AMAG PHARMACEUTICALS INC.
Form 10-Q
November 07, 2014
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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, 2014

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 Smaller Reporting Company o
(Do not check if a smaller reporting company)

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, 2014, there were 22,094,769 shares of the registrant s common stock, par value $0.01 per share, outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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AMAG PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

(Unaudited)

	September 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 196,154	$ 26,986
Investments	190,088	186,803
Accounts receivable, net	10,873	6,842
Inventories	19,580	17,217
Receivable from collaboration	932	278
Prepaid and other current assets	9,357	3,396
Restricted cash		2,883
Total current assets	426,984	244,405
Property and equipment, net	1,582	1,846
Intangible assets, net	16,597	16,844
Restricted cash	400	400
Other long-term assets	5,829	1,964
Total assets	$ 451,392	$ 265,459
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,899	$ 2,629
Accrued expenses	27,521	22,266
Deferred revenues	9,419	8,226
Total current liabilities	38,839	33,121
Long-term liabilities:		
Convertible 2.5% senior notes, net	165,778	
Deferred revenues	36,682	44,534
Acquisition-related contingent consideration	11,188	13,609
Other long-term liabilities	1,924	1,787
Total liabilities	254,411	93,051
Commitments and contingencies		
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; 22,026,189 and 21,772,571 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	220	218
Additional paid-in capital	673,767	641,941
Accumulated other comprehensive loss	(3,555)	(3,491)
Accumulated deficit	(473,451)	(466,260)
Total stockholders equity	196,981	172,408
Total liabilities and stockholders equity	$ 451,392	$ 265,459

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,	
	2014	2013	2014	2013
Revenues:				
U.S. *Feraheme* product sales, net	$ 22,547	$ 19,347	$ 62,147	$ 52,381
License fee and other collaboration revenues	2,182	1,998	7,424	6,056
Other product sales and royalties	765	271	1,560	708
Total revenues	25,494	21,616	71,131	59,145
Costs and expenses:				
Cost of product sales	2,968	2,547	8,548	8,634
Research and development expenses	5,358	4,530	16,396	13,983
Selling, general and administrative expenses	12,875	14,934	46,650	44,150
Total costs and expenses	21,201	22,011	71,594	66,767
Operating income (loss)	4,293	(395)	(463)	(7,622)
Other income (expense):				
Interest expense	(3,129)		(7,656)	
Interest and dividend income, net	291	246	809	773
Gains on sale of assets			102	865
Gains on investments, net	3	4	17	36
Total other income (expense)	(2,835)	250	(6,728)	1,674
Net income (loss)	$ 1,458	$ (145)	$ (7,191)	$ (5,948)
Net income (loss) per share:				
Basic	$ 0.07	$ (0.01)	$ (0.33)	$ (0.28)
Diluted	$ 0.06	$ (0.01)	$ (0.33)	$ (0.28)
Weighted average shares outstanding used to compute net income (loss) per share:				
Basic	21,984	21,691	21,912	21,613
Diluted	23,467	21,691	21,912	21,613

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,	
	2014	2013	2014	2013
Net income (loss)	$ 1,458	$ (145)	$ (7,191)	$ (5,948)
Other comprehensive income (loss):				
Unrealized gains (losses) on securities:				
Holding gains (losses) arising during period, net of tax	(305)	399	(76)	(310)
Reclassification adjustment for (gains) losses included in net income (loss)	9		12	21
Net unrealized gains (losses) on securities	(296)	399	(64)	(289)
Total comprehensive income (loss)	$ 1,162	$ 254	$ (7,255)	$ (6,237)

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,	
	2014	**2013**
Cash flows from operating activities:		
Net loss	$ (7,191)	$ (5,948)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	655	2,935
Amortization of premium/discount on purchased securities	1,823	2,076
Write-down of inventory to net realizable value	1,119	502
Non-cash equity-based compensation expense	6,153	5,886
Amortization of debt discount and debt issuance costs	4,531	
Gains on sale of assets	(102)	(865)
Gains on investments, net	(17)	(36)
Change in fair value of contingent consideration	(2,535)	279
Changes in operating assets and liabilities:		
Accounts receivable, net	(4,031)	(2,368)
Inventories	(2,496)	640
Receivable from collaboration	(654)	13
Prepaid and other current assets	(2,211)	313
Other long-term assets	1,001	
Accounts payable and accrued expenses	87	(7,033)
Deferred revenues	(6,659)	(4,999)
Other long-term liabilities	137	(305)
Total adjustments	(3,199)	(2,962)
Net cash used in operating activities	(10,390)	(8,910)
Cash flows from investing activities:		
Proceeds from sales or maturities of investments	58,592	84,454
Purchase of investments	(63,747)	(88,629)
Acquisition of MuGard Rights and inventory		(3,434)
Proceeds from sale of assets	102	977
Capital expenditures	(144)	(1,206)
Change in restricted cash	2,883	(400)
Net cash used in investing activities	(2,314)	(8,238)
Cash flows from financing activities:		
Payment of contingent consideration	(186)	(4)
Proceeds from issuance of convertible debt	200,000	
Payment of debt issuance costs	(6,711)	
Proceeds from issuance of warrants	25,620	
Purchase of convertible bond hedges	(39,760)	
Proceeds from the exercise of stock options	2,909	1,629
Proceeds from the issuance of common stock under ESPP		176
Net cash provided by financing activities	181,872	1,801
Net increase (decrease) in cash and cash equivalents	169,168	(15,347)
Cash and cash equivalents at beginning of the period	26,986	46,293
Cash and cash equivalents at end of the period	$ 196,154	$ 30,946

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, 2014

(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 (IV) use to treat iron deficiency anemia (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 (FDA) for use as an IV iron replacement therapy for the treatment of IDA in adult patients with chronic kidney disease (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 (EU) for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. In March 2010, we entered into a License, Development and Commercialization Agreement (the Takeda Agreement), which was amended in June 2012 (the Amended Takeda Agreement) with Takeda Pharmaceutical Company Limited (Takeda). Under the Amended Takeda Agreement, Takeda has an exclusive license to market and sell ferumoxytol in Canada, the EU and Switzerland, as well as certain other geographic territories. The European marketing authorization for *Rienso* in the EU is valid in the 28 EU Member States as well as in Iceland, Liechtenstein and Norway. The trade name for ferumoxytol in Canada is *Feraheme* and outside of the U.S. and Canada the trade name is *Rienso*.

On June 6, 2013 (the Acquisition Date) we entered into a License Agreement with PlasmaTech Biopharmaceuticals, Inc. (PlasmaTech) (formerly known as Access Pharmaceuticals, Inc.) under which we acquired the U.S. commercial rights to *MuGard* (the MuGard License Agreement). *MuGard* was launched in the U.S. by PlasmaTech 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 MuGard 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 (the U.S. Territory) for the management of all diseases or conditions of the oropharyngeal cavity, including mucositis (the MuGard Rights). Additional details regarding the MuGard License Agreement and the MuGard Rights can be found in Note H, *Business Combination.*

On September 28, 2014, we entered into a definitive agreement to acquire Lumara Health Inc. (Lumara), a privately-held pharmaceutical company specializing in women s health, for $675.0 million ($600.0 million in cash and $75.0 million in stock) and additional contingent consideration of up to $350.0 million based on the achievement of certain sales milestones. Lumara markets Makena® (hydroxyprogesterone caproate injection), a progestin indicated to reduce the risk of preterm birth in

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women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Additional details regarding the definitive agreement with Lumara can be found in Note S, *Subsequent Event.*

Throughout this Quarterly Report on Form 10-Q, AMAG Pharmaceuticals, Inc. and our consolidated subsidiaries are collectively referred to as the Company, AMAG, we, us, or our. Unless the context suggests otherwise, references to Feraheme refer to both *Feraheme* (the trade na ferumoxytol in the U.S. and Canada) and *Rienso* (the trade name for ferumoxytol in the EU and Switzerland).

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 (GAAP).

In accordance with GAAP 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, 2013. 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, 2013.

Use of Estimates and Assumptions

The preparation of condensed consolidated financial statements in conformity with GAAP 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, determining the fair values of our investments, assets acquired in a business combination, debt obligations, and 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.

Cash and Cash Equivalents

Cash and cash equivalents consists principally of cash held in commercial bank accounts, money market funds and U.S. Treasury securities having an original maturity of less than three months. We consider all highly liquid investments with a maturity of three months or less as of the acquisition date to be cash equivalents. At September 30, 2014, substantially all of our cash and cash equivalents were held in either commercial bank accounts or money market funds.

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Principles of Consolidation

The accompanying condensed consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiaries. 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.

Revenue Recognition and Related Sales Allowances and Accruals

We recognize revenue from the sale of our products as well as license fee and other collaboration revenues, including milestone payments, other product sale revenues, and royalties we receive from our licensees. We recognize revenue in accordance with current accounting guidance related to the recognition, presentation and disclosure of revenue in financial statements, which outlines the basic criteria that must be met to recognize revenue and provides guidance for disclosure of revenue in financial statements. We recognize revenue when:

- Persuasive evidence of an arrangement exists;
- Delivery of product has occurred or services have been rendered;
- The sales price charged is fixed or determinable; and
- Collection is reasonably assured.

U.S. Feraheme Product Sales, Net

An analysis of our U.S. *Feraheme* product sales allowances and accruals for the three and nine months ended September 30, 2014 and 2013 is as follows (in thousands):

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	Three Months Ended September 30,	
	2014	2013
Provision for U.S. *Feraheme* product sales allowances and accruals		
Discounts and chargebacks	$ 13,876	$ 10,205
Government and other rebates	4,161	3,044
Medicaid rebate reserve adjustment		(625)
Returns	212	265
Total provision for U.S. *Feraheme* product sales allowances and accruals	18,249	12,889
Total gross U.S. *Feraheme* product sales	$ 40,796	$ 32,236
Total provision for U.S. *Feraheme* product sales allowances and accruals as a percent of total gross U.S. *Feraheme* product sales	45%	40%

	Nine Months Ended September 30,	
	2014	2013
Provision for U.S. *Feraheme* product sales allowances and accruals		
Discounts and chargebacks	$ 37,824	$ 26,925
Government and other rebates	11,300	8,106
Medicaid rebate reserve adjustment		(568)
Returns	584	697
Total provision for U.S. *Feraheme* product sales allowances and accruals	49,708	35,160
Total gross U.S. *Feraheme* product sales	$ 111,855	$ 87,541
Total provision for U.S. *Feraheme* product sales allowances and accruals as a percent of total gross U.S. *Feraheme* product sales	44%	40%

Consistent with industry practice, we generally offer our wholesalers, specialty distributors and other customers a limited right to return *Feraheme* based on the product s expiration date which, once packaged, is currently five years in the U.S. We estimate product returns based on the historical return patterns and known or expected changes in the marketplace. We track actual returns by individual production lots. Returns on lots eligible for credits under our returned goods policy are monitored and compared with historical return trends and rates.

We expect that wholesalers and healthcare providers will not stock significant inventory due to the cost and expense to store *Feraheme*. We record an estimate of returns at the time of sale. If necessary, our estimated rate of returns may be adjusted for actual return experience as it becomes available and for known or expected changes in the marketplace. During the nine months ended September 30, 2014, we reduced our reserve for product returns by $0.3 million due to the lapse of the product return period on certain manufactured *Feraheme* lots. We did not significantly adjust our reserve for product returns during the nine months ended September 30, 2013. To date, returns of *Feraheme* have been relatively limited; however returns experience may change over time. As we continue to gain more historical experience with actual returns, we may be required to make a future adjustment to our product returns estimate, which would result in a corresponding change to our net product sales in the period of adjustment and could be significant.

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. We did not adjust our Medicaid reserve balance during the nine months ended September 30, 2014. During the nine months ended September 30, 2013, we revised our

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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 reduction of our then estimated Medicaid rebate reserve related to prior period *Feraheme* sales. This change in estimate was reflected as an increase in our net product sales for the nine months ended September 30, 2013 and resulted in reductions to our gross to net percentage in that period. The reduction of our estimated Medicaid rebate reserve had an impact of $0.03 per basic and diluted share for the nine months ended September 30, 2013. 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 would affect our net product sales in the period of the adjustment and could be significant.

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, 2014, our cash, cash equivalents and investments amounted to approximately $386.2 million. We currently invest our excess cash primarily in U.S. government and agency money market funds, and investments in corporate debt securities, U.S. treasury and government agency securities, and commercial paper. As of September 30, 2014, we had approximately $191.3 million of our total $196.2 million cash and cash equivalents balance invested in institutional money market funds, of which $179.9 million was invested in a single fund.

Our operations are located solely within the U.S. We are currently focused principally on developing, manufacturing, and commercializing *Feraheme* 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, 2014 and 2013:

	Nine Months Ended September 30,	
	2014	2013
AmerisourceBergen Drug Corporation	39%	43%
McKesson Corporation	24%	23%
Cardinal Health, Inc.	18%	16%
Takeda Pharmaceuticals Company Limited	10%	11%

In addition, approximately 27% and 32% of our end-user demand during the nine months ended September 30, 2014 and 2013, respectively, was generated by members of a single group purchasing organization (GPO) with which we have contracted. Revenues from customers outside of the U.S. amounted to approximately 11% of our total revenues for the nine months ended September 30, 2014 and 2013 and were principally 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* drug substance and finished drug product. We would be exposed to a significant loss of revenue from the sale of *Feraheme* if our suppliers and/or manufacturers cannot fulfill demand for any reason.

C. Investments

As of September 30, 2014 and December 31, 2013, our investments equaled $190.1 million and $186.8 million, respectively, and consisted of securities classified as available-for-sale in accordance with

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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, 2014 and December 31, 2013 (in thousands):

	September 30, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	$ 47,057	$ 56	$ (5)	$ 47,108
Due in one to three years	87,529	100	(147)	87,482
U.S. treasury and government agency securities				
Due in one year or less	22,978	27		23,005
Due in one to three years	30,986	32	(25)	30,993
Commercial paper				
Due in one year or less	1,500			1,500
Total investments	$ 190,050	$ 215	$ (177)	$ 190,088

	December 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	$ 42,609	$ 44	$ (4)	$ 42,649
Due in one to three years	91,443	137	(106)	91,474
U.S. treasury and government agency securities				
Due in one year or less	18,526	19		18,545
Due in one to three years	34,123	37	(25)	34,135
Total investments	$ 186,701	$ 237	$ (135)	$ 186,803

Impairments and Unrealized Gains and 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, 2014 and 2013. We considered various factors, including our current intentions to sell, 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. As of September 30, 2014, an insignificant portion of our investments has been in an unrealized loss position for more than one year. 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.

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Realized Gains and Losses on Investments

Gains and losses are determined on the specific identification method. Realized gains were insignificant during the three and nine months ended September 30, 2014 and 2013.

D. Fair Value Measurements

The following tables represent the fair value hierarchy as of September 30, 2014 and December 31, 2013 for those assets and liabilities that we measure at fair value on a recurring basis (in thousands):

		Fair Value Measurements at September 30, 2014 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	$ 191,258	$ 191,258	$	$
Corporate debt securities	134,590		134,590	
U.S. treasury and government agency securities	53,998		53,998	
Commercial paper	1,500		1,500	
Total Assets	$ 381,346	$ 191,258	$ 190,088	$
Liabilities:				
Acquisition-related contingent consideration	$ 11,848			11,848
Total Liabilities	$ 11,848	$	$	$ 11,848

		Fair Value Measurements at December 31, 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	$ 18,767	$ 18,767	$	$
Corporate debt securities	134,123		134,123	
U.S. treasury and government agency securities	52,680		52,680	
Total Assets	$ 205,570	$ 18,767	$ 186,803	$
Liabilities:				
Acquisition-related contingent consideration	$ 14,550	$	$	$ 14,550
Total Liabilities	$ 14,550	$	$	$ 14,550

With the exception of our money market funds and our acquisition-related contingent consideration, the fair value of our investments 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 September 30, 2014. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the nine months ended September 30, 2014.

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Contingent consideration

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

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, 2014 (in thousands):

Balance as of December 31, 2013	$	14,550
Payments made		(186)
Adjustments to fair value of contingent consideration		(2,535)
Other adjustments		19
Balance as of September 30, 2014	$	11,848

During the three months ended September 30, 2014, we revised our forecast of total projected net sales for *MuGard* and reassessed the fair value of the contingent consideration liability related to the MuGard Rights. As a result, we reduced our contingent consideration liability by $3.7 million and $2.5 million for the three and nine months ended September 30, 2014, respectively. This adjustment is included in selling, general and administrative expenses in our condensed consolidated statements of operations. The $3.7 million adjustment to our contingent consideration liability had an impact of increasing our net income (loss) by $0.17 and $0.16 per basic and diluted share for the three months ended September 30, 2014, respectively, and the $2.5 million adjustment to our contingent consideration liability had an impact of increasing our net income (loss) by $0.12 per basic and diluted share for the nine months ended September 30, 2014. As of September 30, 2014, we estimate that the undiscounted royalty amounts we could pay under the MuGard License Agreement may range from $20.0 million to $28.0 million over a ten year period beginning on the Acquisition Date, 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%. We have classified $0.7 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, 2014.

Debt

In February 2014, we issued $200.0 million of 2.5% convertible senior notes due February 15, 2019 (the Convertible Notes). Interest is payable semi-annually in arrears on February 15 and August 15 of each year, beginning on August 15, 2014. As of September 30, 2014, the fair value of our Convertible Notes was $271.2 million, which differs from their carrying values. The fair value of our Convertible Notes is influenced by interest rates and our stock price and stock price volatility and is determined by prices for the Convertible Notes observed in market trading, which are Level 2 inputs. In addition, in connection with the pricing of the Convertible Notes, we entered into convertible bond hedge transactions (convertible bond hedges) and separate warrant transactions (warrants), as discussed in more detail in Note P, *Debt.*

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E. Accounts Receivable, Net

Our net accounts receivable were $10.9 million and $6.8 million as of September 30, 2014 and December 31, 2013, 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.

Customers which represented greater than 10% of our accounts receivable balances as of September 30, 2014 and December 31, 2013 were as follows:

	September 30, 2014	December 31, 2013
AmerisourceBergen Drug Corporation	51%	43%
McKesson Corporation	26%	29%
Cardinal Health, Inc.	15%	19%

F. Inventories

Our major classes of inventories were as follows as of September 30, 2014 and December 31, 2013 (in thousands):

	September 30, 2014	December 31, 2013
Raw materials	$ 4,341	$ 3,157
Work in process	7,158	8,322
Finished goods	8,081	5,738
Total inventories	$ 19,580	$ 17,217

During the nine months ended September 30, 2014, we expensed $0.7 million of commercial inventory, which we determined would be solely used in development activities at our third-party suppliers, which we have recorded in research and development expenses. In addition, during the nine months ended September 30, 2014, we expensed $0.4 million of commercial inventory deemed no longer saleable, which we have recorded in cost of goods sold.

G. Property and Equipment, Net

Property and equipment consisted of the following as of September 30, 2014 and December 31, 2013 (in thousands):

	September 30, 2014	December 31, 2013

Furniture and fixtures	$	1,509	$	1,536
Leasehold improvements		430		430
Laboratory and production equipment		492		376
		2,431		2,342
Less - accumulated depreciation		(849)		(496)
Property and equipment, net	$	1,582	$	1,846

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H. Business Combination

As part of our strategy to expand our portfolio with additional commercial-stage products, in June 2013, we entered into the MuGard 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.

In consideration for the license, we paid PlasmaTech an upfront payment of $3.3 million in June 2013. We are required to pay royalties to PlasmaTech on net sales of *MuGard* until the later of (a) the expiration of the licensed patents or (b) the tenth anniversary of the first commercial sale of *MuGard* under the MuGard License Agreement in the U.S. Territory (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 PlasmaTech, 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 accounted for the acquisition of the MuGard Rights as a business combination under the acquisition method of accounting. 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.

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

Transaction costs were not included as a component of consideration transferred and were expensed as incurred. We incurred approximately $0.8 million of acquisition-related costs in the nine months ended September 30, 2013. These costs were primarily related to professional and legal fees and were 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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I. Intangible Assets, Net

In June 2013, we acquired the MuGard Rights from PlasmaTech 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 amortize the MuGard Rights using an economic consumption model over ten years from the Acquisition Date, 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 approximately $0.1 million and $0.2 million of amortization related to the MuGard Rights in cost of product sales in our condensed consolidated statements of operations for the three and nine months ended September 30, 2014, respectively, and as a result, our intangible asset related to the MuGard Rights was $16.6 million as of September 30, 2014.

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 did not record any impairment losses in the nine months ended September 30, 2014 and 2013.

J. Income Taxes

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

For the nine months ended September 30, 2014 and 2013, we did not recognize any tax expense or benefit due to our continued net operating loss position. Due to the uncertainty surrounding the realization of favorable tax attributes in future tax returns, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets.

The interest expense related to the Convertible Notes is deductible for income tax purposes, subject to certain limitations.

On September 26, 2014, we adopted an amendment to our Rights Agreement to help preserve our substantial tax assets associated with net operating loss carry forwards (NOLs) and other tax benefits by deterring certain stockholders from increasing their percentage ownership in our stock (the NOL Amendment). The NOL Amendment is discussed in more detail in Note Q, *Stockholders Equity*.

K. Accumulated Other Comprehensive Loss

The changes in accumulated other comprehensive loss, net of tax, for the three and nine months ended September 30, 2014 and 2013 consisted of the following (in thousands):

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Beginning Balance	$ (3,259)	$ (3,935)	$ (3,491)	$ (3,247)
Other comprehensive income (loss) before reclassifications	(305)	399	(76)	(310)
Gain reclassified from other accumulated comprehensive loss	9		12	21
Ending Balance	$ (3,555)	$ (3,536)	$ (3,555)	$ (3,536)

The amounts reclassified from other comprehensive loss for the three and nine months ended September 30, 2014, primarily represented realized gains on investments, which are included in our condensed consolidated statement of operations under Gains on investments, net.

L. Basic and Diluted Net Income (Loss) per Share

We compute basic net income (loss) per share by dividing net income (loss) by the weighted average number of common shares outstanding during the relevant period. Diluted net income per common share has been computed by dividing net income by the diluted number of shares outstanding during the period. Except where the result would be antidilutive to net income, diluted net income per common share has been computed assuming the conversion of the Convertible Notes, the exercise of outstanding stock options, and the vesting of restricted stock units (RSUs).

As we have a choice to settle the conversion obligation under the Convertible Notes in cash, shares or any combination of the two, we currently intend to settle the principal value of the Convertible Notes in cash and the excess conversion premium in shares. The dilutive effect of the conversion premium is reflected in the calculation of diluted earnings per share as if it were a freestanding written call option on our shares. The impact of the conversion premium has been considered in the calculation of diluted net income per share by applying the closing price of our common stock on September 30, 2014 to calculate the number of shares issuable under the conversion premium. The principal value of the Convertible Notes is not included in the calculation of diluted income per share, as we intend to settle this in cash. In February 2014, in connection with the issuance of the Convertible Notes, we entered into convertible bond hedges. The convertible bond hedges are not included for purposes of calculating the number of diluted shares outstanding, as their effect would be anti-dilutive. The convertible bond hedges are generally expected, but not guaranteed, to reduce the potential dilution and/or offset the cash payments we are required to make upon conversion of the Convertible Notes. See Note P, *Debt,* for additional information.

The dilutive effect of the stock options and RSUs has been calculated using the treasury stock method.

The components of basic and diluted net income (loss) per share for the three and nine months ended September 30, 2014 and 2013 were as follows (in thousands, except per share data):

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net income (loss)	$ 1,458	$ (145)	$ (7,191)	$ (5,948)
Weighted average common shares outstanding	21,984	21,691	21,912	21,613
Effect of dilutive securities:				
Stock options and restricted stock units	369			
Convertible 2.5% senior notes	1,114			
Shares used in calculating dilutive net income (loss) per share	23,467	21,691	21,912	21,613
Net income (loss) per share:				
Basic	$ 0.07	$ (0.01)	$ (0.33)	$ (0.28)
Diluted	$ 0.06	$ (0.01)	$ (0.33)	$ (0.28)

As discussed above in Note D, *Fair Value Measurements*, we reduced our contingent consideration liability by $3.7 million and $2.5 million for the three and nine months ended September 30, 2014, respectively, in connection with our reassessment of the fair value of the contingent consideration liability relating to our acquisition of the MuGard Rights. The $3.7 million adjustment to our contingent consideration liability increased our net income (loss) by $0.17 and $0.16 per basic and diluted share, respectively, for the three months ended September 30, 2014 and the $2.5 million adjustment to our contingent consideration liability increased our net income (loss) by $0.12 per basic and diluted share for the nine months ended September 30, 2014.

The following table sets forth the potential common shares issuable upon the exercise of outstanding options, the vesting of RSUs and warrants (prior to consideration of the treasury stock method), which were excluded from our computation of diluted net income (loss) per share because their inclusion would have been anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Options to purchase shares of common stock	2,013	2,717	3,081	2,717
Shares of common stock issuable upon the vesting of restricted stock units	289	497	760	497
Warrants	7,382		7,382	
Total	9,684	3,214	11,223	3,214

During the three and nine months ended September 30, 2014, the average common stock price was below the exercise price of the warrants.

M. Equity-Based Compensation

We currently maintain two equity compensation plans, our Third Amended and Restated 2007 Equity Incentive Plan (the 2007 Plan) and our Amended and Restated 2000 Stock Plan (the 2000 Plan) (under which we no longer grant awards). During the nine months ended September 30, 2014, we also granted equity to certain newly hired executive officers through inducement grants outside of these plans.

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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, 2014, we have granted options and RSUs covering 7,523,252 shares of common stock under our 2007 Plan, of which 3,014,117 stock options and 688,824 RSUs have expired or terminated, and of which 314,295 options have been exercised and 527,546 shares of common stock have been issued pursuant to RSUs that became fully vested. The number of options and RSUs outstanding under this plan as of September 30, 2014, was 2,423,758 and 554,712, respectively. The remaining number of shares available for future grants as of September 30, 2014 was 1,579,800, 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

Our 2000 Plan provided for the grant of options and other equity-based awards to our directors, officers, employees and consultants. As of September 30, 2014, we have granted stock options and RSUs covering 2,182,700 shares of common stock under the 2000 Plan, of which 1,034,339 stock options and 1,500 RSUs have expired or terminated, and of which 1,052,045 stock options have been exercised and 42,500 shares of common stock have been issued pursuant to RSUs that became fully vested. The remaining number of shares underlying outstanding stock options which were issued pursuant to our 2000 Plan as of September 30, 2014, was 52,316. There were no remaining RSUs which were issued pursuant to our 2000 Plan as of September 30, 2014. All outstanding stock options granted under the 2000 Plan have an exercise price equal to the closing price of our common stock on the grant date and have a ten year term. 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 August 2014, we granted certain members of our senior management performance-based RSUs covering a maximum of 195,000 shares of common stock, which will be earned, if at all, based on the achievement of certain (a) targets based upon the calculated value expected to be realized with respect to certain business and corporate development transactions and (b) stock price minimums, during the 30-month period ending January 2, 2017, measured as of January 4, 2016 and January 2, 2017. Fifty percent of the RSU grant that is earned through January 4, 2016 shall vest as of such date, and 100% of the RSU grant that is earned through January 2, 2017 (less the portion previously vested) shall vest as of January 2, 2017, subject to the continued employment of the grantee through each such date. In the event that the minimum conditions of these RSUs are not met as of the measurement dates, none of the RSUs will vest. The maximum total fair value of these RSUs is $6.3 million, which will be recognized to expense over a period of approximately three years from the date the vesting conditions outlined in these grants are deemed probable, net of any estimated and actual forfeitures.

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During the nine months ended September 30, 2014, our Board granted options to purchase 165,000 shares of our common stock and 65,300 RSUs to certain new-hire members of our senior management to induce them to accept employment with us. The 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 and will be exercisable in four equal annual installments beginning on the first anniversary of the respective grant dates. The RSU grants will vest in four equal annual installments beginning on the first anniversary of the respective grant dates. 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. During 2012, we began issuing grants pursuant to inducement grants outside of our 2007 Plan as permitted under the NASDAQ Global Market rules. Since then, we have issued a total of 1,015,300 shares of common stock pursuant to inducement grants outside of our 2007 Plan, of which 101,250 stock options and 41,250 RSUs have been forfeited and of which 28,750 options have been exercised and 33,750 shares of common stock have been issued pursuant to RSUs that became fully vested.

Equity-based compensation expense

Equity-based compensation expense for the three and nine months ended September 30, 2014 and 2013 consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Cost of product sales	$ 32	$ 25	$ 89	$ 83
Research and development	466	337	1,274	1,634
Selling, general and administrative	1,448	1,303	4,790	4,169
Total equity-based compensation expense	$ 1,946	$ 1,665	$ 6,153	$ 5,886

We reduce the compensation expense being recognized to account for estimated forfeitures, which we estimate based primarily on historical experience, adjusted for unusual events such as corporate restructurings, which may result in higher than expected turnover and forfeitures. 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.

N. Commitments and Contingencies

Legal Proceedings

We accrue a liability for legal contingencies when we believe that it is both probable that a liability has been incurred and 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, unless otherwise noted, 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 (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 (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 (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. On November 6, 2013, we filed a renewed Motion to Dismiss the SAC s surviving claims. On December 6, 2013, the plaintiffs filed a brief in opposition to our Motion to Dismiss and we filed a reply brief in support of our Motion on December 27, 2013. On April 7, 2014, the District Court denied our renewed Motion to Dismiss. On May 7, 2014, the parties filed a joint status report with the District Court in advance of a status conference held on May 14, 2014. All defendants filed answers and affirmative defenses to the pending complaint on May 19, 2014. On June 6, 2014, the parties requested the District Court to stay the proceedings, which the Court allowed on June 9, 2014. On September 12, 2014, we and the other defendants entered into a stipulation of settlement that will resolve the class action securities lawsuit. Pursuant to the stipulation of settlement, and in exchange for a release of all claims by the class members, among others, and dismissal of the lawsuit with prejudice, we have agreed to cause our insurer to pay eligible class members and their attorneys a total of $3.75 million. On October 2, 2014, the U.S. District Court preliminarily approved the settlement, and potential class members have been notified of the proposed settlement and the procedures by which they can seek to recover from the settlement fund, object to the settlement or request to be excluded from the settlement class. A settlement hearing has been scheduled for January 20, 2015, at which time the stipulation of settlement will be subject to final approval by the U.S. District Court. We have recorded the $3.75 million settlement amount in prepaid and other current assets and a corresponding amount in accrued expenses on our condensed consolidated balance sheet as of September 30, 2014, as the settlement amount will be fully covered by our insurance carrier. There was no impact to our condensed consolidated statement of operations for the nine months ended September 30, 2014.

In July 2010, Sandoz GmbH (Sandoz) filed with the European Patent Office (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 filed a reply to that response on March 17, 2014 and oral proceedings for the appeal is scheduled for June 16, 2015. We will continue to defend the validity of this patent

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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, 2014. 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, 2014. 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 patents that have been issued or that are pending in the field of research on which we are focused. Other than the above actions, we are not aware of any material claims against us at September 30, 2014. We expense legal costs as they are incurred.

O. Collaborative Agreements

Our commercial strategy includes the formation of collaborations with other pharmaceutical companies to facilitate the sale and distribution of *Feraheme*, primarily outside of the U.S., as well as expanding our portfolio through the in-license or acquisition of additional pharmaceutical products or companies, including revenue-generating commercial products and late-stage development assets. As of September 30, 2014, we were a party to the following collaborations:

Takeda

In March 2010, we entered into the Takeda Agreement with Takeda under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey. In June 2012, we entered into 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.* In addition, the Amended Takeda Agreement modified the timing and pricing arrangements under a supply agreement to be entered into between us and Takeda, and which was entered into in February 2014 and discussed below. The terms of the Amended Takeda Agreement 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 (a) there were no changes to the deliverables under the original Takeda Agreement as a result of the amendment, and (b) the change in arrangement consideration as a result of the amendment was not quantitatively material in relation to the total arrangement consideration.

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

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over a period of ten years from March 31, 2010, the date on which we originally entered the Takeda Agreement, which represents the then-current patent life of *Feraheme* 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* 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. 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 the three and nine months ended September 30, 2014, we recorded $2.0 million and $5.9 million, respectively, in revenues associated with the amortization of the upfront payments in license fee and other collaboration revenues in our condensed consolidated statement of operations. As of September 30, 2014, we had approximately $43.4 million remaining in deferred revenues related to the $61.0 million in upfront payments and the $18.0 million in non-substantive milestone payments previously received from Takeda, of which $7.9 million was classified as short-term and $35.5 million was classified as long-term. 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.

Under the terms of the Amended Takeda Agreement, Takeda is responsible for reimbursing us for certain out-of-pocket regulatory and clinical trial supply costs associated with carrying out our regulatory and clinical research activities under the collaboration agreement. Because we are acting as the principal in carrying out these services, any reimbursement payments received from Takeda 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. We recorded $0.2 million and $0.5 million for the three and nine months ended September 30, 2014, respectively, associated with other reimbursement revenues received from Takeda.

At the time of shipment, we defer recognition of all revenue for *Feraheme* sold to Takeda in our condensed consolidated balance sheets. We recognize revenues from product sales to Takeda, the related cost of goods sold, and any royalty revenues due from Takeda, in our condensed consolidated statement of operations at the time Takeda reports to us that sales have been made to its customers. During the three and nine months ended September 30, 2014, we recognized $0.3 million and $0.7 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, 2014, we had approximately $2.7 million in deferred revenue related to product shipped to Takeda but not yet sold through to Takeda s customers, of which $1.5 million was classified as short-term and $1.2 million was classified as long-term. In addition, we had $2.4 million in deferred cost of product sales, of which $1.4 million was classified as short-term and $1.0 million was classified as long-term. These deferred revenue and deferred cost of product sales are recorded in our condensed consolidated balance sheet as of September 30, 2014.

In February 2014, we entered into a Supply Agreement with Takeda pursuant to which we sell *Feraheme* to Takeda to meet Takeda s requirements for commercial use of *Feraheme* in the licensed territory. Under the Supply Agreement, Takeda is obligated to periodically provide us with demand forecasts of Takeda s future *Feraheme* requirements, which will direct the forecasting and ordering process as well as our supply obligations. Takeda may order *Feraheme* for commercial use in excess of the forecasts, which we agreed to use commercially reasonable efforts to supply. In addition, the Supply Agreement provides the minimum quantity of *Feraheme* that shall be ordered in each purchase order for

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commercial supply. Takeda shall have the right to use the *Feraheme* ordered under the Supply Agreement for clinical use, provided that the product be subject to all of the terms of the Supply Agreement, including commercial specifications. Takeda shall be solely responsible for labeling and packaging vials of the product in accordance with the terms of the Supply Agreement and the Amended Takeda Agreement. If we are unable, for any reason beyond our reasonable control (including an unanticipated increase in demand beyond the production capacity of the manufacturing sites), to supply sufficient quantities of *Feraheme*, we agree to promptly establish an allocation procedure with respect to the available supply of *Feraheme* for the licensed territory and outside the licensed territory. Takeda may obtain *Feraheme* from a designated second source established by us if necessary to meet increased demand, or upon the occurrence of certain defined insolvency events. If we are unable to perform our supply obligations under the Supply Agreement after a negotiated period of time following an insolvency event, Takeda can seek permanent alternative supply sources and the parties supply and purchase obligations under the Supply Agreement will terminate. The Supply Agreement provides that it will otherwise remain in place for the duration of the Amended Takeda Agreement.

In addition, the Supply Agreement provides pricing terms and provides that Takeda will reimburse us for certain capital expenditures and shall pay us a per-vial manufacturing fee. The Supply Agreement also specifies cost-sharing arrangements relating to future process changes or improvements to the manufacturing process for *Feraheme*. We generally agree to indemnify Takeda and its affiliates for damages resulting from the willful misconduct or gross negligence by us or a designated second source with respect to the manufacture of *Feraheme*, or resulting from our breach of the Supply Agreement. Takeda generally agrees to indemnify us, our affiliates and any designated second source for damages resulting with respect to the manufacture of *Feraheme* by Takeda or its affiliates, or resulting from Takeda s breach of the Supply Agreement. The Supply Agreement includes quality control and testing terms, representations and warranties of the parties and other provisions customary for an agreement of this type.

3SBio, Inc.

In 2008, we entered into a Collaboration and Exclusive License Agreement with 3SBio Inc. (3SBio) for the development and commercialization of *Feraheme* as an IV iron replacement therapeutic agent in China. In consideration of the grant of the license, we received an upfront payment of $1.0 million. In January 2014, we mutually terminated the agreement with 3SBio, effective immediately, due to the fact that, despite the best efforts of the parties, regulatory approval in China could not be obtained within the agreed upon time period. During the nine months ended September 30, 2014, we recognized the $1.0 million upfront payment into revenue as we have no future continuing obligations and have included it in license fee and other collaboration revenues in our condensed consolidated statement of operations.

PlasmaTech

Please refer to Note H, *Business Combination,* for a detailed description of the MuGard License Agreement.

P. Debt

2.5% Convertible Notes

On February 14, 2014, we issued $200.0 million aggregate principal amount of Convertible Notes, which includes $25.0 million principal amount of Convertible Notes issued pursuant to the full exercise of an over-allotment option granted to the underwriters in the offering. We received net proceeds of

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$193.3 million from the sale of the Convertible Notes, after deducting fees and expenses of $6.7 million. We used $14.1 million of the net proceeds from the sale of the Convertible Notes to pay the cost of the convertible bond hedges, as described below (after such cost was partially offset by the proceeds to us from the sale of warrants in the warrant transactions described below).

The Convertible Notes are governed by the terms of an indenture between us, as issuer, and Wilmington Trust, National Association, as the Trustee. The Convertible Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi-annually in arrears on February 15 and August 15 of each year, beginning on August 15, 2014. The Convertible Notes will mature on February 15, 2019, unless earlier repurchased or converted. The Convertible Notes will be convertible into cash, shares of our common stock, or a combination thereof, at our election, at an initial conversion rate of approximately 36.9079 shares of common stock per $1,000 principal amount of the Convertible Notes, which corresponds to an initial conversion price of approximately $27.09 per share of our common stock and represents a conversion premium of approximately 35% based on the last reported sale price of our common stock of $20.07 on February 11, 2014, the date the notes offering was priced.

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of stock dividends and payment of cash dividends. At any time prior to the close of business on the business day immediately preceding May 15, 2018, holders may convert their Convertible Notes at their option only under the following circumstances:

(1) during any calendar quarter commencing after the calendar quarter ended on March 31, 2014 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

(2) during the five business day period after any five consecutive trading day period (the measurement period) in which the trading price per $1,000 principal amount of the Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; or

(3) upon the occurrence of specified corporate events.

On or after May 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all or any portion of their Convertible Notes, in multiples of $1,000 principal amount, at the option of the holder regardless of the foregoing circumstances.

If a make-whole fundamental change, as described in the indenture, occurs and a holder elects to convert its Convertible Notes in connection with such make-whole fundamental change, such holder may be entitled to an increase in the conversion rate as described in the indenture.

We may not redeem the Convertible Notes prior to the maturity date and no sinking fund is provided for the Convertible Notes, which means that we are not required to periodically redeem or retire the Convertible Notes. Upon the occurrence of certain fundamental changes involving us, holders of the Convertible Notes may require us to repurchase for cash all or part of their Convertible Notes at a repurchase price equal to 100% of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest.

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The indenture does not contain any financial or maintenance covenants or restrictions on the payments of dividends, the incurrence of indebtedness or the issuance or repurchase of securities by us or any of our subsidiaries. The indenture contains customary terms and covenants and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving us) occurs and is continuing, the Trustee by notice to us, or the holders of at least 25% in principal amount of the outstanding Convertible Notes by written notice to us and the Trustee, may declare 100% of the principal of and accrued and unpaid interest, if any, on all of the Convertible Notes to be due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving us, 100% of the principal of and accrued and unpaid interest, if any, on all of the Convertible Notes will become due and payable automatically. Notwithstanding the foregoing, the indenture provides that, to the extent we elect and for up to 270 days, the sole remedy for an event of default relating to certain failures by us to comply with certain reporting covenants in the indenture consists exclusively of the right to receive additional interest on the Convertible Notes.

In accordance with accounting guidance for debt with conversion and other options, we separately account for the liability and equity components of the Convertible Notes by allocating the proceeds between the liability component and the embedded conversion option (equity component) due to our ability to settle the Convertible Notes in cash, common stock or a combination of cash and common stock, at our option. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected our non-convertible debt borrowing rate for similar debt. The equity component of the Convertible Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the Convertible Notes and the fair value of the liability of the Convertible Notes on their respective dates of issuance. The excess of the principal amount of the liability component over its carrying amount (debt discount) is amortized to interest expense using the effective interest method over five years (the life of the Convertible Notes). The equity component is not remeasured as long as it continues to meet the conditions for equity classification.

Our outstanding convertible note balances as September 30, 2014 consisted of the following (in thousands):

		September 30, 2014
Liability component:		
Principal	$	200,000
Less: debt discount, net		(34,222)
Net carrying amount	$	165,778
Equity component	$	38,188

In connection with the issuance of the Convertible Notes, we incurred approximately $6.7 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs to the liability and equity components based on the allocation of the proceeds. Of the total $6.7 million of debt issuance costs, $1.3 million were allocated to the equity component and recorded as a reduction to additional paid-in capital and $5.4 million were allocated to the liability component and recorded as assets on the balance sheet. The portion allocated to the liability component is amortized to interest expense over the expected life of the Convertible Notes using the effective interest method.

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We determined the expected life of the debt was equal to the five year term on the Convertible Notes. As of September 30, 2014, the carrying value of the Convertible Notes was $165.8 million and the fair value of the Convertible Notes was $271.2 million. The effective interest rate on the liability component was 7.23% for the period from the date of issuance through September 30, 2014. The following table sets forth total interest expense recognized related to the Convertible Notes during the three and nine months ended September 30, 2014 (in thousands):

	Three Months Ended September 30, 2014	Nine Months Ended September 30, 2014
Contractual interest expense	$ 1,250	$ 3,125
Amortization of debt issuance costs	234	564
Amortization of debt discount	1,645	3,967
Total interest expense	$ 3,129	$ 7,656

Convertible Bond Hedge and Warrant Transactions

In connection with the pricing of the Convertible Notes and in order to reduce the potential dilution to our common stock and/or offset cash payments due upon conversion of the Convertible Notes, on February 11, 2014 and February 13, 2014, we entered into convertible bond hedge transactions covering approximately 7.4 million shares of our common stock underlying the $200.0 million aggregate principal amount of the Convertible Notes, including the exercise of the over-allotment option, with JPMorgan Chase Bank, National Association, London Branch, Morgan Stanley & Co. International plc and Royal Bank of Canada (together the Call Spread Counterparties). The convertible bond hedges have an exercise price of approximately $27.09 per share, subject to adjustment upon certain events, and are exercisable when and if the Convertible Notes are converted. If upon conversion of the Convertible Notes, the price of our common stock is above the exercise price of the convertible bond hedges, the Call Spread Counterparties will deliver shares of our common stock and/or cash with an aggregate value approximately equal to the difference between the price of our common stock at the conversion date and the exercise price, multiplied by the number of shares of our common stock related to the convertible bond hedges being exercised. The convertible bond hedges are separate transactions entered into by us and are not part of the terms of the Convertible Notes or the warrants, discussed below. Holders of the Convertible Notes will not have any rights with respect to the convertible bond hedges. We paid $39.8 million for these convertible bond hedges and recorded this amount as a reduction to additional paid-in capital, net of tax, in the first quarter of 2014.

At the same time, we also entered into separate warrant transactions with each of the Call Spread Counterparties relating to, in the aggregate, approximately 7.4 million shares of our common stock underlying the $200.0 million aggregate principal amount of the Convertible Notes, including the exercise of the over-allotment option. The initial exercise price of the warrants is $34.12 per share, subject to adjustment upon certain events, which is 70% above the last reported sale price of our common stock of $20.07 on February 11, 2014. The warrants would separately have a dilutive effect to the extent that the market value per share of our common stock, as measured under the terms of the warrants, exceeds the applicable exercise price of the warrants. The warrants were issued to the Call Spread Counterparties pursuant to the exemption from registration set forth in Section 4(a)(2) of the Securities Act of 1933, as amended. We received $25.7 million for these warrants and recorded this amount to additional paid-in capital in the first quarter of 2014.

Aside from the initial payment of a $39.8 million premium to the Call Spread Counterparties under the convertible bond hedges, which amount is partially offset by the receipt of a $25.7 million premium

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under the warrants, we are not required to make any cash payments to the Call Spread Counterparties under the convertible bond hedges and will not receive any proceeds if the warrants are exercised.

Q. Stockholders Equity

In connection with the pricing of the Convertible Notes, on February 11, 2014, we and American Stock Transfer & Trust Company, LLC (the Rights Agent) entered into an amendment (the Convertible Notes Amendment) to our shareholder rights plan, dated as of September 4, 2009 (the Rights Agreement) between us and the Rights Agent. The Convertible Notes Amendment, among other things, provides that, notwithstanding anything in the Rights Agreement to the contrary, each Call Spread Counterparty shall be deemed not to beneficially own any common shares underlying, or synthetically owned pursuant to, any warrant held by such Call Spread Counterparty, any common shares held by such Call Spread Counterparty (or any affiliate thereof) to hedge its exposure with respect to the convertible bond hedges and warrants, any common shares underlying, or synthetically owned pursuant to, any Derivative Securities (as such term is defined in the Rights Agreement), including the Convertible Notes, held, or entered into, by such Call Spread Counterparty (or any affiliate thereof) to hedge its exposure with respect to the convertible bond hedges and warrants or any Convertible Notes held by such Call Spread Counterparty (or any affiliate thereof) in its capacity as underwriter in the notes offering.

On September 26, 2014, we adopted the NOL Amendment to our Rights Agreement to help preserve our substantial tax assets associated with NOLs and other tax benefits by deterring certain stockholders from increasing their percentage ownership in our stock. The NOL Amendment shortens the expiration date of the Rights Agreement from September 17, 2019 to March 31, 2017, decreases the exercise price of the rights from $250.0 to $80.0 in connection therewith, and makes changes to the definition of beneficial ownership, as used in the Rights Agreement, as amended, to make it consistent with how ownership is defined under Section 382 of the Internal Revenue Code of 1986, as amended. The original Rights Agreement provided for a dividend distribution of one preferred share purchase right (a Right) for each outstanding share of our common stock, which dividend was paid on September 17, 2009. Rights will separate from the common stock and will become exercisable upon the earlier of (a) the close of business on the 10th calendar day following the first public announcement that a person or group of affiliated or associated persons has acquired beneficial ownership of 4.99% or more (which percentage had been 20% before the NOL Amendment) of the outstanding shares of common stock, other than as a result of repurchases of stock by us or certain inadvertent actions by a stockholder or (b) the close of business on the 10th business day (or such later day as the Board may determine) following the commencement of a tender offer or exchange offer that could result, upon its consummation, in a person or group becoming the beneficial owner of 4.99% or more (which percentage had been 20% before the NOL Amendment) of the outstanding shares of common stock (the earlier of such dates being herein referred to as the Distribution Date).

The NOL Amendment provides that the Rights are not exercisable until the Distribution Date and will expire at the earliest of (a) March 31, 2017, (b) the time at which the Rights are redeemed or exchanged, (c) the effective date of the repeal of Section 382 or any successor statute if the Board determines that the NOL Rights Plan is no longer necessary or desirable for the preservation of our tax benefits, (d) the first day of our taxable year to which the Board determines that no tax benefits may be carried forward or (e) September 26, 2015 if stockholder approval of the NOL Amendment has not been obtained by or on such date.

We expect to submit the NOL Amendment to a vote of our stockholders at our 2015 annual meeting of stockholders. There can be no assurance that the NOL Amendment will result in us being able to preserve all or any of the substantial tax assets associated with NOLs and other tax benefits.

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Total stockholders equity increased $24.6 million compared to December 31, 2013. This increase was primarily driven by $38.2 million allocated to the equity portion of our Convertible Notes, as described in Note P, *Debt*, $6.2 million in stock-based compensation expense and $2.9 million from the exercise of stock options. These increases were partially offset by our net loss of $7.2 million, $14.1 million paid for the cost of the convertible bond hedges, net of the sale of warrants, and $1.3 million in debt issuance costs that were allocated to the equity component of the Convertible Notes, also described further in Note P *Debt*.

R. Recently Issued and Proposed Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers, as a new Topic, Accounting Standards Codification Topic 606*. The new revenue recognition standard provides a five-step analysis of transactions to determine when and how revenue is recognized. The core principle is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This ASU is effective for us on January 1, 2017 and shall be applied retrospectively to each period presented or as a cumulative-effect adjustment as of the date of adoption. We are in the process of evaluating the effect of adopting this new accounting guidance and are uncertain at this point of the impact on our results of operations, cash flows or financial position.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements - Going Concern: Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern*. ASU No. 2014-15 is intended to define management s responsibility to evaluate whether there is substantial doubt about an organization s ability to continue as a going concern and to provide related footnote disclosures, if required. ASU 2014-15 will be effective for annual reporting periods ending after December 15, 2016, which will be our fiscal year ending December 31, 2016, and to annual and interim periods thereafter. We are in the process of evaluating the impact of adoption of ASU 2014-15 on our condensed consolidated financial statements and related disclosures and currently do not expect it to have a material impact our results of operations, cash flows or financial position.

From time to time, new accounting pronouncements are issued by FASB or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

S. Subsequent Event

Lumara Agreement

On September 28, 2014, we entered into an Agreement and Plan of Merger (the Lumara Agreement) with *inter alia,* Lumara. The Lumara Agreement provides that, at the effective time of the merger, upon the terms and subject to the conditions set forth in the Lumara Agreement, a wholly-owned merger subsidiary of AMAG will merge with and into Lumara, with Lumara continuing as the surviving entity and our wholly-owned subsidiary. Lumara is a privately held pharmaceutical company specializing in women s health which markets Makena® (hydroxyprogesterone caproate injection), a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

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Subject to the terms and conditions of the Lumara Agreement, we have agreed to pay an aggregate of $675.0 million in upfront merger consideration consisting of a combination of $600.0 million in cash (the Cash Consideration) and 3,209,971 unregistered shares of our common stock.

The Lumara Agreement includes future contingent payments of up to $350.0 million in cash (or upon mutual agreement between us and the Lumara security holders, future contingent payments may also be made in stock or some combination thereof) payable by us to the Lumara security holders based upon the achievement of certain sales milestones through calendar year 2019.

The Lumara Agreement contains customary representations, warranties and covenants of the parties as well as customary conditions to closing, including among other things, the representations and warranties of Lumara being true and correct at the closing subject to the terms of the Lumara Agreement and the absence of any material adverse changes affecting Lumara. In addition, the Lumara Agreement provides for limited termination rights, including but not limited to, by the mutual consent of us and the stockholders representative; upon certain breaches of representations, warranties, covenants or agreements; and in the event the merger has not been consummated before January 31, 2015. We expect to consummate the merger in the fourth quarter of 2014. We will not incur any termination fees in the event the merger is not consummated.

Commitment Letter

Pursuant to the Lumara Agreement, we are obligated to obtain financing to fund a portion of the Cash Consideration. Receipt of financing by us is not a condition to our obligations under the Lumara Agreement.

Concurrently with the execution and delivery of the Lumara Agreement, Jefferies Finance LLC (Jefferies) entered into a commitment letter with us (the Commitment Letter), pursuant to which Jefferies and other lenders have committed to provide a senior secured term loan facility to us of up to $340.0 million (the Term Loan Facility) subject to customary conditions set forth in the Commitment Letter. We expect to enter into the Term Loan Facility and to use the proceeds of the Term Loan Facility, together with cash on hand and other available sources of funding, to (a) pay a portion of the Cash Consideration and (b) pay various fees and expenses incurred in connection with the Lumara merger and the Term Loan Facility.

The obligations of the Lenders to provide the financing under the Commitment Letter for the Term Loan Facility are subject to customary conditions for acquisition financings, including conditions that do not relate directly to the Lumara Agreement, such as the tolling of a 15-business-day marketing period (with customary exclusions for holidays) for Jefferies to syndicate the Term Loan Facility. The Commitment Letter expires on the earliest of (a) the date that is five business days after the valid termination of the Lumara Agreement, (b) the closing of the Lumara merger (unless the lenders have failed to fund in breach of their obligations under the Commitment Letter) and (c) January 30, 2015. The Term Loan Facility amortizes in quarterly installments over the term of the Term Loan Facility, is secured by substantially all of our assets and the assets of our subsidiaries and is guaranteed by certain of our subsidiaries.

Pursuant to the Commitment Letter and in accordance with the terms of a fee letter entered into between Jefferies and us, Jefferies and the lenders expect to receive certain customary fees, some of which are based on their pro rata participation under the Commitment Letter, from us, including certain fees payable depending on various circumstances and contingencies. In addition, the fee letter includes certain market-flex

provisions. The Term Loan Facility contemplated by the Commitment Letter will impose restrictive covenants on us, including a requirement that we reduce our leverage over time, and obligate us to make certain payments of principal and interest over time.

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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2013 (our Annual Report).

Unless the context suggests otherwise, references to Feraheme refer to both Feraheme (the trade name for ferumoxytol in the U.S. and Canada) and Rienso (the trade name for ferumoxytol in the EU and Switzerland).

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, among others, statements regarding the following: our plan to grow Feraheme in the U.S. chronic kidney disease market and through international expansion, IV iron market expansion and potential label expansion; the expected timing of our acquisition of Lumara; the expansion of our portfolio through the in-license or purchase of additional pharmaceutical products or companies, late-stage development assets and revenue-generating commercial products; the amount of resources that we intend to dedicate to the commercialization of Feraheme; our beliefs about the market opportunities for Feraheme; expectations regarding our supplemental New Drug Application for Feraheme, our plans for addressing the complete response letter from the FDA and the path forward for Feraheme in the broad iron deficiency anemia patient population; expectations regarding feedback from and discussions with the FDA; the timing of the opinion of the Committee for Medicinal Products for Human Use and the related decision by the European Commission regarding Takeda Pharmaceutical Company Limited s application for Type II Variation of the marketing authorization for Rienso in the EU; our expectations regarding the results of discussions with the Committee for Medicinal Products for Human Use in the EU and with Health Canada, including our belief that approval of the broader indication in such territories is unlikely without additional clinical data; our proposed or potential future label changes; our expectations regarding the timing for enrollment in and commencement of our pediatric studies and a post-approval trial to assess the safety and efficacy of repeat doses of Feraheme for the treatment of iron deficiency anemia; 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 contribution of Makena sales to the funding of our on-going operations; the potential significance of costs in integrating Lumara into our current business; the potential impact of continued regulatory developments; 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 drug substance and drug product at our third-party manufacturers; our expectations regarding customer returns and other revenue-related reserves and accruals; expectations regarding the marketing authorization for Rienso in the EU that may result from the review by the CHMP 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 regarding government regulations, including the Branded Drug Fee under the Healthcare Reform Act and the Medicare reimbursement rate for Feraheme and estimates for

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Medicaid rebates; our expectations regarding our license fee and other collaboration revenues; expected customer mix and utilization rates; our beliefs concerning the mix of non-dialysis patients who were administered IV iron in the U.S. in 2013; the impact of volume rebates and other incentives; provider purchase patterns and use of competitive products; expectations regarding MuGard and our license arrangement with PlasmaTech Biopharmaceuticals, Inc. (formerly known as Access Pharmaceuticals, Inc.); the valuation of certain intangible assets, contingent consideration, debt and other assets and liabilities, including our methodology and assumptions regarding fair value measurements; our gross-to-net sales adjustments; our expectations regarding competitive pressures and the impact on growth on our product sales; expectations regarding our Citizen Petition; our expectations regarding sales and royalties, including our expectations of increased sales of Feraheme in the fourth quarter of 2014 ; our expectations regarding the costs of sales and costs of royalties; our plans regarding manufacturing; our expectations for product sales and fluctuations in net revenue per gram of Feraheme 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; expectations for our debt, including the Convertibles Notes, the Term Loan Facility, and use of proceeds for each; the manner in which intend to settle the conversion of our Convertible Notes; the impact of our Convertible Notes, and the convertible bond hedges and warrants, on a potential change in control transaction; our belief regarding the potential impact of the adoption of newly issued and future accounting guidance on our financial statements; the submission of the NOL Amendment to our Rights Plan to our shareholders for approval; and our expectations for our cash, revenue, 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 (IV) use to treat iron deficiency anemia (IDA) in adult patients with chronic kidney disease (CKD) and MuGard® Mucoadhesive Oral Wound Rinse for the management of oral mucositis. Along with driving continued growth of our products, we intend to continue to expand and diversify our portfolio through the in-license or purchase of additional pharmaceutical products or companies, including revenue-generating commercial products and late-stage development assets that leverage our corporate infrastructure, sales force call points and commercial expertise. Our primary goal is to bring to market therapies that provide clear benefits and improve patients lives.

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 (the FDA) for use as an IV iron replacement therapy for the treatment of IDA in adult patients with 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*

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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 international expansion, IV iron market expansion and potential label expansion. We are also focusing a portion of our efforts on marketing and selling *MuGard* in the U.S.

Outside of the U.S., ferumoxytol was granted marketing approval for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD in Canada in December 2011, in Switzerland in June 2012 and in the European Union (EU) in August 2012. The marketing authorization granted in the EU is valid in the 28 EU Member States as well as in Iceland, Liechtenstein and Norway. The trade name for ferumoxytol in Canada is *Feraheme* and outside of the U.S. and Canada the trade name is *Rienso*. Under our amended agreement with Takeda Pharmaceutical Company Limited (Takeda) described below, Takeda has an exclusive license to market and sell ferumoxytol in Canada, the EU and Switzerland, as well as certain other geographic territories.

Portfolio Expansion

On September 28, 2014, we entered into an Agreement and Plan of Merger (the Lumara Agreement) to acquire Lumara Health Inc. (Lumara) for $675.0 million ($600.0 million in cash and $75.0 million in stock (consisting of 3,209,971 shares of our common stock, as valued at the time of signing)) and additional contingent consideration of up to $350.0 million based on the achievement of certain sales milestones. Lumara is a privately held pharmaceutical company specializing in women s health which markets Makena® (hydroxyprogesterone caproate injection), a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. We expect this transaction to be completed in the fourth quarter of 2014.

In June 2013, we entered into a License Agreement with PlasmaTech Biopharmaceuticals, Inc. (PlasmaTech) (formerly known as Access Pharmaceuticals, Inc.) under which we acquired the U.S. commercial rights to *MuGard* (the MuGard License Agreement). *MuGard* was launched in the U.S. by PlasmaTech 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 MuGard 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 (the U.S. Territory) for the management of all diseases or conditions of the oropharyngeal cavity, including mucositis (the MuGard Rights). We sell *MuGard* to wholesalers and specialty and retail pharmacies. See Note H, *Business Combination*, to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information regarding the MuGard License Agreement and the MuGard Rights.

To further build our business, we intend to continue to expand and diversify our portfolio through the in-license or purchase of additional pharmaceutical products or companies. We are seeking complementary products that will leverage our corporate infrastructure, sales force call points and commercial expertise, with a particular focus on women s health (assuming the consummation of the acquisition of Lumara), hematology and oncology centers, nephrology clinics and hospitals. In the near-term, our primary focus will be the pursuit of revenue-generating commercial products. Longer-term, we expect to also evaluate late-stage development assets. In addition, we are contemplating transactions that would be financially beneficial to us, including those that allow us to realize cost synergies to increase cash flows, as well as transactions that potentially optimize after-tax cash flows.

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We expect the pending acquisition of Lumara, once completed, to have a significant impact on our business and results of operations, including revenues, cost of product sales, research and development expenses, selling, general and administrative expenses, and net income (loss), which we are in the process of assessing. Our expectations of income and expenses discussed throughout this Item 2. *Management s Discussion and Analysis of Financial Condition and Results of Operations* do not include the impact of the pending Lumara acquisition and the resulting commercialization of *Makena*.

Feraheme for the treatment of IDA in patients with CKD

In June 2009, *Feraheme* was approved for marketing in the U.S. by the FDA for use as an IV iron replacement therapeutic for the treatment of IDA in adult patients with CKD. In June 2014, based on a review of global post-marketing data, we proposed changes to the FDA related to our current U.S. label of *Feraheme* to strengthen the warnings and precautions section of the label to enhance patient safety and mitigate the risk of serious hypersensitivity reactions, including anaphylaxis. These proposed label changes are currently under review with the FDA.

In Europe, Takeda has been commercializing ferumoxytol since its approval in June 2012 under the trade name *Rienso*, currently in nine EU countries. In March 2014, the European Medicines Agency s (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) initiated an evaluation of a Periodic Safety Update Report (PSUR) concerning *Rienso.* This PSUR had been submitted to the EMA by Takeda, the marketing authorization holder (the MAH) in February 2014. The PSUR is a pharmacovigilance document intended to provide a safety update permitting an evaluation of the risk-benefit balance of a medicinal product.

As part of its assessment of the PSUR, which included the review of a high rate of hypersensitivity reactions with fatal outcomes with *Rienso*, PRAC requested that Takeda, the MAH for *Rienso* in Europe, submit supplementary information to enable further assessment and discussion about *Rienso.* In agreement with PRAC, Takeda issued a Direct Healthcare Professional Communication (DHPC) letter in May 2014. This DHPC letter reminded physicians in the EU of the existing risk minimization measures for all IV iron products to manage and minimize the risk of serious hypersensitivity reactions that were included in the special warnings and precautions sections of the *Rienso* label. In addition, at PRAC s request, we and Takeda participated in an Oral Explanation meeting held on July 8, 2014 at the premises of the EMA.

On July 10, 2014, PRAC confirmed that the benefit-risk balance of *Rienso* in the currently approved CKD indication remains favorable subject to a number of proposed changes to the product information. These recommendations included proposed changes to the product label. These changes included the recommendation, among other measures, that *Rienso* should be administered to patients by infusion over at least 15 minutes (replacing injection) and that it should be contraindicated in patients with any known history of drug allergy. The PRAC recommendation was sent to the EMA s Committee for Medicinal Products for Human Use (CHMP). On July 23, 2014, the CHMP issued its opinion and agreed with PRAC s recommendations. Takeda has updated the product s label accordingly and issued a DHPC letter in August 2014 informing physicians of these changes. In addition, the CHMP recommended that amendments be made to the Risk Management Plan for *Rienso* and that Takeda conduct a new Post Authorization Safety Study (PASS) to further characterize the risk of hypersensitivity with *Rienso.* The final PASS report is due at the end of 2017. Until Takeda has further discussions with the CHMP, we cannot predict the design, cost or timing of any additional clinical trials we will be required to conduct to maintain the CKD marketing authorization application. We expect that the cost of such trials, if pursued, will be allocated between us and Takeda according to the cost-sharing arrangement under the terms of the Amended Takeda Agreement. Even if such clinical studies are approved and undertaken, the resulting clinical data may not support approval of a broader indication.

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Feraheme for the treatment of IDA in a broad range of patients

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 851,000 grams of IV iron were administered for the treatment of non-dialysis patients with IDA in 2013. We believe that approximately half, or 425,000 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 December 2012, we submitted a supplemental new drug application (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 included data from two controlled, multi-center Phase III clinical trials (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 (IDA-303) and receive treatment with *Feraheme,* as defined in the protocol.

In January 2014, we received a complete response letter from the FDA for the sNDA informing us that our sNDA could not be approved in its present form and stating that we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for the proposed broader indication. The FDA indicated that its decision was based on the cumulative ferumoxytol data, including the global Phase III IDA program and global post-marketing safety reports for the currently indicated CKD patient population. The FDA suggested, among other things, that we submit additional clinical trial data in the proposed broad IDA patient population with a primary composite safety endpoint of serious hypersensitivity/anaphylaxis, cardiovascular events and death, events that are included in the labels of *Feraheme* and other IV irons and that have been reported in the post-marketing environment for *Feraheme*. Additionally, the FDA proposed potentially evaluating alternative dosing and/or administration of *Feraheme* as well as potential changes to labeling that would be intended to reduce the risk of serious hypersensitivity reactions associated with *Feraheme*. In June 2014, we met with the FDA to discuss our proposed approach to resolving the points that were raised in the complete response letter. Based on the FDA s feedback, we submitted a revised proposal that includes the design of a potential clinical trial, a safety endpoint for such trial and alternative methods of administration of *Feraheme*. We expect to receive feedback from the FDA during the fourth quarter of 2014 and expect to thereafter be able to assess and determine the path forward, if any, for *Feraheme* in the broad IDA patient population in the U.S., including the related timing and cost of any clinical trials.

In June 2013, Takeda filed a Type II Variation to update the marketing authorization for *Rienso* in the EU to extend the therapeutic indication from adult patients with IDA associated with CKD to adult patients with iron deficiency from any underlying cause. As a result of PRAC s review of *Rienso*, as discussed above, the CHMP delayed the timing of its decision and has informed Takeda that it will render an opinion or request supplementary information in the fourth quarter of 2014. During the review of the file, Takeda has received inquiries focused on similar issues and questions that were raised by the FDA in our complete response letter, including the need for additional clinical trials and safety data. Based on these inquiries and interactions, we believe that approval in the broader IDA indication is unlikely in the EU without additional clinical data. Even if clinical studies are approved and undertaken, the resulting clinical data may not support approval of a broader indication. If the

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CHMP issues a positive opinion for *Rienso* for the treatment of IDA generally without limit to a specific patient population or sub-population and the European Commission adopts a decision approving this variation, which, as discussed above, we think is unlikely, the Amended Takeda Agreement (defined below) provides that a significant milestone payment from Takeda will become payable to us. We cannot predict whether the CHMP will issue its opinion in the fourth quarter of 2014 as expected.

In addition, in October 2013, Takeda filed a Supplemental New Drug Submission (sNDS) with Health Canada seeking marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients. In October 2014, we were informed by Takeda that a final decision on the sNDS is expected by Health Canada in the first quarter of 2015. Like its counterparts in the EU, Health Canada has focused on similar issues and questions that were raised by the FDA in our complete response letter, including the need for additional clinical trials and safety data. Takeda has 90 days to respond to the inquiries received in October 2014. Based on these inquiries and interactions, we similarly believe that approval in the broader indication is unlikely in Canada without additional clinical data and that, even if clinical studies are approved and undertaken the resulting clinical data may not support approval of a broader indication. No milestones are contingent upon approval of the sNDS. We cannot predict whether Health Canada will issue a final decision on the sNDS in the first quarter of 2015 as expected. Further, until Takeda has further conversations with Health Canada, we cannot predict whether their concerns with regard to approval of the broader IDA indication, including with regard to the need for additional clinical data, will cause Health Canada to impose additional restrictions on the current CKD indication.

We, in collaboration with Takeda, are in the process of assessing the information and inquiries provided by the EU and Canadian regulators and will evaluate our options to make a final determination on how best to address the regulators concerns, including whether to pursue any required clinical trials. Until Takeda has further discussions with the regulators, we cannot predict the path forward, if any, for *Feraheme* in the broad IDA patient population in the EU and Canada, including the related timing and cost of any clinical trials. We note, too, that even if such clinical studies are approved and undertaken, the resulting clinical data may not support approval of a broader indication.

Takeda Collaboration

In March 2010, we entered into a License, Development and Commercialization Agreement (the Takeda Agreement), which was amended in June 2012 (the Amended Takeda Agreement) with Takeda under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey. In February 2014, we entered into a supply agreement with Takeda, which provides the terms under which we sell *Feraheme* to Takeda in order for Takeda to meet its requirements for commercial use of *Feraheme* in its licensed territories. The Amended Takeda Agreement and related Supply Agreement are discussed in further detail in Note O, *Collaborative Agreements*, to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Post-Marketing Commitments of Feraheme in CKD

We have initiated a randomized, active-controlled pediatric study 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 study covers both dialysis-dependent and non-dialysis dependent CKD pediatric patients and 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 (MAA) for ferumoxytol, was approved by the EMA in December 2009 and

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amended in 2012, and includes the pediatric study as 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 pediatric study 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 global 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 commitment we made to the EMA as a condition of the marketing authorization for ferumoxytol in the EU, this study includes a treatment arm with iron sucrose using a magnetic resonance imaging (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 believe enrollment could be completed 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.

We are currently assessing the impact of the July 2014 CHMP decision on our ongoing clinical trials to determine if an amendment to any of the protocols is necessary.

Convertible Notes Offering

To help facilitate the activities described above, in February 2014 we issued $200.0 million of 2.5% convertible senior notes due February 15, 2019 (the Convertible Notes). Interest is payable semi-annually in arrears on February 15 and August 15 of each year, beginning on August 15, 2014. The initial conversion rate is 36.9079 shares of our common stock per $1,000 principal amount of the Convertible Notes, which corresponds to an initial conversion price of approximately $27.09 per share of our common stock and represents a conversion premium of approximately 35% based on the last reported sale price of our common stock of $20.07 on February 11, 2014, the date the Convertible Notes offering was priced. In addition, in connection with the pricing of the Convertible Notes and in order to reduce the potential dilution to our common stock and/or offset cash payments due upon conversion of the Convertible Notes, we also entered into convertible bond hedge and warrant transactions in February 2014. The initial exercise price of the warrants is $34.12 per share, subject to adjustment upon certain events, which is 70% above the last reported sale price of our common stock of $20.07 on February 11, 2014. Please refer to Note P, *Debt,* to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information regarding the Convertible Notes and the bond hedge and warrant transactions.

Our Acquisition of Lumara

On September 28, 2014, we entered into the Lumara Agreement with, *inter alia*, Lumara. Subject to the terms and conditions of the Lumara Agreement, we have agreed to pay an aggregate of $675.0 million in upfront merger consideration consisting of a combination of $600.0 million in cash (the Cash Consideration) and 3,209,971 unregistered shares of our common stock (as valued at the time of signing).

The Lumara Agreement includes future contingent payments of up to $350.0 million in cash (or upon mutual agreement between us and the Lumara security holders, future contingent payments may also be made in common stock or some combination thereof) payable by us to the

Lumara security holders based upon the achievement of certain sales milestones through calendar year 2019.

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The Lumara Agreement contains customary representations, warranties and covenants of the parties as well as customary conditions to closing, including among others the representations and warranties of Lumara being true and correct at the closing subject to the terms of the Lumara Agreement and the absence of any material adverse changes affecting Lumara. In addition, the Lumara Agreement provides for limited termination rights, including but not limited to, by the mutual consent of us and the stockholders representative; upon certain breaches of representations, warranties, covenants or agreements; and in the event the merger has not been consummated before January 31, 2015. We expect to consummate the merger in the fourth quarter of 2014.

Pursuant to the Lumara Agreement, we are obligated to obtain financing to fund a portion of the Cash Consideration. Receipt of financing by us is not a condition to our obligations under the Lumara Agreement.

Concurrently with the execution and delivery of the Lumara Agreement, Jefferies Finance LLC (Jefferies) entered into a commitment letter with us (the Commitment Letter), pursuant to which Jefferies and additional lenders (together, the Lenders) have committed to provide a senior secured term loan facility to us of up to $340.0 million (the Term Loan Facility) subject to customary conditions set forth in the Commitment Letter. We expect to enter into the Term Loan Facility and to use the proceeds of the Term Loan Facility, together with cash on hand and other available sources of funding, to (a) pay the Cash Consideration and (b) pay various fees and expenses incurred in connection with the merger and the Term Loan Facility.

The obligations of the Lenders to provide the financing under the Commitment Letter for the Term Loan Facility are subject to customary conditions for acquisition financings, including conditions that do not relate directly to the Lumara Agreement such as the tolling of a 15 business day marketing period (with customary exclusions for holidays) for Jefferies to syndicate the Term Loan Facility. The Commitment Letter expires on the earliest of (a) the date that is five business days after the valid termination of the Lumara Agreement, (b) the closing of the merger (unless the Lenders have failed to fund in breach of their obligations under the Commitment Letter) and (c) January 30, 2015. The Term Loan Facility amortizes in quarterly installments over the term of the Term Loan Facility, is secured by substantially all of our assets and the assets of our subsidiaries and is guaranteed by certain of our subsidiaries.

Pursuant to the Commitment Letter and in accordance with the terms of a fee letter entered into between Jefferies and us, Jefferies and the Lenders expect to receive certain customary fees, some of which are based on their pro rata participation under the commitment letter, from us, including certain fees payable depending on various circumstances and contingencies. In addition, the fee letter includes certain market-flex provisions. The Term Loan Facility contemplated by the Commitment Letter will impose restrictive covenants on us, including a requirement that we reduce our leverage over time, and obligate us to make certain payments of principal and interest over time.

Results of Operations Three Months Ended September 30, 2014 and 2013

Revenues

Total revenues for the three months ended September 30, 2014 and 2013 consisted of the following (in thousands):

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	Three Months Ended September 30,			
	2014	2013	$ Change	% Change
U.S. *Feraheme* product sales, net	$ 22,547	$ 19,347	$ 3,200	17%
License fee and other collaboration revenues	2,182	1,998	184	9%
Other product sales and royalties	765	271	494	>100%
Total	$ 25,494	$ 21,616	$ 3,878	18%

Our total revenues during the three months ended September 30, 2014 increased by $3.9 million, or 18%, as compared to the same period in 2013, primarily as the result of a $3.2 million increase in U.S. net *Feraheme* product sales, as discussed in more detail below. Included in our net product sales for the three months ended September 30, 2013 was $0.6 million resulting from a reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales, 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, 2014 and 2013 consisted of the following (in thousands):

	Three Months Ended September 30,					
	2014	Percent of gross U.S. Feraheme product sales	2013	Percent of gross U.S. Feraheme product sales	$ Change	% Change
Gross U.S. *Feraheme* product sales	$ 40,796		$ 32,236		$ 8,560	27%
Less provision for product sales allowances and accruals:						
Discounts and chargebacks	13,876	34%	10,205	32%		
Government and other rebates	4,161	10%	3,044	9%		
Medicaid rebate reserve adjustment		0%	(625)	-2%		
Returns	212	1%	265	1%		
Total	18,249	45%	12,889	40%		
Net U.S. *Feraheme* product sales	$ 22,547		$ 19,347		$ 3,200	17%

Our gross U.S. *Feraheme* product sales increased by $8.6 million, or 27%, during the three months ended September 30, 2014 as compared to the same period in 2013. Of the $8.6 million increase, $5.0 million was due to price increases and $3.6 million was due to increased units sold. This increase was partially offset by $4.7 million of additional allowances and accruals in the third quarter of 2014, excluding a $0.6 million reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales for the three months ended September 30, 2013. As a result, total net U.S. *Feraheme* product sales increased by $3.2 million, or 17%, during the three months ended September 30, 2014 as compared to the same period in 2013. Although we expect *Feraheme* revenues to increase for the remainder of 2014, as compared to 2013, we anticipate increasing competitive pressures, which may lead to a slower growth rate in product sales as compared to the growth rate in 2013.

As noted above, during the three months ended September 30, 2013, 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 July 2009 launch of *Feraheme*, our expectations of state level

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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 was a credit of $0.6 million, resulting in an increase to product sales during that period. 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 adjustment and could be significant.

Total discounts and chargebacks for the three months ended September 30, 2014 were $13.9 million, or 34% of total gross U.S. *Feraheme* product sales, as compared to $10.2 million, or 32%, in the same period in 2013. The increase in total discounts and chargebacks as a percentage of total gross U.S. *Feraheme* product sales was related primarily to a change in our customer mix.

Total government and other rebates were $4.2 million, or 10% of total gross U.S. *Feraheme* product sales, in the three months ended September 30, 2014 as compared to $3.0 million, or 9%, in the three months ended September 30, 2013. 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 third quarter of 2014 as compared to the same period in 2013 and changes in the structure of our performance-based rebate programs.

For further details related to our revenue recognition and related sales allowances policy, please 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 for the year ended December 31, 2013 and Note B to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

In addition, our results of operations, including, in particular, product sales, fluctuate from quarter to quarter due to the demand patterns of wholesalers, distributors, clinics and hospitals, the reasons for which may vary. We have limited visibility into our customers buying decisions, which may be affected from time to time by incentives we make available to wholesalers, clinics, hospitals and single group purchasing organizations (GPOs), including volume rebates. During the third quarter of 2014, our increased *Feraheme* product sales resulted in part from a 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, to the extent they are offered, which may result in uneven purchasing patterns, causing *Feraheme* sales to fluctuate in subsequent quarters.

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;

- 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 U.S. approval of Injectafer® for a broad patient population or potential generic versions of new or currently available drug therapies;

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- 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*;

- The impact of any actual or perceived safety or efficacy issues with *Feraheme* and any related product recalls or changes to our current label based on post-marketing safety data, including our proposed June 2014 label changes;

- 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 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 (the Healthcare Reform Act) and the Budget Control Act of 2011;

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

- The frequency of re-orders by existing customers; and

- The impact of any difficulties, disruptions or delays in the manufacturing process for *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. In addition, we cannot predict whether or when we will be able to satisfactorily address the issues raised in the complete response letter we received from the FDA in January 2014 related to our sNDA for *Feraheme* for the treatment of IDA in a broad range of patients; nor can we predict the impact that our proposed label changes or regulatory actions, including the recent developments in the EU and Canada discussed above, will have on product revenues.

License Fee and Other Collaboration Revenues

License fee and other collaboration revenues for the three months ended September 30, 2014 and 2013 consisted of the following (in thousands):

Three Months Ended September 30,

	2014	2013	$ Change	% Change
Deferred license fee revenues recognized from Takeda	$ 1,974	$ 1,974	$	0%
Reimbursement revenues from Takeda	208	24	184	>100%
Total	$ 2,182	$ 1,998	$ 184	9%

Our license fee and other collaboration revenues remained relatively consistent in the three months ended September 30, 2014 as compared to the three months ended September 30, 2013. In each of the three months ended September 30, 2014 and 2013, we recorded $2.0 million of revenues associated with the amortization of the upfront payments and the milestone payments we have received since the inception of our agreement with Takeda. As of September 30, 2014, we had approximately $43.4 million remaining in deferred revenues related to the $61.0 million in upfront payments and the $18.0 million in non-substantive milestone payments previously received from Takeda, of which $7.9 million was classified as short-term and $35.5 million was classified as long-term.

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Under the terms of the Amended Takeda Agreement, Takeda is responsible for reimbursing us for certain out-of-pocket development costs we incur in the conduct of certain activities we manage under the agreement. Because we are acting as the principal in carrying out these activities, any reimbursement payments received from Takeda are recorded in license fee and other collaboration revenues and offset the costs that we incur during the period in which we perform those services. During each of the three months ended September 30, 2014 and 2013, we recorded $0.2 million and less than $0.1 million, respectively, of revenues associated with certain out-of pocket development costs in connection with the Amended Takeda Agreement.

We anticipate that our license fee and other collaboration revenues will remain relatively constant for the remainder of 2014 as compared to quarter ended September 30, 2014. Our license fees and other collaboration revenues will increase significantly if we receive a significant milestone payment from Takeda in the event that Takeda receives approval of its Type II Variation in the EU for *Rienso* in the indication for the treatment of IDA generally without limit to a specific patient population or sub-population. As discussed above, based on preliminary information received by Takeda regarding its pending Type II Valuation, we believe such approval is unlikely without additional clinical data. Even if clinical studies are approved and undertaken, the resulting clinical data may not support approval of a broader indication.

Other Product Sales and Royalties

Other product sales and royalties for the three months ended September 30, 2014 and 2013 included net product sales of *MuGard* and product sales and royalties of *Feraheme* from Takeda. For the three months ended September 30, 2014 as compared to the same period in 2013, other product sales and royalties increased by $0.5 million.

As of September 30, 2014, we had approximately $2.7 million in deferred revenue related to product shipped to Takeda, but not yet sold through to Takeda s customers, of which $1.5 million was classified as short-term and $1.2 million was classified as long-term. In addition, we had $2.4 million in deferred cost of product sales, of which $1.4 million was classified as short-term and $1.0 million was classified as long-term. These deferred revenues and deferred cost of product sales are recorded in our condensed consolidated balance sheet as of September 30, 2014.

We expect other product sales and royalties to remain relatively constant for the remainder of 2014 as compared to the quarter ended September 30, 2014.

Costs and Expenses

Cost of Product Sales

Cost of product sales for the three months ended September 30, 2014 and 2013 consisted of the following (in thousands):

	Three Months Ended September 30,			
	2014	2013	$ Change	% Change
Cost of Product Sales	$ 2,968	$ 2,547	$ 421	17%
Percentage of Net Product Sales and Royalties	13%	13%		

Our cost of product sales are primarily comprised of costs of production of ferumoxytol, including the costs of managing our contract manufacturers, costs for quality assurance and quality control associated with our sales of *Feraheme* and *MuGard* in the U.S., and sales of *Feraheme* by Takeda to its customers.

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The $0.4 million increase in our cost of product sales for the three months ended September 30, 2014 as compared to the same period in 2013 was attributable to the following factors:

- $0.6 million decrease due to a lower average cost per vial sold, partially offset by a $0.5 million increase due to a higher volume of *Feraheme* vials sold in 2014;

- $0.3 million increase in costs related to higher sales of *Feraheme* by Takeda to its customers and higher *MuGard* sales; and

- $0.2 million increase in costs related to other production-related activities.

We expect our cost of product sales as a percentage of net product sales and royalties to remain relatively consistent for the remainder of 2014 as compared to the quarter ended September 30, 2014.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2014 and 2013 consisted of the following (in thousands):

	Three Months Ended September 30,			
	2014	2013	$ Change	% Change
External Research and Development Expenses				
Feraheme to treat IDA in CKD patients	$ 2,111	$ 1,068	$ 1,043	98%
Feraheme manufacturing process development and materials	495	327	168	51%
Other external costs	205	421	(216)	-51%
Total	2,811	1,816	995	55%
Internal Research and Development Expenses				
Compensation, payroll taxes, benefits and other	2,081	2,377	(296)	-12%
Equity-based compensation	466	337	129	38%
Total	2,547	2,714	(167)	-6%
Total Research and Development Expenses	$ 5,358	$ 4,530	$ 828	18%

Total research and development expenses incurred in the three months ended September 30, 2014 increased by $0.8 million, or 18%, as compared to the same period in 2013. The increase was primarily due to a $1.0 million increase in external research and development costs pertaining to our CKD-related trials during the three months ended September 30, 2014, partially offset by reduced internal research and development costs of $0.2 million in the three months ended September 30, 2014 as compared to the same period in 2013.

We expect research and development expenses to remain relatively consistent for the remainder of 2014 as compared to the quarter ended September 30, 2014.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2014 and 2013 consisted of the following (in thousands):

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	Three Months Ended September 30,			
	2014	2013	$ Change	% Change
Compensation, payroll taxes and benefits	$ 6,499	$ 5,398	$ 1,101	20%
Sales and marketing consulting, professional fees, and other	3,481	3,042	439	14%
General and administrative consulting, professional fees and other	5,159	4,912	247	5%
Fair value of contingent consideration liability	(3,712)	279	(3,991)	<(100)%
Equity-based compensation expense	1,448	1,303	145	11%
Total	$ 12,875	$ 14,934	$ (2,059)	-14%

Total selling, general and administrative expenses incurred in the three months ended September 30, 2014 decreased by $2.1 million, or 14%, as compared to the same period in 2013 for the following reasons:

- $1.1 million increase in compensation, payroll taxes and benefits primarily due to increased costs associated with additional personnel in our commercial functions and certain of our general and administrative functions;

- $0.4 million increase in sales and marketing consulting, professional fees and other expenses primarily as the result of an increase in certain sales-force-related charges and a $0.2 million accrual to comply with and reflect recent accounting changes related to the Branded Drug Fee;

- $0.2 million increase in general and administrative consulting, professional fees and other expenses primarily due to a $2.1 million increase in consulting, business development and legal expenses primarily related to pre-acquisition activities related to our planned acquisition of Lumara, offset by a $1.3 million decrease of non-recurring accelerated depreciation expense recognized during 2013 related to our prior office facility and a $0.4 million decrease of non-recurring cost associated with the relocation of our corporate headquarters in 2013;

- $4.0 million decrease to the contingent consideration liability related to the MuGard Rights due to a revision of our total projected sales for *MuGard*; and

- $0.1 million increase in equity-based compensation expense due primarily to equity awards to new and existing employees.

We expect total selling, general and administrative expenses will increase for the remainder of 2014 as compared to the quarter ended September 30, 2014 as a result of the one-time benefit of the $3.7 million reduction to the contingent consideration liability related to the MuGard Rights made in the third quarter of 2014.

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Other Income (Expense)

Other income (expense) for the three months ended September 30, 2014 and 2013 consisted of the following (in thousands):

	Three Months Ended September 30,			
	2014	2013	$ Change	% Change
Interest expense	$ (3,129)	$	$ (3,129)	N/A
Interest and dividend income, net	291	246	45	18%
Gains on investments, net	3	4	(1)	-25%
Total	$ (2,835)	$ 250	$ (3,085)	<(100)%

Other income (expense) for the three months ended September 30, 2014 decreased by $3.1 million as compared to the same period in 2013 primarily as the result of the recognition of $3.1 million of interest expense, which was comprised of the amortization of debt discount, 2.5% contractual interest expense and amortization of debt issuance costs in connection with the issuance of the Convertible Notes.

Net Income (Loss)

For the reasons stated above, we earned net income of $1.5 million, or $0.07 per basic share and $0.06 per diluted share, for the three months ended September 30, 2014 as compared to a net loss of $0.1 million, or $0.01 per basic and diluted share, for the three months ended September 30, 2013. Included in the $1.5 million net income during the three months ended September 30, 2014, is a benefit of $3.7 million due to the reduction of the contingent consideration liability related to the MuGard Rights based on a revision of our projected net sales for *MuGard* during the term of the license.

Results of Operations Nine months Ended September 30, 2014 and 2013

Revenues

Total revenues for the nine months ended September 30, 2014 and 2013 consisted of the following (in thousands):

	Nine Months Ended September 30,			
	2014	2013	$ Change	% Change
U.S. *Feraheme* product sales, net	$ 62,147	$ 52,381	$ 9,766	19%
License fee and other collaboration revenues	7,424	6,056	1,368	23%
Other product sales and royalties	1,560	708	852	>100%
Total	$ 71,131	$ 59,145	$ 11,986	20%

Our total revenues during the nine months ended September 30, 2014 increased by $12.0 million, or 20%, as compared to the same period in 2013, primarily as the result of a $9.8 million increase in U.S. net *Feraheme* product sales and a $1.4 million increase in license fee revenues primarily due to the recognition of $1.0 million of previously deferred revenue from our former partnership with 3SBio, Inc. (3SBio) as the result of the termination of our license agreement in January 2014. We have no further obligations under the agreement with 3SBio. Included in our net product sales for the nine months ended September 30, 2013, was a $0.6 million reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales, as discussed below.

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U.S. Feraheme Product Sales, Net

U.S. *Feraheme* product sales and product sales allowances and accruals for the nine months ended September 30, 2014 and 2013 consisted of the following (in thousands):

	Nine Months Ended September 30,					
	2014	Percent of gross U.S. Feraheme product sales	2013	Percent of gross U.S. Feraheme product sales	$ Change	% Change
Gross U.S. *Feraheme* product sales	$ 111,855		$ 87,541		$ 24,314	28%
Less provision for product sales allowances and accruals:						
Discounts and chargebacks	37,824	34%	26,925	31%		
Government and other rebates	11,300	10%	8,106	9%		
Medicaid rebate reserve adjustment		0%	(568)	-1%		
Returns	584	0%	697	1%		
Total	49,708	44%	35,160	40%		
Net U.S. *Feraheme* product sales	$ 62,147		$ 52,381		$ 9,766	19%

Our gross U.S. *Feraheme* product sales increased by $24.3 million, or 28%, during the nine months ended September 30, 2014 as compared to the same period in 2013. Of the $24.3 million increase, $13.0 million was due to price increases and $11.3 million was due to increased units sold. This increase was partially offset by $14.0 million of additional allowances and accruals in 2014, excluding a $0.6 million reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales for the nine months ended September 30, 2013. As a result, total net U.S. *Feraheme* product sales increased by $9.8 million, or 19%, during the nine months ended September 30, 2014 as compared to the same period in 2013.

As noted above, during the nine months ended September 30, 2013, 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 July 2009 launch of *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 nine months ended September 30, 2013 was a credit of $0.6 million, resulting in an increase to product sales during that period.

Total discounts and chargebacks for the nine months ended September 30, 2014 were $37.8 million, or 34% of total gross U.S. *Feraheme* product sales, as compared to $26.9 million, or 31%, in the same period in 2013. The increase in total discounts and chargebacks as a percentage of total gross U.S. *Feraheme* product sales was related primarily to a change in our customer mix.

Total government and other rebates were $11.3 million, or 10% of total gross U.S. *Feraheme* product sales, in the nine months ended September 30, 2014 as compared to $8.1 million, or 9%, in the nine months ended September 30, 2013. 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 2014 as compared to 2013 and changes in the structure of our performance-based rebate programs.

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An analysis of the amount of, and change in, reserves for the nine months ended September 30, 2014 and 2013 is as follows (in thousands):

	Discounts and Chargebacks	Government and Other Rebates	Returns	Total
Balance at January 1, 2014	$ 2,683	$ 2,837	$ 1,962	$ 7,482
Current provisions relating to sales in current year	37,824	11,300	916	50,040
Adjustments relating to sales in prior years			(332)	(332)
Payments/returns relating to sales in current year	(33,351)	(7,169)		(40,520)
Payments/returns relating to sales in prior years	(2,851)	(2,126)	(169)	(5,146)
Balance at September 30, 2014	$ 4,305	$ 4,842	$ 2,377	$ 11,524

	Discounts and Chargebacks	Government and Other Rebates	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

During the nine months ended September 30, 2013, we decreased our product sales allowances and accruals by approximately $0.6 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.

During 2014 and 2013, we implemented gross price increases for *Feraheme,* some portion of which were discounted back to customers under volume or market share based contracts. When portions of price increases are discounted back to customers, it can have the effect of widening the gross to net adjustment percentage while still resulting in a greater net price per gram. For the remainder of 2014, we expect discounts, chargebacks and government and other rebates to continue to increase as a percentage of gross sales due to increasing competitive pressure caused by the July 2013 approval of Injectafer® in the U.S., our contracting and discounting strategy and the mix of business for *Feraheme*. As a result, we expect the average net revenue per gram for the remainder of 2014 to be relatively consistent with the average net revenue per gram in the quarter ended September 30, 2014.

Healthcare Reform Legislation

The Healthcare 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 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

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of companies in the pharmaceutical industry, including us, and other healthcare related industries by imposing on them additional costs.

The Healthcare 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 the 2014 and 2013 annual periods 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 Healthcare 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 Healthcare Reform Act. *Feraheme* sold to 340B eligible entities comprised approximately 17% and 14% of our total *Feraheme* sales in grams for the nine months ended September 30, 2014 and 2013, respectively. Because these institutions are eligible for federal pricing discounts, the revenue realized per unit of *Feraheme* sold to 340B institutions is lower than from some of 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 (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. 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 in the first nine months of 2014 as compared to first nine months of 2013.

We were not materially impacted by recent healthcare reform legislation during 2014 or 2013. Presently, we have not identified any provisions that could materially impact our business but we continue to monitor ongoing legislative developments and we are assessing what impact recent healthcare reform legislation will have on our business following the consummation of our acquisition of Lumara.

License Fee and Other Collaboration Revenues

License fee and other collaboration revenues for the nine months ended September 30, 2014 and 2013 consisted of the following (in thousands):

	Nine Months Ended September 30,			
	2014	2013	$ Change	% Change
Deferred license fee revenues recognized from Takeda	$ 5,922	$ 5,922	$	0%
Deferred revenues recognized from 3SBio termination	1,000		1,000	N/A
Reimbursement revenues from Takeda	502	134	368	>100%
Total	$ 7,424	$ 6,056	$ 1,368	23%

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Our license fee and other collaboration revenues in the nine months ended September 30, 2014 increased by $1.4 million as compared to the same period in 2013 primarily as the result of the recognition of $1.0 million of previously deferred revenue we received from 3SBio in 2008 in connection with our license agreement, which was mutually terminated in January 2014. In each of the nine months ended September 30, 2014 and 2013, we also recorded $5.9 million of revenues associated with the amortization of the upfront payments and the milestone payments we have received since the inception of our agreement with Takeda.

During the nine months ended September 30, 2014 and 2013, we also recorded $0.5 million and $0.1 million, respectively, of revenues associated with certain out-of pocket development costs in connection with the Amended Takeda Agreement.

Other Product Sales and Royalties

Other product sales and royalties increased by $0.9 million for the nine months ended September 30, 2014 as compared to the same period in 2013 due to the increase of *MuGard* sales and sales by Takeda to its customers, offset by the elimination in 2014 of any sales of *GastroMARK,* a legacy product of the Company.

Costs and Expenses

Cost of Product Sales

Cost of product sales for the nine months ended September 30, 2014 and 2013 consisted of the following (in thousands):

	Nine Months Ended September 30,			
	2014	**2013**	**$ Change**	**% Change**
Cost of Product Sales	$ 8,548	$ 8,634	$ (86)	-1%
Percentage of Net Product Sales and Royalties	13%	16%		

The $0.1 million decrease in our cost of product sales for the nine months ended September 30, 2014 as compared to the same period in 2013 was attributable to the following factors:

- $1.9 million decrease due to a lower average cost per vial sold, partially offset by a $1.3 million increase due to a higher volume of *Feraheme* vials sold in 2014;

- $0.1 million net decrease in inventory write-downs for product deemed not commercially saleable;

- $0.3 million increase in costs related to other production-related activities; and

- $0.5 million increase in costs related to sales of *Feraheme* to Takeda and *MuGard* sales, offset by a $0.2 million decrease in costs related to sales of *GastroMark*.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2014 and 2013 consisted of the following (in thousands):

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	Nine Months Ended September 30, 2014	2013	$ Change	% Change
External Research and Development Expenses				
Feraheme to treat IDA in CKD patients	$ 6,075	$ 2,633	$ 3,442	>100%
Feraheme manufacturing process development and materials	1,723	1,267	456	36%
Other external costs	738	1,168	(430)	-37%
Total	8,536	5,068	3,468	68%
Internal Research and Development Expenses				
Compensation, payroll taxes, benefits and other	6,586	7,281	(695)	-10%
Equity-based compensation	1,274	1,634	(360)	-22%
Total	7,860	8,915	(1,055)	-12%
Total Research and Development Expenses	$ 16,396	$ 13,983	$ 2,413	17%

Total research and development expenses incurred in the nine months ended September 30, 2014 increased by $2.4 million, or 17%, as compared to the same period in 2013. The increase was primarily due to a $3.4 million increase in external research and development costs pertaining to our CKD-related trials during the nine months ended September 30, 2014. This increase was partially offset by reduced internal research and development costs of $1.1 million primarily related to decreased consulting and professional fees costs in the nine months ended September 30, 2014 as compared to the same period in 2013.

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. As of September 30, 2014, we considered our efforts related to *Feraheme* to treat IDA in CKD patients as one research project, which includes the following (a) a completed clinical study evaluating *Feraheme* treatment as compared to treatment to another IV iron to support the 2010 MAA submission; (b) 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*; (c) two additional pediatric studies to be completed in accordance with our approved pediatric investigation plan to support the MAA submission; and (d) an ongoing multi-center clinical trial to be conducted to determine the safety and efficacy of repeat doses of *Feraheme* for the treatment of IDA in patients with hemodialysis dependent CKD, including a treatment arm with iron sucrose using an MRI sub-analysis to evaluate the potential for iron to accumulate in the body following repeated IV iron administration.

Through September 30, 2014, we have incurred aggregate external research and development expenses of approximately $34.3 million related to our current program for the development of *Feraheme* to treat IDA in CKD patients, described above. We currently estimate that the total remaining external costs associated with this development project will be in the range of approximately $20.0 million to $30.0 million over the next several years, not including any potential costs related to the July 2014 CHMP decision, discussed above.

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In accordance with our policy of tracking external research and development costs through the later of the completion of the last trial in a project or the last submission of a regulatory filing to the FDA, we discontinued tracking our expenses related to *Feraheme* to treat IDA regardless of the underlying cause in the third quarter of 2013, at which point we had incurred $57.8 million of external research and development expenses. In January 2014, we received a complete response letter from the FDA in response to our sNDA submission for *Feraheme* for the treatment of IDA in adult patients who had failed or could not use oral iron. We are currently unable to estimate with any certainty the future costs we will incur, if any, related to our project for *Feraheme* to treat IDA regardless of the cause. In future periods, we may resume the disclosure of such expected future costs as the facts and circumstances warrant.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the nine months ended September 30, 2014 and 2013 consisted of the following (in thousands):

	Nine Months Ended September 30,			
	2014	2013	$ Change	% Change
Compensation, payroll taxes and benefits	$ 20,162	$ 16,989	$ 3,173	19%
Sales and marketing consulting, professional fees, and other	10,299	9,208	1,091	12%
General and administrative consulting, professional fees and other	13,934	13,505	429	3%
Fair value of contingent consideration liability	(2,535)	279	(2,814)	<(100)%
Equity-based compensation expense	4,790	4,169	621	15%
Total	$ 46,650	$ 44,150	$ 2,500	6%

Total selling, general and administrative expenses incurred in the nine months ended September 30, 2014 increased by $2.5 million, or 6%, as compared to the same period in 2013 for the following reasons:

- $3.2 million increase in compensation, payroll taxes and benefits primarily due to increased costs associated with additional personnel in our commercial functions and certain of our general and administrative functions as well as one-time costs associated with the departure of our Chief Business Officer in June 2014;

- $1.1 million increase in sales and marketing consulting, professional fees, and other expenses primarily due to increased consulting costs related to the commercialization of *MuGard* and increased sales-force-related costs, partially offset by lower spending in sales and marketing activities;

- $0.4 million increase in general and administrative consulting, professional fees and other expenses primarily due $3.4 million of increased costs associated with business development, consulting and other legal-related activities in support of our product portfolio expansion. These increased costs were offset primarily by $1.9 million of accelerated depreciation expense recognized during 2013 related to our prior corporate headquarters, $0.6 million of costs incurred during 2013 related to the closure of our Cambridge, Massachusetts manufacturing facility and $0.4 million of costs associated with the relocation of our corporate headquarters in 2013;

- $2.8 million decrease to the contingent consideration liability related to the MuGard Rights due to a revision of our total projected sales for *MuGard;* and

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- $0.6 million increase in equity-based compensation expense due primarily to one-time charges associated with the departure of our Chief Business Officer in June 2014 as well as the expense associated with equity awards to new and existing employees.

Other Income (Expense)

Other income (expense) for the nine months ended September 30, 2014 and 2013 consisted of the following (in thousands):

	Nine Months Ended September 30,			
	2014	2013	$ Change	% Change
Interest expense	$ (7,656)	$	(7,656)	N/A
Interest and dividend income, net	809	773	36	5%
Gains on sale of assets	102	865	(763)	-88%
Gains on investments, net	17	36	(19)	-53%
Total	$ (6,728)	$ 1,674	$ (8,402)	<(100)%

Other income (expense) for the nine months ended September 30, 2014 decreased by $8.4 million as compared to the same period in 2013 primarily as the result of the recognition of $7.7 million of interest expense, which was comprised of the amortization of debt discount, 2.5% contractual interest expense and amortization of debt issuance costs in connection with the issuance of the Convertible Notes. In addition, the decrease in other income (expense) reflects non-recurring gains of $0.5 million in connection with the sale of Combidex®, a legacy product of the Company, and $0.4 million in connection with the sale of fixed assets related to our previously owned Cambridge, Massachusetts manufacturing facility, recognized during the nine months ended September 30, 2013.

Net Loss

For the reasons stated above, we incurred a net loss of $7.2 million and $5.9 million, or $0.33 and $0.28 per basic and diluted share, for the nine months ended September 30, 2014 and 2013, respectively. Included in the $7.2 million net loss incurred during the nine months ended September 30, 2014, is a benefit of $2.5 million due to the reduction of the contingent consideration liability related to the MuGard Rights based on a revision of our forecasted total projected net sales for *MuGard* during the term of the license.

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Liquidity and Capital Resources

General

We currently finance our operations primarily from the sale of *Feraheme* and *MuGard*, including payments from our licensees, cash generated from our investing activities and the sale of our common stock. We expect sales of *Makena* will contribute to the financing of our operations following the consummation of our acquisition of Lumara. We expect to continue to incur significant expenses as we and our partners continue to manufacture, market and sell *Feraheme* as an IV iron replacement therapy 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 and if we further develop and seek regulatory approval for *Feraheme* for the treatment of IDA in a broad range of patients in and outside of the U.S. We expect to incur significant expenses as we integrate Lumara and commercialize *Makena*.

As of September 30, 2014, our investments consisted of corporate debt securities, U.S. treasury and government agency securities and commercial paper. We place our cash 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, investments and certain financial obligations as of September 30, 2014 and December 31, 2013 consisted of the following (in thousands):

	September 30, 2014	December 31, 2013	$ Change	% Change
Cash and cash equivalents	$ 196,154	$ 26,986	$ 169,168	>100%
Investments	190,088	186,803	3,285	2%
Total	$ 386,242	$ 213,789	$ 172,453	81%
Outstanding principal on convertible notes	$ 200,000	$	$ 200,000	N/A
Total	$ 200,000	$	$ 200,000	N/A

The $172.5 million increase in cash, cash equivalents and investments as of September 30, 2014, as compared to December 31, 2013, was primarily due to net proceeds of $179.1 million received in the nine months ended September 30, 2014 in connection with issuance of $200.0 million aggregate principal amount of the Convertible Notes, net of (a) $6.7 million in fees and expenses associated with the issuance of the Convertible Notes and (b) $14.1 million to pay the cost of convertible bond hedges (after such cost was partially offset by the proceeds to us from the sale of warrants). We issued the Convertible Notes to help facilitate our corporate, clinical and commercial activities, and which, along with the convertible bond hedge transactions, are discussed in greater detail in Note P, *Debt*, to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. In addition, the increase in cash was partially offset by net cash expended to fund our operations and working capital.

As discussed above under the caption *Our Acquisition of Lumara*, on September 28, 2014, we entered into the Lumara Agreement to acquire Lumara for $675.0 million ($600.0 million in cash and $75.0 million in stock (consisting of 3,209,971 shares of our common stock, as valued at the time of signing)) and additional contingent cash consideration of up to $350.0 million based on the achievement of certain sales milestones (or upon mutual agreement between us and the Lumara security holders, future contingent payments may also be made in common stock or

some combination thereof). We expect this transaction

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to be completed in the fourth quarter of 2014, at which time we will pay approximately $600.0 million in cash to Lumara, $340.0 million of which we expect to be paid with funds obtained through the Term Loan Facility. We have paid and will continue to pay substantial costs and expenses associated with the transaction and many of these costs and expenses will be payable whether or not the transaction is consummated. The Term Loan Facility contemplated by the Commitment Letter will impose restrictive covenants on us, including a requirement that we reduce our leverage over time, and obligate us to make certain payments of principal and interest over time.

We expect that our current cash, cash equivalents and investments balances, in the aggregate, will decrease in the fourth quarter of 2014 due to the net cash payment of approximately $260.0 million expected to be paid in the fourth quarter of 2014 for the purchase of Lumara, partially offset by increased sales from *Feraheme* and, following and assuming the closing of the Lumara acquisition, *Makena,* during the remainder of 2014. Our expectation also takes into account estimated cash outflows that would occur as a result of our continued investment in the development and commercialization of *Feraheme* and the continued pursuit of business development transactions but does not include potential expenses associated with further clinical development if we were to pursue the broad IDA indication for *Feraheme*. We believe that our cash, cash equivalents and investments as of September 30, 2014, and the cash we currently expect to receive from sales of *Feraheme* and *MuGard* (and following the consummation of the acquisition of Lumara, sales of *Makena*), earnings on our investments, and potential product sales and milestone and royalty payments from Takeda will be sufficient to satisfy our cash flow needs for at least the next twelve months.

Cash flows from operating activities

During the nine months ended September 30, 2014, our use of $10.4 million of cash in operations was attributable principally to our net loss of approximately $7.2 million, adjusted for the following:

- Non-cash operating items totaling $11.6 million which include equity-based compensation expense, a write-down of inventory, amortization of debt discount and debt issuance costs, amortization of premium/discount on purchased securities, change in fair value of contingent consideration, depreciation and amortization, and other non-cash items;

- $9.4 million of cash used in operating activities due to increases in accounts receivable, inventories and prepaid assets;

- $0.1 million of cash provided by operating activities due to increases in accounts payable and accrued expenses;

- $6.5 million of cash used in operating activities due to decreases in deferred revenues and other long-term liabilities; and

- $1.0 million of cash provided by operating activities due to decreases in other long-term assets.

Our net loss of $7.2 million was primarily the result of our costs to operate our business, including compensation to employees, commercialization expenses, including marketing and promotion costs, costs to manufacture our products, research and development costs, including costs associated with our clinical trials, general and administrative costs, and interest from our debt obligations, partially offset by net product sales and collaboration revenues.

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Cash flows from investing activities

Cash used in investing activities during the nine months ended September 30, 2014 totaled $2.3 million and was primarily attributable to the purchases of investments partially offset by proceeds from the sales and maturities of our investments, as well as a $2.9 million change in restricted cash following the return of escrowed funds related to a 2013 business development transaction that we did not complete.

Cash flows from financing activities

Cash provided by financing activities during the nine months ended September 30, 2014 was $181.9 million and was primarily attributable to the $179.1 million in net proceeds received from the issuance of the Convertible Notes in February 2014 and $2.9 million in proceeds received from the exercise of stock options.

Off-Balance Sheet Arrangements

As of September 30, 2014, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

Contractual Obligations

Although there were no material changes outside the ordinary course of our business in the contractual obligations specified in Regulation S-K, Item 303(a)(5) during the quarter ended September 30, 2014, during the nine months ended September 30, 2014, we completed the offering of the $200.0 million aggregate principal amount of our 2.5% Convertible Notes, which are due in 2019. See Note P, *Debt,* to our condensed consolidated financial statements included in the Quarterly Report on Form 10-Q for additional information.

Impact of Recently Issued and Proposed Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, Revenue from Contracts with Customers, as a new Topic, Accounting Standards Codification Topic 606. The new revenue recognition standard provides a five-step analysis of transactions to determine when and how revenue is recognized. The core principle is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This ASU is effective for annual periods beginning after December 15, 2016 (fiscal 2017) and shall be applied retrospectively to each period presented or as a cumulative-effect adjustment as of the date of adoption. We are in the process of evaluating the effect of adopting this new accounting guidance and are uncertain at this point of the impact on our results of operations, cash flows or financial position.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements - Going Concern: Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern*. ASU No. 2014-15 is intended to define management s responsibility to evaluate whether there is substantial doubt about an organization s ability to continue as a going concern and to provide related footnote disclosures, if required. ASU 2014-15 will be effective for annual reporting periods ending after December 15, 2016, which will be our fiscal year ending December 31, 2016, and to annual and interim periods thereafter. We are in the process of evaluating the impact of adoption of ASU 2014-15 on our condensed consolidated financial statements and related disclosures and currently do not expect it to have a material impact on our results of operations, cash flows or financial position.

From time to time, new accounting pronouncements are issued by FASB or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe

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that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

In February 2014, we issued $200.0 million of 2.5% Convertible Notes due February 15, 2019. The Convertible Notes have a fixed annual interest rate of 2.5% and we, therefore, do not have economic interest rate exposure on the Convertible Notes. However, the fair value of the Convertible Notes is exposed to interest rate risk. We do not carry the Convertible Notes at fair value but present the fair value of the principal amount for disclosure purposes. Generally, the fair value of the Convertible Notes will increase as interest rates fall and decrease as interest rates rise. These Convertible Notes are also affected by the price and volatility of our common stock and will generally increase or decrease as the market price of our common stock changes. As of September 30, 2014, the fair value of the Convertible Notes was estimated by us to be $271.2 million. We determined the estimated fair value of the Convertible Notes by using quoted market prices. Other than the above 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.

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, 2014 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

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

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Item 1A. Risk Factors:

Unless the context suggests otherwise, references to Feraheme refer to both *Feraheme* (the trade name for ferumoxytol in the U.S. and Canada) and *Rienso* (the trade name for ferumoxytol in the EU and Switzerland).

We are primarily dependent on the success of Feraheme.

We currently derive substantially all of our revenue from sales of *Feraheme* by us in the U.S. and by our licensee, Takeda Pharmaceutical Company Limited (Takeda), outside of the U.S. and, therefore, our ability to continue our current operations or become profitable is significantly dependent on our and Takeda s successful commercialization and development of *Feraheme*, which in turn is dependent upon the regulatory status of *Feraheme* and its availability for commercial use in patients. On September 28, 2014, we entered into the Lumara Agreement (defined below) to acquire Lumara Health Inc. (Lumara) and its product *Makena* (described below), which we expect to consummate in the fourth quarter of 2014. If we are unable to generate sufficient revenues from sales of *Feraheme* (and following the consummation of the acquisition of Lumara, sales of *Makena*) or from milestone payments and royalties we may receive related to *Feraheme* outside the U.S., we may have to restructure our current operations, 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 commercialization of *Feraheme*. However, we or Takeda may not be successful in our efforts to continue to successfully commercialize *Feraheme* in its current indication for adult patients with iron deficiency anemia (IDA) associated with chronic kidney disease (CKD). In addition, especially in light of the recent regulatory development described in this risk factor, *Feraheme* could be the subject of continued or increased regulatory scrutiny or become subject to increased regulatory restrictions or a more restrictive label, which could have a negative impact on our commercialization efforts. For example, in June 2014, based on a review of global post-marketing data, we proposed changes to the U.S. Food and Drug Administration (FDA) related to our current U.S. label of *Feraheme* to strengthen the warnings and precautions section of the label to enhance patient safety and mitigate the risk of serious hypersensitivity reactions, including anaphylaxis. These proposed label changes are currently under review with the FDA. In addition, we are currently working with Takeda regarding changes being effected to the current label of *Feraheme* in Canada. We cannot predict the impact any of these or any other label changes will have on the commercialization of *Feraheme* in the U.S. or Canada, but they could result in reduced revenues, litigation or a decline in our stock price.

In addition, as discussed above in *Item II. Management s Discussion and Analysis of Financial Condition and Results of Operations - Overview - Feraheme for the treatment of IDA in patients with CKD*, in May 2014, the European Medicines Agency s (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) met to discuss the benefit-risk balance of *Rienso* as part of a Periodic Safety Update Report (PSUR) review. As part of its assessment, which included a review of the overall rate of hypersensitivity reactions with fatal outcomes with *Rienso*, PRAC requested that Takeda, the marketing authorization holder (MAH) for *Rienso* in Europe, submit supplementary information to enable further assessment and discussion about *Rienso*.

On July 10, 2014, PRAC confirmed that the benefit-risk balance of *Rienso* in the currently approved CKD indication remains favorable subject to a number of proposed changes to the product information. These recommendations included proposed changes to the product label, including the recommendation, among other measures, that *Rienso* should be administered to patients by infusion over at least 15 minutes

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(replacing injection) and that it should be contraindicated in patients with any known history of drug allergy. The PRAC recommendation was sent to the EMA s Committee for Medicinal Products for Human Use (CHMP). On July 23, 2014, the CHMP issued its opinion and agreed with PRAC s recommendations. Takeda has updated the product s label accordingly and issued a Direct Healthcare Professional Communication (DHPC) letter in August 2014 informing physicians of these changes. In addition, the CHMP recommended that amendments be made to the Risk Management Plan and that Takeda conduct a new Post Authorization Safety Study (PASS) to further characterize the risk of hypersensitivity with *Rienso* in patients with CKD. The final PASS clinical study report is due at the end of 2017 and is expected to compare *Rienso* against another approved intravenous (IV) iron product in the EU. Conducting the PASS may be time-consuming and expensive and could impact our profitability. In addition, non-compliance with any of the CHMP recommendations, including conducting a PASS, can lead to the variation, suspension or withdrawal of the marketing authorization for *Rienso* or imposition of financial penalties or other enforcement measures and, given our arrangement with Takeda, we do not have direct control over compliance with the CHMP recommendations. Moreover, the new restrictions added to the *Rienso* label and the change in the method of administration could result in a significant drop in sales of the affected products, could increase regulator scrutiny in other territories and could have a materially adverse effect on our product revenues and reputation in the marketplace, and we could become the target of lawsuits.

The size of the future market opportunity for *Feraheme* will be negatively impacted if we or Takeda do not receive regulatory approval to expand the current indication of *Feraheme* to include additional indications. In December 2012, we filed a supplemental new drug application (sNDA) in the U.S. for *Feraheme* in patients with IDA who had failed or could not use oral iron. In January 2014, we received a complete response letter from the FDA for the sNDA informing us that our sNDA could not be approved in its present form and stating that we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for the proposed broader patient population. The FDA indicated that its decision was based on the cumulative ferumoxytol data, including the global Phase III IDA program and global post-marketing safety reports since *Feraheme s* launch in 2009. The FDA suggested, among other things, that we submit additional clinical trial data in the proposed broad IDA patient population with a primary composite safety endpoint of serious hypersensitivity/anaphylaxis, cardiovascular events and death, events that are included in the labels of *Feraheme* and other IV irons and that have been reported in the post-marketing environment for *Feraheme*. Additionally, the FDA proposed potentially evaluating alternative dosing and/or administration of *Feraheme* as well as potential changes to labeling that would be intended to reduce the risk of serious hypersensitivity reactions associated with *Feraheme*. In June 2014, we met with the FDA to discuss our proposed approach to resolving the points that were raised in the complete response letter. Based on the FDA s feedback at the June 2014 meeting, we submitted a revised proposal that includes the design of a potential clinical trial, a safety endpoint for such trial and additional trials to study alternative methods of administration of *Feraheme*. We expect to receive feedback from the FDA on our most recent proposal during the fourth quarter of 2014 and expect to thereafter be able to assess and to determine the path forward, if any, for *Feraheme* in the broad IDA patient population in the U.S., including the related timing and cost of any clinical trials.

Generating additional clinical trial data is typically costly and time-consuming. Responding to the issues raised by the FDA in the complete response letter and any other issues or requests for information that may be raised by the FDA will likely cause us to incur significant additional costs, experience further delays and/or narrow our currently approved indication, as discussed in more detail in the following risk factor. Because of these factors, we may not pursue or may otherwise be prevented from obtaining, U.S. regulatory approval for *Feraheme* in the broader IDA population. Any of these results could, in turn, materially adversely impact our cash position, our ability to increase or maintain revenues, and the future prospects of our business.

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In June 2013, Takeda filed a Type II Variation to update the marketing authorization for *Rienso* in the EU to extend the therapeutic indication from adult patients with IDA associated with CKD to adult patients with iron deficiency from any underlying cause. In October 2014, the CHMP informed Takeda that it expects to discuss the Type II Variation during the fourth quarter of 2014. In addition, 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, regardless of the underlying cause. In October 2014, we were informed that a final decision on the sNDS was expected by Health Canada in the first quarter of 2015. Given this late stage in the regulatory review process in both the EU and Canada, the CHMP and Health Canada (or their affiliated regulators) have questions about the respective application in these territories. Recent interactions suggest that regulatory agencies in the EU and Canada are focused on similar issues and questions that were raised by the FDA in the complete response letter we received in January 2014, including the need for additional clinical trials and safety data. Based on these inquiries and interactions, we believe that approval in the broader IDA indication is unlikely in the EU and Canada without additional clinical data. We do not have direct control over interactions with the EU or Canadian regulatory agencies since Takeda is the primary holder of the regulatory filings in each of these territories. We can provide no assurance that the CHMP or Health Canada will provide an official opinion on the expected timelines. Any failure by Takeda to gain marketing approval for *Rienso* in the EU for the treatment of IDA regardless of the underlying cause in a timely manner, or at all, or any adverse label changes or restrictions to the current approved CKD indication, could adversely affect our revenues and cash milestones from Takeda, which in turn would adversely affect results of operations or the future prospects of our business and the commercial attractiveness to Takeda of *Feraheme* in Canada or *Rienso* in the EU. No milestone payments are associated with approval of the sNDS in Canada; however, any such adverse developments in the EU or Canada could cause regulators in other jurisdictions to undertake similar actions, which could have a negative impact on our results of operations.

We are not currently conducting or sponsoring research to expand our product development pipeline beyond *Feraheme.* However, we expect to continue with our efforts to complete additional business development transactions, such as in-licensing, acquisitions or collaborations that would be complementary to our business. For example, in September 2014, we entered into the Lumara Agreement (defined below) to acquire Lumara and in June 2013, we entered into a license agreement with PlasmaTech (formerly known as Access Pharmaceuticals, Inc.) pursuant to which we acquired the U.S. commercial rights to market and sell *MuGard*. Even if we continue to expand our product portfolio and successfully commercialize *Makena* and *MuGard*, our revenues and operations may not be diversified enough to alleviate our dependence upon the sales of *Feraheme* or we may not successfully integrate such products into our business. Please see the risk factor, *The acquisition of Lumara, if consummated, will create numerous risks and uncertainties which could adversely affect our operating results* for additional details regarding the risks associated with the Lumara acquisition.

Our ability to grow revenues from U.S. sales of Feraheme is limited to the IDA-CKD market and we may never receive regulatory approval to market and sell Feraheme to the broader IDA patient population. In addition, sales may be further limited or may decrease as a result of our proposed label changes, if we are required to provide additional warnings and/or restrictions related to Feraheme s current or future indications or as a result of limitations and/or changes to the method of administering the drug.

As discussed above, in December 2012, we submitted an sNDA to the FDA for *Feraheme* for the treatment of IDA in a broad range of patients and we received a complete response letter from the FDA in January 2014 informing us that our sNDA could not be approved in its present form. In the letter, the FDA stated that we have not provided sufficient information to permit labeling of *Feraheme* for safe and

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effective use for the proposed indication. This decision by the FDA represents a significant set-back in our efforts to obtain U.S. approval for *Feraheme* for a broader indication as the issues raised and information requested by the FDA may be costly and time-consuming to address and generate. Further, there is no guarantee that any efforts that we decide to undertake will meet the FDA s requirements, and we may not receive approval at all for *Feraheme* in a broader indication despite such efforts.

Although we are continuing to work with the FDA, we may decide not to pursue regulatory approval for the broader indication. If we continue to pursue approval in the U.S. for the commercial marketing and sale of *Feraheme* for the broad IDA indication, we will have to demonstrate, through the submission of clinical study reports and data sets from one or more controlled clinical trials (the proposed clinical trials), that the benefit of *Feraheme* use in the proposed population would warrant the risks associated with *Feraheme*, including the potential for adverse events, including anaphylaxis, cardiovascular events, and death. The FDA advised that such trials should address mechanisms to reduce the risk for serious, including fatal, hypersensitivity reactions. Conducting these and other clinical trials is a complex, time-consuming and expensive process that requires adherence to a wide range of regulatory requirements. Depending on the incidence rate of the safety end-point being studied, these studies could require a significant number of patients such that the study cannot be enrolled in a reasonable time or at a reasonable cost to support commercialization. The FDA has substantial discretion in the approval process and may decide that the results of any such additional trials and the information we submit seeking approval in the broader patient population or other information reviewed, such as post-marketing safety data, including reports of serious anaphylaxis, cardiovascular events, and death, or any information we provide in response to FDA requests, are insufficient for approval or that *Feraheme* is not effective or safe for the proposed broader indication. For example, in our Phase III clinical trial in the broader patient population, *Feraheme*-treated patients experienced a 0.5% rate of serious hypersensitivity reactions as compared to a 0.2% rate of serious hypersensitivity reactions from our current *Feraheme* label for the treatment of IDA in adult patients with CKD. The FDA indicated that its decision outlined in the complete response letter was based on the cumulative ferumoxytol data, including the global Phase III IDA program and global post-marketing safety reports. 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 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, and any additional clinical trials will likely have a similar mix of patients. There is no guarantee that the FDA will determine that the results of our clinical trials of *Feraheme* for the treatment of IDA in adult patients who have failed or could not tolerate oral iron (including any proposed clinical trials) will adequately support approval of *Feraheme* in this broader patient population, or any of the individual subpopulations of IDA patients, to grant approval. Further, we may not realize the full benefit of the Lumara acquisition (described below) if we do not obtain U.S. approval to market and sell *Feraheme* for the treatment of IDA in a broad range of patients, as we expect the current Lumara sales force call points will facilitate entry into the women s health physician specialty if the broader indication for *Feraheme* is sought and received.

The FDA could also determine that our clinical trials (including any proposed 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 (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 (CROs) or our study sites fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials (including the proposed clinical trials) may be deemed

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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 further adversely impact our ability to obtain marketing approval in the U.S. for *Feraheme* in the broad IDA indication or which could have a negative impact on our current indication. Any such deficiency in the design, implementation or oversight of our clinical development programs or post-approval clinical studies could cause us to incur significant additional costs, experience further delays or prevent us from obtaining marketing approval for *Feraheme* for the broad IDA indication, if such approval is pursued.

As a result of any information submitted to the FDA in our regulatory filings, by other regulators or in response to any information requests or issues raised by the FDA during the review of our regulatory filings, including the FDA s review of post-marketing safety data in connection with our sNDA and any reevaluation by the FDA of existing data, such as reports of serious anaphylaxis, cardiovascular events, and death, the FDA may request additional information. The additional information may include technical or scientific information, new studies or reanalysis of existing data or risk evaluation and mitigation strategies (REMS) in the current indication, or we may be required to provide additional warnings and/or restrictions on our current or future *Feraheme* package inserts, change the rate or method of administration of *Feraheme*, 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* or incur significant costs related to post-marketing requirements/commitments, which could put us at a disadvantage to our competitors. Such adverse developments could also arise with respect to *Feraheme* in Canada and/or *Rienso* in the EU. Our efforts to obtain approval for the broad IDA indication could adversely affect the commercialization of *Feraheme* in its current indication as healthcare providers may choose to treat all their IDA patients with competing IV irons which may have the broad indication.

If, for any of these or other reasons, we do not obtain U.S. approval to market and sell *Feraheme* for the treatment of IDA in a broad range of patients, if the current indication is narrowed in the U.S. or elsewhere, if we and/or Takeda are required to include additional warnings and/or restrictions on the *Feraheme* package insert, including a boxed warning in the U.S. or similar warnings outside of the U.S., or if we experience additional significant delays or setbacks in obtaining approval, or if we 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 leverage our product portfolio, our ability to achieve profitability, and the future prospects of our business could be materially adversely affected. Also, we are unable to predict what impact the proposed label changes that we submitted to FDA in June 2014 will have on our future U.S. sales, or if they will be acceptable to the FDA, and what impact regulatory activities outside of the U.S., including recent developments in the EU and Canada discussed in the risk factor, *We are primarily dependent on the success of Feraheme*, will have on our business.

Significant safety or drug interaction problems, or the evaluation or reevaluation of existing or future data by the FDA or other regulators, could result in further restrictions in or changes to the Feraheme label, recalls, withdrawal of Feraheme from the market, an adverse impact on Feraheme 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, Takeda s Type II Variation or similar applications, any of which would adversely impact our future business prospects.

Significant safety or drug interaction problems with respect to *Feraheme*, including an increase in the severity or frequency of known problems or the discovery of previously unknown problems, or the evaluation or reevaluation of existing or future data by the FDA, the EMA or other regulators, could result in a variety of adverse regulatory actions. In the U.S., under the Federal Food, Drug and Cosmetic Act (the FDC Act), 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:

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- 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;

- Requiring manufacturers to implement a REMS where necessary to assure safe use of the drug; or

- Removing an already approved product from the market.

Both *Feraheme* and *Makena* are subject to such laws and similar laws and regulations exist in countries outside of the U.S. In addition, actual or perceived safety or drug interaction problems could result in product recalls, restrictions on the product s permissible uses, changes to the product label, a negative impact on our current or future sNDAs, or similar applications, or withdrawal of the product from the U.S. and/or foreign markets. For example, and as discussed above, on July 23, 2014, the CHMP issued its opinion and agreed with PRAC s recommendations that, among other measures, *Rienso* should be administered to patients by infusion over at least 15 minutes (replacing injection) and that it should be contraindicated in patients with any known history of drug allergy.

In addition, 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 notified 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. Similarly, in June 2014, based on a review of global post-marketing data, we submitted to the FDA proposed changes to the current *Feraheme* label to strengthen the warnings and precautions section of the label and to mitigate the risk of serious hypersensitivity reactions, including anaphylaxis, in order to enhance patient safety. In addition, Takeda has implemented changes to *Rienso s* label in the EU as required by the CHMP. These or any future changes to the package insert, including the use of infusion instead of injection as the only method of administration, 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.

The data submitted to both the FDA as part of our NDA and sNDA 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* is used over longer periods of time by a wider group of patients, some of whom may be taking other medicines or by patients with additional underlying health problems.. In addition, if and 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 and which could also negatively impact the use and/or regulatory status of *Feraheme* for the treatment of IDA in patients with CKD in the U.S., the EU, Canada or other territories, as well as the prospects for approval if we or Takeda continue to pursue a broader indication for *Feraheme* for the treatment of IDA regardless of the underlying cause. For example, even if we conduct additional clinical studies, the FDA may determine that any application for *Feraheme* for the treatment of IDA in adult patients who have failed or could not tolerate oral iron does not establish a sufficiently acceptable safety profile for the approval of a broader *Feraheme* label in the U.S.

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As more data become available and an increased number of patients are treated with *Feraheme*, new or increased safety or drug interaction issues may require us to, among other things, provide additional warnings and/or restrictions on the 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, change the rate or method of administration, alter or terminate current or future trials for additional uses of *Feraheme*, or even remove *Feraheme* from the market, any of which could have a significant adverse impact on potential sales of *Feraheme* or require us to expend significant additional funds. For example, in 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 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,* which we believe did not identify any issues that would have impacted the quality of the recalled batch, and we gathered all available information for the reported adverse events. Takeda has filed a report with SwissMedic, the Swiss Agency for Therapeutic Products, and we and Takeda are awaiting feedback on SwissMedic s review of the findings from the investigation. We and Takeda are unable to predict when or if *Rienso* will be reintroduced into the Swiss market.

We have undertaken efforts to expand our product portfolio with our pending acquisition of Lumara and therefore will be relying on our ability to generate significant revenues from sales of Makena to support our post-closing operations and become profitable.

On September 28, 2014, we entered into an agreement and plan of merger (the Lumara Agreement) with, *inter alia*, Lumara, a privately held pharmaceutical company specializing in women s health which markets *Makena*, a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Upon consummation of our acquisition of Lumara, the size of our combined business will be significantly larger than our business today. If the acquisition is consummated, our future success will significantly depend upon our ability to manage this expanded business, which will pose substantial challenges for management, including challenges related to the management and monitoring of new operations and associated increased costs and complexity. In order to support this expanded business, we will need to achieve revenues from the sales of *Makena* and synergies consistent with our business expectations, which may prove more difficult than currently expected. For example, with the announcement of the acquisition of Lumara, we indicated that we believe we could achieve annual cost synergies of approximately $20.0 million per annum. Any failure to achieve this level of synergies could affect our profitability, our ability to service the debt that we are taking on to partially fund this acquisition, and our ability to meet the financial covenants under the credit agreement with the lenders.

We have no experience commercializing *Makena* and will be dependent upon the contributions of the *Makena* commercial organization and sales force and Lumara s relationships to drive *Makena* sales, and we may be unable to retain and motivate the commercial sales force or successfully maintain Lumara s current relationships following the closing of the transaction. The success of our commercialization of *Makena* is dependent upon a number of other factors, including successfully obtaining agreements for coverage and reimbursement rates on behalf of patients and medical practitioners prescribing *Makena* with third-party payors, including government authorities, private health insurers and other organizations, such as health maintenance organizations (HMOs), insurance companies, and Medicaid programs and administrators, the extent to which pharmaceutical compounders continue to produce non-FDA approved purported substitute product, patient access to the product, patient compliance and adherence, our ability to maintain certain net pricing levels and unit sales for *Makena*.

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Safety and brand reputation will also be important in achieving expected revenues from the commercialization of *Makena* and in the past Lumara (then-named K-V Pharmaceuticals, Inc.) has been criticized for the initial list pricing of *Makena* in numerous news articles and internet postings at the time of FDA approval in February 2011. The list price of *Makena* was subsequently reduced significantly in March 2011; however, *Makena* is still priced at a significant premium to certain non-FDA approved versions that are produced by compounding pharmacies, which has limited the ability for many patients or healthcare providers to gain favorable reimbursement for the product. In addition, Lumara has in the past received letters criticizing the list pricing of *Makena* from numerous medical practitioners and advocacy groups, including the March of Dimes, American College of Obstetricians and Gynecologists, American Academy of Pediatrics and the Society for Maternal Fetal Medicine. Several of these advocacy groups issued their own press releases regarding their criticism of the pricing of *Makena* and endorsed statements made by the FDA in 2011 regarding compounded product. In addition, Lumara is aware that certain doctors have chosen to continue prescribing non-FDA approved purported substitute products made by pharmaceutical compounders in lieu of even considering prescribing *Makena*.

In addition, *Makena* has been granted orphan drug exclusivity for prevention of premature birth in singleton pregnancies until February 3, 2018. If one or more generic manufacturers were to receive approval to sell a generic version of *Makena* for the orphan indication after the termination of the exclusivity period, those generic products could be marketed as early as 2018 and we would become subject to increased competition and our *Makena* revenues could be materially adversely affected. While we plan to implement a lifecycle development program to extend the brand franchise beyond the 2018 exclusivity date by exploring new routes of administration, the use of new delivery technologies, as well as reformulation technologies, there can be no assurances that this program will be successful in continuing the growth in *Makena* sales or countering competition from compounding pharmacies or generic manufacturers.

Upon the closing of the acquisition, our commercial success and growth prospects for our business will be largely dependent upon continuing to improve the reputation of *Makena*, our commercialization efforts, including gaining broader and more favorable reimbursement for *Makena*, educating physicians and patients about the benefits of prescribing an FDA-approved product over any non-FDA approved compounded product, and appropriately responding to any additional media, physician, institutional, advocacy group and governmental concerns and actions regarding the pricing and sales of *Makena*.

The consummation of the Lumara merger is subject to a number of closing conditions, some of which are out of our control. A portion of the cash consideration for the acquisition will be funded with a new debt facility, the terms of which remain subject to changes in certain market conditions and demand for our credit.

Completion of the Lumara merger is subject to certain conditions contained in the Lumara Agreement, some of which are beyond our control, and we can make no assurances that the transaction will close in a timely manner or at all; such conditions include, among other things, the representations and warranties of Lumara being true and correct at the closing subject to the terms of the Lumara Agreement and the absence of any material adverse changes affecting Lumara. In addition, a portion of the cash consideration to Lumara will be provided by debt financing, for which we have received a binding commitment from Jefferies Finance LLC (Jefferies) to provide up to $340.0 million in term B financing (the Commitment Letter). We have certain obligations under the Commitment Letter with Jefferies to assist them in syndicating the loan to other institutions and lenders, and Jefferies commitment is also subject to a number of closing conditions. Also, the terms of the Commitment Letter provide for certain flexibility to change the terms under which Jefferies will provide the debt financing based on the market conditions encountered during the marketing period for the debt to other lenders. The need to utilize some or all of the flexibility could results in less favorable financing terms for us and increase the cost of the capital required to fund the acquisition of Lumara resulting in an adverse impact on our financial condition, our results of operations and our ability to service the debt in the future if our projections for Lumara are not achieved. If the Lumara merger is not consummated for any reason, our business may be materially and adversely affected as we will have incurred substantial costs and expenses, utilized considerable resources, our employees may be distracted and we may suffer reputational harm if we are viewed as an undesirable candidate in our business development endeavors, even if the merger failed to close because of factors beyond our control.

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The acquisition of Lumara, if consummated, will create numerous risks and uncertainties which could adversely affect our financial condition and operating results.

Strategic and transformative transactions like our potential acquisition of Lumara create numerous uncertainties and risks. Upon consummation of the merger, Lumara will become a wholly-owned subsidiary of AMAG and will significantly broaden our operations. This addition to our business will entail many changes, including our integration with Lumara and its personnel and changes in systems and employee benefit plans. These transition activities are complex and we may encounter unexpected difficulties, incur unexpected costs or experience business disruptions, including as a result of:

- the diversion of management s attention to integration matters;

- difficulties realizing the revenue projections, financial benefits, cost synergies and other strategic opportunities anticipated in connection with the transaction;

- challenges in leveraging our in-office injectables commercial expertise, which could result in unforeseen expenses and disrupt our business operations;

- difficulties in the assimilation and retention of employees, including key personnel responsible for achieving continued growth of *Makena*; and

- challenges in maintaining and progressing *Makena s* lifecycle development program.

If any of these factors limits our ability to integrate our operations with those of Lumara successfully or on a timely basis, the expectations of future results of operations, including certain cost savings and synergies expected to result from the business combination, might not be met. As a result, we may not be able to realize the expected benefits that we seek to achieve from the acquisition, which could also affect our ability to service our debt obligations. In addition, we may be required to spend additional time or money on integration that otherwise would be spent on the development and expansion of our business, including efforts to further expand our product portfolio.

In addition, the market price of our stock may decline following the consummation of the merger if our integration with Lumara is unsuccessful, takes longer than expected or fails to achieve financial benefits to the extent anticipated by us, financial analysts or investors, causes us to miss a financial covenant under our credit agreement with lenders, or the effect of the merger on our post-closing financial results is otherwise not consistent with the expectations of us, financial analysts or investors.

Throughout these *Risk Factors* we have identified risks and uncertainties related to Lumara s business and the *Makena* product that we expect to encounter as a result of the consummation of (and assuming the consummation of) the Lumara acquisition. Following the consummation of the Lumara acquisition, as we undertake integration activities and pursue the commercialization of *Makena*, we may identify additional risks and uncertainties not yet known to us, which we will identify in our subsequent SEC filings.

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 by allowing us to

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utilize only a portion of the net operating losses and tax credits that would otherwise be available but for 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 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. In addition, any net operating loss and tax credit carryforwards that are associated with Lumara are already limited following Lumara s emergence from bankruptcy in September 2013, and could become further limited as a result of the change in control of Lumara in connection with the acquisition. In September 2014, we adopted an amendment to our shareholder rights plan to help preserve our tax assets by deterring certain stockholders from increasing their percentage ownership in our stock; however, such amendment is merely a deterrent does not actually prevent Section 382 ownership limitations and there can be no assurance that we will not undergo an ownership change. Even minor accumulations by certain of our stockholders could result in an ownership change under Section 382. If such an ownership change were to occur, we expect that our net operating losses could become limited; however, the amount of the limitation would depend on a number of factors including our market value at the time of the ownership change. For a discussion of the amendment to our shareholder rights plan, see the discussion in Note Q, *Stockholders Equity*, to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

The FDA has required post-marketing studies to verify and describe the clinical benefit of Makena, and the agency may limit further marketing of the product based on the results of these post-marketing studies, failure to complete these trials in a timely manner, or evidence of safety risks or lack of effectiveness.

Makena was approved by the FDA in February 2011 under the provisions of the agency s Subpart H Accelerated Approval regulations. The Subpart H regulations allow certain drugs, for serious or life-threatening conditions, to be approved on the basis of surrogate endpoints or clinical endpoints other than survival or irreversible morbidity. As a condition of approval under Subpart H, the FDA required that *Makena* s sponsor perform certain adequate and well-controlled post-marketing clinical studies to verify and describe clinical benefit of *Makena* as well as fulfill certain other post-marketing commitments. If the required post-marketing studies fail to verify the clinical benefit of the drug, or if the applicant fails to perform the required post-marketing studies with due diligence, FDA may withdraw approval of the drug following a hearing conducted under the agency s regulations. We cannot be certain of the results of the confirmatory clinical studies, which are expected in 2016, or what action the FDA may take if the results of those studies are not as expected based on clinical data that FDA has already reviewed. Under Subpart H, the agency may also withdraw approval of a drug if, among other things, the promotional materials for the product are false or misleading, or other evidence demonstrates that the drug product is not shown to be safe or effective under its conditions of use.

Following the Lumara merger, we will have significantly less cash on hand than we currently have and we will need to generate cash from operations or find new sources of capital in order to service our debt obligations, including contingent payments that may become due under the Lumara Agreement.

On September 28, 2014, we entered into the Lumara Agreement to acquire Lumara for $675.0 million, consisting of $600.0 in cash and 3,209,971 shares of newly issued common stock (valued at the time of signing). We intend to finance the cash portion of the transaction with a combination of cash on hand and $340.0 million in committed term loan B financing (the Term Loan Facility) from Jefferies. The commitment from Jefferies to provide financing is subject to the satisfaction of customary conditions, which we can make no guarantee will be satisfied. In addition to the consideration to be paid at closing,

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the Lumara Agreement provides for contingent consideration of up to an additional $350.0 million based on the achievement of various sales milestones for *Makena,* which could be paid in all cash. In addition, we will pay substantial costs and expenses associated with the transaction and many of these costs and expenses will be payable whether or not the transaction is consummated. As a result, we will, following the merger, have significantly less cash on hand than we currently have, which may limit our ability to take advantage of attractive business development opportunities and execute on our strategic plan. In addition, our cash on hand may not be sufficient to service the principal and interest payments under this new debt, that of our existing Convertible Notes, and any cash required to pay Lumara upon the achievement of sales milestones. Our ability to make these required payments could be adversely affected if we do not achieve the revenue and cash flow forecasts or if we are unable to find other sources of cash in the future.

Our level of indebtedness and the terms and financial covenants in the Term Loan Facility following consummation of the Lumara merger could adversely affect our operations and limit our ability to plan for or respond to changes in our business or acquire additional products for our portfolio. If we are unable to comply with restrictions in the proposed financing package with Jefferies, the indebtedness thereunder could be accelerated.

We have obtained a commitment, subject to customary conditions, from Jefferies under the Commitment Letter to provide up to $340.0 million under the Term Loan Facility. Our level of indebtedness following consummation of the acquisition of Lumara could adversely affect our business by, among other things:

- requiring us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow for other purposes, including further diversification of our product portfolio and expansion of sales of *Feraheme* in the current or broader indications;

- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate, thereby placing us at a competitive disadvantage compared to our competitors that may have less debt; and

- increasing our vulnerability to adverse economic and industry conditions.

The Term Loan Facility contemplated by the Jefferies Commitment Letter for the financing in connection with the acquisition of Lumara will impose restrictive covenants on us, including a requirement that we reduce our leverage over time, and obligate us to make certain payments of principal and interest over time. A failure to comply with these restrictions or to make these payments could lead to an event of default that could result in an acceleration of the indebtedness. In addition to the required principal and interest payments due under the Term Loan Facility with Jefferies, we will be obligated to use a portion of the excess cash flow generated by our business to pay down debt under the Term Loan Facility.

The Term Loan Facility will also contain an number of other restrictive covenants, including a financial covenant that will be based on the total amount of debt we have as a multiple of our cash flow, as defined in the credit agreement. The Term Loan Facility will also contain covenants and terms limiting our ability to enter into new acquisitions, licenses, mergers, foreign investments, to take on new debt and sell assets, and require us to pay penalties in the event we want to prepay the Term Loan Facility early. The maturity date of the Term Loan Facility could also be accelerated in certain circumstances if we are not able to repay or refinance our Convertible Notes that are due in 2019. The Term Loan

Facility will have a floating interest rate based on the prevailing London Interbank Offered Rate (LIBOR) rate,

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making required the interest payments subject to adjustment depending on the interest rate environment. These and other terms in the Term Loan Facility will have to be monitored closely for compliance and could restrict our ability to grow our business or enter into transactions that we believe will be beneficial to our business. We cannot make any assurances that our future operating results will be sufficient to ensure compliance with the covenants in these arrangements or to remedy any such default. In the event of an acceleration of this indebtedness, we may not have or be able to obtain sufficient funds to make any accelerated payments.

In the event the financing contemplated by the Commitment Letter is not available, other financing may be available only on less favorable terms or may not be available on acceptable terms, in a timely manner or at all.

Servicing our debt requires a significant amount of cash. We may not have sufficient cash flow from our business to make payments on our debt, and we may not have the ability to raise the funds necessary to settle conversions of our 2.50% Convertible Senior Notes due 2019 or to repurchase the Convertible Notes upon a fundamental change, which could adversely affect our business, financial condition and results of operations.

We incurred significant indebtedness in the amount of $200.0 million in aggregate principal with additional accrued interest under our Convertible Notes. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Convertible Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors that may be beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including the Convertible Notes.

In addition, holders of the Convertible Notes have the right to require us to repurchase their notes upon the occurrence of a fundamental change at a repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest. Upon conversion of the Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the notes being converted. We may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Convertible Notes surrendered therefor or at the time Convertible Notes are being converted. Our failure to repurchase Convertible Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the Convertible Notes would constitute an event of default. If the repayment of any indebtedness were to be accelerated because of such event of default (whether under the Convertible Notes, our arrangement with Jefferies or otherwise), we may not have sufficient funds to repay the indebtedness and repurchase the Convertible Notes or make cash payments upon conversions thereof.

In addition, our significant indebtedness, which will increase considerably upon the closing of the Lumara merger and our entry into the Term Loan Facility, combined with our other financial obligations and contractual commitments, could have other important consequences. For example, it could:

- make us more vulnerable to adverse changes in general U.S. and worldwide economic, industry and competitive conditions and adverse changes in government regulation;

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- limit our flexibility in planning for, or reacting to, changes in our business and our industry;

- place us at a disadvantage compared to our competitors who have less debt; and

- limit our ability to borrow additional amounts for working capital and other general corporate purposes, including to fund possible acquisitions of, or investments in, complementary businesses, products, services and technologies.

Any of these factors could materially and adversely affect our business, financial condition and results of operations. In addition, if we incur additional indebtedness, the risks related to our business and our ability to service or repay our indebtedness would increase.

We are substantially dependent upon our collaboration with Takeda to commercialize Feraheme in certain regions outside of the U.S., including Canada, Switzerland and the EU (where it is marketed as Rienso), and if Takeda fails to successfully fulfill its obligations, or is unsuccessful in the regulatory approval process or commercialization of Feraheme in its licensed territories, or if our collaboration is terminated or materially amended, our plans to commercialize Feraheme 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* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey. Takeda markets *Feraheme* under the trade name *Rienso* in the licensed territories other than Canada, where it is marketed as *Feraheme*. We are highly dependent on Takeda for certain regulatory filings outside of the U.S. with respect to *Feraheme* and the commercialization of *Feraheme* outside of the U.S. To date, Takeda has launched *Feraheme* in 11 countries (Finland, the Netherlands, Ireland, UK, Norway, Austria, Slovenia, Denmark, Sweden, Canada and Switzerland). However, revenues from sales of *Feraheme* outside of the U.S. are not currently a material part of our business.

In June 2013, Takeda filed a Type II Variation to update the marketing authorization for *Rienso* in the EU to extend the therapeutic indication from adult patients with IDA associated with CKD to adult patients with iron deficiency from any underlying cause. In October 2014, the CHMP informed Takeda that it expects to discuss the Type II Variation during the fourth quarter of 2014. In addition, 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, regardless of the underlying cause. In October 2014, we were also informed that a final decision on the sNDS was expected by Health Canada in the first quarter of 2015. Given this late stage in the regulatory review process for each of these applications, the CHMP and Health Canada (or their affiliated regulators) have questions about the respective application in these territories. Recent interactions suggest that regulatory agencies in the EU and Canada are focused on similar issues and questions that were raised by the FDA in the complete response letter we received in January 2014, including the need for additional clinical trials and safety data. Based on these inquiries and interactions, we believe that approval in the broader IDA indication is unlikely in the EU and Canada without additional clinical data. Even if clinical studies are approved and undertaken, the resulting clinical data may not support approval of a broader indication. We do not have direct control over interactions with the EU or Canadian regulatory agencies since Takeda is the primary holder of the regulatory filings in each of these territories. We can provide no assurance that the CHMP or Health Canada will provide an official opinion on the expected timelines. It is unclear whether the FDA s January 2014 complete response letter regarding our sNDA for *Feraheme* for the treatment of IDA in a broad range of patients, and any efforts we or the FDA take in connection with the broader indication, had and will continue to have any impact on the outcome of Takeda s efforts, but, any regulatory action taken by the FDA with respect to a product under review in the U.S. has the potential to affect the regulatory requirements or decisions made by foreign regulatory bodies with regard to the regulatory approval of products outside of the U.S. and, similarly, any regulatory action taken by foreign regulatory bodies, including European and Canadian authorities, with regard to the regulatory approval of products in such territories

may influence actions taken by the FDA.

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The level of success of Takeda s current and future commercialization efforts outside of the U.S. would be significantly harmed as the result of a number of factors, including but not limited to the following:

- If approval for the broad IDA indication is not granted or is granted with significant restrictions to the proposed label;

- If the currently approved CKD indication or product label is further narrowed, restricted or changed;

- Negative reaction from providers or the market in light of the recent DHPC letter issued by Takeda and the recommendations by the CHMP, which resulted in changes to the product label and the method of administration and any future DHPC letters;

- If *Feraheme* is linked to serious unexpected adverse reactions in patients or a higher rate of expected adverse reactions in patients;

- If Takeda experiences significant delays or setbacks in obtaining approval in the broad IDA patient population;

- If Takeda is required to incur significant costs as post-marketing commitments or in furtherance of efforts, including clinical studies, to potentially obtain approval in the broad IDA patient population;

- If Takeda is unsuccessful in its commercialization of *Feraheme* in the agreed-upon territories due to market, competitive or pricing dynamics, or other reasons; and

- If we fail to effectively manage our relationship with Takeda.

All of the above factors would have an adverse effect on future royalties or milestone payments we may receive from Takeda, including a significant milestone payment for the grant of marketing authorization in the EU for *Rienso* for the treatment of IDA generally without limit to a specific patient population or sub-population, which authorization, as discussed above, we think is unlikely without additional clinical data. Even if clinical studies are approved and undertaken, the resulting clinical data may not support approval of a broader indication.

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* in the agreed-upon territories, which would increase the cost of and potentially delay the *Feraheme* 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 *Feraheme* would not be in the best interest of patient welfare. If Takeda terminates the agreement or if we and Takeda agree to terminate the Amended Takeda Agreement and we choose to continue to commercialize *Feraheme* in Takeda s territories, we would be required to either:

- enter into alternative arrangements with third parties to commercialize *Feraheme* in Takeda s current territories, which we may be unable to do in a timely and cost effective manner, or at all; or

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- increase our internal infrastructure for the commercialization of *Feraheme* in Takeda s current territories.

Both entering into alternative arrangements and increasing our internal infrastructure would result in significant additional expense and the disruption or failure of commercial efforts outside of the U.S. In order to continue commercialization efforts, we would also have to assume the full cost of any post-marketing commitments, both currently and in the future, some of which might have been Takeda s responsibility under a cost-sharing arrangement. In addition, such a termination would prevent us from receiving the milestone payments and royalties we may otherwise receive under the Amended Takeda Agreement.

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 industries are intensely competitive and subject to rapid technological change. Many of our competitors for *Feraheme* 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. For *Makena*, most of our competition comes from pharmacies that compound a non-FDA approved version of *Makena*, which is sold at a much lower cost that *Makena*. Our existing or potential new competitors for *Feraheme* and *Makena* 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 and *Makena* 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, reimbursement levels or patient co-pays for available products; and
- Product characteristics such as the method of administration and dosing regimens.

The introduction by our competitors of alternatives to *Feraheme, Makena* 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 may not receive the same level of market acceptance as competing iron replacement therapy products, which could have a material adverse effect on our operations and our ability to become profitable.

Feraheme 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, a 2013 CHMP review of IV iron-containing medications used to treat iron deficiency and anemia 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

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these products be given in an environment where patients who develop an allergic reaction can be treated immediately and ceasing to rely on a lack of allergic reaction to a test dose as an indication of tolerance of larger doses.These conclusions coupled with the July 2014 recommendations of the CHMP and the DHPC letter issued by Takeda at the request of PRAC could cause physicians to elect non-IV iron alternatives which may be easier to administer or dose or which may be perceived as less risky. See the discussion under our risk factor *We are primarily dependent on the success of Feraheme* for additional details on the July 2014 CHMP recommendations and the DHPC letter.

Feraheme currently competes with several IV iron replacement therapies in the U.S., certain of which are approved for the treatment of IDA in a broader group of patients than *Feraheme.* For example, 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® is approved in the U.S. with a recommended dose of two slow injections or infusions of 750 milligrams each separated by at least seven days apart for a total of 1,500 milligrams. While this dosing regimen is different from *Feraheme*, it does offer similar convenience benefits to *Feraheme* for patients and healthcare providers. If our method of administration changes in the future away from the current rapid injection, *Feraheme* could lose a competitive advantage to Injectafer®. Injectafer® is also priced at a significant premium to many other IV irons, which may provide more opportunity to offer discounts, incentives and rebates to new or existing customers to attract new business. The recent decision by the FDA that we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for the proposed indication will likely make it more difficult for us to compete with Injectafer® for certain customers in the U.S. because Injectafer® has been approved for a broader patient population than *Feraheme*. Even if we continue to seek and eventually obtain labeling of *Feraheme* in a broader population, Injectafer® will have already been available for a considerable period of time. During this period, physicians may increase their use of Injectafer® and gain familiarity with the product, making it more difficult for us to cause these physicians to use *Feraheme* in the future. In addition, manufacturers of Injectafer® may enter into commercial contracts with key customers or group purchasing organizations (GPOs) during this period, which could prevent or make it more difficult for *Feraheme* to retain its existing customers, gain sales to new customers and gain market share in its existing indication with customers or GPOs, if we were to continue to seek and receive approval for the broader patient population in the future. Injectafer® s U.S. approval or the approval of any other iron replacement product for an indication broader than *Feraheme*, could adversely affect our efforts to market and sell *Feraheme* in the U.S., even in *Feraheme s* currently approved CKD population, and our ability to generate additional revenues and achieve profitability.

Feraheme 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 62 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,* 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, most 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. *Rienso* (the trade name for *ferumoxytol* outside of the EU and Canada) was approved only for use in adult CKD patients, which could put it at a competitive disadvantage unless and until it receives approval for a broader indication outside of the U.S. (which, as discussed above, we think is unlikely without additional clinical data based on inquiries and requests for information received by European and Canadian regulators). In addition, as noted above, in July 2014, the CHMP issued its opinion and agreed with PRAC s recommendations that, among other measures, *Rienso* should be administered to patients by infusion over at least 15 minutes (replacing injection) and that it should be

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contraindicated in patients with any known history of drug allergy in the current CKD indication. Based on the change in method of administration away from the current rapid injection, *Rienso* may be at a further competitive disadvantage to its competitors outside of the U.S. If we or Takeda are not able to differentiate *Rienso* from other marketed IV iron products, our ability to maintain a premium price, our ability to generate revenues and achieve and maintain profitability, our or Takeda s ability to continue to support commercialization outside the U.S., and our long-term business prospects could be adversely affected.

We have no experience facing competition from compounded products and if we are unsuccessful in differentiating Makena from compounded 17P products, sales of Makena, and thus our profitability, could be materially adversely affected.

We are aware that 17-alpha-hydroxyprogesterone caproate (17P) (the active ingredient in *Makena*), has been available from compounding pharmacies for many years and will likely remain available even though *Makena* has been granted orphan drug exclusivity until February 3, 2018 and we have no prior experience with facing such competition. In March 2011, the FDA communicated to Lumara and also separately issued a press release that, in order to ensure continued access for patients needing 17P, the FDA intended to refrain from taking enforcement action with respect to compounding pharmacies producing compounded 17P in response to individual prescriptions for individual patients. The FDA s statement had an adverse effect on Lumara s ability to realize the benefit of orphan drug exclusivity and its ability to grow sales of *Makena* following the launch of the product in March 2011. The failure by the FDA to take enforcement action against compounding pharmacies resulted in substantial sales of compounded alternatives to *Makena* and effective loss of some or all of such marketing exclusivity for the affected period of time. Although in June 2012 the FDA recommended using an FDA-approved drug product, such as *Makena*, instead of a compounded drug except when there is a specific medical need (e.g., an allergy) that cannot be met by the approved drug, and despite recent negative publicity regarding compounding pharmacies, including the meningitis outbreak involving compounded drugs in 2013, the enactment in November 2013 of the Drug Quality and Security Act (DQSA), and recent enforcement actions against compounders who were violating the DQSA, *Makena* may continue to face competition from compounded versions of 17P, especially in light of the long-standing availability of such compounded products, their substantially lower cost and the criticism Lumara received in the past in connection with the pricing of *Makena*. Further, if any safety or efficacy concerns arise with respect to the compounded 17P products, it may negatively impact sales of *Makena* if healthcare providers and patients do not distinguish between the compounded product and the FDA-approved *Makena*.

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, we are seeking to in-license or acquire additional pharmaceutical products or companies that leverage our corporate infrastructure and commercial expertise. For example, in September 2014, we entered into the Lumara Agreement to acquire Lumara and in June 2013, we entered into a license agreement with PlasmaTech, under which we acquired 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 additional transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated financial benefits of any such transaction, including our pending acquisition of Lumara and our acquisition of the MuGard Rights. Also, upon the closing of the acquisition of Lumara we will have utilized a considerable amount of our cash on hand and will have incurred a substantial amount of

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indebtedness with restrictive covenants, which could impair our ability to undertake further business development activities.

Further, 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. In addition, acquisitions may cause significant changes to our current structure, organization and operations, may subject us to more rigid or constraining regulations or government oversight and may have negative tax and accounting consequences. These results could have a negative impact on our financial position or results of operations and result in significant charges in future periods. We may not be successful in acquiring or in-licensing any product, product candidate or business that will provide us with commercial, development and/or financial synergies with our products and organization such that we will be able to eliminate expenses either from our existing operations or from the cost structure of the acquired product. We may not be successful in acquiring or in-licensing products, product candidates or businesses to diversify our product portfolio, or in commercializing any products that we do acquire, such as *Makena* and *MuGard*, and our business would therefore continue to be dependent upon the sales of *Feraheme* (see the discussion under the risk factor *We are primarily dependent on the success of Feraheme* for a discussion of the associated risks).

In addition, proposing, negotiating and implementing collaborations, in-licensing arrangements or acquisition agreements is 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 additional debt and contingent liabilities, each of which may contain restrictive covenants that could adversely impact or limit our ability to grow our business, enter into new agreements, and adversely affect 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* and, in the future, *Makena*. In addition, our cash, cash equivalents and investments may not be sufficient to finance any additional strategic transactions, and 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, and our stockholders may experience significant dilution. Our Term Loan Facility will contain restrictions on our ability to acquire additional pharmaceutical products and companies, to enter into exclusive licensing arrangements, to incur additional indebtedness and will require us to use a portion of our free cash flow to repay indebtedness annually commencing in 2015. These provisions will limit our ability to pursue attractive business development opportunities. 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 Lumara or the MuGard Rights or any future acquisitions or product licenses and the integration of Lumara and 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 pharmaceutical products such as we did with *MuGard* and as we have pending with *Makena*. The integration of the operations of acquired products or businesses, including *Makena* and *MuGard*, requires significant efforts, including the

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coordination of information technologies, sales and marketing, operations, manufacturing, safety and pharmacovigilance, medical and finance. These efforts result in additional expenses and involve significant amounts of management s time. In addition, we rely on PlasmaTech, 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 PlasmaTech 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. Similarly, we will be relying on the *Makena* commercial team and other key Lumara personnel to assist with the integration and operations of Lumara and the commercialization of *Makena*. We may not realize the anticipated benefits of Lumara or the 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, or markets where we compete with non-traditional pharmaceutical companies such as compounding pharmacies, and where competitors in such markets have stronger market positions;

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

- Our ability to train our sales force, and the ability of our sales force, to successfully incorporate new products and devices, including *MuGard*, into their call points, or to successfully integrate and leverage sales forces that we retain, such as the *Makena* commercial team;

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

- The introduction by our competitors of alternatives to *Makena*, *MuGard* or any other future product 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 for acquisitions or product licenses, including Lumara and *MuGard*, and any resulting impact that may have on our quarterly financial results. For example, during the quarter ended September 30, 2014, we recorded a benefit of $3.7 million due to the reduction of the contingent consideration liability related to the MuGard Rights based on a revision of our projected net sales for *MuGard* during the term of the license, to reflect our belief that MuGard sales will be lower than previously expected; and

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

If we cannot successfully integrate the Lumara or *MuGard* businesses, or other businesses or products we may acquire or in-license, 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 or in-licenses, including Lumara and *MuGard*, we will achieve the expected synergies to justify such transaction.

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

We do not currently own or operate, and currently do not plan to own or operate, facilities for the manufacture of *Feraheme, Makena* or *MuGard*, and we do not plan to own or operate facilities for the manufacture of any commercial products we may acquire or in-license. We currently rely solely on our third-party contract manufacturers to manufacture *Feraheme* for our commercial and clinical use and rely on PlasmaTech for the manufacture of *MuGard*. We expect to rely on Lumara s third-party contract manufacturers to manufacture *Makena*. We do not currently have an alternative manufacturer for our *Feraheme* drug substance and finished drug product and will not have an alternative manufacturer for *Makena* active pharmaceutical ingredient (API) or 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 (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 our products 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 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 in a timely and cost-effective manner. Furthermore, our current third-party manufacturer for *Feraheme* and that of Lumara s 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* or *Makena* 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* or *Makena*.

In addition, securing additional third-party contract manufacturers for *Feraheme* or *Makena* will require significant time for transitioning the necessary manufacturing processes, gaining regulatory approval, and 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* or *Makena* in accordance with cGMP. If we are unable to have *Feraheme* or *Makena* 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* or *Makena* or may not be able to manufacture *Makena* or *Feraheme* in a cost-effective manner, particularly in light of the current fixed price at which we are required to supply *Feraheme* to Takeda under the Amended Takeda Agreement. As a result, we may lose sales, fail to generate increased revenues, fail to launch the product in markets that cannot support a price in excess of our costs, suffer regulatory setbacks and/or we may lose money on our supply of *Feraheme* to Takeda, any of which could have an adverse impact on our potential profitability and future business prospects.

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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 contract manufacturers ability to manufacture our products, the loss of inventory, an inability to manufacture sufficient quantities of product to meet U.S. or foreign demand, as applicable, or other unanticipated compliance costs.

Our third-party contract manufacturing facilities, and those of Lumara, are subject to cGMP regulations enforced by the FDA and equivalent foreign regulations and regulatory agencies through periodic inspections to confirm such compliance. Similarly, we rely on PlasmaTech for the manufacture of *MuGard* and third-party contract manufacturing facilities engaged by PlasmaTech are subject to cGMP regulations. 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 our products from the marketplace, total or partial suspension of product production, the loss of inventory, suspension of the review of our current or 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 our products 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 or PlasmaTech s contract manufacturers otherwise determine that they are not in compliance with these regulations, as applicable, such contract manufacturers could experience an inability to manufacture sufficient quantities of product to meet U.S. or foreign demand, as applicable, 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 *Feraheme* finished product to be used for commercial sale. If our *Feraheme* 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. We will also establish similar testing and release specifications for *Makena*. Release testing must be performed in order to allow *Makena* finished product to be used for commercial sale. If our *Makena* 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. We monitor annual batches of *Feraheme* and, in the future, *Makena*, for ongoing stability after it has been released for commercial sale. If a particular batch of *Feraheme* or *Makena* exhibits variations in its stability or begins to generate test results that demonstrate an adverse trend against our specifications, we may need to conduct an investigation into the test results, quarantine the product to prevent further use, destroy existing inventory no longer acceptable for commercial sale, or recall the batch. In addition, variations in the regulatory approval of *Feraheme* 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* sales, our potential profitability and the future prospects of our business.

Our products may not be widely adopted or continue to be used 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 and continued use by physicians, hospitals, patients, and healthcare payors, including HMOs, managed care organizations and GPOs, and, specialty pharmacies with the addition of *Makena* to our product portfolio. 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*, *Makena* and *MuGard* each represent an alternative to other products in their respective markets and might not be

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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, including, in the case of *Makena*, compounded products.

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

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

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

- The actual or perceived safety and efficacy profile of *Feraheme* as compared to alternative iron replacement therapeutic agents, particularly in light of the complete response letter, recent and proposed changes to the product label, the DHPC letter issued by Takeda, the recommendation of the CHMP and if unanticipated adverse reactions to *Feraheme* result in further changes to or restrictions in the *Feraheme* package insert, voluntary or involuntary product recalls and/or otherwise create safety concerns among potential prescribers;

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

- The actual or perceived convenience and ease of administration of *Feraheme* as compared to alternative iron replacement therapeutic agents, including iron administered orally, in light of recent or potential changes to the methods of administration;

- Current and future limitations on the approved indications and patient populations for *Feraheme* in the U.S., the EU, Canada and other territories, especially in light of FDA s decision that we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use in the broad IDA patient population; and

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

The key component of our U.S. commercialization strategy for *Feraheme* 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: hospitals, hematology and oncology centers, 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

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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.

Additionally, our ability to successfully commercialize *Makena* in the U.S. following consummation of the acquisition of Lumara, depends on a number of factors, including but not limited to the following:

- The impact of competitive, commercial payor, governmental (including state Medicaid programs), physician, patient, public or political responses and reactions, and responses and reactions by medical professional associations and advocacy groups, on our sales, marketing, product pricing, product access and strategic efforts;

- The possibility that the benefit of the remaining exclusivity period resulting from the designation of *Makena* as an orphan drug may not be realized as a result of long-standing use by physicians and reimbursement by payors of compounded alternatives in the market where *Makena* competes;

- The number of preterm birth risk pregnancies for which *Makena* may be prescribed, its safety and side effects profiles and acceptance of pricing;

- Our ability to increase patient compliance in line with the current label either by starting patients on *Makena* earlier in the pregnancy or ensuring they receive each weekly injection through the time of delivery resulting in a greater number of injections per patient;

- The successful integration and retention of the *Makena* commercial sales team and any other key employees into our business structure;

- The level of enforcement by the FDA to ensure non-FDA approved products provided by compounding pharmacies in violation of the DQSA;

- Our ability to maintain and progress *Makena s* lifecycle development program, particularly after the expiration of exclusivity in February 2018; and

- Our ability to successfully leverage Lumara s commercial organizations and distribution networks in marketing, selling and supplying *Makena*.

Failure to achieve any or all of these commercial objectives could have an adverse material effect on the growth of *Makena* and our ability to achieve our revenue forecasts which could impact our financial condition or results of operations.

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

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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.

One of our U.S. *Feraheme* patents is subject to a patent term extension under U.S. patent law and FDA regulations and will expire in June 2023. Our other U.S. patents relating to *Feraheme* expire in 2020. Our licensed patents relating to *MuGard* expire in 2022. These and any other patents issued to or acquired by us may be contested or invalidated. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the 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. There are no patents covering *Makena*.

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.

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

Generic ferumoxytol and hydroxyprogesterone caproate competitors could enter the market through approval of abbreviated new drug applications (ANDAs) that use *Feraheme* or *Makena* as a reference listed drug, which would allow generic competitors to rely on *Feraheme s* or *Makena s* safety and effectiveness trials instead of conducting their own studies. An ANDA may be submitted four years after approval of a subject drug with a five-year exclusivity period if the ANDA contains a certification of patent invalidity or non-infringement, known as a Paragraph IV certification, with respect to patents listed for *Feraheme* in the Orange Book. In recent years, generic manufacturers have used Paragraph IV certifications extensively to challenge the protection of Orange Book-listed patents on a wide array of innovative pharmaceuticals, and we expect this trend to continue.

Further, in December 2012, the FDA published a draft guidance containing product-specific bioequivalence recommendations 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. The published bioequivalence guidance could encourage a generic entrant seeking a path to approval of a generic ferumoxytol to file an ANDA. As a result, 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 requesting that the FDA not approve any ANDAs for a generic ferumoxytol product until FDA completes certain planned studies addressing concerns with other generic IV iron products and imposes additional bioequivalence requirements for sponsors seeking approval of generic ferumoxytol products. However, we cannot predict when or if the FDA will respond 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. *Makena* does not have any patents currently listed in the Orange Book and therefore a Paragraph IV certification would not be required for an ANDA submission.

Additionally, the FDA, in 1956, approved the drug Delalutin (hydroxyprogesterone caproate) (the original version of 17P) for conditions other than reducing the risk of preterm birth and it was marketed by a large pharmaceutical company. That company stopped marketing and manufacturing the FDA-approved product and it was withdrawn from the market. In 2010, the FDA determined that Delalutin was not withdrawn from sale for reasons of safety or effectiveness, which determination allows the FDA to approve ANDAs for hydroxyprogesterone caproate injection under that indication, if all other legal and regulatory requirements are met. Although *Makena* has orphan drug exclusivity for prevention of premature birth in singleton pregnancies until February 2018, the FDA can approve drug products containing hydroxyprogesterone caproate at the same strengths as the other previously approved hydroxyprogesterone caproates for other indications, under an NDA or as an ANDA, with the appropriate supporting data. If such an approval is granted, doctors may elect to prescribe such approved drug off-label for the orphan drug indication under which *Makena* was approved. The history of 17P, including its previous approval for other indications, the availability of compounded versions of the product, and the determination that the FDA can approve an ANDA for 17P, could encourage other competitors to seek to commercialize 17P for various indications, which could have an adverse impact on our business and results of operations.

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If we fail to maintain orphan drug exclusivity for Makena that may reduce the length of time that we can prevent competitors from selling generic versions of hydroxyprogesterone caproate.

Makena has been granted orphan drug exclusivity in the U.S. for prevention of premature birth in singleton pregnancies until February 2018. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, defined, in part, as a patient population of fewer than 200,000 in the U.S. In the U.S., the company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application for the same drug for the same orphan indication during the exclusivity period, except in very limited circumstances. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusivity marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even though we have orphan drug exclusivity for *Makena*, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. In the U.S., even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care.

Further, if one or more ANDA filers or a generic manufacturer were to receive approval to sell a generic or follow-on version of *Makena* for the orphan indication, those generic products could be marketed as early as 2018 and we would become subject to increased competition and our revenues for *Makena* would be adversely affected.

The success of Feraheme 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 described above under the risk factor *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 (the EPO) or similar adversarial proceedings, regarding intellectual property rights with respect to *Rienso*. For example, in July 2010, Sandoz GmbH (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, which also suspended the revocation of our patent. In May 2013, we filed a statement of grounds of appeal and in September 2013, Sandoz filed a response to that statement. We filed a reply to that response in March 2014 and oral proceedings for the appeal are scheduled in June 2015. We will continue to defend the validity of this patent throughout the appeals process, which we expect to take two to three years. 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 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* or increase the risk that a generic version of *Feraheme* could enter the market to compete with *Feraheme*. In countries where we do not have or have not applied for patents for ferumoxytol, 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.* Our inability to protect *Feraheme* 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.

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, may vary from period to period due to a variety of factors, including the buying patterns of our U.S. wholesalers, distributors, pharmacies, clinics or hospitals, and, upon the addition of *Makena* to our product portfolio, specialty pharmacies, which vary from quarter to quarter. In addition, our *Feraheme* contracts with GPOs often require certain performance from the members of the GPOs, on an individual account level or group level 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 members. In the event wholesalers, distributors, pharmacies, 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. Further, in the event wholesalers, distributors, pharmacies, clinics or hospitals purchase increased quantities of our products to take advantage of volume discounts or similar benefits, our quarterly results will fluctuate as re-orders become less frequent, and our overall net pricing may decrease as a result of such discounts and similar benefits. In addition, these contracts are often cancellable at any time by our customers, often without notice, and are non-exclusive agreements within the *Feraheme* or *Makena* markets. While these contracts are intended to support the use of our products, our competitors could offer better pricing, incentives,

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higher rebates or exclusive relationships. Because *Feraheme* is not indicated for the broad IDA population, the incentives in our contracts for a particular site of care are capped based on our estimate of their patients covered by our current CKD label. Because some of our competitors products have the broad IDA label, they may provide additional incentives for all of a customer s IV iron usage, essentially becoming an exclusive provider to that particular customer.

Our contracting strategy can also have an impact on the timing of certain purchases causing product 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 (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.

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 92% of our total revenues during the nine months ended September 30, 2014, and three customers accounted for 92% of our accounts receivable balance as of September 30, 2014. 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 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 27% of our end-user demand during the first nine months of 2014 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, HMOs, managed care organizations and private health insurers.

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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, such as through the use of prior authorizations and step therapy. 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. Further, following our acquisition of Lumara, we may face increased scrutiny by third-party payors for *Makena* in light of the pricing criticism Lumara has received in the past from such payors and advocacy groups - see the discussion under our risk factor *We have undertaken efforts to expand our product portfolio with our pending acquisition of Lumara and therefore will be relying on our ability to generate significant revenues from sales of Makena to support our post-closing operations and become profitable*.

In addition, U.S. and many foreign governments continue to propose and pass legislation designed to reduce the cost of health care for patients. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (the Healthcare Reform Act) 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, recent legislation has resulted in Medicare payments being subject to a 2% reduction, referred to as sequestration, until 2024. Because the majority of our *Feraheme* business is through hematology/oncology clinics and outpatient 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 *Feraheme* for treatment of patients with CKD and for *Makena*, 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 or private third-party payors reimbursement policies may reduce the extent of reimbursement for our products and adversely affect our future operating results.

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, in the U.S., for the inpatient hospital setting, most drugs are not reimbursed separately within the Medicare prospective payment system based on the drug costs, but are bundled as 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, we do not expect *Feraheme* to be broadly used in the inpatient hospital setting.

Currently, in U.S. physician clinic and hospital outpatient settings, Medicare Part B generally reimburses for physician-administered drugs at a rate of 106% of the drug s ASP. ASP is defined by statute based on certain historical sales and sales incentive data, including rebates and chargebacks, for a defined period of time. Manufacturers submit the required information to the Centers for Medicare and Medicaid Services (CMS) on a quarterly basis. In advance of the quarter in which the payment limit for drugs reimbursed under Medicare Part B program will go into effect, CMS calculates and publishes the

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payment limit. Under this methodology, payment rates change on a quarterly basis, and significant downward fluctuations in ASP, and therefore reimbursement rates, could negatively impact sales of a product. Because ASP is defined by statute, and changes to Medicare payment methodologies require legislative change, it is unclear if and when ASP reimbursement methodology will change for the physician office setting. For hospital outpatient departments, the Medicare payment methodology for many covered Part B drugs also is at 106% of ASP, but CMS could change the payment methodology through regulations, without any intervening legislation. We cannot predict the impact that any changes in reimbursement policies may have on our ability to compete effectively.

In addition, it is also possible that a bundled payment approach, like for renal dialysis services under Medicare, may be applied to other 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 countries outside of the U.S., market acceptance of *Feraheme* may also depend, in part, upon the availability of reimbursement within existing healthcare payment systems. Generally, in Europe and other countries outside of the U.S., the government sponsored healthcare system is the primary payor of healthcare costs of patients and therefore enjoys significant market power. Some foreign countries also set prices for pharmaceutical products as part of the regulatory process, and we cannot guarantee that the prices set by such governments will be sufficient to generate substantial revenues or allow sales of *Feraheme* to be profitable in those countries. In addition, Takeda may be unable to obtain favorable pricing in certain countries in Europe making the commercialization impractical and preventing them from launching in those countries. Any such limitations on the reimbursement for *Feraheme* in countries outside of the U.S. would have an adverse impact on Takeda s ability to generate product sales of *Feraheme* in such territories, which would, in turn, limit the amount of royalties we may receive under our amended agreement with Takeda.

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 Healthcare Reform Act contains a number of provisions that significantly impact the pharmaceutical industry and may negatively affect our business, including potential revenues. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges, expansion of the 340B program, and fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

The Healthcare Reform Act made significant changes to the Medicaid program, including an increase to the minimum rebates for products covered by Medicaid programs from 15.1% to 23.1% of the average manufacturer price for most innovator products and the expansion of the 340B Drug Discount Program under the Public Health Service Act. Effective March 2010, the Healthcare Reform Act expanded manufacturer rebate liability under the Medicaid program from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. In addition, the Healthcare Reform Act and subsequent legislation changed the definition of average manufacturer price. Finally, the Healthcare Reform Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each individual pharmaceutical manufacturer

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pays a prorated share of the branded prescription drug fee of $3.0 billion in 2014 (and set to increase in ensuing years), based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Substantial new provisions affecting compliance have also been added, which may require us to modify our business practices with healthcare providers and potentially incur additional costs. While we are continuing to evaluate this legislation and its potential impact on our business, this legislation may adversely affect the demand for *Feraheme* and *Makena* in the U.S. or cause us to incur additional expenses and therefore adversely affect our financial position and results of operations.

Many of the Healthcare Reform Act s most significant reforms do not take effect until 2014. In 2012, CMS, the federal agency that administers the Medicare and Medicaid programs, issued proposed regulations to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act but has not yet issued final regulations. CMS may release the final regulations late in 2014 or in 2015.

The Healthcare Reform Act also expanded the Public Health Service s 340B drug pricing program. Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the 340B program in order for federal funds to be available for the manufacturer s drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B ceiling price for the manufacturer s covered outpatient drugs. The Healthcare Reform Act expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Healthcare Reform Act. For example, the percentage of *Feraheme* business sold to 340B institutions has grown from 11% in 2011 to 17% in 2013. Since these institutions are granted lower prices than those offered to our other customers, any further growth in our 340B business may have a negative impact on our sales price per gram and operating margins.

The Healthcare Reform Act exempts orphan drugs from the ceiling price requirements for the covered entities added to the program by the Healthcare Reform Act. On July 21, 2014, the Health Resources and Services Administration (HRSA), which administers the 340B program, issued an interpretive rule to implement the orphan drug exception which interprets the orphan drug exception narrowly. It exempts orphan drugs from the ceiling price requirements for the newly-eligible entities only when the orphan drug is used for its orphan indication. The newly-eligible entities are entitled to purchase orphan drugs at the ceiling price when the orphan drug is not used for its orphan indication. A manufacturer trade group has filed a lawsuit challenging the interpretive rule as inconsistent with the statutory language. That challenge remains ongoing. The uncertainty regarding how the statutory orphan drug exception will be applied will increase the complexity of compliance, will make compliance more time-consuming, and could negatively impact our results of operations. If HRSA s narrow interpretation of the scope of the orphan drug exemption prevails, it could potentially negatively impact the price we are paid for our *Makena* product by certain entities and increase the complexity of compliance with the 340B program.

The Healthcare Reform Act also obligates the Secretary of the Department of Health and Human Services to create regulations and processes to improve the integrity of the 340B program and to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. HRSA previously was expected to issue a comprehensive proposed regulation in 2014 that would have addressed many aspects of the 340B program. However, it is unclear if HRSA now will issue this proposed regulation in 2014. If that regulation is proposed and finalized, it could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further

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expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Moreover, legislative changes to the Healthcare Reform Act remain possible. We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase our product sales. 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 opportunities for our products, including its acceptance by healthcare payors.

Our inability to obtain raw and other materials used in the manufacture of Feraheme, and, following consummation of the Lumara merger, Makena, could adversely impact our ability to manufacture sufficient quantities of Feraheme and Makena, 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* and *Makena* 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* and *Makena* 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;

- Changes to the specifications of the raw materials such that they no longer meet our standards;

- Lack of sufficient quantities or profit on the production of raw materials to interest suppliers;

- 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* or *Makena* 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

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manufacture *Feraheme* 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*. In addition, there is only one FDA-approved supplier of the API for *Makena* and, currently, Lumara does not have a long-term supply agreement with that supplier. Since *Makena* is approved for an orphan indication and only marketed in the U.S., there is limited demand for the product resulting in small quantities of the product to be produced each year to fulfill Lumara s needs. Because of this, the supplier of API may determine that it is not financially attractive for them to continue to supply API for *Makena* at current prices, or at all.

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* or *Makena* 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* or *Makena*, 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* or *Makena* and could have a material adverse impact on our ability to generate additional revenues and to achieve profitability. Moreover, the manufacture and supply of *MuGard* are also subject to many of the same third party risks, which would impact our ability to generate revenues of *MuGard* in the U.S.

If we or Takeda market or distribute Feraheme or if we market or distribute Makena or 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 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* through Takeda. 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 Takeda fail to comply with any of these laws or regulations, a range of fines, penalties

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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* and how we market and sell *MuGard*, and, upon the closing of the Lumara merger, *Makena*, 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 Healthcare Reform Act, the federal government has enacted the Physician Payment Sunshine Act and related regulations. Since August 2013, manufacturers of drugs have been 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, we are required to calculate and report certain pricing information to U.S. federal and state healthcare agencies. We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program, and we have obligations to report average sales price (ASP) for the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient products that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our products under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to the CMS. These data include the average manufacturer price and, in the case of innovator products such as *Feraheme* and *Makena*, the best price for each drug.

The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current average manufacturer prices and best prices for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed 12 quarters from the quarter in which the data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the 340B ceiling price. The 340B pricing program

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requires participating manufacturers to agree to charge statutorily-defined covered entities, such as safety-net providers, no more than the 340B ceiling price for the manufacturer s covered outpatient drugs. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program.

Federal law also requires that a company that participates in the Medicaid program report ASP information to CMS for certain categories of drugs that are paid under Part B of the Medicare program, such as *Feraheme* and *Makena*. This ASP information forms the basis for reimbursement for the majority of our current *Feraheme* business, and to a lesser extent, for *Makena* business upon the closing of the Lumara merger, in the U.S. Manufacturers calculate ASP based on a statutorily defined formula and interpretations of the statute by CMS as to what should or should not be considered in computing ASP. An ASP for each National Drug Code for a product that is subject to the ASP reporting requirement must be submitted to CMS no later than 30 days after the end of each calendar quarter. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Changes affecting the calculation of ASP could affect the ASP calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Price reporting and payment obligations are highly complex and vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The calculations of average manufacturer price, best price, and ASP include a number of inputs from our contracts with wholesalers, specialty distributors, GPOs and other customers. The calculations also require us to make an assessment of whether these agreements are deemed to be for *bona fide* services and whether the fees we pay for any bona fide services represent fair market value in our industry and for our products. These calculations are very complex and could involve the need for us to unbundle or reallocate discounts or rebates offered over multiple quarters or across multiple products. Our processes for estimating amounts due under these governmental pricing programs involve subjective decisions and estimates. For example, almost 45% of *Makena* is reimbursed through state Medicaid programs and is subject to the statutory Medicaid rebate, and in some cases, supplemental rebates offered by Lumara. Often, state Medicaid programs may be slow to invoice pharmaceutical companies for these rebates resulting in a significant lag between the time a sale is recorded and the time the rebate is paid. This results in Lumara carrying a significant liability on its balance sheet for its estimate of rebate claims expected for Medicaid patients. If actual claims are higher than current estimates, our financial position and results of operations could be adversely effected. The unbundling of discounts and rebates across multiple reporting periods can also result in a restatement of government price reports and changes to the reimbursement rates for various customers covered under federal programs, such as Medicare, Medicaid or the 340B program.

If we have to restate our calculation of government price reports, we may be forced to refund certain monies back to payers to comply with federal pricing agreements. Such a restatement of our government price reports would also adversely impact our reported financial results of operations in the period of such restatement. 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 Healthcare Reform Act modified the rules related to certain price reports, 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

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or fines, which could have a material adverse effect on our business, financial condition and results of operations.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false average manufacturer price, average sales price, or best price information to the government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. If we are found to have made a misrepresentation in the reporting of our average sales price, the Medicare statute provides for civil monetary penalties of up to $10,000 for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly/quarterly average manufacturer price, average sales price, and best price data on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid Drug Rebate program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

If we overcharge the government, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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 debt and equity securities, cash from sales of *Feraheme*, cash generated by our investing activities, and payments from our licensees. As of September 30, 2014, we had an accumulated deficit of approximately $473.5 million. Our losses were 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. We expect to continue to incur significant expenses as we continue to market and sell and contract for the manufacture of *Feraheme* as an IV iron replacement therapeutic for use in adult CKD patients in the U.S., integrate Lumara and market and sell *Makena*, market and sell *MuGard* and if we further develop and seek marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients, which would include conducting additional human trials for which we would incur significant research and development costs over a long period of time. As a result, we will need to generate sufficient revenues in future periods to achieve and maintain profitability. There is no guarantee that we will achieve profitability or maintain profitability, if achieved, and there is no guarantee that we will be able to maintain positive cash flow from operations. We anticipate that the majority of any revenue we generate in the next 12 months will be from:

- sales of *Feraheme* as an IV iron replacement therapeutic agent for use in adult CKD patients in the U.S.;

- sales of *Makena,* following the acquisition of Lumara;

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- royalties we may receive with respect to sales of *Rienso* in the EU and *Feraheme* in Canada under the Amended Takeda Agreement;

- sales of *MuGard*; and

- revenue from the amortization of the up front and previously received milestones from Takeda.

We have never independently marketed or sold any products prior to *Feraheme*, and we may not be successful in marketing or selling *Feraheme*, *Makena* or *MuGard* in the U.S., and Takeda may not be successful in marketing or selling *Feraheme* outside of the U.S. If we or Takeda are not successful in marketing and selling our products, if revenues grow more slowly than we anticipate, if our operating expenses exceed our expectations, if the anticipated opportunities and synergies with regard to the acquisition of Lumara are not realized to the extent anticipated or at all, 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.

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, Makena 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. We have an internal commercial infrastructure to market and sell *Feraheme* and *MuGard* in the U.S. and, upon the closing of the Lumara merger, we will be relying on the *Makena* commercial team to market and sell *Makena*. If we are unsuccessful in maintaining an effective commercial function with multiple products, integrating *MuGard* into our existing sales infrastructure and integrating and leveraging Lumara s *Makena* commercial platform, including the sales force, 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*, *Makena* or *MuGard* in the U.S. Any failure by us to successfully commercialize *Feraheme*, *Makena* 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.

We are a pharmaceutical company focused on marketing commercial products and we plan to expand our product portfolio with additional commercial-stage products through acquisitions and in-licensing; thus, the range of skills of our executive officers needs to be broad and deep. If we are not able to hire and retain talent to drive commercialization and expansion of our product portfolio, we will be unlikely to achieve profitability. For example, in October 2014 our Senior Vice President and Chief Development and Regulatory Officer resigned from the Company to pursue other opportunities, which may be disruptive to our regulatory discussions with the FDA or other regulators. Further, because of the specialized nature of our business, our success depends to a significant extent on our ability to continue to attract, retain and motivate qualified sales, technical operations, managerial, scientific, and medical personnel of all levels. We have entered into employment agreements with all 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

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our activities, and we may not be able to continue to attract and retain the qualified personnel necessary for the development of our business.

We have no experience commercializing *Makena* and following the closing of the acquisition of Lumara, we will be primarily dependent upon the contributions of the *Makena* commercial organization and sales force, key employees related to the commercialization of Makena and the integration of Lumara and Lumara s business relationships to drive *Makena* sales. We may be unable to retain and motivate the commercial sales force, certain key employees or successfully maintain Lumara s current relationships following the closing of the transaction, which would have a material adverse impact on our ability to generate revenues, our ability to achieve or maintain profitability, and the future prospects for our business.

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 sales, technical operations, managerial, scientific, and medical personnel who are critical to our business. Any future employee turnover, whether occurring as part of a restructuring plan, following the integration of a new business 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 personnel-related 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 pharmaceutical products, 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* and *MuGard*, and will include such activities for *Makena* following our acquisition of Lumara. In addition, the distribution process for *Makena* differs significantly from our current distribution process for *Feraheme* and *MuGard* in that the majority of sales of *Makena* is sold to specialty pharmacies and specialty distributors with a very small amount being sold through the traditional wholesaler channel. If our third-party supply chain service providers are unable to provide uninterrupted labeling, packaging and storage services or other supply chain services, respectively, we may incur substantial losses of sales to wholesalers, specialty pharmacies or distributors, 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 s, and PlasmaTech s 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

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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 on 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, including those engaged by PlasmaTech and we expect to rely on those arrangements acquired in connection with our pending acquisition of Lumara, 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 and timely 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 current and future development plans and 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* sales in additional indications and/or outside of the U.S.

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

Our future operating results will likely vary from quarter to quarter depending on a number of factors (including factors which assume the consummation of the acquisition of Lumara), some of which we cannot control, including but not limited to:

- The magnitude of U.S. *Feraheme, Makena* 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;

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- 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;

- Any expansion or contraction of the overall size of the maternal health market, which could result from a number of factors including but not limited to changes in treatment guidelines or practices related to the risk of premature birth;

- Changes in the DQSA legislation, new regulations or enforcement actions taken by FDA against compounding pharmacies to prevent the sale and distribution of non-FDA approved versions of *Makena*;

- Changes in the actual or perceived safety or efficacy profile of our products, especially in light of the recent complete response letter we received from the FDA and recent and proposed changes to the product label, the DHPC letter issued by Takeda and the recommendation of the CHMP, that could cause healthcare providers to decrease or discontinue their use of our products or could affect the regulatory status of our products in the U.S. or elsewhere;

- Changes in the actual or perceived safety or efficacy profile of products that compete with our products that could cause healthcare services providers and patients to decrease or discontinue their use of our products;

- The timing and magnitude of costs and liabilities incurred in connection with business development activities or business development transactions into which we may enter, including costs and liabilities that we may inherit or incur in connection with the purchase of target companies or assets, such as Lumara;

- The timing and magnitude of *Makena* milestone payments we may be required to pay to Lumara s stockholders;

- Any changes to the mix of our business;

- 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 our ability to preserve our net operating loss carryforwards and other tax assets, including those we expect to acquire in connection with the Lumara merger;

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

- The timing and magnitude of *Feraheme* 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 pursuing a broader indication of *Feraheme* or the *Makena*

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lifecycle development program, maintaining our commercial infrastructure, integrating Lumara s 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;

- The timing and magnitude of costs associated with the manufacture of our products, 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* in connection with our pediatric program, our current or future post-marketing commitments for the EMA and other regulatory agencies, our pursuit, if any, of additional indications and our development of *Feraheme* in countries outside of the U.S;

- The timing and magnitude of costs associated with the ongoing and planned clinical studies of *Makena* in connection with current or future post-marketing commitments, and our pursuit, if any, of additional indications or lifecycle development program;

- 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; 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 U.S. generally accepted accounting principles. 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 fair values of our investments, the fair value of our

debt obligations, the fair value of assets acquired in a business combination, contingent consideration, the impairment of long-lived assets, including intangible assets, accrued expenses, 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

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about matters that are inherently uncertain. The same estimates will need to be made for *Makena* sales since much of Lumara s business provides for discounts, fees, rebates and chargebacks, in particular, a significant amount of *Makena* sales are to Medicaid patients. Any significant differences between our actual results and our estimates could materially affect our financial position and results of operations.

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 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. We expect to encounter the same challenges when we begin to commercialize *Makena* following the Lumara merger and will have had no experience making such judgments and estimates in the past, and the necessary personnel may not be available to assist us in making such judgments and estimates in the future. 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. For example, during the quarter ended September 30, 2014, we recorded a benefit of $3.7 million due to the reduction of the contingent consideration liability related to the MuGard Rights based on a revision of our projected net sales for *MuGard* during the term of the license, to reflect our belief that *MuGard* sales will be lower than previously expected.

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

We and/or Takeda are subject to ongoing regulatory requirements and review, including by periodic audits, 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 respective 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;

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- Variation, 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* 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 and post-marketing obligations;

- 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. Moreover, PlasmaTech is subject to many of the same regulatory requirements and sanctions related to *MuGard*, which would impact our ability to generate revenues of *MuGard* in the U.S.

Additionally, Lumara, as our wholly-owned subsidiary following consummation of the acquisition, may be subject to certain continuing obligations under a Consent Decree of Permanent Injunction (Consent Decree) between the FDA and Lumara s predecessor company, KV Pharmaceutical Corp. In particular, Lumara may be bound by a number of provisions and requirements in the Consent Decree including, but not limited to, inspection of Lumara s places of business by the FDA without prior notice, and notification of FDA of particular actions and events. If Lumara fails to comply with applicable provisions in the Consent Decree, the Food, Drug, and Cosmetic Act, or the Act s implementing regulations, the FDA may impose specific sanctions including, but not limited to, cessation of any Lumara manufacturing operations, financial penalties under the Consent Decree up to $5.0 million per year, and the requirement to implement corrective actions.

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 as reflected in the product s approved labeling.

For drug products like *Makena* that are approved by the FDA under the Agency s accelerated approval regulations, unless otherwise informed by the FDA, the sponsor must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the promotional materials.

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.

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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 $16.49 and $35.40 in the fifty-two week period through October 31, 2014. The stock market has from time to time experienced extreme price and volume fluctuations, particularly in the biotechnology and pharmaceuticals sectors, which have often been unrelated to the operating performance of particular companies. Various factors and events, many of which are beyond our control, may have a significant impact on the market price of our common stock. Factors which may affect the market price of our common stock include, among others:

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

- Our ability to close on the acquisition of and successfully integrate Lumara, and our ability to realize the expected opportunities, synergies and revenues in connection with the *Makena* platform;

- Our ability to increase or maintain sales and utilization of *Feraheme* in the current indication or the results of our efforts to expand the indications for *Feraheme* for the treatment of IDA in adult patients who have failed or could not use oral iron, especially in light of FDA s recent decision that we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for this population and similar concerns being communicated by European and Canadian regulators;

- Fluctuations in our net revenue per unit of products sold in the U.S. in future periods as a result of our pricing and contracting strategy and the purchase patterns of our customers;

- Actual or perceived safety concerns related to our products, product candidates or products of our competitors, including as a result of the FDA s recent complete response letter addressing our sNDA, recent and proposed changes to the product label, the DHPC letter issued by Takeda, the recommendation of the CHMP and any other actions taken by U.S. or foreign regulatory authorities in connection with safety concerns, or any voluntary or involuntary product recalls;

- Significant collaboration, product or business acquisitions, joint venture, in-licensing or similar agreements by us or our competitors or the termination of any such current or future material 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 an ANDA filing by a generic entrant;

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- Our ability to successfully market *MuGard* in the U.S.;

- Our ability to repay our obligations under the Term Loan Facility and maintain compliance with all financial and other covenants;

- 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 *Makena* 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;

- Cash milestones required to be paid, if any, under the Lumara 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 or the dilutive effect of our Convertible Notes or any other equity or equity-linked financings or alternative strategic arrangements.

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

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

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us and our business. As of October 31, 2014, five 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, lower their price target 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.

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

In October 2014, we publicly reiterated our financial guidance, including expected 2014 total revenues and U.S. *Feraheme* net sales. If, for any reason, we are unable to realize our projected 2014 revenue, we may not realize our publicly announced revenue and other 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* and will expend additional substantial funds to consummate the acquisition of Lumara and in satisfaction of any milestone payments that may become payable under the Lumara Agreement. Our long-term capital requirements will depend on many factors, including, but not limited to:

- Our ability to successfully commercialize *Feraheme* and *Makena*, upon the closing of the Lumara transaction, in the U.S. and Takeda s ability to successfully commercialize *Feraheme* in its licensed territories outside of the U.S.;

- Our ability to realize the benefits, synergies and opportunities anticipated in connection with the acquisition of Lumara;

- Our ability to obtain regulatory approval for *Feraheme* to treat IDA regardless of the underlying cause both within the U.S. and Takeda s ability to do so outside of the U.S., particularly in the EU an Canada, especially in light of FDA s recent decision that we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for this population and the need to undertake additional clinical trials in order to pursue the broader indication and our belief that Takeda s Type II Variation in the EU and sNDS in Canada are unlikely to be approved without additional clinical data;

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

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

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

- Costs associated with the U.S. commercialization of our products, including costs associated with maintaining our commercial infrastructure, integrating the infrastructure of businesses we acquire, 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;

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- The timing and magnitude of our principal and interest payments under our Term Loan Facility and our Convertible Notes;

- 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, 2014, combined with cash we currently expect to receive from product sales, including those from *Makena,* 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 12 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, subject to the covenants in our Term Loan Facility. 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.

The Convertible Notes are, and any additional equity or equity-linked financings or alternative strategic arrangements would be, dilutive to our stockholders. In addition, the terms of any additional 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, impose restrictions on our day-to-day operations or place limitations on our ability to enter into combination transactions with other entities. 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, 2014, we had $196.2 million in cash and cash equivalents and $190.1 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. Much of these cash and investments will be used to fund a portion of the upfront consideration upon closing of the Lumara transaction.

The condition of the credit markets can be 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 (NASDAQ) and the Securities and Exchange Commission (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.

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

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

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we, or our independent registered public accounting firm, determine that our internal controls over our financial reporting are not effective, or we discover areas that need improvement in the future, 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. Because Lumara is a private company, it may not have all the controls in place to fully comply with the Sarbanes-Oxley Act of 2002. As such, we will need develop and/or integrate our policies and procedures related to the sale of *Makena* upon consummation of the Lumara acquisition. 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 (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 (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

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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 (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 (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. On November 6, 2013, we filed a renewed Motion to Dismiss the SAC s surviving claims. On December 6, 2013, the plaintiffs filed a brief in opposition to our Motion to Dismiss and we filed a reply brief in support of our Motion on December 27, 2013. On April 7, 2014, the District Court denied our renewed Motion to Dismiss. On May 7, 2014, the parties filed a joint status report with the District Court in advance of a status conference held on May 14, 2014. All defendants filed answers and affirmative defenses to the pending complaint on May 19, 2014. On June 6, 2014, the parties requested the District Court to stay the proceedings, which the Court allowed on June 9, 2014. On September 12, 2014, we and the other defendants entered into a stipulation of settlement that will resolve the class action securities lawsuit. Pursuant to the stipulation of settlement, and in exchange for a release of all claims by the class members, among others, and dismissal of the lawsuit with prejudice, we have agreed to cause our insurer to pay eligible class members and their attorneys a total of $3.75 million. On October 2, 2014, the U.S. District Court preliminarily approved the settlement, and potential class members have been notified of the proposed settlement and the procedures by which they can seek to recover from the settlement fund, object to the settlement or request to be excluded from the settlement class. A settlement hearing has been scheduled for January 20, 2015, at which time the stipulation of settlement will be subject to final approval by the U.S. District Court.

In addition, the liabilities we are assuming in connection with the acquisition of Lumara, including the class action litigation In Re K-V Pharmaceutical Company Securities Litigation, Case No. 4:11CV1816 AGF, may be higher than expected.

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 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, or the use of our products by, 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* 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*, can cause patients to experience serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-

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threatening and/or fatal. We have proposed changes to the *Feraheme* labeling to mitigate the risk of serious adverse reactions, and label changes to mitigate safety risks have the potential to result in claims challenging the adequacy of prior safety warnings. *Makena* is a prescription hormone medicine (progestin) used to lower the risk of preterm birth in women who are pregnant and who have previously delivered preterm in the past. It is not known if *Makena* is safe and effective in women who have other risk factors for preterm birth. In one clinical study, certain complications or events associated with pregnancy occurred more often in women who received Makena. These included miscarriage (pregnancy loss before 20 weeks of pregnancy), hospital admission for preterm labor, preeclampsia, gestational hypertension and gestational diabetes. In addition, other hormones administered during pregnancy have in the past been shown to cross the placenta and have negative effects on the offspring. 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 provisions of our Convertible Notes, 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 the current members of our Board.

We have 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, as amended in September 2014, become exercisable generally upon the earlier of 10 days after a person or group acquires 4.99% or more of our outstanding common stock or 10 business days after the announcement by a person or group of an intention to acquire 4.99% of our outstanding common stock via tender offer or similar transaction. The shareholder rights plan could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which stockholders might otherwise receive a premium for their shares over then-current prices.

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

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

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

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

- Non-cumulative voting for directors; and

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

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As a Delaware corporation, we are subject to the provisions of Section 203 of the Delaware General Corporation Law (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.

Furthermore, holders of the Convertible Notes have the right to require us to repurchase their notes at a price equal to 100% of the principal amount thereof and the conversion rate for the Convertible Notes may be increased as described in the indenture, in each case, upon the occurrence of certain change of control transactions. Additionally, upon certain change of control transactions, the offsetting convertible bond hedge and warrant transactions that we entered into at the time we issued the Convertible Notes may be exercised and/or terminated early. Upon any such exercise and/or early termination, the proceeds we receive upon the exercise of the convertible bond hedge transactions may prove to be significantly lower than the amounts we would be required to pay upon termination of the warrant transactions. These features of the Convertible Notes and the convertible bond hedge and warrants, including the financial implications of any renegotiation of the above-mentioned provisions, could have the effect of preventing a change of control, whether or not it is desired by, or beneficial to, our stockholders, or may result in the acquisition of us being on terms less favorable to our stockholders than it would otherwise be.

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Item 6. Exhibits

(a) List of Exhibits

Exhibit Number		Description
2.1		Agreement and Plan of Merger, dated as of September 28, 2014, by and among Lumara Health Inc., AMAG Pharmaceuticals, Inc., Snowbird, Inc., and Lunar Representative, LLC as the Stockholders Representative (incorporated herein by reference to Exhibit 2.1 to the Company s Current Report on Form 8-K filed September 29, 2014, File No. 001-10865).
4.1		NOL Amendment, dated September 26, 2014, to Shareholder Rights Plan (incorporated herein by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K filed September 29, 2014, File No. 001-10865).
4.2		Summary of Amended Rights to Purchase Preferred Shares (including Exhibit B, the Summary of Amended Rights to Purchase Preferred Shares) (incorporated herein by reference to Exhibit 4.2 to the Company s Current Report on Form 8-K filed September 29, 2014, File No. 001-10865).
10.1		Commitment Letter, dated September 28, 2014, by and between AMAG Pharmaceuticals, Inc. and Jefferies Finance LLC. (incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed September 29, 2014, File No. 001-10865).
10.2	+	Amendment No. 1 to Pharmaceutical Manufacturing and Supply Agreement, dated July 5, 2014, by and between the Company and Patheon Manufacturing Services LLC (as assignee from DSM Pharmaceuticals, 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, 2014, 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.

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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 7, 2014

AMAG PHARMACEUTICALS, INC.

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

Date: November 7, 2014

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