were no restricted stock units outstanding as of September 30, 2013. In November 2007, the 2000 Plan was succeeded by our 2007 Plan and, accordingly, no further grants may be made under this plan. Any shares that remained available for issuance under the 2000 Plan as of the date of adoption of the 2007 Plan are included in the number of shares that may be issued under the 2007 Plan. Any shares subject to outstanding awards granted under the 2000 Plan that expire or terminate for any reason prior to exercise will be added to the total number of shares available for issuance under the 2007 Plan.

Other Equity Compensation Grants

In February 2013, we granted restricted stock units to certain members of our senior management covering a maximum of 82,500 shares of common stock, which are subject to a performance condition tied to the price of our common stock. These restricted stock units vest, if at all, at the end of the three-year period ending December 31, 2015 based on the achievement of a minimum, target or maximum

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stock price range. In the event that the minimum stock price range is not achieved at the measurement date, none of the restricted stock units will vest. The maximum total fair value of these restricted stock units is $0.7 million, which are being recognized to expense over a period of three years from the date of grant, net of any estimated and actual forfeitures.

During the nine months ended September 30, 2013 and 2012, our Board of Directors, or the Board, granted options to purchase 210,000 and 300,000 shares of our common stock, respectively, to certain members of our senior management to induce them to accept employment with us. These options were granted at an exercise price equal to the fair market value of a share of our common stock on the respective grant dates. The options will be exercisable in four equal annual installments beginning on the first anniversary of the respective grant dates. Of the 210,000 options granted in 2013, 45,000 were forfeited during the nine months ended September 30, 2013. The assumptions used to value these options are substantially the same as those described in Note I to the Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2012. In addition, during the nine months ended September 30, 2013 and 2012, our Board granted 95,000 and 100,000 restricted stock units, respectively, to certain members of our senior management to induce them to accept employment with us. These grants will vest in four equal annual installments beginning on the first anniversary of the respective grant dates. Of the 95,000 restricted stock units granted in 2013, 15,000 were forfeited during the nine months ended September 30, 2013. The foregoing grants were made pursuant to inducement grants outside of our 2007 Plan as permitted under the NASDAQ Global Market rules. We assessed the terms of these awards and determined there was no possibility that we would have to settle these awards in cash and therefore, equity accounting was applied.

Equity-based compensation expense

Equity-based compensation expense, for the three and nine months ended September 30, 2013 and 2012 consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Cost of product sales	$ 25	$ 52	$ 83	$ 198
Research and development	337	473	1,634	1,420
Selling, general and administrative	1,303	1,525	4,169	3,694
Total equity-based compensation expense	$ 1,665	$ 2,050	$ 5,886	$ 5,312

We reduce the equity-based compensation expense being recognized to account for estimated forfeitures, which we estimate based primarily on historical experience, adjusted for unusual events such as our corporate restructuring in 2012, which resulted in higher than expected turnover and forfeitures in that year. Under 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.

M. Commitments and Contingencies

Facility Lease Obligations

In June 2013, we entered into a lease agreement with BP Bay Colony LLC, or the Landlord, for the lease of certain real property located at 1100 Winter Street, Waltham, Massachusetts, or the Premises, for use as our principal executive offices. The Landlord agreed to build out the Premises, which was completed in September 2013. The initial term of the lease is five years and two months with one five-

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year extension term at our option. During the extension period, the base rent will be an amount agreed upon by us and the Landlord. In addition to base rent, we are also required to pay a proportionate share of the Landlord s operating costs. The lease requires us to pay base rent during the initial term as follows:

Period		Minimum Lease Payments
Year Ended December 31, 2013	$	131,553
Year Ended December 31, 2014		1,127,595
Year Ended December 31, 2015		1,127,595
Year Ended December 31, 2016		1,127,595
Year Ended December 31, 2017		1,127,595
Thereafter		1,033,629
Total	$	5,675,562

The Landlord agreed to pay for certain agreed-upon improvements and we agreed to pay for any increased costs due to changes by us to the agreed-upon plans. We record all tenant improvements paid by us as leasehold improvements and amortize these improvements over the shorter of the estimated useful life of the improvement or the remaining life of the initial lease term. Amortization of leasehold improvements is included in depreciation expense.

In addition, in connection with our new facility lease, in June 2013 we delivered to the Landlord a security deposit of $0.4 million in the form of an irrevocable letter of credit. This security deposit will be reduced to $0.3 million on the second anniversary of the date the lease commenced. The cash securing this letter of credit is classified on our balance sheet as of September 30, 2013 as a long-term asset and is restricted in its use.

In June 2013, we also entered into an Assignment and Assumption of Lease, or the Assignment Agreement, with Shire Human Genetic Therapies, Inc., or Shire, effecting the assignment to Shire of the right to occupy our former office space located at 100 Hayden Avenue, Lexington, Massachusetts, or the Prior Space. Under the Assignment Agreement, the assignment to Shire became effective on September 21, 2013, the date of our departure from the Prior Space, and Shire assumed all of our obligations as the tenant of the Prior Space. The Assignment Agreement also provided for the conveyance of furniture and other personal property by us to Shire.

Legal Proceedings

We accrue a liability for legal contingencies when we believe that it is both probable that a liability has been incurred and that we can reasonably estimate the amount of the loss. We review these accruals and adjust them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and our views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in our accrued liabilities would be recorded in the period in which such determination is made. For the matters referenced below, the liability is not probable or the amount cannot be reasonably estimated and, therefore, accruals have not been made. In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, we will provide disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, we will provide disclosure to that effect.

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A purported class action complaint was originally filed on March 18, 2010 in the U.S. 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 Chief Financial Officer, the then-members of our Board, 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 Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged omissions in a registration statement filed in January 2010. The plaintiffs 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 and 15, 2011, respectively, the District Court issued an Opinion and Order dismissing the SAC with prejudice 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 U.S. Court of Appeals for the First Circuit, or the Court of Appeals. The Court of Appeals heard oral argument on May 11, 2012. On February 4, 2013, the Court of Appeals affirmed in part and reversed in part the District Court s Opinion and Order and remanded the case to the District Court. On February 19, 2013, we filed a Petition for Panel Rehearing and Rehearing *En Banc*, which was denied on March 15, 2013. On March 22, 2013, we filed a Motion to Stay the Mandate remanding the case to the District Court pending review by the U.S. Supreme Court of the Court of Appeals February 4, 2013 decision. The Court of Appeals granted the Motion to Stay the Mandate on April 8, 2013. On June 13, 2013, we filed a Petition for a Writ of Certiorari, or the Petition, with the U.S. Supreme Court seeking review of the Court of Appeal s decision and to have that decision overturned. On October 7, 2013 the U.S. Supreme Court denied our Petition, resulting in the case s return to the District Court for further proceedings relative to the SAC s surviving claims. Our response to the SAC is due on or before November 6, 2013. The plaintiffs will submit an opposition to our response on or before December 6, 2013. We are currently unable to predict the outcome or reasonably estimate the range of potential loss associated with this matter, if any, and have therefore not recorded any potential estimated liability as we do not believe that such a liability is probable nor do we believe that a range of loss is currently estimable.

In July 2010, Sandoz GmbH, or Sandoz, filed with the European Patent Office, or the EPO, an opposition to a previously issued patent which covers ferumoxytol in EU jurisdictions. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked this patent. In December 2012, our notice of appeal of that decision was recorded with the EPO, which also suspended the revocation of our patent. On May 13, 2013, we filed a statement of grounds of appeal and on September 27, 2013, Sandoz filed a response to that statement. We will continue to defend the validity of this patent throughout the appeals process, which we expect to take two to three years. However, in the event that we do not experience a successful outcome from the appeals process, under EU regulations ferumoxytol would still be entitled to eight years of data protection and ten years of market exclusivity from the date of approval, which we believe would create barriers to entry for any generic version of ferumoxytol into the EU market until sometime between 2020 and 2022. This decision had no impact on our revenues for the nine months ended September 30, 2013. However, any future unfavorable outcome in this matter could negatively affect the magnitude and timing of future revenues, including royalties and milestone payments we may receive from Takeda pursuant to our collaboration agreement with Takeda. We do not expect to incur any related liability regardless of the outcome of the appeal and therefore have not recorded any liability as of September 30, 2013. We continue to believe the patent is valid and intend to vigorously appeal the decision.

We may periodically become subject to other legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to product liability matters or 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, 2013. We expense legal costs as they are incurred.

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Acquisition-related Contingent Consideration

In connection with the acquisition of the MuGard Rights, we have agreed to pay Access royalties on future sales of *MuGard*. We have estimated the fair value of the contingent consideration related to the acquisition of the MuGard Rights to be $14.0 million as of September 30, 2013. The fair value of these contingent payments was calculated based on estimated sales and were discounted using a rate of approximately 15%. Changes in contingent consideration expense result from changes in the assumptions regarding probabilities of the estimated timing and amount of royalty payments to Access and the discount rate used to estimate the fair value of the liability. Contingent consideration expense may change significantly as we gain more information related to sales of *MuGard*, impacting our assumptions. The assumptions used in estimating fair value require significant judgment. The use of different assumptions and judgments could result in a materially different estimate of fair value.

N. Collaborative Agreements

Our commercial strategy includes the formation of collaborations with other pharmaceutical companies to facilitate the sale and distribution of *Feraheme/Rienso*, primarily outside of the U.S, as well as expanding our portfolio through the in-license or purchase of additional commercialized specialty pharmaceutical products. In addition to our collaborative agreements described in Note N to the Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2012, we were a party to the collaboration arrangements described below as of September 30, 2013.

Takeda

In March 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme/Rienso* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey. In June 2012, we entered into an amendment to the Takeda Agreement, or the Amended Takeda Agreement, which removed the Commonwealth of Independent States from the territories under which Takeda has the exclusive rights to develop and commercialize *Feraheme/Rienso.* In addition, the Amended Takeda Agreement modified the timing and pricing arrangements for a supply agreement to be entered into between us and Takeda in the future, the terms related to primary and secondary manufacturing for drug substance and drug product, certain patent-related provisions, and the re-allocation of certain of the agreed-upon milestone payments. We analyzed the Amended Takeda Agreement and determined that the amended terms did not result in a material modification of the original Takeda Agreement (and thus did not require us to change our accounting model) because (i) there were no changes to the deliverables under the original Takeda Agreement as a result of the amendment, and (ii) the change in arrangement consideration as a result of the amendment was not quantitatively material in relation to the total arrangement consideration.

Under the Amended Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme/Rienso* and, accordingly, are responsible for supply of *Feraheme/Rienso* to Takeda at a fixed price per unit, which is capped for a certain period of time. 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. We have determined that our obligations under the Amended Takeda Agreement have not changed from those under the original Takeda Agreement and include the following four deliverables: the license, access to future know-how and improvements to the *Feraheme/Rienso* technology, regulatory and clinical research activities, and the manufacturing and supply of product.

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Pursuant to the accounting guidance in effect in March 2010, when we signed the original Takeda Agreement and which governed revenue recognition on multiple element arrangements, we evaluated the four deliverables under the original Takeda Agreement and determined that our obligation to provide manufacturing supply of product meets the criteria for separation and is therefore treated as a single unit of accounting, which we refer to as the supply unit of accounting. Further, we concluded that the license is not separable from the undelivered future know-how and technological improvements or the undelivered regulatory and clinical research activities. Accordingly, these deliverables are being combined and also treated as a single unit of accounting, which we refer to as the combined unit of accounting. With respect to the combined unit of accounting, our obligation to provide access to our future know-how and technological improvements is the final deliverable and is an obligation which exists throughout the term of the Amended Takeda Agreement.

In connection with the execution of the original Takeda Agreement, we received a $60.0 million upfront payment from Takeda in April 2010, which we recorded as deferred revenue, 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. Because we cannot reasonably estimate the total level of effort required to complete the obligations under the combined deliverable, we are recognizing the entire $60.0 million upfront payment, the $1.0 million reimbursed to us in 2010, as well as any non-substantive milestone payments that are achieved into revenues on a straight-line basis over a period of ten years from March 31, 2010, the date on which we originally entered the Takeda Agreement, which represented the then-current patent life of *Feraheme/Rienso* and our best estimate of the period over which we will substantively perform our obligations. We continue to believe that the then-current patent life of *Feraheme/Rienso* is our best estimate of the period over which we will substantively perform our obligations under this agreement.

In addition, the remaining milestone payments we may be entitled to receive under the Amended Takeda Agreement could over time equal up to $186.0 million. For any milestone payments we may receive based upon the approval by certain regulatory agencies, we have determined that these will be deemed substantive milestones and, therefore, will be accounted for as revenue in the period in which they are achieved. In June 2012, we earned a $15.0 million milestone payment from Takeda based on the European Commission marketing authorization for ferumoxytol. We deemed the $15.0 million milestone payment as a substantive milestone and therefore recognized the full amount as revenue in the six months ended June 30, 2012 in our condensed consolidated statements of operations. We have also determined that any non-substantive milestone payments will be accounted for in accordance with our revenue attribution method for the upfront payment, as described above. During 2012, we received an aggregate of $18.0 million in milestone payments from Takeda associated with the commercial launches of *Feraheme/Rienso* in Canada and the EU, which we deemed to be non-substantive milestone payments. Revenues related to the combined unit of accounting 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, 2013, we recorded $2.0 million and $5.9 million in revenues, respectively, associated with the upfront payment and the $18.0 million in non-substantive milestone payments we received in 2012. Any potential non-substantive milestone payments that may be received in the future will be recognized as revenue on a cumulative catch up basis when they become due and payable.

We have received and may also receive additional regulatory approval and performance-based milestone payments, reimbursement of certain out-of-pocket regulatory and clinical supply costs, defined payments for supply of *Feraheme/Rienso,* and tiered double-digit royalties on net product sales in the agreed-upon territories under the Amended Takeda Agreement.

Under the terms of the Amended Takeda Agreement, Takeda is responsible for reimbursing us for certain out-of-pocket regulatory and clinical trial supply costs associated with carrying out our regulatory

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and clinical research activities under the collaboration agreement. Because we are acting as the principal in carrying out these services, any reimbursement payments received from Takeda 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. During the three and nine months ended September 30, 2013, we recorded less than $0.1 million and $0.1 million associated with other reimbursement revenues received from Takeda, respectively.

At the time of shipment, we defer recognition of all revenue for *Feraheme/Rienso* sold to our licensees in our condensed consolidated balance sheets. We recognize revenues from product sales to our licensees, the related cost of goods sold, and any royalty revenues due from our licensees, in our condensed consolidated statement of operations at the time our licensees report to us that sales have been made to their customers. During the three and nine months ended September 30, 2013, we recognized $0.1 million and $0.3 million, respectively, in product sales and royalty revenue related to the Amended Takeda Agreement and we have included this revenue in other product sales and royalties in our condensed consolidated statement of operations. As of September 30, 2013, we had approximately $2.1 million in deferred revenue related to product shipped to Takeda but not yet sold through to Takeda s customers, and $1.9 million in deferred cost of product sales, which are included in our condensed consolidated balance sheet.

O. Restructuring

During 2012 and 2011, we initiated corporate restructurings, including a workforce reduction plan. The majority of the workforce reduction plan in 2012 was associated with our manufacturing and development infrastructure, including our decision to divest our Cambridge, Massachusetts manufacturing facility. The workforce reductions were substantially completed by the end of 2012 and the majority of the related expenses were paid by the end of 2012.

The following table outlines the components of our restructuring expenses which were recorded in operating expenses and current liabilities for the three and nine months ended September 30, 2013 and 2012 (in thousands):

	Three Months Ended September 30,	
	2013	2012
Accrued restructuring, beginning of period	$ 329	$ 1,728
Employee severance, benefits and related costs		441
Payments	(213)	(902)
Inventory and other adjustments		166
Accrued restructuring, end of period	$ 116	$ 1,433

	Nine Months Ended September 30,	
	2013	2012
Accrued restructuring, beginning of period	$ 1,383	$ 2,366
Employee severance, benefits and related costs		1,019
Payments	(1,267)	(2,029)
Inventory and other adjustments		77
Accrued restructuring, end of period	$ 116	$ 1,433

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P. Subsequent Event

On October 22, 2013, we entered into an Agreement of Sale with 61 Mooney Street LLC for the sale of our Cambridge, Massachusetts manufacturing facility, including the land, building and related personal property. The closing occurred on October 30, 2013, at which time we received $2.0 million in consideration. We do not expect to recognize a material gain or loss on this transaction.

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, 2012, or our Annual Report.

Except for the historical information contained herein, the matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q, words such as may will, expect, intend, and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Examples of forward-looking statements contained in this report include statements regarding the following: our plan to grow Feraheme in the U.S. chronic kidney disease market and through international and label expansion; the expansion of our portfolio through the in-license or purchase of additional specialty pharmaceutical products; expectations regarding our supplemental New Drug Application for Feraheme; the timing of the response from the EMA and Health Canada regarding Takeda Pharmaceutical Company Limited s Type II variation and Supplemental New Drug Submission, respectively; our expectations regarding the timing for enrollment in and commencement of our pediatric study and post-approval trials; our plans for a post-approval trial to assess the safety and efficacy of repeat doses of Feraheme for the treatment of iron deficiency anemia; our expectation that 3SBio, Inc. will begin a clinical trial if approved by the Chinese State Food and Drug Administration; our expectation of costs to be incurred in connection with and revenue sources to fund our future operations; our expectation for the patient population for Feraheme in the U.S.; our expectations regarding the success of our collaboration with Takeda Pharmaceutical Company Limited, including any potential milestone payments, product sales or royalties we may receive; our expectations regarding the manufacture of all Feraheme/Rienso drug substance and drug product at our third-party manufacturers; our expectations regarding customer returns and related reserves and accruals; labeling and other changes for Rienso in the EU expected as a result of the review by the Medicinal Products for Human Use of IV iron-containing medications used to treat iron deficiency anemia; our expectations regarding the validity of our European ferumoxytol patent and timing of the appeals process; our expectations

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regarding the Branded Drug Fee under the Health Care Reform Act and the Medicare reimbursement rate for Feraheme and estimates for Medicaid rebates; our expectations regarding our license fee and other collaboration revenues; the effect of price increases; expected customer mix and utilization rates; the impact of volume rebates and other incentives; provider purchase patterns and use of competitive products; expectations regarding MuGard and our license arrangement with Access Pharmaceuticals, Inc.; the valuation of certain intangible assets, contingent consideration and other assets and liabilities, including our methodology and assumptions regarding fair value measurements; our gross-to-net sales adjustments; our Citizen s Petition; our expectation for product sales and our costs of product sales as a percentage of net product sales and royalties, our research and development expenses, external expenses and the timing of our planned research and development projects, and selling, general and administrative expenses; our belief regarding the potential impact of the adoption of newly issued and future accounting guidance on our financial statements; our expectations for our cash, cash equivalents and investments balances 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 Part II, Item 1A below under Risk Factors in this Quarterly Report on Form 10-Q and in Part I, Item 1A in our Annual Report. 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 U.S. Securities and Exchange Commission to publicly update or revise any such statements to reflect any change in company expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a specialty pharmaceutical company that markets Feraheme® (ferumoxytol) Injection for Intravenous, or IV, use to treat iron deficiency anemia, or IDA, and MuGard® Mucoadhesive Oral Wound Rinse for the management of oral mucositis.

Currently, our principal source of revenue is from the sale of *Feraheme*, which was approved for marketing in the U.S. in June 2009 by the U.S. Food and Drug Administration, 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 began selling *Feraheme* in the U.S. in July 2009 through our own commercial organization, including a specialty sales force. We sell *Feraheme* to authorized wholesalers and specialty distributors, who in turn, sell *Feraheme* to healthcare providers who administer *Feraheme* primarily within hospitals, hematology and oncology centers, and nephrology clinics. We are working to continue to grow *Feraheme* in the U.S. CKD market and to drive additional growth of *Feraheme* through both international and label expansion. We are also focusing our efforts on marketing and selling *MuGard* in the U.S.

Portfolio Expansion

To further build our business, we intend to continue to expand our portfolio through the in-license or purchase of additional commercialized specialty pharmaceutical products. In particular, we are seeking complementary products that will leverage our commercial infrastructure and focus on hematology and oncology centers, hospital infusion centers or other sites of care where IV iron is administered or where IDA patients are diagnosed or treated. We are also looking at the potential addition of products outside of our current sales force s call points, which would potentially benefit *Feraheme* through increased referrals from certain physician specialists, such as gastroenterologists or rheumatologists. These new call points could be synergistic with the potential label expansion of *Feraheme*, if regulatory approval is obtained.

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On June 6, 2013, or the Acquisition Date, we entered into a License Agreement with Access Pharmaceuticals, Inc., or Access, under which we acquired the U.S. commercial rights to *MuGard*, or the Access License Agreement. *MuGard* was launched by Access in 2010 after receiving 510(k) clearance from the FDA and is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces. Under the Access License Agreement, we obtained an exclusive, royalty-bearing license, with the right to grant sublicenses, to certain intellectual property rights, including know-how, patents and trademarks, to use, import, offer for sale, sell, manufacture and commercialize *MuGard* in the U.S. and its territories, or the U.S. Territory, for the management of all diseases or conditions of the oropharyngeal cavity, including mucositis, or the MuGard Rights. In addition, we obtained all rights, title and interest in *MuGard*-related internet and social media outlets and other sales, marketing and promotional materials currently owned or controlled by Access, because, pursuant to the Access License Agreement, Access will no longer commercialize, market, promote, sell or make public communications relating to *MuGard* in the U.S. Territory, except as may be agreed to by us. We sell *MuGard* to wholesalers and specialty and retail pharmacies. See Note G to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information regarding the Access License Agreement and the MuGard Rights.

Label Expansion of Ferumoxytol

We believe that a significant opportunity exists in the U.S. for *Feraheme* beyond the treatment of IDA in adult patients with CKD. In the U.S., approximately 800,000 grams of IV iron were administered for the treatment of non-dialysis patients with IDA in 2012. We believe that approximately half, or 400,000 grams, of the IV iron administered in the U.S. was for the treatment of non-dialysis patients with CKD and the other half was for non-CKD patients with IDA due to other causes, including patients with gastrointestinal diseases or disorders, abnormal uterine bleeding, inflammatory diseases, and chemotherapy-induced anemia.

In 2012, we completed a phase III clinical program for *Feraheme* in patients with IDA who had failed or could not use oral iron. The IDA program consisted of two controlled, multi-center phase III clinical trials, or IDA-301 and IDA-302, including more than 1,400 patients, which evaluated the safety and efficacy of ferumoxytol for the treatment of IDA in this broader patient population. Both studies met the primary efficacy endpoints related to improvements in hemoglobin. In these studies no new safety signals were observed with *Feraheme* treatment and the types of reported adverse events were consistent with those seen in previous studies and those contained in the approved U.S. package insert for *Feraheme*. In addition, patients from IDA-301 were eligible to enroll in an open-label extension study, or IDA-303, and receive treatment with *Feraheme,* as defined in the protocol.

In December 2012, we submitted a supplemental new drug application, or sNDA, to the FDA, seeking approval for *Feraheme* for the treatment of IDA in adult patients who had failed or could not use oral iron. The sNDA submission was primarily based on the data from IDA-301 and IDA-302. In addition, the sNDA included data from an interim analysis of IDA-303 and a previously completed post-approval clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron. We believe that approval for *Feraheme* for this expanded indication would effectively double the market opportunity for *Feraheme*, by allowing us the potential to access the half of the non-dialysis IV iron market that is beyond our current approved indication to treat IDA in adult patients with CKD. In March 2013, the FDA accepted our sNDA for review. Under the guidelines of the Prescription Drug User Fee

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Act, or PDUFA, the FDA initially set October 21, 2013 as a target date for completion of their review, with a target date of September 23, 2013 for communicating proposed labeling changes and/or post-marketing requirements/commitments. On September 23, 2013, we received a notification from the FDA stating that, as part of its ongoing review of our sNDA, the FDA had identified deficiencies that precluded discussion of labeling and post-marketing requirements/commitments at that time. In response to requests from the FDA, we have submitted additional information to support our sNDA. On October 15, 2013, we received notification from the FDA that our PDUFA date has been extended by three months to January 21, 2014 and that the FDA has set December 23, 2013 as the new date to communicate proposed labeling changes and/or post-marketing requirements/commitments, if necessary. This three-month extension is intended to give the FDA time for a full review of additional information related to the sNDA we submitted in response to FDA requests and during this extension we plan to continue our dialogue with the FDA.

In June 2013, Takeda filed a Type II Variation, which is the EU equivalent of a U.S. sNDA, with the European Medicines Agency, or EMA, seeking marketing approval for *Rienso* for the treatment of IDA in adult patients. Takeda has recently received the Day 90 List of Questions from the EMA and is in the process of responding to their questions. Takeda currently expects a decision from the EMA on the Type II Variation in the first half of 2014. In addition, in October 2013, Takeda filed a Supplemental New Drug Submission, or sNDS, with Health Canada seeking marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients.

International Expansion of Ferumoxytol

Outside of the U.S., ferumoxytol has been granted marketing approval in Canada, Switzerland and the European Union, or EU, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. The European marketing authorization is valid in the current EU member states as well as in Iceland and Norway. Under our amended agreement with Takeda Pharmaceutical Company Limited, or Takeda, Takeda has an exclusive license to market and sell ferumoxytol in Canada, the EU and Switzerland, as well as certain other geographic territories. In Canada, Takeda promotes ferumoxytol under the trade name *Feraheme* and in the EU and Switzerland, Takeda promotes ferumoxytol under the trade name Rienso® 30mg/ml solution for Injection.

Takeda Collaboration

In March 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme/Rienso* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey. In June 2012, we entered into an amendment to the Takeda Agreement, or the Amended Takeda Agreement, as discussed in further detail in Note N to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. In connection with the 2012 commercial launches of *Feraheme/Rienso* by Takeda, we recorded revenue from product sales to Takeda and royalties on sales by Takeda of $0.1 million and $0.3 million during the three and nine months ended September 30, 2013, respectively. In addition, as of September 30, 2013, we had approximately $2.1 million in deferred revenue related to product shipped to Takeda, but not yet sold through to Takeda s customers and $1.9 million in deferred cost of product sales.

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Clinical Development of Feraheme

We have recently amended and combined into one study, two previously initiated 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* in the U.S. The amended study covers both dialysis-dependent and non-dialysis dependent CKD pediatric patients. The combined study will assess the safety and efficacy of *Feraheme* treatment as compared to oral iron in approximately 288 pediatric patients.

Our pediatric investigation plan, which was a requirement for submission of the Marketing Authorization Application, or MAA, for ferumoxytol, was approved by the EMA in December 2009 and amended in 2012, and includes the pediatric study as amended and described above, and two additional pediatric studies requested by the EMA. These additional studies include a rollover extension study in pediatric CKD patients and a study in pediatric patients with IDA regardless of the underlying cause. The rollover study is open for enrollment. The pediatric IDA study will commence once the appropriate dose of *Feraheme* is determined from the study data resulting from the amended pediatric studies of *Feraheme*, described above.

As part of our obligations under the Amended Takeda Agreement and as part of our post-approval commitments to the EMA, we initiated a multi-center clinical trial to determine the safety and efficacy of repeat doses of ferumoxytol for the treatment of IDA in patients with hemodialysis-dependent CKD. As part of the post-approval commitment we made to the EMA as a condition of the approval of the MAA for ferumoxytol in the EU, this study includes a treatment arm with iron sucrose using a magnetic resonance imaging, or MRI, sub-analysis to evaluate the potential for iron to accumulate in the body following treatment with IV iron, specifically in the heart and liver, and, where possible, other major organs following repeated IV iron administration over a two year period. Enrollment is currently ongoing and we expect enrollment to be complete by the end of 2014. The costs related to the MRI portion of this study are subject to our established cost-sharing arrangement with Takeda.

In addition, certain clinical trials may be necessary to secure desired pricing in various European markets. If so, the cost of any future trials may be allocated between us and Takeda according to the cost-sharing arrangement under the Amended Takeda Agreement.

Our licensee in China, 3SBio Inc., or 3SBio, filed an application with the Chinese State Food and Drug Administration, or the SFDA, to obtain approval to begin a clinical trial necessary to file for marketing approval of *Feraheme* in China. If approved by the SFDA, 3SBio plans to commence a multi-center randomized efficacy and safety study of *Feraheme* in China involving approximately 200 CKD patients with IDA.

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Results of Operations Three Months Ended September 30, 2013 and 2012

Revenues

Total revenues for the three months ended September 30, 2013 and 2012 consisted of the following (in thousands):

	Three Months Ended September 30,			
	2013	2012	$ Change	% Change
U.S. *Feraheme* product sales, net	$ 19,347	$ 16,186	$ 3,161	20%
License fee and other collaboration revenues	1,998	1,566	432	28%
Other product sales and royalties	271	(10)	281	>100%
Total	$ 21,616	$ 17,742	$ 3,874	22%

Total revenues during the three months ended September 30, 2013 increased by $3.9 million, or 22%, as compared to the same period in 2012, primarily as the result of a $3.2 million increase in U.S. net *Feraheme* product sales, a $0.4 million increase in license fee and other collaboration revenues associated with our collaboration agreement with Takeda, and a $0.3 million increase in other product sales and royalties. Included in our net product sales for the three months ended September 30, 2013 and 2012 was a $0.6 million and $0.9 million reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales, respectively, as discussed below. In addition, our net product sales for the three months ended September 30, 2012 included a $1.3 million reduction of our estimated product return reserve, as discussed below.

U.S. Feraheme Product Sales, Net

U.S. *Feraheme* product sales and product sales allowances and accruals for the three months ended September 30, 2013 and 2012 consisted of the following (in thousands):

	Three Months Ended September 30,					
	2013	Percent of gross U.S. Feraheme product sales	2012	Percent of gross U.S. Feraheme product sales	$ Change	% Change
Gross U.S. *Feraheme* product sales	$ 32,236		$ 22,442		$ 9,794	44%
Less provision for product sales allowances and accruals:						
Discounts and chargebacks	10,205	32%	6,644	30%		
Government and other rebates	3,044	9%	1,595	7%		
Medicaid rebate reserve adjustment	(625)	-2%	(861)	-4%		
Returns	265	1%	(1,122)	-5%		
Total	12,889	40%	6,256	28%		
Net U.S. *Feraheme* product sales	$ 19,347		$ 16,186		$ 3,161	20%

Our gross U.S. *Feraheme* product sales increased by $9.8 million during the three months ended September 30, 2013 as compared to the same period in 2012. Of the $9.8 million increase, $7.4 million was due to increased units sold and $2.4 million was due to price increases. This increase was partially offset by $5.0 million of additional allowances and accruals in 2013, excluding a $1.3 million reduction of our estimated product return reserves for the three months ended September 30, 2012 and a $0.6 million and $0.9 million reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales for the three months ended September 30, 2013 and 2012, respectively, as described below. As a result of these factors, total U.S. net *Feraheme* product sales increased by $3.2 million during the three months ended September 30, 2013 as compared to the same period in 2012.

As noted above, during the three months ended September 30, 2013 and 2012, we reduced our estimated Medicaid rebate reserve related to prior *Feraheme* sales by approximately $0.6 million and $0.9 million, respectively, based on actual product-specific rebate claims received since the July 2009 launch of

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Feraheme, our expectations of state level activity, and estimated rebate claims not yet submitted. As a result, the Medicaid rebate reserves adjustment applied to gross U.S. *Feraheme* product sales for the three months ended September 30, 2013 and 2012 was a credit of $0.6 million and a credit of $0.9 million, respectively, resulting in an increase to product sales during those periods. In addition, during the three months ended September 30, 2012, we reduced our reserve for product returns by approximately $1.3 million due to a lower expected rate of product returns based on returns experience developed to date as well as the lapse of the product return period on certain manufactured *Feraheme* lots that carried a two-year expiration. As a result, the product returns provision applied to gross U.S. *Feraheme* product sales for the three months ended September 30, 2012 was a credit of $1.1 million resulting in an increase to product sales during that period. We did not make any adjustment to our reserve for product returns during the three months ended September 30, 2013. Actual Medicaid rebate claims to date and actual product returns to date have been limited. In future periods, we may be required to adjust our estimates based on additional experience or other changes in expectations, which would result in a corresponding change to our net product sales in the period in which the change is made and could be significant. If actual future results vary from any of our estimates, we may need to adjust our previous estimates, which would also affect our earnings in the period of the adjustment and could be significant.

Total discounts and chargebacks in the three months ended September 30, 2013 were $10.2 million, or 32% of total gross U.S. *Feraheme* product sales, as compared to $6.6 million, or 30%, in the same period of 2012. The increase in total discounts and chargebacks as a percentage of gross U.S. *Feraheme* product sales was related primarily to a change in our customer mix.

Total government and other rebates (excluding any changes in estimates related to Medicaid rebate reserves) were $3.0 million, or 9% of total gross U.S. *Feraheme* product sales, in the three months ended September 30, 2013 as compared to $1.6 million, or 7%, in the three months ended September 30, 2012. The increase in total government and other rebates as a percentage of gross U.S. *Feraheme* product sales was related primarily to increased sales to clinics and hospitals that had volume or market share contracts with us during the three months ended September 30, 2013 as compared to the same period in 2012.

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 and Note B to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Overall, we expect that our reserves as a percentage of gross sales of *Feraheme* will increase slightly during the remainder of 2013 as compared to the three months ended September 30, 2013 due primarily to our efforts to continue to increase adoption and utilization of *Feraheme*, our efforts to address continuing reimbursement pressures, our entry into volume or market share based contracts which offer discounts and rebates, and the expected customer mix and utilization rates. We recently implemented gross price increases for *Feraheme,* some portion of which were discounted back to customers under volume or market share based contracts. We anticipate that the effect of these price increases should offset the impact of the widening gross to net adjustment and that the average net revenue per gram of *Feraheme* should continue to increase in future periods.

In addition, our results of operations, including, in particular, product sales revenues, fluctuate from quarter to quarter due to the demand patterns of wholesalers, distributors, clinics and hospitals, the reasons for which may vary. We also have limited or no visibility into our customers buying decisions, which may be affected from time to time by incentives we make available to clinics, hospitals and group purchasing organizations, or GPOs, including volume rebates. During the third quarter of 2013, our increased *Feraheme* product sales resulted in part from an effective contracting strategy that provided incentives for clinics and hospitals to have *Feraheme* available. We expect clinics and hospitals to continue to take advantage of such incentives in the future, which may result in uneven purchasing patterns, causing *Feraheme* sales to fluctuate in subsequent quarters.

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

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

- The impact of the FDA s decision on our sNDA for *Feraheme* for the treatment of IDA in a broad range of patients;

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

- The introduction of new competitive products in the iron replacement therapeutic market, such as the July 2013 approval of Injectafer® or potential generic versions of new or currently available drug therapies;

- The effect of federal and other legislation such as The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the Health Care Reform Act, and the Budget Control Act of 2011, including the effect of the recent federal budget sequester on Medicare reimbursement rates which may cause a shift in where patients are treated to sites of care that have a lower mandated price for *Feraheme*, such as 340B institutions;

- The inventory levels maintained by *Feraheme* wholesalers, distributors and clinics or hospitals;

- The frequency of re-orders by existing customers;

- The fees charged, and reserves required, related to fees for services provided to wholesalers, distributors, GPOs and others involved in the purchase or distribution of *Feraheme*;

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

- The impact of any difficulties, disruptions or delays in the manufacturing process for *Feraheme*/*Rienso*; 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.

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License Fee and Other Collaboration Revenues

License fee and other collaboration revenues for the three months ended September 30, 2013 and 2012 consisted of the following (in thousands):

	Three Months Ended September 30,			
	2013	2012	$ Change	% Change
Deferred license fee revenues recognized from Takeda	$ 1,974	$ 1,524	$ 450	30%
Reimbursement revenues from Takeda	24	42	(18)	-43%
Total	$ 1,998	$ 1,566	$ 432	28%

Our license fee and other collaboration revenues in the three months ended September 30, 2013 increased by $0.4 million as compared to the same period in 2012 primarily as the result the recognition of $0.5 million of revenue during the three months ended September 30, 2013, which represents the amortized portion of an aggregate of $18.0 million in milestone payments we received from Takeda during the second half of fiscal 2012 related to the commercial launches of *Feraheme*/*Rienso* in Canada and the EU. At the time of receipt, we determined that the $18.0 million milestone payments were considered non-substantive milestones and are amortizing them into revenue using the proportional performance method extended over the original life of the Takeda Agreement. We did not receive any non-substantive milestone payments prior to or during the three months ended September 30, 2012. As of September 30, 2013, we had approximately $11.7 million remaining in deferred revenues related to the $18.0 million milestone payments received from Takeda in 2012.

In addition, during each of the three months ended September 30, 2013 and 2012, we recorded $1.5 million of revenues associated with the amortization of $61.0 million of deferred revenues recorded in connection with the original Takeda Agreement. As of September 30, 2013, we had approximately $39.6 million remaining in deferred revenues related to the $61.0 million upfront payments received from Takeda.

We anticipate that our license fee and other collaboration revenues will remain relatively stable for the remainder of 2013 as compared to the three months ended September 30, 2013.

Other Product Sales and Royalties

Other product sales and royalties include product sales of *Feraheme/Rienso* and GastroMARK® to our licensees, product sales of *MuGard* and royalties received from our licensees sales of *Feraheme/Rienso* and *GastroMARK*. The $0.3 million increase in our other product sales and royalties in the three months ended September 30, 2013 as compared to the three months ended September 30, 2012 was due to increased MuGard sales and increased sales and royalty revenue related to the Amended Takeda Agreement, partially offset by decreased *GastroMARK* sales as a result of our 2012 termination of our agreements with our *GastroMARK* licensees. We have since ceased commercially manufacturing and selling *GastroMARK*.

As of September 30, 2013, we had approximately $2.1 million in deferred revenue related to product shipped to Takeda, but not yet sold through to Takeda s customers and $1.9 million in deferred cost of product sales, which are included in our condensed consolidated balance sheet.

We expect other product sales and royalties to increase for the remainder of 2013 as compared to the three months ended September 30, 2013 due to increased *MuGard* sales and increased sales and royalty revenue associated with the Amended Takeda Agreement.

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Costs and Expenses

Cost of Product Sales

Cost of product sales are primarily comprised of manufacturing costs, costs of managing our contract manufacturers, and costs for quality assurance and quality control associated with our sales of *Feraheme* in the U.S., sales of *Feraheme*/*Rienso* to Takeda, and *MuGard* sales, including the amortization expense associated with the *MuGard*-related intangible asset. Cost of product sales, for the three months ended September 30, 2013 and 2012 consisted of the following (in thousands):

	Three Months Ended September 30,			
	2013	2012	$ Change	% Change
Cost of Product Sales	$ 2,547	$ 4,323	$ (1,776)	-41%
Percentage of Net Product Sales and Royalties	13%	27%		

The $1.8 million decrease in our cost of product sales for the three months ended September 30, 2013 as compared the three months ended September 30, 2012 was attributable to the following factors:

- $1.7 million decrease primarily related to the 2012 closure of our Cambridge, Massachusetts manufacturing facility;
- $0.3 million decrease due to a lower average cost per vial sold, partially offset by higher volume of *Feraheme* vials sold; and
- $0.2 million increase related to sales of *Feraheme*/*Rienso* to Takeda.

We expect our cost of product sales as a percentage of net product sales and royalties to remain relatively consistent for the remainder of 2013 as compared to the three months ended September 30, 2013.

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Research and Development Expenses

Research and development expenses for the three months ended September 30, 2013 and 2012 consisted of the following (in thousands):

	Three Months Ended September 30, 2013	2012	$ Change	% Change
External Research and Development Expenses				
Feraheme to treat IDA in CKD patients	$ 1,068	$ 841	$ 227	27%
Feraheme to treat IDA regardless of the underlying cause	(34)	(340)	306	90%
Feraheme as a therapeutic agent, general	238	432	(194)	-45%
Feraheme manufacturing process development and materials	327	727	(400)	-55%
Other external costs	217	33	184	>100%
Total	$ 1,816	$ 1,693	$ 123	7%
Internal Research and Development Expenses				
Compensation, payroll taxes, benefits and other expenses	2,377	3,094	(717)	-23%
Equity-based compensation expense	337	473	(136)	-29%
Total	$ 2,714	$ 3,567	$ (853)	-24%
Total Research and Development Expenses	$ 4,530	$ 5,260	$ (730)	-14%

Total research and development expenses incurred in the three months ended September 30, 2013 decreased by $0.7 million, or 14%, as compared to the three months ended September 30, 2012. The $0.7 million decrease was primarily due to decreased internal research and development costs of $0.9 million in the three months ended September 30, 2013 as compared to the same period in 2012, partially offset by increased external research and development costs of $0.1 million in the three months ended September 30, 2013, as discussed below.

The $0.1 million increase in our external research and development expenses for the three months ended September 30, 2013 as compared to the three months ended September 30, 2012, was due primarily to the following reasons:

- $0.3 million overall increase in expenses associated with our Phase III clinical development program for *Feraheme* to treat IDA regardless of the underlying cause due to a $1.2 million credit recorded in the three months ended September 30, 2012 primarily related to cost savings below the contracted rates passed on by a certain third-party service provider, which resulted in changes in estimated clinical trial costs, partially offset by $0.9 million decrease in costs incurred for our IDA program in 2013;

- $0.2 million increase in costs associated with our CKD-related clinical trials; and

- $0.4 million decrease in costs related to manufacturing process improvement activities.

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The $0.9 million, or 24%, decrease in internal research and development expenses in the three months ended September 30, 2013 as compared to the three months ended September 30, 2012 was primarily attributable to the decrease in compensation and related benefits following our 2012 corporate restructurings, which resulted in lower headcount in our research and development departments.

We expect research and development expenses to increase during the remainder of 2013 as compared to the three months ended September 30, 2013, primarily due to expenses associated with our clinical trial to determine the safety and efficacy of repeat doses of ferumoxytol for the treatment of IDA in patients with hemodialysis-dependent CKD, which began enrollment in 2013, and increased development costs related to manufacturing process improvement activities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2013 and 2012 consisted of the following (in thousands):

	Three Months Ended September 30,			
	2013	2012	$ Change	% Change
Compensation, payroll taxes and benefits	$ 5,398	$ 5,034	$ 364	7%
Sales and marketing consulting, professional fees, and other expenses	3,042	2,620	422	16%
General and administrative consulting, professional fees and other expenses	5,191	2,981	2,210	74%
Equity-based compensation expense	1,303	1,525	(222)	-15%
Total	$ 14,934	$ 12,160	$ 2,774	23%

Total selling, general and administrative expenses incurred in the three months ended September 30, 2013 increased by $2.8 million, or 23%, as compared to the three months ended September 30, 2012 for the following reasons:

- $0.4 million increase in compensation, payroll taxes and benefits primarily due to increased headcount in our sales and marketing organizations;

- $0.4 million increase in sales and marketing consulting, professional fees, and other expenses primarily due to increased consulting costs related to the acquisition and commercialization of *MuGard;*

- $2.2 million increase in general and administrative consulting, professional fees and other expenses primarily due to $1.2 million of accelerated depreciation expense related to certain leasehold improvements and furniture and fixtures associated with our prior office facility, $0.4 million of costs associated with the relocation of our corporate headquarters, a $0.3 million adjustment in the third quarter of 2013 to our contingent consideration liability associated with the MuGard Rights, and approximately $0.5 million of increased costs associated with consulting, business development and other legal-related activities; and

- $0.2 million decrease in equity-based compensation expense.

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We expect total selling, general and administrative expenses will decrease slightly for the remainder of 2013 as compared to the three months ended September 30, 2013 due to the non-recurring nature of certain expenses incurred during the three months ended September 30, 2013 related to the relocation of our corporate headquarters.

Other Income (Expense)

Other income (expense) for the three months ended September 30, 2013 and 2012 consisted of the following (in thousands):

	Three Months Ended September 30,			
	2013	2012	$ Change	% Change
Interest and dividend income, net	$ 246	$ 295	$ (49)	-17%
Gains (losses) on investments, net	4	2	2	100%
Total	$ 250	$ 297	$ (47)	-16%

We expect other income (expense) for the remainder of 2013 to remain relatively consistent as compared to the three months ended September 30, 2013.

Net Loss

For the reasons stated above, we incurred a net loss of $0.1 million, or $0.01 per basic and diluted share, for the three months ended September 30, 2013 as compared to a net loss of $4.0 million, or $0.19 per basic and diluted share, for the three months ended September 30, 2012.

Results of Operations - Nine Months Ended September 30, 2013 and 2012

Revenues

Total revenues for the nine months ended September 30, 2013 and 2012 consisted of the following (in thousands):

	Nine Months Ended September 30,			
	2013	2012	$ Change	% Change
U.S. *Feraheme* product sales, net	$ 52,381	$ 43,906	$ 8,475	19%
License fee and other collaboration revenues	6,056	19,911	(13,855)	-70%

Other product sales and royalties	708	417	291	70%
Total	$ 59,145	$ 64,234	$ (5,089)	-8%

Total revenues during the nine months ended September 30, 2013 decreased by $5.1 million as compared to the same period in 2012, primarily as the result of our receipt of a $15.0 million milestone payment earned by us in June 2012, partially offset by a $8.5 million increase in U.S. net *Feraheme* product sales, a $1.1 million increase in license fee and other collaboration revenues associated with our

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collaboration agreement with Takeda, and a $0.3 million increase in other product sales and royalties. Included in our net product sales for each of the nine months ended September 30, 2013 and 2012 was a $0.6 million reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales, as discussed below. In addition, our net product sales for the nine months ended September 30, 2012 included the impact of a $2.1 million reduction of our estimated product return reserve, as discussed below.

U.S. Feraheme Product Sales, Net

U.S. *Feraheme* product sales and product sales allowances and accruals for the nine months ended September 30, 2013 and 2012 consisted of the following (in thousands):

	Nine Months Ended September 30,					
	2013	Percent of gross U.S. Feraheme product sales	2012	Percent of gross U.S. Feraheme product sales	$ Change	% Change
Gross U.S. *Feraheme* product sales	$ 87,541		$ 65,474		$ 22,067	34%
Less provision for product sales allowances and accruals						
Discounts and chargebacks	26,925	31%	19,382	30%		
Government and other rebates	8,106	9%	4,487	7%		
Medicaid rebate reserve adjustment	(568)	-1%	(621)	-1%		
Returns	697	1%	(1,680)	-3%		
Total	35,160	40%	21,568	33%		
Net U.S. *Feraheme* product sales	$ 52,381		$ 43,906		$ 8,475	19%

Our gross U.S. *Feraheme* product sales increased by $22.1 million during the nine months ended September 30, 2013 as compared to the same period in 2012. Of the $22.1 million increase, $15.7 million was due to increased units sold and $6.4 million was due to price increases. This increase was partially offset by $11.5 million of additional allowances and accruals in 2013, excluding a $2.1 million reduction of our estimated product return reserves for the nine months ended September 30, 2012 and a $0.6 million reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales for the each of the nine months ended September 30, 2013 and 2012, as described below. As a result of these factors, total net U.S. *Feraheme* product sales increased by $8.5 million during the nine months ended September 30, 2013 as compared to the same period in 2012.

As noted above, during each of the nine months ended September 30, 2013 and 2012, we reduced our estimated Medicaid rebate reserve related to prior *Feraheme* sales by approximately $0.6 million based on actual product-specific rebate claims received since the launch of *Feraheme* in 2009, our expectations of state level activity, and estimated rebate claims not yet submitted. As a result, the Medicaid rebate reserves adjustment applied to gross U.S. *Feraheme* product sales for each of the nine months ended September 30, 2013 and 2012 was a credit of $0.6 million, resulting in an increase to product sales during those periods. In addition, during the nine months ended September 30, 2012, we reduced our reserve for product returns by approximately $2.1 million due to lower expected rate of product returns based on returns experience developed to date as well as the lapse of the product return period on certain manufactured *Feraheme* lots that carried a two-year expiration. As a result, the product returns provision

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applied to gross U.S. *Feraheme* product sales for the nine months ended September 30, 2012 was a credit of $1.7 million resulting in an increase to product sales during that period. We did not make any adjustment to our reserve for product returns during the nine months ended September 30, 2013.

Total discounts and chargebacks in the nine months ended September 30, 2013 were $26.9 million, or 31% of total gross U.S. *Feraheme* product sales, as compared to $19.4 million, or 30%, in the same period of 2012. The increase in total discounts and chargebacks as a percentage of gross U.S. *Feraheme* product sales was related primarily to a change in our customer mix.

Total government and other rebates (excluding any changes in estimates related to Medicaid rebate reserves) were $8.1 million, or 9% of total gross U.S. *Feraheme* product sales, in the nine months ended September 30, 2013 as compared to $4.5 million, or 7%, in the nine months ended September 30, 2012. The increase in total government and other rebates as a percentage of gross U.S. *Feraheme* product sales was related primarily to increased sales to clinics and hospitals that had volume or market share contracts with us during the nine months ended September 30, 2013 as compared to same period in 2012.

An analysis of the amount of, and change in, reserves for the nine months ended September 30, 2013 and 2012 is as follows (in thousands):

	Discounts	Rebates and Fees	Returns	Total
Balance at January 1, 2013	$ 1,771	$ 2,430	$ 1,018	$ 5,219
Current provisions relating to sales in current year	26,925	8,106	697	35,728
Adjustments relating to sales in prior years		(568)		(568)
Payments/returns relating to sales in current year	(26,314)	(5,116)		(31,430)
Payments/returns relating to sales in prior years	(202)	(1,565)	(9)	(1,776)
Balance at September 30, 2013	$ 2,180	$ 3,287	$ 1,706	$ 7,173

	Discounts	Rebates and Fees	Returns	Total
Balance at January 1, 2012	$ 1,822	$ 3,101	$ 2,842	$ 7,765
Current provisions relating to sales in current year	19,382	4,581	413	24,376
Adjustments relating to sales in prior years		(715)	(2,093)	(2,808)
Payments/returns relating to sales in current year	(17,446)	(3,239)		(20,685)
Payments/returns relating to sales in prior years	(1,859)	(1,584)	(308)	(3,751)
Balance at September 30, 2012	$ 1,899	$ 2,144	$ 854	$ 4,897

During the nine months ended September 30, 2013 and 2012, we decreased our product sales allowances and accruals by approximately $0.6 million and $2.8 million for changes in estimates relating to sales in prior years. The $0.6 million of adjustments in the nine months ended September 30, 2013 were primarily caused by differences between actual Medicaid utilization and claims experience to date as compared to our initial estimates. The $2.8 million of adjustments in the nine months ended September 30, 2012 were primarily caused by the reduction of our reserve by $2.1 million for previously reserved returns, as well as the lapse of the return period on certain manufactured *Feraheme* lots that carried a two-year expiration. Additionally, $0.6 million of the $2.8 million of adjustments was due to differences between actual Medicaid utilization and claims experience to date as compared to our initial estimates.

Recent Healthcare Reform Legislation

The Health Care Reform Act was enacted in the U.S. 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

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Medicaid managed care organizations as well as the expansion of the 340B Drug Discount Program under the Public Health Service Act. This legislation contains provisions that can affect the operational results of companies in the pharmaceutical industry, including us, and other healthcare related industries by requiring them to pay additional rebate costs.

The Health Care Reform Act also requires pharmaceutical manufacturers to pay a prorated share of the overall Branded Drug Fee, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the legislation. The amount of our annual share of the Branded Drug Fee for each of 2013 and 2012 was less than $0.1 million and these payments were non-deductible for income tax purposes. We have included these amounts in selling, general and administrative expense in our condensed consolidated statements of operations. The amount of this annual payment could increase in future years due to both higher eligible *Feraheme* sales and the increasing amount of the overall fee assessed across manufacturers, but any such increases are not expected to be material to our results of operations or financial condition.

In addition, the number of 340B institutions, which provide drugs at reduced rates, was expanded by the Health Care Reform Act to include additional hospitals. As a result, the volume of *Feraheme* business sold to 340B eligible entities has increased since the implementation of the Health Care Reform Act Because these institutions are eligible for federal pricing discounts, the revenue realized per unit of *Feraheme* sold to 340B institutions is lower than from our other customers.

Further, under the sequestration required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, Medicare payments for all items and services under Parts A and B incurred on or after April 1, 2013 have been reduced by up to 2%. Therefore, after adjustment for deductible and co-insurance, the reimbursement rate for physician-administered drugs, including *Feraheme*, under Medicare Part B has been reduced from average selling price, or ASP, plus 6% to ASP plus 4.3%. Because the majority of our business is through hematology/oncology clinics and out-patient hospital infusion centers, this reduction in the Medicare reimbursement payment for *Feraheme* may adversely impact our future revenues. We have not determined the magnitude of the impact of this reduction in the Medicare reimbursement rate on our net sales; however, beginning in April 2013, we amended certain of our customer contracts to try to partially address the impact of sequestration on our customers and their patients. These amendments have led to increased discounts and rebates.

License Fee and Other Collaboration Revenues

License fee and other collaboration revenues for the nine months ended September 30, 2013 and 2012 consisted of the following (in thousands):

	Nine Months Ended September 30,			
	2013	2012	$ Change	% Change
Milestone revenues recognized from Takeda	$	$ 15,000	$ (15,000)	-100%
Deferred license fee revenues recognized from Takeda	5,922	4,572	1,350	30%
Reimbursement revenues from Takeda	134	339	(205)	-60%
Total	$ 6,056	$ 19,911	$ (13,855)	-70%

Our license fee and other collaboration revenues in the nine months ended September 30, 2013 decreased by $13.9 million as compared to the same period in 2012 primarily as the result of the $15.0 million milestone payment earned in June 2012 under the Amended Takeda Agreement upon the marketing authorization granted for ferumoxytol by the European Commission. This $15.0 million

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decrease was partially offset by an additional $1.4 million of revenue recognized during the nine months ended September 30, 2013 as compared to the same period in 2012 as the result of the amortization of the $18.0 million milestone payments we received from Takeda during 2012, as discussed above in *Results of Operations Three Months Ended September 30, 2013 and 2012*. We did not receive any non-substantive milestone payments prior to or during the nine months ended September 30, 2012. In addition, during each of the nine months ended September 30, 2013 and 2012, we recorded $4.6 million of revenues associated with the amortization of $61.0 million of deferred revenues recorded in connection with the original Takeda Agreement, as discussed above.

During the nine months ended September 30, 2013 and 2012, we also recorded $0.1 million and $0.3 million, respectively, of revenues associated with the reimbursement of out-of pocket regulatory and clinical supply costs in connection with the Amended Takeda Agreement.

Other Product Sales and Royalties

Our other product sales and royalties in the nine months ended September 30, 2013 increased by $0.3 million as compared to the nine months ended September 30, 2012 as a result of increased *MuGard* sales and increased sales and royalty revenue related to the Amended Takeda Agreement, partially offset by decreased *GastroMARK* sales to our licensees as a result of the 2012 termination of our agreements with our *GastroMARK* licensees.

Costs and Expenses

Cost of Product Sales

Cost of product sales, for the nine months ended September 30, 2013 and 2012 consisted of the following (in thousands):

	Nine Months Ended September 30,			
	2013	2012	$ Change	% Change
Cost of Product Sales	$ 8,634	$ 10,193	$ (1,559)	-15%
Percentage of Net Product Sales and Royalties	16%	23%		

The $1.6 million decrease in our cost of product sales for the nine months ended September 30, 2013 as compared to the nine months ended September 30, 2012 and was attributable to the following factors:

- $3.4 million decrease due to the 2012 closure of our Cambridge, Massachusetts manufacturing facility and other related production costs;

- $0.8 million increase due to the sale of pre-approval validation lots in the nine months ended September 30, 2012, which in accordance with our capitalization policy, excluded costs that had been expensed prior to FDA approval of the manufacturing process;

- $0.5 million increase due to a write-off of inventory that was affected by a voluntary recall of a specific batch of *Rienso* from the Swiss market in May 2013;

- $0.3 million increase due to the higher volume of *Feraheme* vials sold, partially offset by a lower average cost per vial sold; and

- $0.2 million increase related to sales of *Feraheme/Rienso* to Takeda and *GastroMARK* sales.

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Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2013 and 2012 consisted of the following (in thousands):

	Nine Months Ended September 30, 2013	2012	$ Change	% Change
External Research and Development Expenses				
Feraheme to treat IDA in CKD patients	$ 2,633	$ 2,836	$ (203)	-7%
Feraheme to treat IDA regardless of the underlying cause	64	8,682	(8,618)	-99%
Feraheme as a therapeutic agent, general	586	604	(18)	-3%
Feraheme manufacturing process development and materials	1,267	1,945	(678)	-35%
Other external costs	518	111	407	>100%
Total	$ 5,068	$ 14,178	$ (9,110)	-64%
Internal Research and Development Expenses				
Compensation, payroll taxes, benefits and other expenses	7,281	9,795	(2,514)	-26%
Equity-based compensation expense	1,634	1,420	214	15%
Total	$ 8,915	$ 11,215	$ (2,300)	-21%
Total Research and Development Expenses	$ 13,983	$ 25,393	$ (11,410)	-45%

Total research and development expenses incurred in the nine months ended September 30, 2013 decreased by $11.4 million, or 45%, as compared to the nine months ended September 30, 2012. The $11.4 million decrease was primarily due to reduced external research and development costs of $9.1 million. In addition, internal research and development costs decreased by $2.3 million in the nine months ended September 30, 2013 as compared to the same period in 2012.

The $9.1 million decrease in our external research and development expenses for the nine months ended September 30, 2013 as compared to the nine months ended September 30, 2012, was due primarily to the following reasons:

- $8.6 million decrease in costs incurred in connection with our Phase III clinical development program for *Feraheme* to treat IDA regardless of the underlying cause, which was completed in 2012. This decrease also reflects a $1.2 million credit from a certain third-party service provider recorded during the nine months ended September 30, 2012 related to changes in estimated clinical trial costs for *Feraheme* to treat IDA regardless of the cause, partially offset by a $0.5 million credit received in the nine months ended September 30, 2013 to close out our *Feraheme* IDA program;

- $0.7 million decrease in manufacturing-related costs due primarily to the write-off of $0.6 million of pre-approval inventory in 2012 which was produced to validate the manufacturing process at third-party suppliers and which we no longer believed was suitable for sale; and

- $0.2 million decrease in costs associated with our CKD-related clinical trials.

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The $2.3 million, or 21%, decrease in internal research and development expenses in the nine months ended September 30, 2013 as compared to the nine months ended September 30, 2012 was primarily attributable to the decrease in compensation and related benefits following our 2012 corporate restructurings, which resulted in lower headcount in our research and development departments.

Research and Development Activities

We do not track our internal costs by project since our research and development personnel work on a number of projects concurrently and much of our fixed costs benefit multiple projects or our operations in general. We track our external costs on a major project basis, in most cases through the later of the completion of the last trial in the project or the last submission of a regulatory filing to the FDA or applicable foreign regulatory body. The following major research and development project was currently ongoing as of September 30, 2013:

- *Feraheme* to treat IDA in CKD patients. This project currently includes: (1) a completed clinical study evaluating *Feraheme* treatment as compared to treatment to another IV iron to support the 2010 MAA submission; (2) a pediatric study that is 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 completed in accordance with our approved pediatric investigation plan to support the MAA submission; (4) an ongoing multi-center clinical trial to determine the safety and efficacy of repeat doses of *Feraheme* for the treatment of IDA in patients with hemodialysis-dependent CKD, including a treatment arm with iron sucrose using an MRI sub-analysis to evaluate the potential for iron to accumulate in the body following repeated IV iron administration.

Through September 30, 2013, we have incurred aggregate external research and development expenses of approximately $26.5 million related to our current program for the development of *Feraheme* to treat IDA in CKD patients. We currently estimate that the total remaining external costs associated with this development project will be in the range of approximately $20.0 to $30.0 million over the next several years.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the nine months ended September 30, 2013 and 2012 consisted of the following (in thousands):

	Nine Months Ended September 30,			
	2013	2012	$ Change	% Change
Compensation, payroll taxes and benefits	$ 16,989	$ 17,992	$ (1,003)	-6%
Sales and marketing consulting, professional fees, and other expenses	9,208	8,646	562	7%
General and administrative consulting, professional fees and other expenses expenses	13,784	10,110	3,674	36%
Equity-based compensation expense	4,169	3,694	475	13%
Total	$ 44,150	$ 40,442	$ 3,708	9%

Total selling, general and administrative expenses incurred in the nine months ended September 30, 2013 increased by $3.7 million, or 9%, as compared to the nine months ended September 30, 2012 for the following reasons:

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- $1.0 million decrease in compensation, payroll taxes and benefits due to reduced headcount in our sales and marketing functions and the correspondingly lower compensation and benefit expenses;

- $0.6 million increase in sales and marketing consulting, professional fees, and other expenses primarily due to increased consulting costs related to the acquisition and commercialization of *MuGard*;

- $3.7 million increase in general and administrative consulting, professional fees and other expenses primarily due to $1.9 million of accelerated depreciation expense related to certain leasehold improvements and furniture and fixtures associated with our prior office facility, $0.4 million of costs associated with the relocation of our corporate headquarters, $0.8 million of transaction and other costs related to the acquisition of the MuGard Rights, $0.8 million of increased costs associated with consulting, business development and other legal-related activities, and $0.6 million of costs related to the closure of our Cambridge, Massachusetts manufacturing facility. These increased costs were partially offset by $1.6 million in termination fees which we paid during the second quarter of 2012 to our *GastroMARK* licensees in connection with the termination our license agreements with them; and

- $0.5 million increase in equity-based compensation expense due primarily to the expense associated with equity awards to new and existing employees.

Other Income (Expense)

Other income (expense) for the nine months ended September 30, 2013 and 2012 consisted of the following (in thousands):

	Nine Months Ended September 30,			
	2013	**2012**	**$ Change**	**% Change**
Interest and dividend income, net	$ 773	$ 1,026	$ (253)	-25%
Gains on sale of asset	865		865	N/A
Gains (losses) on investments, net	36	(1,469)	1,505	>100%
Total	$ 1,674	$ (443)	$ 2,117	>100%

Other income (expense) for the nine months ended September 30, 2013 increased by $2.1 million as compared to the nine months ended September 30, 2012. This increase was primarily attributable to the non-recurring nature of the June 2012 $1.5 million loss realized on the sale of our then-remaining auction rate securities. Additionally, during the nine months ended September 30, 2013, we recognized $0.5 million of gains in connection with the sale of Combidex®, a molecular imaging agent which we were not actively pursuing development and a $0.4 million gain on the sales of fixed assets related to our Cambridge, Massachusetts manufacturing facility. These increases were partially offset by a decrease in interest and dividend income as the result of lower average cash balances during the nine months ended September 30, 2013 as compared to the same period in 2012.

Net Loss

For the reasons stated above, we incurred a net loss of $5.9 million, or $0.28 per basic and diluted share, for the nine months ended September 30, 2013 as compared to a net loss of $13.1 million, or $0.61 per basic and diluted share, for the nine months ended September 30, 2012.

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Liquidity and Capital Resources

General

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

As of September 30, 2013, our investments consisted of corporate debt securities and U.S. treasury and government agency securities. We place our cash, cash equivalents 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, 2013 and December 31, 2012 consisted of the following (in thousands):

	September 30, 2013	December 31, 2012	$ Change	% Change
Cash and cash equivalents	$ 30,946	$ 46,293	$ (15,347)	-33%
Investments	182,595	180,750	1,845	1%
Total	$ 213,541	$ 227,043	$ (13,502)	-6%

The $13.5 million decrease in cash, cash equivalents and investments as of September 30, 2013 from December 31, 2012 was primarily due to cash expended to fund our operations and working capital and cash used to purchase the MuGard Rights, partially offset by cash received from *Feraheme* sales, other product sales and royalty payments from Takeda and interest income.

During the three months ended September 30, 2013, our cash, cash equivalents and investment balances increased by $1.1 million as compared to the balance as of June 30, 2013. We expect that our cash, cash equivalents and investments balances, in the aggregate, will remain relatively constant from their current balances during the remainder of 2013. Our expectation assumes our continued investment in the development of *Feraheme* and the commercialization of *Feraheme* and *MuGard*. We believe that our cash, cash equivalents and investments as of September 30, 2013 and the cash we currently expect to receive from net products sales of *Feraheme*, earnings on our investments, product sales and royalty payments from Takeda, and net product sales of *MuGard* 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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Cash flows from operating activities

During the nine months ended September 30, 2013, our use of $8.9 million of cash in operations was attributable principally to our net loss of approximately $5.9 million, adjusted for the following:

- Non-cash operating items of $10.8 million including equity-based compensation expense, depreciation and amortization, amortization of premium/discount on purchased securities, gains on the sale of assets, a write-off of inventory, and other non-cash items;

- An aggregate decrease in deferred revenues and other long-term liabilities of $5.3 million;

- An aggregate increase of $1.4 million in accounts receivable, prepaid assets and inventories; and

- An aggregate decrease of $7.0 million in accounts payable and accrued expenses.

Our net loss of $5.9 million was primarily the result of compensation to employees, commercialization expenses, including marketing and promotion costs, research and development costs, including costs associated with our clinical trials, and general and administrative costs, partially offset by net product sales and collaboration revenues.

Cash flows from investing activities

Cash used in investing activities in the nine months ended September 30, 2013 was $8.2 million and was primarily attributable to the purchases of investments, partially offset by proceeds from the sales and maturities of our investments. In addition, we used $3.4 million of available cash and cash equivalents to purchase the MuGard Rights and related inventory and approximately $1.2 million to purchase leasehold improvements and furniture and fixtures for our new corporate headquarters.

Cash flows from financing activities

Cash provided by financing activities in the nine months ended September 30, 2013 was $1.8 million and was primarily attributable to the proceeds from the exercise of stock options.

Contractual Obligations

In June 2013, we entered into a lease agreement with BP Bay Colony LLC, or the Landlord, for the lease of certain real property located at 1100 Winter Street, Waltham, Massachusetts, or the Premises, for use as our principal executive offices. The initial term of the lease is five years and two months with one five-year extension term at our option. During the extension period, the base rent will be an amount agreed upon by us and the Landlord. In addition to base rent, we are also required to pay a proportionate share of the Landlord s operating costs. The Landlord agreed to pay for certain agreed-upon improvements and we agreed to pay for any increased costs due to changes by us to the agreed-upon plans. In connection with our relocation, we purchased $1.4 million of leasehold improvements and furniture and fixtures related to our new facility.

In addition, in connection with our new facility lease, in June 2013 we delivered to the Landlord a security deposit of approximately $0.4 million in the form of an irrevocable letter of credit. This security deposit will be reduced to $0.3 million on the second anniversary of the date the lease commenced.

In June 2013, we also entered into an Assignment and Assumption of Lease, or the Assignment Agreement, with Shire Human Genetic Therapies, Inc., or Shire, effecting the assignment to Shire of the right to occupy our prior office space located at 100 Hayden Avenue, Lexington, Massachusetts, or the Prior Space. Under the Assignment Agreement, the assignment to Shire became effective on September 21, 2013, the date of our departure from the Prior Space, and Shire assumed all of our obligations as the

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tenant of the Prior Space. The Assignment Agreement also provided for the conveyance of furniture and other personal property by us to Shire.

We do not believe that the obligation of the new lease terms are materially different from our prior lease assumed by Shire. See Note M to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information regarding our new facility-related agreements, including payment obligations under the initial term of our lease with the Landlord.

Off-Balance Sheet Arrangements

As of September 30, 2013, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

Critical Accounting Policies

Our management s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make certain estimates and assumptions that affect the reported amount of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The most significant estimates and assumptions are used in, but are not limited to, revenue recognition related to product sales and collaboration agreements, product sales allowances and accruals, assessing investments for potential other-than-temporary impairment and determining values of investments, the fair value of our assets held for sale, contingent consideration, the impairment of long-lived assets, including intangible assets, accrued expenses and equity-based compensation expense. Actual results could differ materially from those estimates. In making these estimates and assumptions, management employs critical accounting policies. Our critical accounting policies include revenue recognition and related sales allowances, valuation of investments, business combinations, intangible assets, contingent consideration, and equity-based compensation. For a detailed description, refer to our critical accounting policies included in Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations of our Annual Report and Note B to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. Other than the following, there have been no material changes to our critical accounting policies discussed in our Annual Report.

Business Combination

In June 2013, we acquired the MuGard Rights and inventory for total consideration of $17.1 million, consisting of a cash payment of $3.4 million and contingent consideration with an estimated fair value of $13.7 million. The transaction was accounted for as a business combination under the acquisition method of accounting, which requires, with limited exceptions, that assets acquired and liabilities assumed be recognized at their estimated fair values as of the Acquisition Date. Transaction costs are expensed as incurred. Any excess of the consideration transferred over the estimated values of the net assets acquired is recorded as goodwill.

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The following table summarizes the estimated fair values of the assets acquired related to the MuGard Rights as of the Acquisition Date (in thousands):

Assets Acquired:		
MuGard intangible asset	$	16,893
Inventory		241
Net identifiable assets acquired	$	17,134

We recorded $16.9 million of finite-lived intangible assets related to the MuGard Rights, which is being amortized using an economic consumption model over ten years, which represents our best estimate of the period over which we expect the majority of the asset s cash flows to be derived. The fair value of the acquired *MuGard* intangible asset was determined using an income approach, including a discount rate of 19%. This approach begins with a forecast of the net cash flows expected to be generated by the asset over its estimated useful life. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. Some of the more significant estimates and assumptions inherent in the income approach include the following:

- The amount and timing of projected future cash flows, adjusted for the probability of marketing success;
- The discount rate selected to measure the risks inherent in the future cash flows; and
- An assessment of the asset s life-cycle and the competitive trends impacting the asset.

Estimating the fair value of assets acquired in a business combination requires significant judgment. We believe the estimated fair values of the assets acquired are based on reasonable assumptions.

Intangible Assets and Impairment

Intangible assets represent the fair value of the MuGard Rights. We will amortize these assets using an economic consumption model over ten years. We believe this is the best approximation of the period over which we will derive the majority of value of the MuGard Rights. Intangible assets are reviewed for impairment at least annually and whenever facts or circumstances suggest that the carrying value of these assets may not be recoverable. Our policy is to identify and record impairment losses, if necessary, on intangible assets when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets.

Acquisition Related Contingent Consideration

The acquisition of the MuGard Rights included contingent consideration to be paid to Access based on the occurrence of future events, in particular the payment of royalties to Access. Acquisition-related contingent consideration is initially recognized at fair value and then remeasured each reporting period, with changes in fair value recorded in our condensed consolidated statements of operations. During the three months ended September 30, 2013, we completed the valuation for the acquisition of the MuGard Rights. Some of the amounts previously estimated have changed during the measurement period, including the amounts and timing of cash flows related to the royalties we expect to pay to Access under the Access License Agreement. As a result of these changes, the fair value of the contingent consideration has been determined to be $13.7 million as the Acquisition Date. The revised Acquisition Date fair value of the contingent consideration was determined based on various market factors, including an analysis of estimated sales using a discount rate of approximately 15%. Each quarter we will revalue the contingent

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consideration obligations associated with the acquisition of the MuGard Rights to their then fair value and record increases in the fair value as contingent consideration expense and record decreases in their fair value as a reduction of contingent consideration expense. Changes in contingent consideration expense result from changes in the assumptions regarding probabilities of the estimated timing and amount of royalty payments to Access and the discount rate used to estimate the fair value of the liability. Contingent consideration expense may change significantly as we gain more information related to sales of *MuGard*, impacting our assumptions. The assumptions used in estimating fair value require significant judgment. The use of different assumptions and judgments could result in a materially different estimate of fair value.

Impact of Recently Issued and Proposed Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board issued an amendment to the accounting guidance for the reporting of amounts reclassified out of accumulated other comprehensive income, or AOCI. The amendment expands the existing disclosure by requiring entities to present information about significant items reclassified out of AOCI by component. In addition, an entity is required to provide information about the effects on net income of significant amounts reclassified out of each component of AOCI to net income either on the face of the income statement or as a separate disclosure in the notes of the financial statements. The amendment is effective for annual or interim reporting periods beginning after December 31, 2012. The adoption of this accounting pronouncement did not have a material impact on our financial statement disclosures. See Note J to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information regarding AOCI.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

There have been no material changes with respect to the information appearing in Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk, of our Annual Report.

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.

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Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the three months ended September 30, 2013 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

A purported class action complaint was originally filed on March 18, 2010 in the U.S. 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 Chief Financial Officer, the then-members of our Board of Directors, or Board , 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 Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged omissions in a registration statement filed in January 2010. The plaintiffs 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 and 15, 2011, respectively, the District Court issued an Opinion and Order dismissing the SAC with prejudice 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 U.S. Court of Appeals for the First Circuit, or the Court of Appeals. The Court of Appeals heard oral argument on May 11, 2012. On February 4, 2013, the Court of Appeals affirmed in part and reversed in part the District Court s Opinion and Order and remanded the case to the District Court. On February 19, 2013, we filed a Petition for Panel Rehearing and Rehearing *En Banc*, which was denied on March 15, 2013. On March 22, 2013, we filed a Motion to Stay the Mandate remanding the case to the District Court pending review by the U.S. Supreme Court of the Court of Appeals February 4, 2013 decision. The Court of Appeals granted the Motion to Stay the Mandate on April 8, 2013. On June 13, 2013, we filed a Petition for a Writ of Certiorari, or the Petition, with the U.S. Supreme Court seeking review of the Court of Appeal s decision and to have that decision overturned. On October 7, 2013 the U.S. Supreme Court denied our Petition, resulting in the case s return to the District Court for further proceedings relative to the SAC s surviving claims. Our response to the SAC is due on or before November 6, 2013. The plaintiffs will submit an opposition to our response on or before December 6, 2013.

In July 2010, Sandoz GmbH, or Sandoz, filed with the European Patent Office, or the EPO, an opposition to a previously issued patent which covers ferumoxytol in EU jurisdictions. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked this patent. In December 2012, our notice of appeal of that decision was recorded with the EPO, which also suspended the revocation of our patent. On May 13, 2013, we filed a statement of grounds of appeal and on September 27, 2013, Sandoz filed a response to that statement. We will continue to defend the validity of this patent throughout the appeals process, which we expect to take two to three years. However, in the event that we do not experience a successful outcome from the appeals process, under EU regulations ferumoxytol would still be entitled to eight years of data protection and ten years of market exclusivity from the date of approval, which we believe would create barriers to entry for any generic version of ferumoxytol into the EU market until sometime between 2020 and 2022. This decision had no impact on our revenues for the nine months ended September 30, 2013. However, any future unfavorable outcome in this matter could negatively affect the magnitude and timing of future revenues, including royalties and milestone payments we may receive from Takeda pursuant to our collaboration agreement with Takeda. We continue to believe the patent is valid and intend to vigorously appeal the decision.

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In July 2013, we submitted a Citizen Petition to the FDA regarding its December 2012 draft guidance providing product-specific bioequivalence recommendations for generic versions of ferumoxytol injection. In the Citizen Petition, we requested that the FDA (i) refrain from approving any abbreviated new drug application referencing *Feraheme* until certain post-market contract studies on Nulecit , the only U.S. approved generic IV iron product, have been completed and have demonstrated that the FDA s proposed pre-market approval standards for generic IV iron formulations are sufficient to ensure therapeutic equivalence, including comparable tissue distribution and no more *in vivo* labile iron leakage than the reference listed drug, or RLD; and (ii) require that any sponsors of proposed generic versions of *Feraheme* show that their products are equivalent to the RLD using (a) a comparative study in patients using clinical endpoints and (b) the additional assays that FDA has described for the proposed Nulecit post-market contract studies. We cannot predict when or if the FDA will respond to, or otherwise take any action with respect to, the Citizen Petition.

See Note M to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information regarding our legal proceedings, including how we accrue liabilities for legal contingencies.

Item 1A. Risk Factors:

We are primarily dependent on the success of Feraheme/Rienso.

We currently derive and expect to continue to derive substantially all of our revenue from sales of *Feraheme/Rienso* by us in the U.S. and by our licensees, including Takeda Pharmaceutical Company Limited, or Takeda, outside of the U.S. and, therefore, our ability to become profitable is primarily dependent on our and our licensees successful commercialization and development of *Feraheme/Rienso.* Accordingly, if we are unable to generate sufficient revenues from sales of *Feraheme/Rienso,* or from milestone payments and royalties we may receive related to *Feraheme/Rienso*, we may never be profitable, our financial condition will be materially adversely affected, and our business prospects will be limited.

We intend to continue to dedicate significant resources to the development and commercialization of *Feraheme/Rienso*. However, we or Takeda may not be successful in our efforts to successfully commercialize *Feraheme/Rienso* in its current indication for patients with iron deficiency anemia, or IDA, associated with chronic kidney disease, or CKD, or to expand the approved indication of *Feraheme/Rienso* to include additional indications. In December 2012, we filed a supplemental New Drug Application, or sNDA, in the U.S. for *Feraheme* in patients with IDA, who had failed or could not use oral iron. In September 2013, we received a notification from the U.S. Food and Drug Administration, or the FDA, stating that, as part of its ongoing review of our sNDA, the FDA had identified deficiencies that precluded discussion of labeling and post-marketing requirements or commitments. In response to requests from the FDA, we have submitted additional information to support our sNDA. In October 2013, we received a notification from the FDA stating that the FDA was extending the target date for a decision on the sNDA until January 21, 2014, as described in more detail under the heading *Label Expansion of Ferumoxytol* in Item 2 above. This represents a three-month extension of the prior target date of October 21, 2013 originally set by the FDA under the Prescription Drug User Fee Act, or PDUFA, and is intended to give the FDA time for a full review of additional information related to the review of the sNDA submitted by us in response to FDA requests. During the extension period, we plan to continue our dialogue with the FDA. Potential topics for discussions with the FDA could include, without limitation, technical and scientific information, labeling, post-marketing requirements/commitments, risk evaluation and mitigation strategies in connection with the current CKD and the proposed IDA populations, new studies or re-analyses of existing data. We will need to address any issuesraised by the FDA or provide additional information requested from the FDA in a timely and satisfactory manner in order to obtain approval to market and sell *Feraheme* in the U.S. in patients with IDA who had failed or could not use oral iron. Our responses to issues

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raised by the FDA or additional information requests from the FDA may cause us to incur significant additional costs, experience further delays in our effort to obtain regulatory approval for *Feraheme* in the broader IDA population, or even prevent us from obtaining regulatory approval for *Feraheme* in the broader IDA population or narrow our currently approved indications as discussed in more detail in the following risk factor. This would, in turn, materially adversely impact our cash position, our ability to increase revenues, our ability to achieve profitability, and the future prospects of our business.

In June 2013, Takeda filed a Type II Variation, which is the European Union, or EU, equivalent of a U.S. sNDA, with the European Medicines Agency, or EMA, seeking marketing approval for *Rienso* for the treatment of IDA in adult patients. In addition, in October 2013, Takeda filed a supplemental New Drug Submission, or sNDS, with Health Canada seeking marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients. However, we have little control over Takeda s interactions with the EU or Canadian regulatory agencies and we cannot be assured when or if the EMA or Health Canada will approve the filings. Any failure by Takeda to gain marketing approval for *Feraheme/Rienso* for the treatment of IDA regardless of the underlying cause in a timely manner, or at all, could adversely affect our results of operations or the future prospects of our business.

We are not currently conducting or sponsoring research to expand our product development pipeline beyond *Feraheme/Rienso.* However, we are seeking to complete additional business development transactions, such as in-licensing, acquisitions or collaborations that would be complementary to our business. For example, in June 2013, we acquired the rights to market and sell MuGard® Mucoadhesive Oral Wound Rinse for the management of oral mucositis. Even if we continue to expand our product portfolio, our revenues and operations may not be as diversified as some of our competitors who may have numerous products or product candidates.

Our and Takeda s ability to grow revenues from sales of Feraheme/Rienso could be limited if we or Takeda do not obtain approval, if we or Takeda experience significant delays in our or Takeda s efforts to obtain approval to market and sell Feraheme/Rienso for the treatment of IDA in a broad range of patients, or if we are required to provide additional warnings and/or restrictions related to Feraheme/Rienso s current or future indications.

As discussed above, in December 2012, we submitted a sNDA to the FDA for *Feraheme* for the treatment of IDA in a broad range of patients and in October 2013 we received a notification from the FDA that the FDA extended the target date for a decision on the sNDA until January 21, 2014. If we are unable to adequately address any current or future issues raised by the FDA, we may experience significant delays in our efforts to obtain approval for *Feraheme* in the broader indication or we may not receive approval at all for *Feraheme* in the broader indication. In addition, Takeda filed a Type II Variation with the EMA in June 2013 seeking marketing approval for *Feraheme/Rienso* for the treatment of IDA in adult patients, and in October 2013 Takeda filed a sNDS with Health Canada seeking marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients.

To receive regulatory approval in the U.S. or foreign countries for the commercial marketing and sale of *Feraheme/Rienso* for the broad IDA indication, we have to demonstrate, through extensive human clinical trials, that *Feraheme/Rienso* is safe and effective for use in this broader patient population. Conducting these and other clinical trials is a complex, time-consuming and expensive process that requires adherence to a wide range of regulatory requirements. The FDA and foreign regulatory agencies have substantial discretion in the approval process and may decide that the results of our recently completed clinical trials, the information we submitted with our sNDA, or any information we provide in response to FDA requests, are insufficient for approval or that *Feraheme/Rienso* is not effective or safe in indications other than the treatment of IDA in adult patients with CKD. For example, in our Phase III clinical trial in the broader patient population, *Feraheme*-treated patients experienced a 0.6% rate of related serious adverse events, or

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SAEs, as compared to a 0.2% rate of related SAEs from our current *Feraheme* label for the treatment of IDA in adult patients with CKD. In addition, 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 or EMA approval for their products. The clinical trials for the broader patient population included patients with various underlying conditions, or subpopulations, in addition to having IDA. There is no guarantee that the FDA or EMA will determine that the results of our clinical trials of *Feraheme/Rienso* for the treatment of IDA in adult patients who have failed or could not tolerate oral iron will adequately support approval of *Feraheme/Rienso* in this broader patient population, or any of the individual subpopulations of IDA patients, to grant approval.

The FDA or EMA could also determine that our clinical trials and/or our manufacturing processes were not properly designed, did not include enough patients or appropriate administration, were not conducted in accordance with applicable 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 CROs, or our study sites fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may disqualify certain data generated from those sites or require us to perform additional clinical trials before approving our marketing application, which could adversely impact our ability to obtain marketing approval in the U.S. for *Feraheme/Rienso* in the broad IDA indication. Any such deficiency in the design, implementation or oversight of our clinical development programs could cause us to incur significant additional costs, experience significant delays or prevent us from obtaining marketing approval for *Feraheme/Rienso* for the broad IDA indication.

As a result of any information submitted to the FDA or EMA in our regulatory filings or in response to any information requests or issues raised by the FDA or EMA during the review of our regulatory filings, we may be required to provide additional warnings and/or restrictions on our current or future *Feraheme/Rienso* package inserts, notify healthcare providers of changes to the package insert, narrow our currently approved or proposed indications, alter or terminate current or future trials for *Feraheme/Rienso* or incur significant costs related to post-marketing commitments. Any failure by us or Takeda to obtain approval for the broad IDA indication could adversely affect the commercialization of *Feraheme/Rienso* in its current indication.

If, for any of these or other reasons, we or Takeda do not obtain approval to market and sell *Feraheme/Rienso* for the treatment of IDA in a broad range of patients, if our current indications are narrowed or if we or Takeda experience significant delays in obtaining approval, receive approval with significant restrictions to our current or proposed package inserts, or are required to incur significant costs as post-marketing commitments, our cash position, our ability to increase revenues, our ability to achieve profitability, and the future prospects of our business could be materially adversely affected.

Significant safety or drug interaction problems could result in restrictions in the Feraheme/Rienso label, recalls, withdrawal of Feraheme/Rienso from the market, an adverse impact on Feraheme/Rienso sales, our need to alter or terminate current or future Feraheme development programs, and/or a negative impact on the approval and/or timing of our current or future sNDAs, any of which would adversely impact our future business prospects.

Significant safety or drug interaction problems with respect to *Feraheme/Rienso*, including an increase in the severity or frequency of known problems or the discovery of previously unknown problems, could result in a variety of adverse regulatory actions. In the U.S., under the Food and Drug Administration

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Amendments Act of 2007, 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 the following:

- Requiring manufacturers to conduct post-approval clinical studies to assess known risks or signals of serious risks, or to identify unexpected serious risks;

- Mandating labeling changes to a product based on new safety information; or

- Requiring manufacturers to implement a Risk Evaluation Mitigation Strategy where necessary to assure safe use of the drug.

Similar laws and regulations exist in countries outside of the U.S. In addition, previously unknown safety or drug interaction problems could result in product recalls, restrictions on the product s permissible uses, a negative impact on our current or future sNDAs or withdrawal of the product from the U.S. and/or foreign markets.

For example, in November 2010, following discussions with the FDA, we revised the *Feraheme* package insert, which includes essential information regarding the FDA-approved use of *Feraheme*, including, among other things, the approved indication, side effects, and dosage instructions, to include bolded warnings and precautions that describe events that have been reported during post-marketing review after *Feraheme* administration, including life-threatening hypersensitivity reactions and clinically significant hypotension. We directly alerted healthcare providers of the changes to the *Feraheme* package insert. In 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/Rienso* package insert could adversely impact our or Takeda s ability to successfully compete in the IV iron market and could have an adverse impact on potential sales of *Feraheme* and our future business prospects.

Also, on June 27, 2013 the EMA s Committee for Medicinal Products for Human Use, or CHMP, completed a review of IV iron-containing medications used to treat iron deficiency and anemia. The CHMP concluded that the benefits of these medications are greater than their risks, provided that adequate measures are taken to ensure the early detection and effective management of allergic reactions that may occur. The measures include ensuring that these products be given in an environment where patients who develop an allergic reaction can be treated immediately, ceasing to rely on a lack of allergic reaction to a test dose as an indication of tolerance of larger doses and amendments to the package leaflet. The CHMP recommendation was sent to the European Commission, which on September 13, 2013 endorsed it and adopted a final decision that is legally binding throughout the EU. Although *Rienso* was not included in the evaluation, Takeda intends to adopt the recommendations, including updates to the label in the EU to harmonize *Rienso s* label with those of other IV irons included in the review.

The data submitted to both the FDA as part of our NDA and to the EMA as part of the Marketing Authorization Application for *Feraheme/Rienso* in the CKD indication was obtained in controlled clinical trials of limited duration. New safety or drug interaction issues may arise as *Feraheme/Rienso* is used over longer periods of time by a wider group of patients, some of whom may be taking numerous other medicines or by patients with additional underlying health problems. In addition, as we conduct and complete other clinical trials for *Feraheme*, new safety issues may be identified which could negatively impact our ability to successfully complete these studies, the use and/or regulatory status of *Feraheme/Rienso* for the treatment of IDA in patients with CKD in the U.S., EU or other territories, and the prospects for approval of

current or future sNDAs, such as our December 2012 sNDA submission for *Feraheme* for the treatment of IDA regardless of the underlying cause. For example, the FDA may determine that our sNDA for *Feraheme* for the treatment of IDA in adult patients who have failed or could

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not tolerate oral iron does not establish a sufficiently acceptable safety profile for the approval of a broader *Feraheme* label.

As more data become available and an increased number of patients are treated with *Feraheme/Rienso*, new or increased safety or drug interaction issues may require us to, among other things, provide additional warnings and/or restrictions on the *Feraheme/Rienso* package insert, including a boxed warning in the U.S. or similar warnings outside of the U.S., notify healthcare providers of new safety information, narrow our approved indications, alter or terminate current or future trials for additional uses of *Feraheme*, or even remove *Feraheme/Rienso* from the market, any of which could have a significant adverse impact on potential sales of *Feraheme/Rienso* or require us to expend significant additional funds. For example, in May 2013, Takeda recalled a single batch of *Rienso* from the Swiss market after becoming aware of four post-marketing adverse event reports relating to potential anaphylaxis/hypersensitivity reactions of varying severity following the administration of *Rienso*. One of these cases included a report of a fatality. The marketing authorization for *Rienso* and other IV iron formulations include, among their special warnings and precautions for use, an indication that the products may cause hypersensitivity reactions including serious and life-threatening anaphylactic/anaphylactoid reactions. The recalled batch was only distributed to and sold in Switzerland and the recall was limited to the specific batch in Switzerland. We and Takeda have completed an investigation regarding the specific Swiss batch of *Rienso* and the reported adverse events and Takeda has filed a report with the Swiss Agency for Therapeutic Products, commonly known as SwissMedic. We are currently unable to predict when or if *Rienso* will be reintroduced into the Swiss market.

Competitors could file applications seeking a path to U.S. approval of a generic ferumoxytol.

Under Sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the Federal Food, Drug, and Cosmetic Act, or FDC Act, as amended by The Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Act, a new chemical entity, or NCE, that is granted regulatory approval may be eligible for five years of marketing exclusivity in the U.S. following regulatory approval. A drug can be classified as an NCE if the FDA has not previously approved any other drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. In 2009, the FDA determined that ferumoxytol did not qualify as an NCE and instead granted *Feraheme* a three-year new use market exclusivity, which expired in June 2012. In March 2010 and December 2012, we formally requested that the FDA reconsider its determination with respect to *Feraheme s* NCE status. The FDA may deny our request for reconsideration of NCE status for *Feraheme*, in which case *Feraheme* may be subjected to early generic competition.

NCE status, if granted, would preclude approval during the exclusivity period of certain applications made under Section 505(b)(2) of the FDC Act, as amended by the Hatch-Waxman Act, or a Section 505(b)(2) new drug application, or NDA, and abbreviated new drug application, or ANDA, submitted by another company for another version of the subject drug; however, under governing law an application may be submitted four years after approval of the subject drug (even with a five year exclusivity period prohibiting approval) if it contains a certification of patent invalidity or non-infringement pursuant to Paragraph IV of the Hatch-Waxman Act, or the Paragraph IV certification procedure. In recent years, generic manufacturers have used Paragraph IV certifications extensively to challenge the applicability of Orange Book-listed patents on a wide array of innovative pharmaceuticals, and we expect this trend to continue. If we are not able to gain or exploit marketing exclusivity beyond the initial three year exclusivity period that expired in June 2012, we may face significant future competitive threats to our commercialization of *Feraheme* from other manufacturers, including the manufacturers of generic alternatives through the submission of Section 505(b)(2) NDAs and ANDAs. Further, even if *Feraheme* is granted NCE status and we are able to gain marketing exclusivity until June 2014, another company could challenge that decision and seek to overturn the FDA s determination. Although costly, another

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company could also gain such marketing exclusivity under the provisions of the FDC Act, as amended by the Hatch-Waxman Act, if such company can, under certain circumstances, complete a human clinical trial process and obtain regulatory approval of its product.

In addition, in December 2012, the FDA published draft guidance regarding new draft product-specific bioequivalence for drug products containing ferumoxytol. The FDA generally publishes product-specific bioequivalence guidance after it has received an inquiry from a generic drug manufacturer about submitting an ANDA for the product in question; thus, it is possible that a generic drug manufacturer has approached the FDA requesting guidance about submitting an ANDA for ferumoxytol, the active ingredient in *Feraheme*, and that such an ANDA may be filed in the near future. Because the FDA may deny our request for reconsideration of NCE status for *Feraheme* and because the published bioequivalence guidance could encourage a generic entrant seeking a path to approval of a generic ferumoxytol to file an ANDA, we could face generic competition in the near-term or have to engage in extensive litigation with a generic competitor to protect our patent rights, either of which could adversely affect our business and results of operations. In July 2013, we filed a Citizen Petition in response to the FDA regarding its December 2012 draft guidance, however we cannot predict when or if the FDA will respond to, or otherwise take any action with respect to the Citizen Petition. Companies that manufacture generic products typically invest far fewer resources in research and development than the manufacturers of branded products and can therefore price their products significantly lower than those branded products already on the market. Therefore, competition from generic IV iron products could limit our U.S. sales and any royalties and milestones we may receive from Takeda, which would have an adverse impact on our business and results of operations.

We are completely dependent on third parties to manufacture Feraheme/Rienso and any difficulties, disruptions or delays in the Feraheme/Rienso manufacturing process, including any transition to alternative source manufacturing facilities, could increase our costs, impact our ability to meet our or Takeda s demand forecasts, or adversely affect our profitability and future business prospects.

In 2012, we ceased our manufacturing operations at our Cambridge, Massachusetts manufacturing facility. Consequently, we currently rely solely on our third-party contract manufacturers to manufacture *Feraheme/Rienso* for our commercial and clinical use in the U.S., the EU, Switzerland and Canada. We do not currently have an alternative manufacturer for our *Feraheme/Rienso* drug substance and finished drug product and we may not be able to enter into agreements with second source manufacturers whose facilities and procedures comply with current good manufacturing practices, or cGMP, regulations and other regulatory requirements on a timely basis and with terms that are favorable to us, if at all.

Our ability to have *Feraheme/Rienso* 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 our third-party contract manufacturing facilities. Any difficulties, disruptions or delays in the *Feraheme/Rienso* manufacturing process could result in product defects or shipment delays, recall or withdrawal of product previously shipped for commercial or clinical purposes, inventory write-offs or the inability to meet commercial demand for *Feraheme/Rienso* in a timely and cost-effective manner. Furthermore, our current third-party manufacturer does not manufacture for us exclusively and may exhaust some or all of its resources meeting the demand of other customers. Any potential manufacturing delays resulting from insufficient manufacturing capacity due to scheduling conflicts at our third-party manufacturers to produce sufficient quantities of *Feraheme/Rienso* to meet our demand forecasts or any other difficulties in our manufacturing process could result in our inability to meet our commercial demand for *Feraheme/Rienso*.

In addition, securing additional third-party contract manufacturers for *Feraheme/Rienso* will require significant time for transitioning the necessary manufacturing processes, gaining regulatory approval, and

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for having the appropriate oversight 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/Rienso* in accordance with cGMP. If we are unable to have *Feraheme/Rienso* manufactured on a timely or sufficient basis because of these or other factors, we may not be able to meet commercial demand or our clinical development needs for *Feraheme/Rienso* or may not be able to manufacture *Feraheme/Rienso* in a cost-effective manner, particularly in light of the current fixed price at which we are required to supply *Feraheme/Rienso* to Takeda under our License, Development and Commercialization Agreement, as amended in June 2012, or the Amended Takeda Agreement. As a result, we may lose sales, fail to generate increased revenues, suffer regulatory setbacks and/or we may lose money on our supply of *Feraheme/Rienso* to Takeda, any of which could have an adverse impact on our potential profitability and future business prospects.

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

Our third-party contract manufacturing facilities are subject to cGMP regulations enforced by the FDA and equivalent foreign regulatory regulations and agencies through periodic inspections to confirm such compliance. Our contract manufacturers must continually expend time, money and effort in production, record-keeping and quality assurance and control to ensure that these manufacturing facilities meet applicable regulatory requirements. Failure to maintain ongoing compliance with cGMP or similar regulations and other applicable manufacturing requirements of various U.S. or foreign regulatory agencies could result in, among other things, the issuance of warning letters, fines, the withdrawal or recall of *Feraheme/Rienso* from the marketplace, total or partial suspension of *Feraheme/Rienso* production, the loss of *Feraheme/Rienso* inventory, suspension of the review of our current or any future sNDAs or equivalent foreign filings, enforcement actions, injunctions or criminal prosecution. A government-mandated recall or a voluntary recall could divert managerial and financial resources, could be difficult and costly to correct, could result in the suspension of sales of *Feraheme/Rienso*, and could have a severe adverse impact on our potential profitability and the future prospects of our business. If any U.S. or foreign regulatory agency inspects any of these manufacturing facilities and determines that they are not in compliance with cGMP or similar regulations or our contract manufacturers otherwise determine that they are not in compliance with these regulations, our contract manufacturers could experience an inability to manufacture sufficient quantities of *Feraheme/Rienso* to meet U.S. or foreign demand or incur unanticipated compliance expenditures.

We have also established certain testing and release specifications with the FDA and other foreign regulatory agencies. This release testing must be performed in order to allow the finished product to be used for commercial sale. If our finished product does not meet these release specifications or if the release testing is variable, we may not be able to supply product to meet our projected demand. In addition, variations in the regulatory approval of *Feraheme/Rienso* in the currently approved territories require that our third-party manufacturers follow different manufacturing processes and analytical testing methods. If we are unable to develop, validate, transfer or gain regulatory approval for the new release test, our ability to supply product to the EU will be adversely affected. Such setbacks could have an adverse impact on *Feraheme/Rienso* sales, our potential profitability and the future prospects of our business.

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We may not be able to further expand our product portfolio by entering into additional business development transactions, such as in-licensing arrangements, acquisitions, or collaborations or if such arrangements are entered into they could disrupt our business, decrease our profitability, result in dilution to our stockholders or cause us to incur debt or significant additional expense.

As part of our business strategy to expand our product portfolio and achieve profitability, we are seeking to acquire or in-license other products that we believe would be complementary to our existing business. For example, in June 2013, we entered into a license agreement with Access Pharmaceuticals, Inc., or Access, under which we acquired the U.S. commercial rights to *MuGard*, or the MuGard Rights. We have limited experience with respect to these business development activities and there can be no assurance that we will be able to identify or complete any such transaction in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated financial benefits of any such transaction, including *MuGard*. The valuation methods that we use for any acquired product or business requires significant judgment and assumptions. Actual results and performance of the product or business that we acquire could differ significantly from our original assumptions, especially during the periods immediately following the closing of the transaction. This could have a negative impact on our financial position or results of operations and result in significant one-time charges in future periods. We may not be successful in acquiring or in-licensing a product or product candidate that will provide us with commercial, development and/or financial synergies with *Feraheme* and our current organization such that we will be able to eliminate expenses either from our existing operations or from the cost structure of the acquired product.

In addition, proposing, negotiating and implementing collaborations, in-licensing arrangements or acquisition agreements may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for these arrangements, and we may not be able to enter into such arrangements on acceptable terms or at all. Further, any such strategic transactions by us could result in large and immediate write-offs or the incurrence of debt and contingent liabilities, any of which could adversely impact our operating results. Management of a license arrangement, collaboration, or other strategic arrangement and/or integration of an acquired asset or company may also disrupt our ongoing business, require management resources that otherwise would be available for ongoing development of our existing business and our U.S. commercialization of *Feraheme*. In addition, to finance any such strategic transactions, we may choose to issue shares of our common or preferred stock as consideration, which would result in dilution to our stockholders. Alternatively, it may be necessary for us to raise additional funds through public or private financings, and such additional funds may not be available on terms that are favorable to us, if at all. If we are unable to successfully obtain rights to suitable products or if any acquisition or in-license arrangement we make is not successful, our business, financial condition and prospects for growth could suffer.

We may not realize the anticipated benefits of the acquisition of the MuGard Rights or any future acquisitions or product licenses and the integration of the MuGard Rights or any future acquisitions and any products or product candidates acquired or licensed may disrupt our business and management.

We have and we may in the future acquire or in-license additional commercialized specialty pharmaceutical products. For example, in June 2013, we entered into a license agreement with Access under which we acquired the MuGard Rights. The integration of the operations of acquired products or businesses, including *MuGard*, requires significant efforts, including the coordination of information technologies, sales and marketing, operations, manufacturing and finance. These efforts result in additional expenses and involve significant amounts of management s time. In addition, we rely on Access, and may in the future have to rely on such other parties with whom we may enter into a future agreement, to perform certain regulatory filings, oversee certain functions, such as pharmacovigilance or the manufacture of the product we license from them, and any failure of Access or any other party to perform these functions for any reason, including ceasing doing business, could have a material effect on our ability to commercialize *MuGard* or any other future product we may acquire. We may not realize the anticipated benefits of the

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MuGard Rights or any future acquisition, license or collaboration, any of which involves numerous risks including the following:

- Difficulty in integrating the products or product candidates into our business;

- Entry into markets in which we have no or limited direct prior experience, including device markets, and where competitors in such markets have stronger market positions;

- Failure to achieve our strategic objectives, including successfully commercializing and marketing *MuGard* or any other products we may acquire;

- Our ability to train our sales force, and the ability of our sales force, to incorporate successfully new products and devices, including *MuGard*, into their call points;

- Additional legal and/or compliance risk associated with the acquisition of *MuGard* or any other future product;

- The introduction by our competitors of alternatives to *MuGard* that would be, or are perceived to be, more efficacious, safer, less expensive, easier to administer, or provide more favorable insurance coverage or reimbursement could reduce our revenues and the value of our product development efforts;

- Potential write-offs of intangible assets or adjustments to contingent consideration related to estimates we make in the accounting of acquisitions or product licenses, including *MuGard*, and any resulting impact that may have on our quarterly financial results; and

- Disruption of our ongoing business and distraction of our management and employees from other opportunities or our core business functions, including *Feraheme/Rienso*.

If we cannot successfully integrate the *MuGard* business into our company, we may experience material negative consequences to our business, financial condition or results of operations. We cannot assure you that, following any such acquisitions, including *MuGard*, we will achieve the expected synergies to justify the transaction.

The success of Feraheme and MuGard in the U.S. depends on our ability to maintain the proprietary nature of our technology.

We rely on a combination of patents, trademarks and copyrights 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 sufficient protection for our technology. The degree of protection afforded by patents for proprietary or licensed technologies or for future discoveries may not be adequate to preserve our ability to protect or commercially exploit those technologies or discoveries. The patents issued to us may provide us with little or no competitive advantage. In addition, there is a risk that others will independently develop or duplicate similar technology or products or circumvent the patents issued to us.

Our U.S. ferumoxytol patents are currently scheduled to expire in 2020. Our licensed patents relating to *MuGard* expire in 2022. These and any other patents issued to us may be contested or invalidated. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the

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pharmaceutical and biotechnology industries. We may become a party to patent litigation and other proceedings, including interference and reexamination proceedings declared by the United States Patent and Trademark Office. Further, our licensed patent rights to *MuGard* may not prevent competitors from independently developing and marketing a competing product that does not infringe our licensed patents or other intellectual property.

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 financial and business costs, including the business cost attributable to the resulting distraction of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling *Feraheme*, increase the risk that a generic version of *Feraheme* could enter the market to compete with *Feraheme*, limit our development and commercialization of *Feraheme*, or otherwise harm our competitive position and result in additional significant costs. In addition, any successful claim of infringement asserted against us could subject us to monetary damages or an injunction, preventing us from making or selling *Feraheme*. We also may be required to obtain licenses to use the relevant technology. Such licenses may not be available on commercially reasonable terms, if at all. Frequently, the unpredictable nature and significant costs of patent litigation leads the parties to settle to remove this uncertainty. Settlement agreements between branded companies and generic applicants may allow, among other things, a generic product to enter the market prior to the expiration of any or all of the applicable patents covering the branded product, either through the introduction of an authorized generic or by providing a license to the applicant for the patents in suit. Moreover, *MuGard* is subject to many of the same third party infringement risks that *Feraheme* is subject to.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our corporate licensees, collaborators, contract manufacturers, 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* or *MuGard*, thereby substantially reducing the value of our proprietary rights. Our inability to protect *Feraheme* or *MuGard* through our patents and other intellectual property rights prior to their expiration could have a material adverse effect on our business, financial condition and prospects.

The success of Feraheme/Rienso abroad depends on our ability to protect our intellectual property rights and the laws of foreign countries may not provide the same level of protection as do the laws of the U.S.

The laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S. and therefore, in addition to similar risks to those describe above under the heading *The success of Feraheme and MuGard in the U.S. depends on our ability to maintain the proprietary nature of our technology,* our intellectual property rights may be subject to increased risk abroad, including opposition proceedings before the patent offices for other countries, such as the European Patent Office, or the EPO, or similar adversarial proceedings, regarding intellectual property rights with respect to *Feraheme/Rienso*. For example, in July 2010, Sandoz GmbH, or Sandoz, filed with the EPO an opposition to one of our previously issued patents which covers ferumoxytol in the EU. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked our European ferumoxytol patent. In December 2012, our notice of appeal was recorded with the EPO. The appeals process is costly and time-consuming and if it results in an unfavorable outcome to us, it could result in a loss of proprietary rights in the EU and may allow Sandoz or other companies to use our proprietary technology without a license from us, which may also result in a loss of future royalty or milestone payments to us, as well as the possibility that Takeda may

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determine that the terms of our agreement are no longer viable. We cannot predict the outcome of our appeal of the EPO decision. This or any future patent interference proceedings involving our patents may result in substantial costs to us, distract our management from day-to-day business operations and responsibilities, prevent us or Takeda from marketing and selling *Feraheme/Rienso* or increase the risk that a generic version of *Feraheme/Rienso* could enter the market to compete with *Feraheme/Rienso.* In countries where we do not have or have not applied for patents for ferumoxytol, such as in China, where we license certain development and commercial rights to *Feraheme* to 3SBio, Inc., 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. Any such limitation on our intellectual property rights would cause substantial harm to our competitive position and to our ability to develop and commercialize *Feraheme/Rienso.* Our inability to protect *Feraheme/Rienso* through our patents and other intellectual property rights in any territory prior to their expiration could have a material adverse effect on our business, financial condition and prospects.

Competition in the pharmaceutical and biopharmaceutical industries is intense. If we fail to compete effectively, our business and market position will suffer.

The pharmaceutical and biopharmaceutical industry is intensely competitive and subject to rapid technological change. Many of our competitors are large, well-known pharmaceutical companies and may benefit from significantly greater financial, sales and marketing capabilities, greater technological or competitive advantages, and other resources. Our competitors may develop products that are more widely accepted than ours and may receive patent protection that dominates, blocks or adversely affects our product development or business.

The markets for our current products are highly sensitive to several factors including, but not limited to the following:

- The actual and perceived safety and efficacy profile of the available products;
- The approved indication for each of the available products;
- The ability to obtain appropriate insurance coverage and reimbursement rates and terms;
- Price competitiveness; and
- Product characteristics such as convenience of administration and dosing regimens.

The introduction by our competitors of alternatives to *Feraheme/Rienso* or *MuGard* that would be, or are perceived to be, more efficacious, safer, less expensive, easier to administer, available for a broader patient population, or provide more favorable insurance coverage or

reimbursement could reduce our revenues and the value of our product development efforts.

Feraheme/Rienso may not receive the same level of market acceptance as competing iron replacement therapy products, in part because most of these products have been on the market longer and are currently widely used by physicians in the U.S. and abroad. In addition, the recent CHMP review of IV iron-containing medications used to treat iron deficiency and anemia (which concluded that the benefits of these medications are greater than their risks, provided that adequate measures are taken to ensure the early detection and effective management of allergic reactions that may occur, including ensuring that these products be given in an environment where patients who develop an allergic reaction can be treated

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immediately and ceasing to rely on a lack of allergic reaction to a test dose as an indication of tolerance of larger doses) could cause physicians to elect non-IV iron alternatives which may be easier to administer or dose. In addition, certain of the IV iron products that we compete with are approved for the treatment of IDA in a broader group of patients than *Feraheme/Rienso,* such as Injectafer® in the U.S. The recent extension of our PDUFA date to January 21, 2014 for our sNDA submission for a broader indication for *Feraheme* for the treatment of IDA, may make it more difficult for us to compete with Injectafer® in the U.S., which was approved in July 2013 because Injectafer® will have been approved for a broader patient population than *Feraheme* for a longer period of time. During this period, physicians may begin to use Injectafer® and gain some familiarity with the product making it more difficult for us to cause these physicians to use *Feraheme* in the future. In addition, Injectafer® may enter into commercial contracts with key customers or group purchasing organizations, or GPOs, during this period, which could prevent or make it more difficult for *Feraheme* to gain sales and market share in those customers or GPOs, if we were to receive approval for the broader patient population in the future. If we or Takeda are not able to differentiate *Feraheme/Rienso* from other marketed IV iron products, our ability to maintain a premium price, our ability to generate revenues and achieve and maintain profitability, and our long-term business prospects could be adversely affected.

Feraheme currently competes with several IV iron replacement therapies in the U.S. In July 2013, Injectafer®, which is known as Ferinject® in Europe and is discussed below, was approved by the FDA for the treatment of IDA in adult patients who have an unsatisfactory response to oral iron or who have intolerance to oral iron, which is a broader indication than our current *Feraheme* indication. Injectafer s U.S. approval or the approval of any other iron replacement product for a broader IDA indication than *Feraheme*, could adversely affect our efforts to market and sell *Feraheme* in the U.S. and our ability to generate additional revenues and achieve profitability.

Feraheme/Rienso also competes with a number of branded IV iron replacement and certain other iron dextran and iron sucrose products outside of the U.S., such as Ferinject® (ferric carboxymaltose injection), which is an IV iron replacement therapy currently approved for marketing in approximately 47 countries worldwide for the treatment of IDA where oral iron is ineffective or cannot be used. If Takeda is unable to convince physicians and other healthcare providers to switch from using the competing IV iron products to *Feraheme/Rienso,* our ability to generate revenues from royalties we may receive from Takeda will be limited and our operating results will be negatively affected. In addition, all other IV iron products currently approved and marketed and sold in the EU are approved for marketing to a broader group of patients with IDA. *Feraheme/Rienso* was approved only for use in adult CKD patients, which could put *Feraheme/Rienso* at a competitive disadvantage unless and until it receives approval for a broader indication outside of the U.S.

There are other companies commercializing products for the management or treatment of oral mucositis that may compete with *MuGard* including two marketed products: Kepivance® (palifermin) an IV human growth factor which is marketed by Swedish Orphan Biovitrum, and Caphosol® a supersaturated calcium phosphate artificial saliva used as an adjunct to other oral care which is marketed by Jazz Pharmaceuticals, PLC. In addition, there are several marketed products available which are indicated for the management of pain associated with oral mucositis including (i) Gelclair®, which is marketed by DARA BioSciences, (ii) GelX Oral Gel, which is marketed by Praelia Pharmaceuticals, Inc., and (iii) Episil, which is marketed by Cangene BioPharma, Inc.

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Wholesaler, distributor and customer buying patterns, particularly those who are members of a GPO, and other factors may cause our quarterly results to fluctuate, and these fluctuations may adversely affect our short-term results.

Our results of operations, including, in particular, product sales revenues, may vary from period to period due to a variety of factors, including the buying patterns of our U.S. wholesalers, distributors, clinics or hospitals, which vary from quarter to quarter. In addition, our contracts with GPOs require certain performance from the members of the GPOs such as growth over prior periods or certain market share attainment goals in order to qualify for discounts off the list price of our products and a GPO may be able to influence the demand for our products from its members in a particular quarter through communications they make to their customers. In the event wholesalers, distributors, clinics or hospitals with whom we do business in the U.S. determine to limit their purchases of our products our product sales could be adversely affected. Our contracting strategy can also have an impact on the timing of certain purchases causing *Feraheme* sales to vary from quarter to quarter. For example, in advance of an anticipated price increase, following the publication of our quarterly average selling price, or ASP, which affects the rate at which *Feraheme* is reimbursed, or a reduction in expected rebates or discounts, customers may order *Feraheme* in larger than normal quantities which could cause *Feraheme* sales to be lower in subsequent quarters than they would have been otherwise. Further, any changes in purchasing patterns or inventory levels, changes to our contracting strategy, increases in product returns, delays in purchasing products or delays in payment for products by one of our distributors or GPOs could also have a negative impact on our revenue and results of operations.

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

The commercial success of our products depends upon the level of market adoption by physicians, hospitals, patients, and healthcare payors, including managed care organizations and GPOs. If our products do not achieve or maintain an adequate level of market adoption for any reason, our potential profitability and our future business prospects will be adversely impacted. *Feraheme/Rienso* and *MuGard* represent an alternative to other products in their respective markets and might not be adopted if perceived to be no safer, less safe, no more effective, less effective, no more convenient, or less convenient than currently available products. In addition, the pricing and/or reimbursement rates and terms of our products may not be viewed as advantageous to potential prescribers and payors as the pricing and/or reimbursement rates and terms of alternative products.

The degree of market acceptance of *Feraheme/Rienso* in the U.S. and abroad depends on a number of factors, including but not limited to the following:

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

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

- The actual or perceived safety and efficacy profile of *Feraheme/Rienso* as compared to alternative iron replacement therapeutic agents, particularly if unanticipated adverse reactions to *Feraheme/Rienso* result in further changes to or restrictions in the *Feraheme/Rienso*

package insert, voluntary or involuntary product recalls and/or otherwise create safety concerns among potential prescribers;

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

- The relative price and/or level of reimbursement of *Feraheme/Rienso* outside of the U.S. as compared to alternative iron replacement therapeutic agents;

- The actual or perceived convenience and ease of administration of *Feraheme/Rienso* as compared to alternative iron replacement therapeutic agents, including iron administered orally;

- The timing and type of response from the FDA on our sNDA and other regulatory filings and any limitation on the approved indications and the patient populations for *Feraheme/Rienso*; and

- The effectiveness of our and Takeda s commercial organizations and distribution networks in marketing, selling and supplying *Feraheme/Rienso*.

The key component of our U.S. commercialization strategy is to market and sell *Feraheme* for use in non-dialysis adult CKD patients. The current U.S. non-dialysis CKD market is comprised primarily of three sites of care where a substantial number of CKD patients are treated: hematology and oncology centers, hospitals, and nephrology clinics. IV iron therapeutic products are not currently widely used by certain physicians who treat non-dialysis CKD patients in the U.S., particularly nephrologists, due to safety concerns and the inconvenience and often impracticability of administering IV iron therapeutic products in their offices. It is often difficult to change physicians existing treatment paradigms even when supportive clinical data is available. In addition, our ability to effectively market and sell *Feraheme* in the U.S. hospital market depends in part upon our ability to achieve acceptance of *Feraheme* onto hospital formularies. Since many hospitals and hematology, oncology and nephrology practices are members of GPOs, which leverage the purchasing power of a group of entities to obtain discounts based on the collective bargaining power of the group, our ability to attract customers in these sites of care also depends in part on our ability to effectively promote *Feraheme* to and enter into pricing agreements with GPOs. The GPOs can also offer opportunities for competitors to *Feraheme* that provide the ability to quickly gain market share by offering a more attractive price or contracts and incentives that encourage the members of the GPO to use or switch to the competing product. If we are not successful in capturing a significant share of the U.S. non-dialysis CKD market or if we are not successful in securing and maintaining formulary coverage for *Feraheme*, or if we cannot maintain strong relationships and offer competitive contracts to key customers and GPOs, our potential profitability as well as our long-term business prospects could be adversely affected.

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

In the U.S., we sell *Feraheme* primarily to wholesalers and specialty distributors and therefore a significant portion of our revenues is generated by a small number of customers. Four customers accounted for 93% of our total revenues during the nine months ended September 30, 2013, and three customers accounted for 95% of our accounts receivable balance as of September 30, 2013. We pay these wholesalers and specialty

distributors a fee for the services that they provide to us. Because our business is concentrated with such a small number of wholesalers and specialty distributors, we could be forced to accept increases in their fees in order to maintain the current distribution networks through which *Feraheme* is sold. Any increase in fees could have a negative impact on our current and future sales of *Feraheme* in the U.S. and could have a negative impact on the reimbursement rate an individual physician, hospital or clinic would

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realize upon using *Feraheme*. In addition, a significant portion of our U.S. *Feraheme* sales are generated through a small number of contracts with GPOs. For example, approximately 32% of our end-user demand during the nine months ended September 30, 2013 was generated by members of a single GPO with which we have contracted. As a result of the significant percentage of our end-user demand being generated by a single GPO, we may be at a disadvantage in future contract or price negotiations with such GPO and that GPO may be able to influence the demand for *Feraheme* from its members in a particular quarter through communications they make to their customers. In addition, the GPOs can also offer opportunities for competitors to *Feraheme* that provide the ability to quickly gain market share by offering a more attractive price or contracts and incentives that encourage the members of the GPO to use or switch to the competing product. The loss of some or all of this demand to a competitor, a material reduction in sales volume, or a significant adverse change in our relationship with any of our key wholesalers, distributors or GPOs could have a material adverse effect on our revenue in any given period and may result in significant annual or quarterly revenue fluctuations.

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

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

In addition, U.S. and many foreign governments continue to propose and pass legislation designed to reduce the cost of health care for patients. In the U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the Health Care Reform Act, was enacted in March 2010 and includes certain cost containment measures including an increase to the minimum rebates for products covered by Medicaid programs, the extension of such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations and the expansion of the 340B Drug Discount Program under the Public Health Service Act. In addition, the heightened focus on the health care industry by the federal government could result in the implementation of significant federal spending cuts, including cuts in Medicare and other health related spending in the near-term. For example, under the sequestration required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, Medicare payments for all items and services under Parts A and B incurred on or after April 1, 2013 have been reduced by up to 2%. Therefore, after adjustment for deductible and co-insurance, the reimbursement rate for physician-administered drugs including *Feraheme*, under Medicare Part B has been reduced from ASP plus 6% to ASP plus 4.3%. Because the majority of our *Feraheme* business is through hematology/oncology clinics and out-patient hospital infusions centers, this reduction in the Medicare reimbursement payment for *Feraheme* may adversely impact our future revenues. The magnitude of the impact of these laws on our business is uncertain. Further, in recent years some states have also passed legislation to control the prices of drugs as well as begun a move toward managed care to relieve some of their Medicaid cost burden. While Medicare is the predominant payor for treatment of patients with CKD, 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. These and any future changes in government regulation

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or private third-party payors reimbursement policies may reduce the extent of reimbursement for our products and adversely affect our future operating results.

In January 2011, a prospective payment system for dialysis services provided to Medicare beneficiaries who have end-stage renal disease, or ESRD, became effective under which all costs of providing dialysis services are bundled together into a single prospective payment per treatment. This bundled approach to reimbursement has and will likely continue to alter the utilization of physician-administered drugs in the ESRD market as well as put downward pressure on the prices pharmaceutical companies can charge ESRD facilities for such drugs, particularly where alternative products are available. In the U.S., *Feraheme* is sold at a price that is substantially higher than alternative IV iron products in the dialysis setting, and as a result, the demand for *Feraheme* in the dialysis setting has largely disappeared. In addition, it is also possible that this bundled approach may be applied to specific disease states other than ESRD. For example, one large insurer in the U.S has attempted to bundle certain costs related to the treatment of cancer patients. Further changes in the Medicare reimbursement rate, which result in lower payment rates from payors, including Medicare payors, would further limit our ability to successfully market and sell our products in the U.S. In addition, in the U.S. hospital in-patient setting, *Feraheme* is reimbursed by Medicare under a diagnosis-related group payment system, which provides a per discharge reimbursement based on the diagnosis and/or procedure rather than actual costs incurred in patient treatments, thereby increasing the incentive for a hospital to limit or control expenditures. As a result, *Feraheme* has not been nor do we expect it to be broadly used in the hospital in-patient setting.

In countries outside of the U.S., market acceptance of *Feraheme/Rienso* may also depend, in part, upon the availability of reimbursement within existing healthcare payment systems. Generally, in Europe and other countries outside of the U.S., the government sponsored healthcare system is the primary payor of healthcare costs of patients and therefore enjoys significant market power. Some foreign countries also set prices for pharmaceutical products as part of the regulatory process, and we cannot guarantee that the prices set by such governments will be sufficient to generate substantial revenues or allow sales of *Feraheme/Rienso* to be profitable in those countries. Any such limitations on the reimbursement for *Feraheme/Rienso* in countries outside of the U.S. would have an adverse impact on Takeda s ability to generate product sales of *Feraheme/Rienso* in such territories, which would, in turn, limit the amount of royalties we may receive under our amended agreement with Takeda.

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

In March 2010, we entered into our initial agreement with Takeda, which was amended in June 2012, under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme/Rienso* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey. We are highly dependent on Takeda for certain regulatory filings outside of the U.S. with respect to *Feraheme/Rienso* and the commercialization of *Feraheme/Rienso* outside of the U.S., including in Canada, Switzerland and the EU. Takeda is in the early stages of the launch in Canada and the EU, and therefore, revenues from sales of *Feraheme/Rienso* in these territories are not a material part of ours or Takeda s business. If Takeda fails to perform its obligations under the Amended Takeda Agreement or is ineffective in its commercialization of *Feraheme/Rienso* in the agreed-upon territories, if revenues fail to materialize due to market or pricing dynamics in Takeda s territories, or if we fail to effectively manage our relationship with Takeda, our ability to and the extent to which we obtain regulatory approvals for *Feraheme/Rienso* and our *Feraheme/Rienso* commercialization efforts outside of the U.S. would be significantly harmed, which would have an adverse effect on milestone payments and

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royalties we may receive under the Amended Takeda Agreement. Further, if we fail to fulfill certain of our obligations under the Amended Takeda Agreement, Takeda has the right to assume the responsibility of clinical development and manufacturing of *Feraheme/Rienso* in the agreed-upon territories, which would increase the cost of and delay the *Feraheme/Rienso* development program outside of the U.S.

Takeda has the unilateral right to terminate the Amended Takeda Agreement under certain conditions, including without cause or if it determines in good faith that the continued development of *Rienso* would not be in the best interest of patient welfare. If Takeda terminates the agreement and we chose to continue to commercialize *Feraheme/Rienso* in Takeda s territories, we would be required to either enter into alternative arrangements with third parties to commercialize *Feraheme/Rienso* in Takeda s territories, which we may be unable to do in a timely and cost effective manner, or at all, or to increase our internal infrastructure, both of which would likely result in significant additional expense and the disruption or failure of commercial efforts outside of the U.S. In addition, such a termination would prevent us from receiving the milestone payments and royalties we may otherwise receive under the Amended Takeda Agreement.

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

In the U.S., there have been, and we expect there will continue to be, a number of legislative and regulatory proposals aimed at changing the U.S. healthcare system. For example, the Health Care Reform Act contains a number of provisions that significantly impact the pharmaceutical industry and may negatively affect our potential product 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 340B Drug Discount Program under the Public Health Service Act. The volume of *Feraheme* business sold to 340B eligible entities has increased since the implementation of the Health Care Reform Act. Because these institutions are eligible for federal pricing discounts, the revenue realized per unit of *Feraheme* sold to 340B institutions is lower than from our other customers. 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 these laws on and their potential impact on our business, these laws may adversely affect the pricing for our products in the U.S. or cause us to incur additional expenses and therefore adversely affect our financial position and results of operations.

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

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

We and our third-party manufacturers currently purchase certain raw and other materials used to manufacture *Feraheme/Rienso* from third-party suppliers and at present do not have long-term supply contracts with most of these third parties. These third-party suppliers may cease to produce the raw or other materials used in *Feraheme/Rienso* or otherwise fail to supply these materials to us or our third-party manufacturers or fail to supply sufficient quantities of these materials to us or our third-party manufacturers 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;
- Adverse financial developments at or affecting the supplier;
- Regulatory requirements or action;
- An inability to provide timely scheduling and/or sufficient capacity;
- Manufacturing difficulties;
- Labor disputes or shortages; or
- Import or export problems.

If any of our third-party suppliers cease to supply certain raw or other materials to us or our third-party manufacturers for any reason we could be unable to manufacture *Feraheme/Rienso* in sufficient quantities, on a timely basis, or in a cost-effective manner until we are able to qualify an alternative source. For example, one of the key components in ferumoxytol is produced specifically for us by a third-party supplier and if our third-party supplier is no longer able to supply it to us we will be unable to manufacture *Feraheme/Rienso* until we are able to identify and qualify an alternative supplier. This or any other interruption in our third-party supply chain could adversely affect our ability to satisfy commercial demand and our clinical development needs for *Feraheme/Rienso*.

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 or our third-party manufacturers 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 or our third-party manufacturers may not be able to obtain such materials of the quality required to manufacture *Feraheme/Rienso* 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/Rienso*, both for commercial sale and for use in our clinical trials, on a timely and cost-effective basis, which could cause us to lose money. Any such difficulty in obtaining raw or other materials could severely hinder our ability to manufacture *Feraheme/Rienso* and could have a material adverse impact on our ability to generate additional revenues and to achieve profitability.

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

In addition to FDA and related regulatory requirements in the U.S. and abroad, we are subject to extensive additional federal, state and foreign healthcare regulation, which includes but is not limited to, the Federal False Claims Act, the Federal Anti-Kickback Statute, the Foreign Corrupt Practices Act, and their state analogues, and similar laws in countries outside of the U.S., laws governing sampling and distribution

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of products, and government price reporting laws. False claims laws prohibit anyone from knowingly presenting, or causing to be presented for payment to third-party payors, including Medicare and Medicaid, false or fraudulent claims for reimbursed drugs or services, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Anti-kickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug, that is reimbursed by a state or federal program. The Foreign Corrupt Practices Act and similar foreign anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Similar laws and regulations exist in many other countries throughout the world in which we intend to commercialize *Feraheme/Rienso* through Takeda and our other licensees. We have developed and implemented a corporate compliance program based on what we believe are current best practices in the pharmaceutical industry, but we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all federal, state and foreign regulations. If we, our representatives, or our licensees, including Takeda, fail to comply with any of these laws or regulations, a range of fines, penalties and/or other sanctions could be imposed on us and/or Takeda, including, but not limited to, restrictions on how we and/or Takeda market and sell *Feraheme/Rienso* and how we market and sell *MuGard*, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation, or other sanctions. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition and results of operations.

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

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

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

As a condition of reimbursement by various U.S. federal and state healthcare programs for *Feraheme*, we are required to calculate and report certain pricing information to U.S. federal and state healthcare agencies. For example, we are required to provide ASP information to the Centers for Medicare and Medicaid Services on a quarterly basis in order to compute Medicare Part B payment rates. This ASP information forms the basis for reimbursement for the majority of our current *Feraheme* business in the U.S.

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Price reporting and payment obligations are highly complex and vary among products and programs. The calculation of ASP includes a number of inputs from our contracts with wholesalers, specialty distributors, GPOs and other customers. It also requires us to make an assessment of whether these agreements are deemed to be for bona fide services and that the services are deemed to be at fair market value in our industry and for our products. These calculations are very complex and could involve the need for us to unbundle discounts or rebates offered over a multiple quarters or across multiple products. Our processes for estimating amounts due under these governmental pricing programs unbundling discounts or rebates involve subjective decisions. 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, restatement or investigation. If we become subject to investigations, restatements, 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 have a history of net losses, and we may not be able to generate sufficient revenues to achieve and maintain profitability in the future.

We have a history of significant operating losses, we may not be profitable in the future, and if we do attain profitability, such profitability may not be sustainable. In the past, we have financed our operations primarily from the sale of our equity securities, cash from sales of *Feraheme/Rienso*, cash generated by our investing activities, and payments from our licensees. As of September 30, 2013, we had an accumulated deficit of approximately $462.6 million. Our losses were primarily the result of costs incurred in our efforts to manufacture, market and sell *Feraheme/Rienso*, including costs associated with maintaining our commercial infrastructure and marketing and promotion costs, research and development costs, such as costs associated with our clinical trials, and selling, general and administrative costs. We expect to continue to incur significant expenses as we continue to manufacture, market and sell *Feraheme* as an IV iron replacement therapeutic for use in adult CKD patients in the U.S., market and sell *MuGard* and as we further develop and seek marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients. As a result, we will need to generate sufficient revenues in future periods to achieve and maintain profitability. Once we achieve profitability or begin to generate positive cash flow from operations, there is no guarantee that we will be able to continue to do so. We anticipate that the majority of any revenue we generate in the next twelve months will be from sales of *Feraheme/Rienso* as an IV iron replacement therapeutic agent for use in adult CKD patients in the U.S., royalties we may receive with respect to sales of *Feraheme/Rienso* in the EU and Canada under the Amended Takeda Agreement, and from sales of *MuGard*. We have never independently marketed or sold any products prior to *Feraheme*, and we may not be successful in marketing or selling *Feraheme* or *MuGard* and Takeda may not be successful in marketing or selling *Feraheme/Rienso*. If we or Takeda are not successful in marketing and selling *Feraheme/Rienso*, if revenues grow more slowly than we anticipate or if our operating expenses exceed our expectations, or if we are otherwise unable to achieve, maintain or increase profitability on a quarterly or annual basis, our business, results of operations and financial condition could be materially adversely affected and the market price of our common stock may decline.

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We have limited experience independently commercializing a pharmaceutical product and no experience independently commercializing multiple products, and any failure on our part to effectively execute our Feraheme or MuGard commercial plans in the U.S. would have an adverse impact on our business.

Prior to our commercialization of *Feraheme* in the U.S., we had never independently marketed or sold a product as we had relied on our licensees to market and sell our previously approved products. We have an internal commercial infrastructure to market and sell *Feraheme* and *MuGard* in the U.S. If we are unsuccessful in maintaining an effective commercial function with multiple products, integrating *MuGard* into our existing sales infrastructure, or experience a high level of employee turnover for any reason, our ability to attract and retain qualified personnel, maintain sales levels, and support potential sales growth could be harmed, all of which could prevent us from successfully commercializing *Feraheme* or *MuGard* in the U.S. Any failure by us to successfully commercialize *Feraheme* or *MuGard* in the U.S. could have a material adverse impact on our ability to generate revenues, our ability to achieve profitability, and the future prospects for our business.

Our success depends on our ability to attract and retain key employees, and any failure to do so may be disruptive to our operations.

Because of the specialized nature of our business, our success depends to a significant extent on the continued service of our executive officers and on our ability to continue to attract, retain and motivate qualified executive, sales, technical operations, managerial, scientific, and medical personnel. We have entered into employment agreements with most of our current senior executives, but such agreements do not guarantee that these executives will remain employed by us for any significant period of time, or at all. There is intense competition for qualified personnel in the areas of our activities, and we may not be able to continue to attract and retain the qualified personnel necessary for the development of our business.

Previously implemented workforce reductions could residually harm our ability to attract and retain qualified personnel. In addition, any restructuring plans we may initiate in the future may be disruptive to our operations and could harm our ability to attract and retain qualified key personnel. 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. Any workforce reductions could also harm our ability to attract and retain qualified executive, sales, technical operations, managerial, scientific, and medical personnel who are critical to our business. Furthermore, because we are currently operating with fewer employees and service providers, any further turnover, whether occurring as part of a restructuring plan or otherwise, could cause significant disruption if we are unable to implement or maintain a sufficient succession plan for certain personnel or departments. Any failure to attract, retain or replace qualified personnel could prevent us from successfully commercializing and developing our products, impair our ability to maintain sales levels and/or support potential sales growth.

Moreover, although we believe it is necessary to closely manage 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 any cost reduction measures, or other measures we may take in the future, will result in the expected cost savings, or that any cost savings will be unaccompanied by these or other unintended consequences.

We have limited experience independently distributing a pharmaceutical product, and our 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/Rienso* and *MuGard*. We have contracted with Packaging Coordinators, Inc. (formerly Catalent

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Pharma Solutions, LLC) to provide certain labeling, packaging and storage services for final U.S. and Canadian *Feraheme* drug product. In addition, we have contracted with Integrated Commercialization Services, Inc. to be our exclusive third-party logistics provider to perform a variety of functions related to the sale and distribution of *Feraheme* in the U.S., including services related to warehousing and inventory management, distribution, chargeback processing, accounts receivable management and customer service call center management. If these or any future third-parties are unable to provide uninterrupted labeling, packaging and storage services or supply chain services, respectively, we may incur substantial losses of sales to wholesalers or other purchasers of our products.

In addition, the packaging, storage and distribution of our products in the U.S. and abroad requires significant coordination among our, Takeda, and Access manufacturing, sales, marketing and finance organizations and multiple third parties including our third-party logistics providers, packaging, labeling and storage 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 our products to meet U.S. or foreign commercial demand could be significantly impaired. The loss of any of our third-party providers, together with a delay or inability to secure an alternate distribution source for end-users in a timely manner, could cause the distribution of our products to be delayed or interrupted, which would have an adverse effect on our business, financial condition and results of operations.

We rely on third parties in the conduct of our business, including our clinical trials and manufacturing, 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 CROs, 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. In addition, we have contracted and plan to continue to contract with certain third parties to provide certain services, including site selection, enrollment, monitoring, data management and other services, in connection with the conduct of our clinical trials and the preparation and filing of our regulatory applications. We have limited experience conducting clinical trials outside the U.S., and, therefore, we are also largely relying on third parties such as CROs to manage, monitor and carry out these 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 and satisfactory manner, if the quality and accuracy of our clinical trial data or our regulatory submissions are compromised due to poor quality or failure to adhere to our protocols or regulatory requirements or if such third parties otherwise fail to adequately discharge their responsibilities or meet deadlines, our development plans and planned regulatory submissions both in and outside of the U.S may be delayed or terminated, which would adversely impact our ability to generate revenues from *Feraheme/Rienso* sales in additional indications and/or outside of the U.S.

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

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

- The magnitude of U.S. *Feraheme* and *MuGard* sales;

- The loss of a key customer or GPO;

- The impact of any pricing or contracting strategies we have implemented or may implement related to our products, including the magnitude of rebates and/or discounts we may offer, or changes in pricing by our competitors or a new entrant into the market;

- The introduction of new competitive products, such as Injectafer or generic versions of new or currently available drug therapies;

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

- Changes in the actual or perceived safety or efficacy profile of our products, or products that compete with *Feraheme/Rienso* or *MuGard* that could cause customers to increase, decrease or discontinue their use of our products or could affect the regulatory status of our products in the U.S. or elsewhere;

- The timing and magnitude of costs incurred in connection with business development activities or business development transactions into which we may enter;

- Any changes to the mix of our business;

- Changes in buying patterns, fees and inventory levels of our wholesalers, distributors, clinics or hospitals;

- The timing and magnitude of *Feraheme/Rienso* milestone payments, product sales revenues and royalties we may receive from Takeda under the Amended Takeda Agreement;

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

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

- Changes in accounting estimates related to reserves on revenue, returns, contingent consideration, impairment of long-lived assets or other accruals or changes in the timing and availability of government or customer discounts, rebates and incentives;

- Further asset write-downs related to property and equipment, intangible assets or assets held for sale;

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

- The timing and magnitude of costs associated with our ongoing and planned clinical studies of *Feraheme/Rienso* in connection with our pediatric program, our current or future post-marketing

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commitments for the EMA and other regulatory agencies, our pursuit of additional indications and our development of *Feraheme/Rienso* in countries outside of the U.S;

- The costs associated with manufacturing batch failures or inventory write-offs due to out-of-specification release testing or ongoing stability testing that results in a batch no longer meeting specifications;

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

- The recognition of deferred tax assets during periods in which we generate taxable income; and

- The implementation of new or revised accounting or tax rules or policies.

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

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 U.S. 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 product sales and collaboration agreements, product sales allowances and accruals, assessing investments for potential other-than-temporary impairment and determining the values of investments, the fair value of our assets held for sale, contingent consideration, the impairment of long-lived assets, including intangible assets, accrued expenses, income taxes and equity-based compensation expense. We base our estimates on market data, our observance of trends in our industry, and various other assumptions that we believe to be reasonable under the circumstances. If actual results differ from these estimates, there could be a material adverse effect on our financial results and the performance of our stock.

As part of our revenue recognition policy, our estimates of product returns, rebates and chargebacks, fees and other discounts require subjective and complex judgments due to the need to make estimates about matters that are inherently uncertain. Any significant differences between our actual results and our estimates could materially affect our financial position and results of operations. For example during each of the nine months ended September 30, 2013 and 2012, we revised our estimated Medicaid reserve rate, which resulted in a reduction of our estimated Medicaid rebate reserve and a corresponding increase in revenue related to prior *Feraheme* sales of $0.6 million. Further, during nine months ended September 30, 2012, we reduced our reserve for product returns by approximately $2.1 million due to a lower than expected actual returns

rate since the 2009 launch of *Feraheme* as well as a reduction in our expected rate of product returns in the future.

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In addition, to determine the required quantities of *Feraheme* and the related manufacturing schedule, we also need to make significant judgments and estimates based on inventory levels, current market trends, anticipated sales, forecasts from our licensees, including Takeda, and other factors. Because of the inherent nature of estimates, there could be significant differences between our and Takeda s estimates and the actual amount of product need. For example, the level of our access to wholesaler and distributor inventory levels and sales data in the U.S., which varies based on the wholesaler, distributor, clinic or hospital, affects our ability to accurately estimate certain reserves included in our financial statements. Any difference between our estimates and the actual amount of product demand could result in unmet demand or excess inventory, each of which would adversely impact our financial results and results of operations.

In connection with our June 2013 acquisition of the MuGard Rights we were and will continue to be required to make estimates related to the fair value of the asset and the related contingent consideration. These estimates require significant judgment and assumptions including but not limited to: estimating future cash flows from product sales and developing appropriate discount and probability rates. If these or any other related estimates made in connection with the acquisition of the MuGard Rights or any future acquisitions require adjustment in the future, we could experience significant write-offs or other adjustments and our operating results could be negatively affected.

We and/or Takeda are subject to ongoing U.S. and foreign regulatory obligations and oversight of Feraheme/Rienso and MuGard, 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 our products, the incurrence of significant additional expense and other limitations on our ability to commercialize our products.

We and/or Takeda are subject to ongoing regulatory requirements and review both in the U.S. and in foreign jurisdictions pertaining to the manufacture, labeling, packaging, adverse event reporting, storage, marketing, promotion and record keeping related to our products. Failure to comply with such regulatory requirements or the later discovery of previously unknown problems with our products or our third-party contract manufacturing facilities or processes by which we manufacture our products may result in restrictions on our ability to manufacture, market or sell our products, including potential withdrawal from the market. Any such restrictions could result in a decrease in our product sales, damage to our reputation or the initiation of lawsuits against us, Takeda, or our third-party contract manufacturers. We and/or Takeda may also be subject to additional sanctions, including but not limited to:

- Warning letters;
- Civil or criminal penalties;
- Suspension or withdrawal of regulatory approvals;
- Changes to the package insert of our products, such as additional warnings regarding potential side effects or potential limitations on the current dosage and administration of *Feraheme/Rienso* or IV irons as a class;

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

- Implementation of risk mitigation programs;

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

- Temporary or permanent closing of the facilities of our third-party contract manufacturers; or

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

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

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. If we are found to have improperly promoted off-label uses, we may become subject to significant fines and other liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product s approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant government fines and other related liability. For example, the U.S. government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that can impose significant restrictions and other burdens on the affected companies.

In addition, incentives exist under applicable U.S. law that encourage employees and physicians to report violations of rules governing promotional activities for pharmaceutical products. These incentives could lead to so called whistleblower lawsuits as part of which such persons seek to collect a portion of moneys allegedly overbilled to government agencies due to, for example, promotion of pharmaceutical products beyond labeled claims. Such lawsuits, whether with or without merit, are typically time consuming and costly to defend. Such suits may also result in related shareholder lawsuits, which are also costly to defend.

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 $13.85 and $28.42 in the fifty-two week period through October 31, 2013. The stock market has from time to time experienced extreme price and volume fluctuations, particularly in the biotechnology and pharmaceuticals sectors, which have often been unrelated to the operating performance of particular companies. Various factors and events, many of which are beyond our control, may have a significant impact on the market price of our common stock. Factors which may affect the market price of our common stock include, among others:

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

- Our ability to increase or maintain sales and utilization of *Feraheme* in the current indication or expand the indications for *Feraheme* for the treatment of IDA in adult patients who have failed or could not use oral iron;

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- Our ability to implement a pricing and contracting strategy that supports an increase in the net revenue per unit of *Feraheme* sold in the U.S. in future periods;

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

- Significant collaboration, product or business acquisitions, joint venture or similar agreements by us or our competitors or the termination of any current or future collaboration agreements;

- The timing and magnitude of product 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;

- Increases or decreases in our operating expenses or our gross margin on our products;

- Developments in patents or other proprietary rights by or for the benefit of us or our competitors, such as the recent decision by the EPO regarding our European ferumoxytol patent or decisions regarding *Feraheme s* NCE status or an ANDA filing by a generic entrant;

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

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

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

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

- Cash milestones earned, if any, under the Amended Takeda Agreement;
- The initiation or outcome of any material litigation or patent challenges to which we are or may become a party;
- Shareholder activism and attempts to disrupt our strategy by activist investors;
- General market conditions; and
- Sales of large blocks of our common stock.

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

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

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us and our business. As of October 31, 2013, seven financial analysts publish reports about us and our business. We do not control these or any other analysts. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. In addition, our future operating results are subject to substantial uncertainty, and our stock price could decline significantly if we fail to meet or exceed analysts forecasts and expectations. If any of the analysts who cover us downgrade our stock or issue commentary or observations about us or our stock that are perceived by the market as negative, our stock price would likely decline rapidly. In addition, if these analysts cease coverage of our company, we could lose visibility in the market, which in turn could also cause our stock price to decline.

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

In 2013, we publicly provided financial guidance, including expected 2013 *Feraheme/Rienso* product sales, total revenue, estimated operating expenses, estimated cost of goods sold as a percent of sales, quarterly cash flow trajectory throughout 2013 and estimated year-end cash and cash equivalents balance. If, for any reason, we are unable to realize our projected 2013 revenue, we may not realize our publicly announced revenue and year-end cash and cash equivalents balance guidance. If we fail to realize or if we change or update any element of our publicly disclosed financial guidance or other expectations about our business, our stock price could decline in value.

We may need additional capital to achieve our business objectives.

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

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

- The magnitude and growth rate of U.S. *Feraheme* sales over prior periods;

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

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

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

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

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

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

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

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

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

We estimate that our cash resources as of September 30, 2013, combined with cash we currently expect to receive from sales of *Feraheme/Rienso* and *MuGard,* earnings on our investments, and royalty and milestone payments we may receive from Takeda will be sufficient to finance our currently planned operations for at least the next twelve months. We may require additional funds or need to establish additional alternative strategic arrangements to execute a business development transaction. We may at any time seek funding through additional arrangements with collaborators through public or private equity or debt financings. We may not be able to obtain financing or to secure alternative strategic arrangements on acceptable terms or within an acceptable timeframe, if at all.

Any additional equity financings or alternative strategic arrangements would be dilutive to our stockholders. In addition, the terms of any potential 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 senior to those of, and 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, 2013, we had $30.9 million in cash and cash equivalents and $182.6 million in investments. These investments are subject to general credit, liquidity, market and interest rate risks, which have been and may, in the future, be exacerbated by a U.S. and/or global financial crisis. We may realize losses in the fair value of certain of our investments or a complete loss of these investments if the credit markets tighten, which would have an adverse effect on our results of operations, liquidity and financial condition.

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

agencies as of the valuation date. These ratings are subject to change. These market risks associated with our investment portfolio may have an adverse effect on our results of operations, cash position, liquidity and overall financial condition.

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

We are subject to changing rules and regulations of U.S. federal and state government as well as the stock exchange on which our common stock is listed. These entities, including the Public Company Accounting Oversight Board, the NASDAQ Stock Market, or NASDAQ, and the 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. Our efforts to comply with these requirements have resulted in, and are likely to continue to result in, an increase in our expenses and a diversion of management s time from other business activities.

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

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses and certain other tax assets to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders lowest percentage ownership during the testing period, which is generally three years. An ownership change could limit our ability to utilize our net operating loss and tax credit carryforwards for taxable years including or following such ownership change. Limitations imposed on the ability to use net operating losses and tax credits to offset future taxable income could require us to pay U.S. federal income taxes earlier than we have estimated would otherwise be required if such limitations were not in effect and could cause such net operating losses and tax credits to expire unused, in each case reducing or eliminating the benefit of such net operating losses and tax credits and potentially adversely affecting our financial position. Similar rules and limitations may apply for state income tax purposes.

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

Proxy contests have been waged against many companies in the biopharmaceutical industry over the last few years. For example, in 2011, MSMB Capital Management LLC, or MSMB Capital, filed a preliminary consent solicitation statement with the SEC seeking to remove and replace most of our then-current directors with MSMB Capital s nominees. The review, consideration and response to efforts by activist shareholders may require the expenditure of significant time and resources by us and may be a significant distraction for our management and employees. The impact of activist shareholders efforts due to these or other factors may undermine our business and have a material adverse effect on our results of operations. If faced with a proxy contest, we may not be able to successfully defend against the contest, which would be disruptive to our business.

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

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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, or we experience high turnover of our personnel in our financial reporting functions, 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, NASDAQ or other regulatory authorities.

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

A purported class action complaint was originally filed on March 18, 2010 in the U.S. 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 Chief Financial Officer, the then-members of our Board of Directors, or Board,, 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 Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged omissions in a registration statement filed in January 2010. The plaintiffs 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 and 15, 2011, respectively, the District Court issued an Opinion and Order dismissing the SAC with prejudice 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 U.S. Court of Appeals for the First Circuit, or the Court of Appeals. The Court of Appeals heard oral argument on May 11, 2012. On February 4, 2013, the Court of Appeals affirmed in part and reversed in part the District Court s Opinion and Order and remanded the case to the District Court. On February 19, 2013, we filed a Petition for Panel Rehearing and Rehearing *En Banc*, which was denied on March 15, 2013. On March 22, 2013, we filed a Motion to Stay the Mandate remanding the case to the District Court pending review by the U.S. Supreme Court of the Court of Appeals February 4, 2013 decision. The Court of Appeals granted the Motion to Stay the Mandate on April 8, 2013. On June 13, 2013, we filed a Petition for a Writ of Certiorari, or the Petition, with the U.S. Supreme Court seeking review of the Court of Appeal s decision and to have that decision overturned. On October 7, 2013 the U.S. Supreme Court denied our Petition, resulting in the case s return to the District Court for further proceedings relative to the SAC s surviving claims. Our response to the SAC is due on or before November 6, 2013. The plaintiffs will submit an opposition to our response on or before December 6, 2013. 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. Though we maintain liability insurance, if any costs

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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 approval for commercial use, may expose us to liability claims, whether or not our products are actually at fault for causing an injury. As *Feraheme/Rienso* 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. While these adverse events are rare, all IV irons, including *Feraheme/Rienso*, can cause patients to experience serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and/or fatal. 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 our products, subject us to product recalls or harm our reputation, cause us to incur substantial costs, and divert management s time and attention.

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

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

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

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

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

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

- Non-cumulative voting for directors; and

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

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

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

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

Because we use certain hazardous materials in the production of our products, we are subject to various federal, state and local environmental laws and regulations that govern our operations, including the import, handling and disposal of non-hazardous and hazardous wastes, and emissions and discharges into the environment. Failure to comply with these laws and regulations could result in costs for corrective action, penalties or the imposition of other liabilities. We also are subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment. Under certain of these laws and regulations, a current or previous owner or operator of property may be liable for the costs of remediating the release or spill of hazardous substances or petroleum products on or from its property, without regard to whether the owner or operator knew of, or caused, the contamination, and such owner or operator may incur liability to third parties impacted by such contamination. The presence of, or failure to remediate properly the release or spill of, these substances could adversely affect the value of, and our ability to transfer or encumber, our real property.

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Item 6. Exhibits

(a) List of Exhibits

Exhibit Number		Description
10.1		Fourth Amendment to Commercial Outsourcing Services Agreement, dated effective as of August 1, 2013, by and between the Company and Integrated Commercialization Services, Inc.
31.1	+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	+	The following materials from AMAG Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2013, formatted in Extensible Business Reporting Language (XBRL), (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements.

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

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

* Exhibits marked with a single asterisk reference management contracts, compensatory plans or arrangements.

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SIGNATURES

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

AMAG PHARMACEUTICALS, INC.

By: /s/ William K. Heiden
William K. Heiden
President and Chief Executive Officer

Date: November 6, 2013

AMAG PHARMACEUTICALS, INC.

By: /s/ Scott A. Holmes
Scott A. Holmes
Chief Accounting Officer,
Vice President of Finance and Treasurer

Date: November 6, 2013

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