

AMAG PHARMACEUTICALS INC.

Form 10-Q

May 05, 2014

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

Washington, D.C. 20549

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**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended March 31, 2014**

**OR**

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

**For the transition period from                      to**

**Commission file number 001-10865**

## AMAG Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

**04-2742593**  
(I.R.S. Employer  
Identification No.)

**1100 Winter Street**  
**Waltham, Massachusetts**  
(Address of Principal Executive Offices)

**02451**  
(Zip Code)

**(617) 498-3300**

(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer ☐

Accelerated filer ☒

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

Smaller Reporting Company ☐

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

As of April 29, 2014, there were 21,915,093 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)

|                                                                                                                                                                                       | March 31, 2014 | December 31, 2013 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|-------------------|
| <b>ASSETS</b>                                                                                                                                                                         |                |                   |
| Current assets:                                                                                                                                                                       |                |                   |
| Cash and cash equivalents                                                                                                                                                             | \$ 200,916     | \$ 26,986         |
| Investments                                                                                                                                                                           | 184,557        | 186,803           |
| Accounts receivable, net                                                                                                                                                              | 10,115         | 6,842             |
| Inventories                                                                                                                                                                           | 20,804         | 17,217            |
| Receivable from collaboration                                                                                                                                                         | 202            | 278               |
| Prepaid and other current assets                                                                                                                                                      | 4,410          | 3,396             |
| Restricted cash                                                                                                                                                                       |                | 2,883             |
| Total current assets                                                                                                                                                                  | 421,004        | 244,405           |
| Property and equipment, net                                                                                                                                                           | 1,837          | 1,846             |
| Intangible assets, net                                                                                                                                                                | 16,815         | 16,844            |
| Restricted cash                                                                                                                                                                       | 400            | 400               |
| Other long-term assets                                                                                                                                                                | 6,407          | 1,964             |
| Total assets                                                                                                                                                                          | \$ 446,463     | \$ 265,459        |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>                                                                                                                                           |                |                   |
| Current liabilities:                                                                                                                                                                  |                |                   |
| Accounts payable                                                                                                                                                                      | \$ 5,125       | \$ 2,629          |
| Accrued expenses                                                                                                                                                                      | 21,851         | 22,266            |
| Deferred revenues                                                                                                                                                                     | 9,118          | 8,226             |
| Total current liabilities                                                                                                                                                             | 36,094         | 33,121            |
| Long-term liabilities:                                                                                                                                                                |                |                   |
| Convertible 2.5% senior notes, net                                                                                                                                                    | 162,561        |                   |
| Deferred revenues                                                                                                                                                                     | 40,567         | 44,534            |
| Acquisition-related contingent consideration                                                                                                                                          | 14,040         | 13,609            |
| Other long-term liabilities                                                                                                                                                           | 2,105          | 1,787             |
| Total liabilities                                                                                                                                                                     | 255,367        | 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; 21,877,192 and 21,772,571 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively | 219            | 218               |
| Additional paid-in capital                                                                                                                                                            | 667,653        | 641,941           |
| Accumulated other comprehensive loss                                                                                                                                                  | (3,414)        | (3,491)           |
| Accumulated deficit                                                                                                                                                                   | (473,362)      | (466,260)         |
| Total stockholders' equity                                                                                                                                                            | 191,096        | 172,408           |
| Total liabilities and stockholders' equity                                                                                                                                            | \$ 446,463     | \$ 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 March 31, |            |
|-------------------------------------------------------------------------|------------------------------|------------|
|                                                                         | 2014                         | 2013       |
| Revenues:                                                               |                              |            |
| U.S. <i>Feraheme</i> product sales, net                                 | \$ 17,375                    | \$ 15,578  |
| License fee and other collaboration revenues                            | 3,120                        | 2,003      |
| Other product sales and royalties                                       | 340                          | 299        |
| Total revenues                                                          | 20,835                       | 17,880     |
| Costs and expenses:                                                     |                              |            |
| Cost of product sales                                                   | 2,837                        | 2,942      |
| Research and development expenses                                       | 6,498                        | 5,404      |
| Selling, general and administrative expenses                            | 17,491                       | 14,005     |
| Total costs and expenses                                                | 26,826                       | 22,351     |
| Other income (expense):                                                 |                              |            |
| Interest expense                                                        | (1,476)                      |            |
| Interest and dividend income, net                                       | 265                          | 271        |
| Gains on sale of assets                                                 | 100                          | 299        |
| Gains on investments, net                                               |                              | 6          |
| Total other income (expense)                                            | (1,111)                      | 576        |
| Net loss                                                                | \$ (7,102)                   | \$ (3,895) |
| Net loss per share:                                                     |                              |            |
| Basic and diluted                                                       | \$ (0.33)                    | \$ (0.18)  |
| Weighted average shares outstanding used to compute net loss per share: |                              |            |
| Basic and diluted                                                       | 21,824                       | 21,544     |

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 LOSS**

**(IN THOUSANDS)**

**(Unaudited)**

|                                                                     | <b>Three Months Ended March 31,</b> |             |
|---------------------------------------------------------------------|-------------------------------------|-------------|
|                                                                     | <b>2014</b>                         | <b>2013</b> |
| Net loss                                                            | \$ (7,102)                          | \$ (3,895)  |
| Other comprehensive income (loss):                                  |                                     |             |
| Unrealized gains (losses) on securities:                            |                                     |             |
| Holding gains (losses) arising during period, net of tax            | 77                                  | (87)        |
| Reclassification adjustment for (gains) losses included in net loss |                                     | (6)         |
| Net unrealized gains (losses) on securities                         | 77                                  | (93)        |
| Total comprehensive loss                                            | \$ (7,025)                          | \$ (3,988)  |

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)

|                                                                             | Three Months Ended March 31, |            |
|-----------------------------------------------------------------------------|------------------------------|------------|
|                                                                             | 2014                         | 2013       |
| Cash flows from operating activities:                                       |                              |            |
| Net loss                                                                    | \$ (7,102)                   | \$ (3,895) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                              |            |
| Depreciation and amortization                                               | 162                          | 650        |
| Amortization of premium/discount on purchased securities                    | 664                          | 681        |
| Write-down of inventory to net realizable value                             | 1,437                        |            |
| Non-cash equity-based compensation expense                                  | 1,930                        | 2,283      |
| Amortization of debt discount and debt issuance costs                       | 851                          |            |
| Gains on sale of assets                                                     | (100)                        | (299)      |
| Gains on investments, net                                                   |                              | (6)        |
| Change in fair value of contingent consideration                            | 789                          |            |
| Changes in operating assets and liabilities:                                |                              |            |
| Accounts receivable, net                                                    | (3,273)                      | (2,109)    |
| Inventories                                                                 | (2,521)                      | 1,834      |
| Receivable from collaboration                                               | 76                           | 155        |
| Prepaid and other current assets                                            | (1,014)                      | (6)        |
| Other long-term assets                                                      | 885                          |            |
| Accounts payable and accrued expenses                                       | (1,101)                      | (7,074)    |
| Deferred revenues                                                           | (3,075)                      | (1,816)    |
| Other long-term liabilities                                                 | 318                          | (111)      |
| Total adjustments                                                           | (3,972)                      | (5,818)    |
| Net cash used in operating activities                                       | (11,074)                     | (9,713)    |
| Cash flows from investing activities:                                       |                              |            |
| Proceeds from sales or maturities of investments                            | 26,706                       | 30,663     |
| Purchase of investments                                                     | (25,046)                     | (33,906)   |
| Proceeds from sale of assets                                                | 100                          | 368        |
| Capital expenditures                                                        | (124)                        | (23)       |
| Change in restricted cash                                                   | 2,883                        |            |
| Net cash provided by (used in) investing activities                         | 4,519                        | (2,898)    |
| Cash flows from financing activities:                                       |                              |            |
| Payment of contingent consideration                                         | (31)                         |            |
| Proceeds from issuance of convertible debt                                  | 200,000                      |            |
| Payment of debt issuance costs                                              | (6,361)                      |            |
| Proceeds from issuance of warrants                                          | 25,620                       |            |
| Purchase of convertible bond hedges                                         | (39,760)                     |            |
| Proceeds from the exercise of stock options                                 | 1,017                        | 163        |
| Net cash provided by financing activities                                   | 180,485                      | 163        |
| Net increase (decrease) in cash and cash equivalents                        | 173,930                      | (12,448)   |
| Cash and cash equivalents at beginning of the period                        | 26,986                       | 46,293     |
| Cash and cash equivalents at end of the period                              | \$ 200,916                   | \$ 33,845  |

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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

MARCH 31, 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, or IV, use to treat iron deficiency anemia, or IDA, and MuGard® Mucoadhesive Oral Wound Rinse for the management of oral mucositis.

Currently, our principal source of revenue is from the sale of *Feraheme*, which was approved for marketing in the U.S. in June 2009 by the U.S. Food and Drug Administration, or the FDA, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with chronic kidney disease, or CKD. We began selling *Feraheme* in the U.S. in July 2009 through our own commercial organization, including a specialty sales force. We sell *Feraheme* to authorized wholesalers and specialty distributors, who in turn, sell *Feraheme* to healthcare providers who administer *Feraheme* primarily within hospitals, hematology and oncology centers, and nephrology clinics.

Outside of the U.S., ferumoxytol has been granted marketing approval in Canada, Switzerland and the European Union, or EU, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. The European marketing authorization for *Rienso* in the EU is valid in the 28 EU Member States as well as in Iceland, Liechtenstein and Norway. Under our amended agreement with Takeda Pharmaceutical Company Limited, or Takeda, Takeda has an exclusive license to market and sell ferumoxytol in Canada, the EU and Switzerland, as well as certain other geographic territories. In Canada, Takeda promotes ferumoxytol under the trade name *Feraheme* and in the EU and Switzerland, Takeda promotes ferumoxytol under the trade name *Rienso*® 30mg/ml solution for Injection.

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

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

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

*Basis of Presentation*

These condensed consolidated financial statements are unaudited and, in the opinion of management, include all adjustments necessary for a fair statement of the financial position and results of operations of the Company for the interim periods presented. Such adjustments consisted only of normal recurring items. The

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year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America.

In accordance with accounting principles generally accepted in the United States of America for interim financial reports and the instructions for Form 10-Q and the rules of the Securities and Exchange Commission, certain information and footnote disclosures normally included in annual financial statements have been condensed or omitted. Our accounting policies are described in the Notes to the Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 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 accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The most significant estimates and assumptions are used in, but are not limited to, revenue recognition related to product sales and collaboration agreements, product sales allowances and accruals, assessing investments for potential other-than-temporary impairment, determining the fair values of our investments, assets acquired in a business combination, our 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 at acquisition date to be cash equivalents. At March 31, 2014, substantially all of our cash and cash equivalents were held in either commercial bank accounts or money market funds.

*Principles of Consolidation*

The accompanying condensed consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiaries, AMAG Europe Limited, AMAG Securities Corporation and Snowbird, Inc. AMAG Europe Limited was incorporated in October 2009 in London, England. AMAG Securities Corporation is a Massachusetts corporation which was incorporated in August 2007. Snowbird, Inc. is a Delaware corporation which was incorporated in December 2013. 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.

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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*

An analysis of our U.S. *Feraheme* product sales allowances and accruals for the three months ended March 31, 2014 and 2013 is as follows (in thousands):

|                                                                                                                                               | Three Months Ended March 31, |           |
|-----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|-----------|
|                                                                                                                                               | 2014                         | 2013      |
| Provision for U.S. <i>Feraheme</i> product sales allowances and accruals                                                                      |                              |           |
| Discounts and chargebacks                                                                                                                     | \$ 10,533                    | \$ 7,493  |
| Government and other rebates                                                                                                                  | 3,187                        | 2,387     |
| Returns                                                                                                                                       | 226                          | 193       |
| Total provision for U.S. <i>Feraheme</i> product sales allowances and accruals                                                                | \$ 13,946                    | \$ 10,073 |
| Total gross U.S. <i>Feraheme</i> product sales                                                                                                | \$ 31,321                    | \$ 25,651 |
| Total provision for U.S. <i>Feraheme</i> product sales allowances and accruals as a percent of total gross U.S. <i>Feraheme</i> product sales | 45%                          | 39%       |

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 currently have limited actual returns data, and therefore are not able to solely rely on our actual returns experience. 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 consider several additional factors in our product return estimation process, including our internal sales forecasts and inventory levels in the distribution channel. We expect that wholesalers and healthcare providers will not stock significant inventory due to the cost and expense to store *Feraheme*. Based on these factors, we determine whether an adjustment to the sales return reserve is appropriate.

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. We did not significantly adjust our reserve for product returns during the three months

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ended March 31, 2014 or 2013. To date, returns of *Feraheme* have been relatively limited and returns experience may change over time. A future adjustment to our product returns estimate 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 three months ended March 31, 2014 or 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 March 31, 2014, our cash, cash equivalents and investments amounted to approximately \$385.5 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 March 31, 2014, we had approximately \$196.3 million of our total \$200.9 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 focused principally on developing, manufacturing, and commercializing *Feraheme/Rienso* and commercializing *MuGard*. We perform ongoing credit evaluations of our customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our total revenues for the three months ended March 31, 2014 and 2013:

|                                        | Three Months Ended March 31, |      |
|----------------------------------------|------------------------------|------|
|                                        | 2014                         | 2013 |
| AmerisourceBergen Drug Corporation     | 39%                          | 43%  |
| McKesson Corporation                   | 22%                          | 22%  |
| Cardinal Health, Inc.                  | 15%                          | 15%  |
| Takeda Pharmaceuticals Company Limited | 11%                          | 12%  |

In addition, approximately 28% and 30% of our end-user demand during the three months ended March 31, 2014 and 2013, respectively, was generated by members of a single group purchasing organization, or GPO, with which we have contracted. Revenues from customers outside of the U.S. amounted to approximately 16% and 12% of our total revenues for the three months ended March 31, 2014 and 2013, respectively, 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/Rienso* drug substance and finished drug product. We are exposed to a significant loss of revenue from the sale of *Feraheme/Rienso* if our suppliers and/or manufacturers cannot fulfill demand for any reason.



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As of March 31, 2014 and December 31, 2013, our investments equaled \$184.6 million and \$186.8 million, respectively, and consisted of securities classified as available-for-sale in accordance with accounting standards which provide guidance related to accounting and classification of certain investments in debt and equity securities.

The following is a summary of our investments as of March 31, 2014 and December 31, 2013 (in thousands):

|                                                | March 31, 2014    |                              |                               | Estimated     |
|------------------------------------------------|-------------------|------------------------------|-------------------------------|---------------|
|                                                | Amortized<br>Cost | Gross<br>Unrealized<br>Gains | Gross<br>Unrealized<br>Losses | Fair<br>Value |
| Corporate debt securities                      |                   |                              |                               |               |
| Due in one year or less                        | \$ 23,492         | \$ 46                        | \$ (2)                        | \$ 23,536     |
| Due in one to three years                      | 108,536           | 159                          | (47)                          | 108,648       |
| U.S. treasury and government agency securities |                   |                              |                               |               |
| Due in one year or less                        | 21,079            | 35                           |                               | 21,114        |
| Due in one to three years                      | 29,772            | 17                           | (28)                          | 29,761        |
| Commercial paper                               |                   |                              |                               |               |
| Due in one year or less                        | 1,499             |                              | (1)                           | 1,498         |
| Total investments                              | \$ 184,378        | \$ 257                       | \$ (78)                       | \$ 184,557    |

|                                                | December 31, 2013 |                              |                               | Estimated     |
|------------------------------------------------|-------------------|------------------------------|-------------------------------|---------------|
|                                                | Amortized<br>Cost | Gross<br>Unrealized<br>Gains | Gross<br>Unrealized<br>Losses | Fair<br>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 the three months ended March 31, 2014 and 2013. We considered various factors, including the length of time that each security was in an unrealized loss position and our ability and intent to hold these securities until the recovery of their amortized cost basis occurs. As of March 31, 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 months ended March 31, 2014 and 2013.

## D. Fair Value Measurements

The following tables represent the fair value hierarchy as of March 31, 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 March 31, 2014 Using:               |                                               |                                           |        |
|------------------------------------------------|----|----------------------------------------------------------------|-----------------------------------------------|-------------------------------------------|--------|
|                                                |    | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |        |
| Total                                          |    |                                                                |                                               |                                           |        |
| <b>Assets:</b>                                 |    |                                                                |                                               |                                           |        |
| Money market funds                             | \$ | 196,297                                                        | \$                                            | 196,297                                   | \$     |
| Corporate debt securities                      |    | 132,184                                                        |                                               | 132,184                                   |        |
| U.S. treasury and government agency securities |    | 50,875                                                         |                                               | 50,875                                    |        |
| Commercial paper                               |    | 1,498                                                          |                                               | 1,498                                     |        |
| Total Assets                                   | \$ | 380,854                                                        | \$                                            | 196,297                                   | \$     |
| <b>Liabilities:</b>                            |    |                                                                |                                               |                                           |        |
| Acquisition-related contingent consideration   | \$ | 15,382                                                         |                                               |                                           | 15,382 |
| Total Liabilities                              | \$ | 15,382                                                         | \$                                            |                                           | \$     |

|                                                |    | Fair Value Measurements at December 31, 2013 Using:            |                                               |                                           |        |
|------------------------------------------------|----|----------------------------------------------------------------|-----------------------------------------------|-------------------------------------------|--------|
|                                                |    | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |        |
| Total                                          |    |                                                                |                                               |                                           |        |
| <b>Assets:</b>                                 |    |                                                                |                                               |                                           |        |
| 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                                    | \$     |
| <b>Liabilities:</b>                            |    |                                                                |                                               |                                           |        |
| Acquisition-related contingent consideration   | \$ | 14,550                                                         |                                               |                                           | 14,550 |
| Total Liabilities                              | \$ | 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

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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 March 31, 2014. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during the three months ended March 31, 2014.

### *Contingent consideration*

We are accounting for the acquisition of the MuGard Rights as a business combination under the acquisition method of accounting. Additional details regarding the Access License Agreement and the

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MuGard Rights can be found in Note H. The fair value measurements of contingent consideration obligations arising from business combinations are determined using unobservable, or Level 3, inputs. 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 (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 March 31, 2014 (in thousands):

|                                                       |    |        |
|-------------------------------------------------------|----|--------|
| Balance as of December 31, 2013                       | \$ | 14,550 |
| Payments made                                         |    | (31)   |
| Adjustments to fair value of contingent consideration |    | 789    |
| Other adjustments                                     |    | 74     |
| Balance as of March 31, 2014                          | \$ | 15,382 |

During the three months ended March 31, 2014, we recorded \$0.8 million in expense related to the increase in fair value of the contingent consideration liability. This expense principally represents the time value of money impact of the contingent consideration fair value assessment as of March 31, 2014 and is included in selling, general and administrative expenses in our condensed consolidated statements of operations. As of March 31, 2014, we estimate that the undiscounted royalty amounts we could pay under the Access License Agreement may range from \$28.0 million to \$34.0 million over a ten year period, which is our best estimate of the period over which we expect the majority of the asset's cash flows to be derived. This measure is based on significant Level 3 inputs not observable in the market. Key assumptions include a discount rate of approximately 15%. We have classified \$1.3 million of the contingent consideration as a short-term liability, which was included in accrued expenses in our condensed consolidated balance sheet as of March 31, 2014.

*Debt*

In February 2014, we issued \$200.0 million of 2.5% convertible senior notes due February 15, 2019, or 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 fair value of our Convertible Notes, which differs from their carrying values, 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. The estimated fair value of the Convertible Notes at March 31, 2014 was \$161.8 million. In addition, in connection with the pricing of the Convertible Notes, we entered into convertible bond hedge transactions, or convertible bond hedges, and separate warrant transactions, or warrants, as discussed in more detail in Note P, *Debt*. The carrying value of long-term debt approximated fair value at March 31, 2014 due to the recent issuance of the Convertible Notes.

**E. Accounts Receivable, Net**

Our net accounts receivable were \$10.1 million and \$6.8 million as of March 31, 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 March 31, 2014 and December 31, 2013 were as follows:

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|                                    | March 31, 2014 | December 31, 2013 |
|------------------------------------|----------------|-------------------|
| AmerisourceBergen Drug Corporation | 52%            | 49%               |
| McKesson Corporation               | 27%            | 27%               |
| Cardinal Health, Inc.              | 15%            | 16%               |

**F. Inventories**

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

|                   | March 31, 2014 | December 31, 2013 |
|-------------------|----------------|-------------------|
| Raw materials     | \$ 4,116       | \$ 3,157          |
| Work in process   | 8,929          | 8,322             |
| Finished goods    | 7,759          | 5,738             |
| Total inventories | \$ 20,804      | \$ 17,217         |

During the three months ended March 31, 2014, we expensed \$1.1 million of commercial inventory, which we determined would be solely used in manufacturing process and development activities at our third-party suppliers, which we have recorded in research and development expenses. In addition, we expensed \$0.3 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 March 31, 2014 and December 31, 2013 (in thousands):

|                                     | March 31, 2014 | December 31, 2013 |
|-------------------------------------|----------------|-------------------|
| Furniture and fixtures              | \$ 1,489       | \$ 1,536          |
| Leasehold improvements              | 430            | 430               |
| Laboratory and production equipment | 493            | 376               |
|                                     | 2,412          | 2,342             |
| Less - accumulated depreciation     | (575)          | (496)             |
| Property and equipment, net         | \$ 1,837       | \$ 1,846          |

**H. Business Combination**

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

In consideration for the license, we paid Access an upfront payment of \$3.3 million in June 2013. We are required to pay royalties to Access on future net sales of *MuGuard* until the later of (a) the expiration of the licensed patents or (b) the tenth anniversary of the first commercial sale of *MuGuard* under the Access License Agreement in the U.S. Territory, or the Royalty Term. These tiered, double-digit royalty rates

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decrease for any part of the Royalty Term occurring after the expiration of the licensed patents and are subject to off-set against certain of our expenses. After the expiration of the Royalty Term, the license shall become a fully paid-up, royalty-free and perpetual license in the U.S. Territory. In addition to making an upfront payment of \$3.3 million, we also acquired \$0.2 million of existing *MuGard* inventory from Access, which was included in our condensed consolidated balance sheet as of the Acquisition Date.

We did not assume any pre-existing liabilities related to the *MuGard* business, contingent or otherwise, arising prior to the Acquisition Date. We are accounting for the acquisition of the MuGard Rights as a business combination under the acquisition method of accounting. 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 are not included as a component of consideration transferred and are expensed as incurred. We incurred approximately \$0.8 million of acquisition-related costs in the second quarter of 2013. These costs were primarily related to professional and legal fees and are included in selling, general and administrative expenses in our condensed consolidated statements of operations for the second quarter of 2013.

**I. Intangible Assets, Net**

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

We will amortize the MuGard Rights using an economic consumption model over ten years, which represents our best estimate of the period over which we expect the majority of the asset's cash flows to be derived. We believe this is the best approximation of the period over which we will derive the majority of value of the MuGard Rights. We recorded less than \$0.1 million of amortization related to the MuGard Rights in cost

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of product sales in our condensed consolidated statements of operations for the three months ended March 31, 2014 and as a result, our intangible asset related to the MuGard Rights was \$16.8 million as of March 31, 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

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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.

## **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 three months ended March 31, 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.

## **K. Accumulated Other Comprehensive Loss**

The changes in accumulated other comprehensive loss, net of tax, for the three months ended March 31, 2014 and 2013 consisted of the following (in thousands):

|                                                                    | Three Months Ended March 31, |         |      |         |
|--------------------------------------------------------------------|------------------------------|---------|------|---------|
|                                                                    | 2014                         |         | 2013 |         |
| Beginning Balance                                                  | \$                           | (3,491) | \$   | (3,247) |
| Other comprehensive income (loss) before reclassifications         |                              | 77      |      | (87)    |
| Gain (loss) reclassified from other accumulated comprehensive loss |                              |         |      | (6)     |
| Ending Balance                                                     | \$                           | (3,414) | \$   | (3,340) |

The amounts reclassified from other comprehensive loss for the three months ended March 31, 2014, primarily represented realized gains on investments, which are included in our condensed consolidated statement of operations under Gains on investments, net.

## **L. Net Loss per Share**

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We compute basic net loss per share by dividing net loss by the weighted average number of common shares outstanding during the relevant period.

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. As we have a choice to settle the conversion obligation under the Convertible Notes in cash, shares or any combination of the two, we have determined that we intend to settle the

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accreted principal value of the Convertible Notes in cash and the excess conversion premium in shares. While the dilutive effect of the conversion premium will be considered in the calculation of diluted net income per share using the treasury stock method, the accreted principal value of the Convertible Notes will not be included in the calculation of diluted income per share, as we intend to settle this in cash.

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

|                                            | Three Months Ended March 31, |            |
|--------------------------------------------|------------------------------|------------|
|                                            | 2014                         | 2013       |
| Net loss                                   | \$ (7,102)                   | \$ (3,895) |
| Weighted average common shares outstanding | 21,824                       | 21,544     |
| Net loss per share:                        |                              |            |
| Basic and diluted                          | \$ (0.33)                    | \$ (0.18)  |

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 loss per share because such instruments were anti-dilutive (in thousands):

|                                                                            | Three Months Ended March 31, |       |
|----------------------------------------------------------------------------|------------------------------|-------|
|                                                                            | 2014                         | 2013  |
| Options to purchase shares of common stock                                 | 3,335                        | 2,750 |
| Shares of common stock issuable upon the vesting of restricted stock units | 481                          | 510   |
| Warrants                                                                   | 7,382                        |       |
| Total                                                                      | 11,198                       | 3,260 |

We have determined that we have the intent and ability to settle the debt component of the Convertible Notes in cash and the excess conversion spread in shares. Therefore, the effect of the Convertible Notes reflected in diluted earnings per share is limited to the conversion premium, which is reflected in the calculation of diluted earnings per share as if it were a freestanding written call option on our shares. During the three months ended March 31, 2014, the weighted average common stock price was below the conversion price of the Convertible Notes.

The dilutive effect of the stock options, RSUs, and warrants is calculated using the treasury stock method. During the three months ended March 31, 2014, the warrants were excluded from diluted shares outstanding because the weighted average common stock price was below the exercise price.

## M. Equity-Based Compensation

We currently maintain two equity compensation plans, including our Third Amended and Restated 2007 Equity Incentive Plan, or the 2007 Plan, and our Amended and Restated 2000 Stock Plan, or the 2000 Plan. During the three months ended March 31, 2014, we also granted equity to certain newly hired executive officers through inducement grants outside of these plans.

*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,

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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 March 31, 2014, we have granted options and RSUs covering 7,076,175 shares of common stock under our 2007 Plan, of which 2,712,957 stock options and 661,811 RSUs have expired or terminated, and of which 210,524 options have been exercised and 500,871 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 March 31, 2014, was 2,684,438 and 305,574, respectively. The remaining number of shares available for future grants as of March 31, 2014 was 1,514,760, 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. The terms and conditions of each such grant, including, but not limited to, the number of shares, the exercise price, term of the option/award and vesting requirements, were determined by our Board or the Compensation Committee of our Board. As of March 31, 2014, we have granted stock options and RSUs covering 2,182,700 shares of common stock under the 2000 Plan, of which 984,339 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 March 31, 2014, was 102,316. There were no remaining restricted RSUs which were issued pursuant to our 2000 Plan as of March 31, 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*

During the three months ended March 31, 2014, our Board granted options to purchase 90,000 shares of our common stock to certain members of our senior management to induce them to accept employment with us. These options were granted at an exercise price equal to the fair market value of a share of our common stock on the respective grant dates. The options will be exercisable in four equal annual installments beginning on the first anniversary of the respective grant dates. In addition, during the three months ended March 31, 2014, our Board granted 35,000 RSUs to certain members of our senior management to induce them to accept employment with us. These grants will vest in four equal annual installments beginning on the first anniversary of the respective grant dates. The foregoing grants were made pursuant to inducement grants outside of our 2007 Plan as permitted under the NASDAQ Global Market rules. We assessed the terms of these awards and determined there was no possibility that we would have to settle these awards in cash and therefore, equity accounting was applied.

*Equity-based compensation expense*

Equity-based compensation expense for the three months ended March 31, 2014 and 2013, consisted of the following (in thousands):

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|                                         | Three Months Ended March 31 |       |      |       |
|-----------------------------------------|-----------------------------|-------|------|-------|
|                                         | 2014                        |       | 2013 |       |
| Cost of product sales                   | \$                          | 28    | \$   | 23    |
| Research and development                |                             | 449   |      | 932   |
| Selling, general and administrative     |                             | 1,453 |      | 1,328 |
| Total equity-based compensation expense | \$                          | 1,930 | \$   | 2,283 |

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

A purported class action complaint was originally filed on March 18, 2010 in the U.S. District Court for the District of Massachusetts, entitled Silverstrand Investments et. al. v. AMAG Pharm., Inc., et. al., Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Chief Financial Officer, the then-members of our Board, and certain underwriters in our January 2010 offering of common stock violated certain federal securities laws, specifically Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, and that our former President and Chief Executive Officer and former Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged omissions in a registration statement filed in January 2010. The plaintiffs sought unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. On August 11 and 15, 2011, respectively, the District Court issued an Opinion and Order dismissing the SAC with prejudice for failure to state a claim upon which relief could be granted. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the U.S. Court of Appeals for the First Circuit, or the Court of Appeals. The Court of Appeals heard oral argument on May 11, 2012. On February 4, 2013, the Court of Appeals affirmed in part and reversed in part the District Court's Opinion and Order and remanded the case to the District Court. On February 19, 2013, we filed a Petition for Panel Rehearing and Rehearing *En Banc*, which was denied on March 15, 2013. On March 22, 2013, we filed a Motion to Stay the Mandate remanding the case to the District Court pending review by the U.S. Supreme Court of the Court of Appeals' February 4, 2013 decision. The Court of Appeals granted the Motion to Stay the Mandate on April 8, 2013. On June 13, 2013, we filed a Petition for a Writ of Certiorari, or the Petition, with the U.S. Supreme Court seeking



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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. A status conference is scheduled for May 14, 2014. We are currently unable to predict the outcome or reasonably estimate the range of potential loss associated with this matter, if any, and have therefore not recorded any potential estimated liability as we do not believe that such a liability is probable nor do we believe that a range of loss is currently estimable.

In July 2010, Sandoz GmbH, or Sandoz, filed with the European Patent Office, or the EPO, an opposition to a previously issued patent which covers ferumoxytol in EU jurisdictions. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked this patent. In December 2012, our notice of appeal of that decision was recorded with the EPO, which also suspended the revocation of our patent. On May 13, 2013, we filed a statement of grounds of appeal and on September 27, 2013, Sandoz filed a response to that statement. We filed a reply to that response on March 17, 2014. We will continue to defend the validity of this patent throughout the appeals process, which we expect to take two to three years. However, in the event that we do not experience a successful outcome from the appeals process, under EU regulations ferumoxytol would still be entitled to eight years of data protection and ten years of market exclusivity from the date of approval, which we believe would create barriers to entry for any generic version of ferumoxytol into the EU market until sometime between 2020 and 2022. This decision had no impact on our revenues for the three months ended March 31, 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 March 31, 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 March 31, 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/Rienso*, primarily outside of the U.S., as well as expanding our portfolio through the in-license or purchase of additional specialty pharmaceutical products.

*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/Rienso* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey. In June 2012, we entered into an amendment to the Takeda Agreement, or the Amended Takeda Agreement, which removed the Commonwealth of Independent States from the territories under which Takeda has the exclusive rights to develop and commercialize *Feraheme/Rienso*. In addition, the Amended Takeda Agreement modified the timing and pricing arrangements for a supply agreement to be entered into between us and Takeda, and which was entered into in February 2014 and discussed below, the terms related to primary and secondary



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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 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/Rienso* and our best estimate of the period over which we will substantively perform our obligations. We continue to believe that the then-current patent life of *Feraheme/Rienso* is our best estimate of the period over which we will substantively perform our obligations under this agreement.

In addition, the remaining milestone payments we may be entitled to receive under the Amended Takeda Agreement could over time equal up to \$186.0 million. For any milestone payments we may receive based upon the approval by certain regulatory agencies, we have determined that these will be deemed substantive milestones and, therefore, will be accounted for as revenue in the period in which they are achieved. 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 months ended March 31, 2014, we recorded \$2.0 million in revenues associated with the amortization of the upfront payments in license fee and other collaboration revenues in our condensed consolidated statement of operations. 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 \$0.1 million and less than \$0.1 million for the three months ended March 31, 2014 and 2013, respectively, associated with other reimbursement revenues received from Takeda.

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At the time of shipment, we defer recognition of all revenue for *Feraheme/Rienso* 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 its customers. During the three months ended March 31, 2014, we recognized \$0.2 million 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 March 31, 2014, we had approximately \$2.3 million in deferred revenue related to product shipped to Takeda but not yet sold through to Takeda's customers, of which \$1.2 million was classified as short-term and \$1.1 million was classified as long-term. In addition, we had \$2.2 million in deferred cost of product sales, of which \$1.1 million was classified as short-term and \$1.1 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 March 31, 2014.

In February 2014, we entered into a Supply Agreement with Takeda pursuant to which we will 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 will 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 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 its 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.

The Supply Agreement provides pricing terms and also provides that Takeda will reimburse us for certain capital expenditures and shall pay us a per-vial manufacturing fee. In addition, the Supply Agreement 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., or 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 late 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 three months ended March 31, 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 statements of operations.

*Access*

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

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**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 \$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, or 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.

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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

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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.

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, or 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, or debt discount, is amortized to interest expense using the effective interest method over five years, or 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 of March 31, 2014 consisted of the following:

|                          | March 31, 2014 |
|--------------------------|----------------|
| Liability component:     |                |
| Principal                | \$ 200,000     |
| Less: debt discount, net | (37,439)       |
| Net carrying amount      | \$ 162,561     |
| 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 March 31, 2014, the carrying value of the Convertible Notes was \$162.6 million and approximated their fair value due to the recent issuance of such Convertible Notes. The effective interest rate on the liability component was 7.23% for the period from the date of issuance through March 31, 2014. The following table sets forth total interest expense recognized related to the Convertible Notes during the three months ended March 31, 2014 (in thousands):

|                                     | March 31, 2014 |       |
|-------------------------------------|----------------|-------|
| Contractual interest expense        | \$             | 625   |
| Amortization of debt issuance costs |                | 102   |
| Amortization of debt discount       |                | 749   |
| Total interest expense              | \$             | 1,476 |

*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, or 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.

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. We received \$25.7 million for these warrants and recorded this amount to additional paid-in capital.

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 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.

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**Q. Stockholders Equity**

In connection with the pricing of the Convertible Notes, on February 11, 2014, we and American Stock Transfer & Trust Company, LLC, or the Rights Agent, entered into an amendment, or the Amendment, to the Rights Agreement, dated as of September 4, 2009, between us and the Rights Agent. The 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.

Total stockholders equity increased \$18.7 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*, and \$1.9 million in stock-based compensation expense. These increases were partially offset by our net loss of \$7.1 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.

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

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board 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.

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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, or our Annual Report.*

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

*Examples of forward-looking statements contained in this report include, 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 expansion of our portfolio through the in-license or purchase of additional specialty pharmaceutical products and companies; expectations regarding our supplemental New Drug Application for Feraheme and our plans for addressing the complete response letter from the FDA and the path forward for Feraheme in the broad IDA patient population; the timing of the opinion of the European Medicines Agency and the related decision by the European Commission regarding Takeda Pharmaceutical Company Limited's application*

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*for Type II Variation of the marketing authorization for Rienso in the EU; 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 success of our collaboration with Takeda Pharmaceutical Company Limited, including any potential milestone payments, product sales or royalties we may receive; our expectations regarding the manufacture of all Feraheme/Rienso drug substance and drug product at our third-party manufacturers; our expectations regarding customer returns and other revenue-related reserves and accruals; variations of the labeling and other elements of the marketing authorization for Rienso in the EU that may be expected as a result of the review by the EMA Committee for Medicinal Products for Human Use of IV iron-containing medications used to treat iron deficiency anemia; our expectations regarding the validity of our European ferumoxytol patent and timing of the appeals process; our expectations regarding government regulations, including the Branded Drug Fee under the Health Care Reform Act and the Medicare reimbursement rate for Feraheme and estimates for Medicaid rebates; our expectations regarding our license fee and other collaboration revenues; expected customer mix and utilization rates; the impact of volume rebates and other incentives; provider purchase patterns and use of competitive products; expectations regarding MuGard and our license arrangement with Access Pharmaceuticals, Inc.; the valuation of certain intangible assets, contingent consideration, 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 in our product sales; our Citizen Petition; 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 Convertible Notes and use of proceeds; our belief regarding the potential impact of the adoption of newly issued and future accounting guidance on our financial statements; our expectations for our cash, cash equivalents and investments balances and information with respect to any other plans and strategies for our business. Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements.*

*Any forward-looking statement should be considered in light of the factors discussed in Part II, Item 1A below under "Risk Factors" in this Quarterly Report on Form 10-Q and in Part I, Item 1A in our Annual Report. We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the U.S. Securities and Exchange Commission to publicly update or revise any such statements to reflect any change in company expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.*

## **Overview**

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a specialty pharmaceutical company that markets Feraheme® (ferumoxytol) Injection for Intravenous, or IV, use to treat iron deficiency anemia, or IDA, in adult patients with chronic kidney disease, or CKD, and MuGard® Mucoadhesive Oral Wound Rinse for the management of oral mucositis. Along with driving organic growth of our products, we intend to expand our portfolio with additional commercial-stage specialty products. 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, or the FDA, for use as an

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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* 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.

*Portfolio Expansion*

To further build our business, we intend to continue to expand our portfolio through the in-license or purchase of additional specialty pharmaceutical products or companies. In particular, we are seeking complementary products that will leverage our commercial infrastructure and focus on hematology and oncology centers, hospital infusion centers or other sites of care where IV iron is administered or where IDA patients are diagnosed or treated. We are also evaluating products in other strategic areas of interest, such as gastroenterology or rheumatology. Since patients within these specialties have high rates of co-morbid IDA, these new call points could be synergistic with the potential label expansion of *Feraheme*, if regulatory approval is obtained. In addition, we are contemplating transactions that would be financially beneficial to us, by providing an additional revenue stream from products that are approved for one or more indication, but that would be accretive to earnings and allow us to eliminate duplicative infrastructure, and potentially optimize after-tax cash flows. Finally, we may opportunistically look at commercial products in other indications or products that we believe entail lower-risk late stage development.

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

*Label Expansion of Ferumoxytol*

In addition to expanding our portfolio through the in-license or purchase of additional specialty pharmaceutical products or companies, 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.



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

On January 21, 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 additions to labeling that would be intended to reduce the risk of serious hypersensitivity reactions associated with *Feraheme*. We are in the process of developing a proposal that we believe would be responsive to the points raised in the complete response letter, including proposed additions to labeling on our current CKD indication, and that we determine would be economically viable. Once we have finalized our proposal we plan to (a) meet with FDA to discuss our proposal and explore the range of possible approaches to the points raised in the complete response letter (currently expected to be scheduled in mid-2014); and (b) assess the FDA's feedback on our proposal and make a final determination on a possible program that would adequately address the FDA's concerns. Until we have further discussions with the FDA and receive its input, we cannot predict the path forward, if any, for *Feraheme* in the broad IDA patient population, including the related timing and cost of any clinical trials.

## *International Expansion of Ferumoxytol*

Outside of the U.S., ferumoxytol has been granted marketing approval in Canada, Switzerland and the European Union, or EU, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. The 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 in the EU and Switzerland it is *Rienso*® 30mg/ml solution for Injection. The EU competent authorities, and recently Canadian regulatory authorities, have implemented class labeling including stronger safety warnings for IV iron products, such as *Feraheme/Rienso*. Under our amended agreement with Takeda Pharmaceutical Company Limited, or Takeda, discussed below, Takeda has an exclusive license to market and sell ferumoxytol in Canada, the EU and Switzerland, as well as certain other geographic territories.

In June 2013, Takeda filed an application for Type II Variation of the marketing authorization for *Rienso* in the EU, which is the EU equivalent of a U.S. sNDA, with the European Medicines Agency, or EMA, seeking marketing authorization for an additional therapeutic indication for *Rienso* for the treatment of IDA in adult patients. Takeda currently expects an opinion from the EMA's Committee for Medicinal Products for Human Use, or CHMP, in the second quarter of 2014. The related ratification of the CHMP opinion by the EMA would then be expected in the third quarter of 2014. If the 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, we expect that a significant milestone

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payment from Takeda will become payable. In addition, in October 2013, Takeda filed a Supplemental New Drug Submission, or sNDS, with Health Canada seeking marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients.

*Takeda Collaboration*

In March 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, which was amended in June 2012, or the Amended Takeda Agreement, with Takeda under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme/Rienso* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey. In February 2014, we entered into the supply agreement with Takeda, which provides the terms under which we will sell *Feraheme* to Takeda in order for Takeda to meet its requirements for commercial use of *Feraheme* in its licensed territories. The 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, or MAA, for ferumoxytol, was approved by the EMA in December 2009 and 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 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, or MRI, sub-analysis to evaluate the potential for iron to accumulate in the body following treatment with IV iron, specifically in the heart and liver, and, where possible, other major organs following repeated IV iron administration over a two year period. Enrollment is currently ongoing and we 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.

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

*Convertible Notes Offering*

To help facilitate the activities described above, in February 2014, we issued \$200.0 million of

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2.5% convertible senior notes due February 15, 2019, or 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.

## Results of Operations Three Months Ended March 31, 2014 and 2013

### Revenues

Total revenues for the three months ended March 31, 2014 and 2013 consisted of the following (in thousands):

|                                              | Three Months Ended March 31, |           |    |           |          |  |
|----------------------------------------------|------------------------------|-----------|----|-----------|----------|--|
|                                              | 2014                         | 2013      |    | \$ Change | % Change |  |
| U.S. <i>Feraheme</i> product sales, net      | \$ 17,375                    | \$ 15,578 | \$ | 1,797     | 12%      |  |
| License fee and other collaboration revenues | 3,120                        | 2,003     |    | 1,117     | 56%      |  |
| Other product sales and royalties            | 340                          | 299       |    | 41        | 14%      |  |
| Total                                        | \$ 20,835                    | \$ 17,880 | \$ | 2,955     | 17%      |  |

Our total revenues during the three months ended March 31, 2014 increased by \$3.0 million, or 17%, as compared to the same period in 2013, primarily as the result of a \$1.8 million increase in U.S. net *Feraheme* product sales and a \$1.1 million increase in license fee revenues primarily due to the recognition of a \$1.0 million upfront payment received from our former partner 3SBio, Inc., or 3SBio, as the result of the termination of our license agreement in January 2014. We have no further obligations under the agreement with 3SBio.

### U.S. *Feraheme* Product Sales, Net

U.S. *Feraheme* product sales and product sales allowances and accruals for the three months ended March 31, 2014 and 2013 consisted of the following (in thousands):

|  | 2014 | Three Months Ended March 31, |      |                 |           |          |
|--|------|------------------------------|------|-----------------|-----------|----------|
|  |      | Percent of                   | 2013 | Percent of      | \$ Change | % Change |
|  |      | gross U.S.                   |      | gross U.S.      |           |          |
|  |      | <i>Feraheme</i>              |      | <i>Feraheme</i> |           |          |
|  |      | product                      |      | product         |           |          |

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|                                                           | sales |            | sales |            |              |
|-----------------------------------------------------------|-------|------------|-------|------------|--------------|
| Gross U.S. <i>Feraheme</i> product sales                  | \$    | 31,321     | \$    | 25,651     | \$ 5,670 22% |
| Less provision for product sales allowances and accruals: |       |            |       |            |              |
| Discounts and chargebacks                                 |       | 10,533 34% |       | 7,493 29%  |              |
| Government and other rebates                              |       | 3,187 10%  |       | 2,387 9%   |              |
| Returns                                                   |       | 226 1%     |       | 193 1%     |              |
| Total                                                     |       | 13,946 45% |       | 10,073 39% |              |
| Net U.S. <i>Feraheme</i> product sales                    | \$    | 17,375     | \$    | 15,578     | \$ 1,797 12% |

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Our gross U.S. *Feraheme* product sales increased by \$5.7 million, or 22%, during the three months ended March 31, 2014 as compared to the same period in 2013. Of the \$5.7 million increase, \$3.8 million was due to price increases and \$1.9 million was due to increased units sold. This increase was partially offset by \$3.9 million of additional allowances and accruals in the first quarter of 2014. As a result, total net U.S. *Feraheme* product sales increased by \$1.8 million, or 12%, during the three months ended March 31, 2014 as compared to the same period in 2013. We anticipate increasing competitive pressures in 2014 may lead to a slower growth rate in product sales as compared to the growth rate in 2013.

Total discounts and chargebacks for the three months ended March 31, 2014 were \$10.5 million, or 34% of total gross U.S. *Feraheme* product sales, as compared to \$7.5 million, or 29%, 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 \$3.2 million, or 10% of total gross U.S. *Feraheme* product sales, in the three months ended March 31, 2014 as compared to \$2.4 million, or 9%, in the three months ended March 31, 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 first quarter of 2014 as compared to the same period in 2013 and changes in the structure of our performance 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 and Note B to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

An analysis of the amount of, and change in, reserves for the three months ended March 31, 2014 and 2013 is as follows (in thousands):

|                                                      | Discounts and<br>Chargebacks | Government<br>and Other<br>Rebates | Returns  | Total    |
|------------------------------------------------------|------------------------------|------------------------------------|----------|----------|
| Balance at January 1, 2014                           | \$ 2,683                     | \$ 2,837                           | \$ 1,962 | \$ 7,482 |
| Current provisions relating to sales in current year | 10,533                       | 3,187                              | 226      | 13,946   |
| Payments/returns relating to sales in current year   | (6,900)                      | (386)                              |          | (7,286)  |
| Payments/returns relating to sales in prior years    | (2,792)                      | (2,049)                            | (70)     | (4,911)  |
| Balance at March 31, 2014                            | \$ 3,524                     | \$ 3,589                           | \$ 2,118 | \$ 9,231 |

|                                                      | Discounts and<br>Chargebacks | Government<br>and Other<br>Rebates | Returns  | Total    |
|------------------------------------------------------|------------------------------|------------------------------------|----------|----------|
| Balance at January 1, 2013                           | \$ 1,771                     | \$ 2,430                           | \$ 1,018 | \$ 5,219 |
| Current provisions relating to sales in current year | 7,493                        | 2,387                              | 193      | 10,073   |
| Payments/returns relating to sales in current year   | (6,620)                      | (282)                              |          | (6,902)  |
| Payments/returns relating to sales in prior years    | (306)                        | (1,470)                            |          | (1,776)  |
| Balance at March 31, 2013                            | \$ 2,338                     | \$ 3,065                           | \$ 1,211 | \$ 6,614 |

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During the first quarter of 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

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adjustment percentage while still resulting in greater net revenue per gram. In 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 recent 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 remaining quarters of 2014 to be relatively consistent with the average net revenue per gram for the first quarter of 2014.

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 also have limited or no visibility into our customers' buying decisions, which may be affected from time to time by incentives we make available to clinics, hospitals and GPOs including volume rebates. During the first 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, 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;
- 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 potential changes to our current label based on post-marketing safety data;
- 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*;

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

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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.

*Healthcare Reform Legislation*

The Health Care Reform Act was enacted in the U.S. in March 2010 and includes certain cost containment measures including an increase to the minimum rebates for products covered by Medicaid programs and the extension of such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations as well as the expansion of the 340B Drug Discount Program under the Public Health Service Act. This legislation contains provisions that can affect the operational results of companies in the pharmaceutical industry, including us, and other healthcare related industries by imposing on them additional costs.

The Health Care Reform Act also requires pharmaceutical manufacturers to pay a prorated share of the overall Branded Drug Fee, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the legislation. The amount of our annual share of the Branded Drug Fee for 2014 and 2013 was less than \$0.1 million and these payments were non-deductible for income tax purposes. We have included these amounts in selling, general and administrative expense in our condensed consolidated statements of operations. The amount of this annual payment could increase in future years due to both higher eligible *Feraheme* sales and the increasing amount of the overall fee assessed across manufacturers, but any such increases are not expected to be material to our results of operations or financial condition.

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

Further, under the sequestration required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, Medicare payments for all items and services under Parts A and B incurred on or after April 1, 2013 have been reduced by up to 2%. Therefore, after adjustment for deductible and co-insurance, the reimbursement rate for physician-administered drugs, including *Feraheme*, under Medicare Part B has been reduced from average selling price, or ASP, plus 6% to ASP plus 4.3%. Because the majority of our business is through hematology/oncology clinics and out-patient hospital infusion centers, this reduction in the Medicare reimbursement payment for *Feraheme* may adversely impact our future revenues. 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 quarter of 2014 as compared to the first quarter of 2013.

We were not materially impacted by recent healthcare reform legislation during the first quarter of 2014 or 2013. Presently, we have not identified any provisions that could materially impact our business but we continue to monitor future legislative developments.

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### License Fee and Other Collaboration Revenues

License fee and other collaboration revenues for the three months ended March 31, 2014 and 2013 consisted of the following (in thousands):

|                                                      | Three Months Ended March 31, |          |    |       | \$ Change | % Change |
|------------------------------------------------------|------------------------------|----------|----|-------|-----------|----------|
|                                                      | 2014                         | 2013     |    |       |           |          |
| Deferred license fee revenues recognized from Takeda | \$ 1,974                     | \$ 1,974 | \$ |       |           | 0%       |
| Deferred revenues recognized from 3SBio termination  | 1,000                        |          |    | 1,000 |           | N/A      |
| Reimbursement revenues from Takeda                   | 146                          | 29       |    | 117   |           | >100%    |
| Total                                                | \$ 3,120                     | \$ 2,003 | \$ | 1,117 |           | 56%      |

Our license fee and other collaboration revenues in the three months ended March 31, 2014 increased by \$1.1 million as compared to the same period in 2013 primarily as the result of the recognition of a \$1.0 million upfront payment we received from 3SBio in 2008 in connection with our license agreement, which was mutually terminated in January 2014. In each of the three months ended March 31, 2014 and 2013, we also 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 March 31, 2014, we had approximately \$47.4 million remaining in deferred revenues related to the \$61.0 million in upfront payments and the \$18.0 million in non-substantive milestone payments received from Takeda, of which \$7.9 million was classified as short-term and \$39.5 million was classified as long-term.

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 the three months ended March 31, 2014 and 2013, we recorded \$0.1 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, excluding the one-time recognition of the \$1.0 million milestone payment from 3SBio, our license fee and other collaboration revenues will remain relatively constant in the remaining quarters of 2014 as compared to the first quarter of 2014. However, our license fees and other collaboration revenues will increase significantly if 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 to the extent that such approval triggers a significant milestone payment. There can be no assurances as to whether or when Takeda will receive such approval or the terms and scope of any approval it may receive in the EU for *Rienso*.

### Other Product Sales and Royalties

Other product sales and royalties for the three months ended March 31, 2014 included product sales and royalties of *Feraheme/Rienso* from Takeda and net product sales of *MuGard*. Other product sales and royalties for the three months ended March 31, 2013 included product sales and royalties of *Feraheme/Rienso* from Takeda and product sales of *GastroMARK* to our licensees. For the three months ended March 31, 2014 as compared to the same period in 2013, other product sales and royalties increased by less than \$0.1 million.

As of March 31, 2014, we had approximately \$2.3 million in deferred revenue related to product shipped to Takeda, but not yet sold through to Takeda's customers, of which \$1.2 million was classified as short-term and \$1.1 million was classified as long-term. In addition, we had \$2.2 million in deferred

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cost of product sales, of which \$1.1 million was classified as short-term and \$1.1 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 March 31, 2014.

We expect other product sales and royalties to increase in the remaining quarters of 2014 as compared to first quarter of 2014 due to increased *MuGuard* sales and increased sales and royalty revenue associated with the Amended Takeda Agreement, particularly if Takeda receives approval of its Type II Variation in the EU for *Rienso* for the treatment of IDA regardless of the underlying cause.

## Costs and Expenses

### Cost of Product Sales

Cost of product sales for the three months ended March 31, 2014 and 2013 consisted of the following (in thousands):

|                                               | Three Months Ended March 31, |          |    |           |          |  |  |
|-----------------------------------------------|------------------------------|----------|----|-----------|----------|--|--|
|                                               | 2014                         | 2013     |    | \$ Change | % Change |  |  |
| Cost of Product Sales                         | \$ 2,837                     | \$ 2,942 | \$ | (105)     | -4%      |  |  |
| Percentage of Net Product Sales and Royalties | 16%                          | 19%      |    |           |          |  |  |

Our cost of product sales are primarily comprised of costs of managing our contract manufacturers, and costs for quality assurance and quality control associated with our sales of *Feraheme* and *MuGuard* in the U.S., sales of *Feraheme/Rienso* to Takeda. The \$0.1 million decrease in our cost of product sales for the three months ended March 31, 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 \$0.2 million increase due to a higher volume of *Feraheme* vials sold in 2014; and
- \$0.3 million increase due to a write-down of inventory that was deemed not commercially saleable in the three months ended March 31, 2014.

We expect our cost of product sales as a percentage of net product sales and royalties to remain relatively consistent for the remaining quarters of 2014 as compared to the first quarter 2014.

*Research and Development Expenses*

Research and development expenses for the three months ended March 31, 2014 and 2013 consisted of the following (in thousands):

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|                                                                 | Three Months Ended March 31, |                 |                 |           |             |
|-----------------------------------------------------------------|------------------------------|-----------------|-----------------|-----------|-------------|
|                                                                 | 2014                         | 2013            |                 | \$ Change | % Change    |
| <b>External Research and Development Expenses</b>               |                              |                 |                 |           |             |
| <i>Feraheme</i> to treat IDA in CKD patients                    | \$ 1,772                     | \$ 820          | \$ 952          |           | >100%       |
| <i>Feraheme</i> manufacturing process development and materials | 1,632                        | 273             | 1,359           |           | >100%       |
| Other external costs                                            | 188                          | 704             | (516)           |           | -73%        |
| <b>Total</b>                                                    | <b>\$ 3,592</b>              | <b>\$ 1,797</b> | <b>\$ 1,795</b> |           | <b>100%</b> |
| <b>Internal Research and Development Expenses</b>               |                              |                 |                 |           |             |
| Compensation, payroll taxes, benefits and other expenses        | 2,457                        | 2,675           | (218)           |           | -8%         |
| Equity-based compensation expense                               | 449                          | 932             | (483)           |           | -52%        |
| <b>Total</b>                                                    | <b>\$ 2,906</b>              | <b>\$ 3,607</b> | <b>\$ (701)</b> |           | <b>-19%</b> |
| <b>Total Research and Development Expenses</b>                  | <b>\$ 6,498</b>              | <b>\$ 5,404</b> | <b>\$ 1,094</b> |           | <b>20%</b>  |

Total research and development expenses incurred in the three months ended March 31, 2014 increased by \$1.1 million, or 20%, as compared to the same period in 2013. The increase was primarily due to a \$1.8 million increase in external research and development costs in the three months ended March 31, 2014, offset by reduced internal research and development costs of \$0.7 million in the three months ended March 31, 2014 as compared to the same period in 2013.

The \$1.8 million, or 100%, increase in our external research and development expenses was due primarily to a \$1.4 million increase in manufacturing process development and materials-related costs, including \$1.1 million of commercial inventory, which we determined would be solely used in manufacturing process and development activities at our third-party suppliers. In addition, the \$1.8 million increase was due to a \$1.0 million increase in costs incurred associated with our CKD-related trials, partially offset by a \$0.5 million decrease in costs related to our Phase III clinical development program for *Feraheme* to treat IDA regardless of the underlying cause and reflected in other external costs in the table above.

The \$0.7 million, or 19%, decrease in our internal research and development expenses was primarily attributable to the decrease in compensation and related benefit costs and equity-based compensation expense in the three months ended March 31, 2014 as compared to the same period in 2013, primarily related to the severance and other related costs following the departure of our chief medical officer in the first quarter of 2013.

We expect research and development expenses to decrease slightly in the remaining quarters of 2014 as compared to the first quarter of 2014 primarily due to a slight decrease in development costs related to manufacturing process improvement activities, partially offset by a slight increase in expenses associated with our ongoing clinical trials to determine the safety and efficacy of repeat doses of ferumoxylol for the treatment of IDA in patients with hemodialysis-dependent CKD. In addition, research and development expenses could increase depending on the outcome of discussions with the FDA on the regulatory path forward for *Feraheme* in the broad IDA indication and any resulting clinical trials or development efforts that we may undertake.

*Research and Development Activities*

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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

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applicable foreign regulatory body. The following major research and development project was ongoing as of March 31, 2014:

- ***Feraheme to treat IDA in CKD patients.*** This project currently includes: (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 March 31, 2014, we have incurred aggregate external research and development expenses of approximately \$30.0 million related to our current program for the development of *Feraheme* to treat IDA in CKD patients. We currently estimate that the total remaining external costs associated with this development project will be in the range of approximately \$20.0 to \$30.0 million over the next several years.

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 three months ended March 31, 2014 and 2013 consisted of the following (in thousands):

|                                                                             | Three Months Ended March 31, |           |          |           |          |  |
|-----------------------------------------------------------------------------|------------------------------|-----------|----------|-----------|----------|--|
|                                                                             | 2014                         | 2013      |          | \$ Change | % Change |  |
| Compensation, payroll taxes and benefits                                    | \$ 6,742                     | \$ 6,026  | \$ 716   |           | 12%      |  |
| Sales and marketing consulting, professional fees, and other expenses       | 3,729                        | 2,947     | 782      |           | 27%      |  |
| General and administrative consulting, professional fees and other expenses | 5,567                        | 3,704     | 1,863    |           | 50%      |  |
| Equity-based compensation expense                                           | 1,453                        | 1,328     | 125      |           | 9%       |  |
| Total                                                                       | \$ 17,491                    | \$ 14,005 | \$ 3,486 |           | 25%      |  |

Total selling, general and administrative expenses incurred in the three months ended March 31, 2014 increased by \$3.5 million, or 25%, as compared to the same period in 2013 for the following reasons:

- \$0.7 million increase in compensation, payroll taxes and benefits;

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- \$0.8 million increase in sales and marketing consulting, professional fees, and other expenses primarily due to increased consulting costs related to the integration and commercialization of *MuGard*, which we did not have in the first quarter of 2013;
- \$1.9 million increase in general and administrative consulting, professional fees and other expenses primarily due to \$1.6 million of increased costs associated with business development, consulting and other legal-related activities in support of portfolio expansion and a \$0.8 million adjustment to the fair value of our contingent consideration liability related to the MuGard Rights. These increased costs in the first quarter of 2014 were partially offset by the following decreased costs related to general and administrative consulting, professional fees and other expenses: \$0.4 million of accelerated depreciation expense related to certain leasehold improvements and furniture and fixtures associated with our prior office facility during the first quarter of 2013 and \$0.2 million of costs related to the closure of our Cambridge, Massachusetts manufacturing facility; and
- \$0.1 million increase in equity-based compensation expense due primarily to the expense associated with equity awards to new and existing employees.

We expect total selling, general and administrative expenses will decrease during the remaining quarters of 2014 as compared to the first quarter of 2014 as the result of a decline in certain non-recurring business development-related legal and professional expenses incurred during the first quarter of 2014.

## Other Income (Expense)

Other income (expense) for the three months ended March 31, 2014 and 2013 consisted of the following (in thousands):

|                                   | Three Months Ended March 31, |            |            |          |
|-----------------------------------|------------------------------|------------|------------|----------|
|                                   | 2014                         | 2013       | \$ Change  | % Change |
| Interest Expense                  | \$ (1,476)                   | \$ (1,476) | (1,476)    | N/A      |
| Interest and dividend income, net | 265                          | 271        | (6)        | -2%      |
| Gains on sale of asset            | 100                          | 299        | (199)      | -67%     |
| Gains on investments, net         |                              | 6          | (6)        | -100%    |
| Total                             | \$ (1,111)                   | \$ 576     | \$ (1,687) | <(100)%  |

Other income (expense) for the three months ended March 31, 2014 decreased by \$1.7 million as compared to the same period in 2013 primarily as the result of the recognition of \$1.5 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 Loss

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For the reasons stated above, we incurred a net loss of \$7.1 million and \$3.9 million, or \$0.33 and \$0.18 per basic and diluted share, for the three months ended March 31, 2014 and 2013, respectively.

### Liquidity and Capital Resources

#### *General*

We finance our operations primarily from the sale of *Feraheme/Rienso* and *MuGard*, including payments from our licensees, cash generated from our investing activities and the sale of our common

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stock. We expect to continue to incur significant expenses as we and our partners continue to manufacture, market and sell *Feraheme/Rienso* 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 we further develop and seek regulatory approval for *Feraheme/Rienso* for the treatment of IDA in a broad range of patients in and outside of the U.S.

As of March 31, 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 March 31, 2014 and 2013 consisted of the following (in thousands):

|                                            | March 31, 2014 | December 31, 2013 | \$ Change  | % Change |
|--------------------------------------------|----------------|-------------------|------------|----------|
| Cash and cash equivalents                  | \$ 200,916     | \$ 26,986         | \$ 173,930 | >100%    |
| Investments                                | 184,557        | 186,803           | (2,246)    | -1%      |
| Total                                      | \$ 385,473     | \$ 213,789        | \$ 171,684 | 80%      |
| Outstanding principal on convertible notes | \$ 200,000     | \$ 200,000        | \$ 200,000 | N/A      |
| Total                                      | \$ 200,000     | \$ 200,000        | \$ 200,000 | N/A      |

The \$171.7 million increase in cash, cash equivalents and investments as of March 31, 2014, as compared to December 31, 2013, was primarily due to net proceeds of \$179.1 million received in the first quarter of 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.

We expect that our cash, cash equivalents and investments balances, in the aggregate, may increase slightly due to positive cash flows from operations for the remaining quarterly periods of 2014. Our expectation assumes our continued investment in the development and commercialization of *Feraheme* and the continued pursuit of business development transactions. We believe that our cash, cash equivalents and investments as of March 31, 2014, and the cash we currently expect to receive from sales of *Feraheme* and *MuGard*, 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.

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*Cash flows from operating activities*

During the three months ended March 31, 2014, our use of \$11.1 million of cash in operations was attributable principally to our net loss of approximately \$7.1 million, adjusted for the following:

- Non-cash operating items of \$5.7 million including 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;
- \$2.8 million of cash used in operating activities due to decreases in deferred revenues and other long-term liabilities;
- \$1.1 million of cash used in operating activities due to decreases in accounts payable and accrued expenses;
- \$6.7 million of cash used in operating activities due to increases in accounts receivable, prepaid assets and inventories; and
- \$0.9 million of cash provided by operating activities due to decreases in other long-term assets.

Our net loss of \$7.1 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, and general and administrative costs, partially offset by net product sales and collaboration revenues.

*Cash flows from investing activities*

Cash provided by investing activities during the three months ended March 31, 2014 totaled \$4.5 million and was primarily attributable to \$2.9 million that was returned to us by an escrow agent related to a 2013 business development transaction that we did not complete, as well as proceeds from the sales and maturities of our investments, partially offset by the purchases of investments.

*Cash flows from financing activities*

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Cash provided by financing activities during the three months ended March 31, 2014, was \$180.5 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 \$1.0 million in proceeds received from the exercise of stock options.

### Off-Balance Sheet Arrangements

As of March 31, 2014, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

### Contractual Obligations

During the quarter ended March 31, 2014, we issued \$200.0 million of 2.5% Convertible Notes due February 15, 2019. 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. In addition, in connection with the pricing of the Convertible Notes, we entered into convertible bond hedge transactions and separate warrant transactions.

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

None.

**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 March 31, 2014, the fair value of the Convertible Notes was estimated by us to be \$161.8 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 March 31, 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:**

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

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

We intend to continue to dedicate significant resources to the commercialization of *Feraheme/Rienso*. However, we or Takeda may not be successful in our efforts to successfully commercialize *Feraheme/Rienso* in its current indication for adult patients with iron deficiency anemia, or IDA, associated with chronic kidney disease, or CKD, or to expand the approved indication of *Feraheme/Rienso* to include additional indications. In December 2012, we filed a supplemental New Drug Application, or sNDA, in the U.S. for *Feraheme* in patients with IDA who had failed or could not use oral iron. In January 2014, we received a complete response letter from the U.S. Food and Drug Administration, or 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 since the 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 additions to labeling that would be intended to reduce the risk of serious hypersensitivity reactions associated with *Feraheme*. We are in the process of developing a proposal that we believe would be responsive to the points raised in the complete response letter, including proposed additions to labeling on our current CKD indication, and that we determine would be economically viable. Once we have finalized our proposal we plan to (a) meet with FDA to discuss our proposal and explore the range of possible approaches to the points raised in the complete response letter; and (b) assess the FDA's feedback on our proposal and make a final determination on a possible program that would adequately address the FDA's concerns. Depending upon the outcome of such evaluations and discussions, we may decide not to pursue regulatory approval for the broader indication. Until we have further discussions with the FDA and receive its input, we cannot predict the path forward, if any, for *Feraheme* in the broad IDA patient population, 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 may even prevent us from obtaining U.S. regulatory approval for *Feraheme* in the broader IDA population or narrow our currently approved indications, as discussed in more detail in the following risk factor. Any of these results would, in turn, materially adversely impact our cash position, our ability to increase revenues, our ability to achieve profitability, and the future prospects of our business.

In June 2013, Takeda filed an application for Type II Variation of the marketing authorization for *Rienso* in the EU, which is the European Union, or EU, equivalent of a U.S. sNDA, with the European Medicines Agency, or EMA, seeking marketing authorization for an additional therapeutic indication for *Rienso* for the treatment of IDA in adult patients. In addition, in October 2013, Takeda filed a supplemental New Drug Submission, or sNDS, with Health Canada seeking marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients. However, we have little control over Takeda's interactions with the EU or Canadian regulatory agencies and we cannot be assured when or if the EMA will issue a positive opinion for the application for variation of the marketing authorization for *Rienso* in the EU.



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Neither can we be assured when or if the European Commission will adopt a decision approving this variation or Health Canada will approve the filings. Any failure by Takeda to gain marketing approval for *Feraheme/Rienso* for the treatment of IDA regardless of the underlying cause in a timely manner, or at all, could adversely affect our revenues and cash milestones from Takeda, which in turn would adversely affect results of operations or the future prospects of our business.

We are not currently conducting or sponsoring research to expand our product development pipeline beyond *Feraheme/Rienso*. However, we 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 June 2013, we entered into a license agreement with Access Pharmaceuticals, Inc., or Access, pursuant to which we acquired the U.S. commercial rights to market and sell MuGard® Mucoadhesive Oral Wound Rinse for the management of oral mucositis, or the MuGard Rights. Even if we continue to expand our product portfolio, our revenues and operations may not be as diversified as some of our competitors who may have numerous products or product candidates.

***Our ability to grow revenues from U.S. sales of Feraheme is limited to the IDA-CKD market given that we have not received regulatory approval to market and sell Feraheme to the broader IDA patient population and may be further limited if we are required to provide additional warnings and/or restrictions related to Feraheme's current or future indications.***

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 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. 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.

Evaluation of the content and recommendations of the FDA's complete response letter and further discussions with the FDA may cause us to 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 prospective, multicenter, randomized controlled trials, or 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 0.6% rate of related serious adverse events, or SAEs, as compared to a 0.2% rate of related SAEs from our current *Feraheme* label for the treatment of IDA in adult patients with CKD. 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.

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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.

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, or cGCP, we are responsible for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA may conduct inspections of clinical investigator sites which are involved in our clinical development programs to ensure their compliance with cGCP regulations. If the FDA determines that we, our clinical research organizations, or CROs, or our study sites fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials (including the proposed clinical trials) may be deemed unreliable and the FDA may disqualify certain data generated from those sites or require us to perform additional clinical trials before approving our marketing application, which could further adversely impact our ability to obtain marketing approval in the U.S. for *Feraheme* in the broad IDA indication. Any such deficiency in the design, implementation or oversight of our clinical development programs could cause us to incur significant additional costs, experience further delays or prevent us from obtaining marketing approval for *Feraheme* for the broad IDA indication.

As a result of any information submitted to the FDA in our regulatory filings 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 in the current indication, or we may be required to provide additional warnings and/or restrictions on our current or future *Feraheme* package inserts, notify healthcare providers of changes to the package insert, narrow our currently approved or proposed indications, alter or terminate current or future trials for *Feraheme* or incur significant costs related to post-marketing requirements/commitments, which could put us at a disadvantage to our competitors. Our efforts to obtain approval for the broad IDA indication could adversely affect the commercialization of *Feraheme* in its current 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 our current indication is narrowed, if we are required to include additional warnings and/or restrictions on the *Feraheme/Rienso* package insert, including a boxed warning in the U.S. or similar warnings outside of the U.S., 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 achieve profitability, and the future prospects of our business could be materially adversely affected.

***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 restrictions in the Feraheme/Rienso label, recalls, withdrawal of Feraheme/Rienso from the market, an adverse impact on Feraheme/Rienso sales, our need***

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*to alter or terminate current or future Feraheme development programs, and/or a negative impact on the approval and/or timing of our current or future sNDAs, any of which would adversely impact our future business prospects.*

Significant safety or drug interaction problems with respect to *Feraheme/Rienso*, including an increase in the severity or frequency of known problems or the discovery of previously unknown problems, or the evaluation or reevaluation of existing or future data by the FDA 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 FDA has broad authority to force drug manufacturers to take any number of actions if safety or drug interaction problems arise, including, but not limited to the following:

- Requiring manufacturers to conduct post-approval clinical studies to assess known risks or signals of serious risks, or to identify unexpected serious risks;
- Mandating labeling changes to a product based on new safety information; or
- Requiring manufacturers to implement a Risk Evaluation Mitigation Strategy where necessary to assure safe use of the drug.

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

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

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

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/Rienso* is used over longer periods of time by a wider group of patients, some of whom may be

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taking other medicines or by patients with additional underlying health problems. As previously discussed, the FDA recently issued a complete response letter for our sNDA that sought expansion of the indication for *Feraheme*; the complete response letter concluded that the sNDA could not be approved as submitted because we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for the proposed 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. In addition, as we conduct and complete other clinical trials for *Feraheme*, new safety issues may be identified which could negatively impact our ability to successfully complete these studies, the use and/or regulatory status of *Feraheme/Rienso* for the treatment of IDA in patients with CKD in the U.S., EU or other territories, and the prospects for approval if we 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.

As more data become available and an increased number of patients are treated with *Feraheme/Rienso*, new or increased safety or drug interaction issues may require us to, among other things, provide additional warnings and/or restrictions on the *Feraheme/Rienso* package insert, including a boxed warning in the U.S. or similar warnings outside of the U.S., notify healthcare providers of new safety information, narrow our approved indications, alter or terminate current or future trials for additional uses of *Feraheme*, or even remove *Feraheme/Rienso* from the market, any of which could have a significant adverse impact on potential sales of *Feraheme/Rienso* or require us to expend significant additional funds. For example, in May 2013, Takeda recalled a single batch of *Rienso* from the Swiss market after becoming aware of four post-marketing adverse event reports relating to potential anaphylaxis/hypersensitivity reactions of varying severity following the administration of *Rienso*. One of these cases included a report of a fatality. The marketing authorization for *Rienso* and other IV iron formulations include, among their special warnings and precautions for use, an indication that the products may cause hypersensitivity reactions including serious and life-threatening anaphylactic/anaphylactoid reactions. The recalled batch was only distributed to and sold in Switzerland and the recall was limited to the specific batch in Switzerland. We and Takeda have completed an investigation regarding the specific Swiss batch of *Rienso*, which we believe did not identify any issues which 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.

***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 are large, well-known pharmaceutical companies and may benefit from significantly greater financial, sales and marketing capabilities, greater technological or competitive advantages, and other resources. Our competitors may develop products that are more widely accepted than ours and may receive patent protection that dominates, blocks or adversely affects our product development or business.

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

- The actual and perceived safety and efficacy profile of the available products;
- The approved indication for each of the available products;



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- The ability to obtain appropriate insurance coverage and reimbursement rates and terms;
- Price competitiveness; and
- Product characteristics such as convenience of administration and dosing regimens.

The introduction by our competitors of alternatives to *Feraheme/Rienso* or *MuGard* that would be, or are perceived to be, more efficacious, safer, less expensive, easier to administer, available for a broader patient population, or provide more favorable insurance coverage or reimbursement could reduce our revenues and the value of our product development efforts.

*Feraheme/Rienso* may not receive the same level of market acceptance as competing iron replacement therapy products, in part because most of these products have been on the market longer and are currently widely used by physicians in the U.S. and abroad. In addition, the recent CHMP review of IV iron-containing medications used to treat iron deficiency and anemia (which concluded that the benefits of these medications are greater than their risks, provided that adequate measures are taken to ensure the early detection and effective management of allergic reactions that may occur, including ensuring that these products be given in an environment where patients who develop an allergic reaction can be treated immediately and ceasing to rely on a lack of allergic reaction to a test dose as an indication of tolerance of larger doses) could cause physicians to elect non-IV iron alternatives which may be easier to administer or dose or which may be perceived as less risky.

In addition, *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. Injectafer® is also priced at a significant premium to many other IV irons, providing 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, Injectafer® may enter into commercial contracts with key customers or group purchasing organizations, or GPOs, during this period, which could prevent or make it more difficult for *Feraheme* to 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 a broader IDA indication than *Feraheme*, could adversely affect our efforts to market and sell *Feraheme* in the U.S. and our ability to generate additional revenues and achieve profitability.

*Feraheme/Rienso* also competes with a number of branded IV iron replacement and certain other iron dextran and iron sucrose products outside of the U.S., such as Ferinject® (ferric carboxymaltose injection), which is an IV iron replacement therapy currently approved for marketing in approximately 47 countries worldwide for the treatment of IDA where oral iron is ineffective or cannot be used. If Takeda is unable to



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convince physicians and other healthcare providers to switch from using the competing IV iron products to *Feraheme/Rienso*, our ability to generate revenues from royalties we may receive from Takeda will be limited and our operating results will be negatively affected. In addition, all other IV iron products currently approved and marketed and sold in the EU are approved for marketing to a broader group of patients with IDA. *Feraheme/Rienso* was approved only for use in adult CKD patients, which could put *Feraheme/Rienso* at a competitive disadvantage unless and until it receives approval for a broader indication outside of the U.S. If we or Takeda are not able to differentiate *Feraheme/Rienso* from other marketed IV iron products, our ability to maintain a premium price, our ability to generate revenues and achieve and maintain profitability, and our long-term business prospects could be adversely affected.

There are other companies in the U.S. commercializing products for the management or treatment of oral mucositis that may compete with *MuGard*, including (a) NeutraSal® (supersaturated calcium phosphate rinse), a prescription mouth rinse marketed by Invado Pharmaceuticals, LLC; (b) Caphosol® a supersaturated calcium phosphate artificial saliva used as an adjunct to other oral care which is marketed by Jazz Pharmaceuticals, PLC; and (c) Kevivance® (palifermin) an IV human growth factor which is marketed by Swedish Orphan Biovitrum AB. In addition, there are several marketed products available which are indicated for the management of pain associated with oral mucositis including (a) Episil, which is marketed by Cangene BioPharma, Inc.; (b) Gelclair®, which is marketed by DARA BioSciences; and (c) GelX Oral Gel, which is marketed by Praelia Pharmaceuticals, Inc. If we are not able to differentiate *MuGard* from other marketed products for the management or treatment of oral mucositis, our ability to generate additional revenues could be adversely affected.

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

As part of our business strategy to expand our product portfolio and achieve profitability, we are seeking to acquire or in-license other products, or acquire businesses that have a commercialized product or products, that we believe would be complementary to our existing business. For example, in June 2013, we entered into a license agreement with Access, 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 such transaction in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated financial benefits of any such transaction, including *MuGard*. The valuation methods that we use for any acquired product or business requires significant judgment and assumptions. Actual results and performance of the product or business that we acquire could differ significantly from our original assumptions, especially during the periods immediately following the closing of the transaction. 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 a product, product candidate or business that will provide us with commercial, development and/or financial synergies with *Feraheme* and our current organization such that we will be able to eliminate expenses either from our existing operations or from the cost structure of the acquired product.

In addition, proposing, negotiating and implementing collaborations, in-licensing arrangements or acquisition agreements 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 debt and contingent liabilities, each of which may contain restrictive covenants that could adversely impact or limit

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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*. In addition, our cash, cash equivalents and investments may not be sufficient to finance any such 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. If we are unable to successfully obtain rights to suitable products or if any acquisition or in-license arrangement we make is not successful, our business, financial condition and prospects for growth could suffer.

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

We have and we may in the future acquire or in-license additional specialty pharmaceutical products such as we did with *MuGard*. The integration of the operations of acquired products or businesses, including *MuGard*, requires significant efforts, including the coordination of information technologies, sales and marketing, operations, manufacturing, 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 Access, and may in the future have to rely on such other parties with whom we may enter into a future agreement, to perform certain regulatory filings, oversee certain functions, such as pharmacovigilance or the manufacture of the product we license from them, and any failure of Access or any other party to perform these functions for any reason, including ceasing doing business, could have a material effect on our ability to commercialize *MuGard* or any other future product we may acquire. We may not realize the anticipated benefits of the MuGard Rights or any future acquisition, license or collaboration, any of which involves numerous risks including the following:

- Difficulty in integrating the products or product candidates into our business;
- Entry into markets in which we have no or limited direct prior experience, including device markets, and where competitors in such markets have stronger market positions;
- Failure to achieve our strategic objectives, including successfully commercializing and marketing *MuGard* or any other products we may acquire;
- Our ability to train our sales force, and the ability of our sales force, to successfully incorporate new products and devices, including *MuGard*, into their call points;
- Additional legal and/or compliance risk associated with the acquisition of *MuGard* or any other future product;

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- The introduction by our competitors of alternatives to *MuGuard* 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 *MuGuard*, and any resulting impact that may have on our quarterly financial results; and

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

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

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

We do not currently own or operate, and currently do not plan to own or operate, facilities for the manufacture of *Feraheme/Rienso* or our other commercial products, including *MuGard*. We currently rely solely on our third-party contract manufacturers to manufacture *Feraheme/Rienso* for our commercial and clinical use and rely on Access for the manufacture of *MuGard*. We do not currently have an alternative manufacturer for our *Feraheme/Rienso* drug substance and finished drug product and we may not be able to enter into agreements with second source manufacturers whose facilities and procedures comply with current good manufacturing practices, or cGMP, regulations and other regulatory requirements on a timely basis and with terms that are favorable to us, if at all.

Our ability to have our products, including *Feraheme/Rienso* and *MuGard* 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/Rienso* does not manufacture for us exclusively and may exhaust some or all of its resources meeting the demand of other customers. Any potential manufacturing delays resulting from insufficient manufacturing capacity due to scheduling conflicts at our third-party manufacturers to produce sufficient quantities of *Feraheme/Rienso* to meet our demand forecasts or any other difficulties in our manufacturing process could result in our inability to meet our commercial demand for *Feraheme/Rienso*.

In addition, securing additional third-party contract manufacturers for *Feraheme/Rienso* will require significant time for transitioning the necessary manufacturing processes, gaining regulatory approval, and for having the appropriate oversight and may increase the risk of certain problems, including cost overruns, process reproducibility, stability issues, the inability to deliver required quantities of product that conform to specifications in a timely manner, or the inability to manufacture *Feraheme/Rienso* in accordance with cGMP. If we are unable to have *Feraheme/Rienso* manufactured on a timely or sufficient basis because of these or other factors, we may not be able to meet commercial demand or our clinical development needs for *Feraheme/Rienso* or may not be able to manufacture *Feraheme/Rienso* in a cost-effective manner, particularly in light of the current fixed price at which we are required to supply *Feraheme/Rienso* to Takeda under our License, Development and Commercialization Agreement, as amended in June 2012, or the Amended Takeda Agreement. As a result, we may lose sales, fail to generate increased revenues, 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/Rienso* 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 our contract manufacturers' ability to manufacture Feraheme/Rienso or MuGard, the loss of Feraheme/Rienso or MuGard inventory, an inability to manufacture sufficient quantities of Feraheme/Rienso and MuGard to meet U.S. or foreign demand, as applicable, or other unanticipated compliance costs.***

Our third-party contract manufacturing facilities are subject to cGMP regulations enforced by the FDA and equivalent foreign regulatory regulations and agencies through periodic inspections to confirm such compliance. Similarly, we rely on Access for the manufacture of *MuGard* and any third-party contract manufacturing facilities engaged by Access 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, including *Feraheme/Rienso* and *MuGard* from the marketplace, total or partial suspension of *Feraheme/Rienso* or *MuGard* production, the loss of *Feraheme/Rienso* inventory or the inability of Access to supply sufficient *MuGard* inventory, suspension of the review of our current or any future sNDAs or equivalent foreign filings, enforcement actions, injunctions or criminal prosecution. A government-mandated recall or a voluntary recall could divert managerial and financial resources, could be difficult and costly to correct, could result in the suspension of sales of our products, including *Feraheme/Rienso* and *MuGard*, 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 Access'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 *Feraheme/Rienso* to meet U.S. or foreign demand and of *MuGard* to meet U.S. demand, or incur unanticipated compliance expenditures.

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

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

We rely on a combination of patents, trademarks and copyrights in the conduct of our business. The patent positions of pharmaceutical and biopharmaceutical firms are generally uncertain and involve complex legal and factual questions. We may not be successful or timely in obtaining any patents for which we submit applications. The breadth of the claims obtained in our patents may not provide sufficient protection

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

Our *Feraheme* patents currently expire in 2020, however, our primary U.S. patent for *Feraheme* may be subject to an extension to 2023 under U.S. patent law and FDA regulations. Our licensed patents relating to *MuGard* expire in 2022. These and any other patents issued to us may be contested or invalidated. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. We may become a party to patent litigation and other proceedings, including interference and reexamination proceedings declared by the United States Patent and Trademark Office. Further, our licensed patent rights to *MuGard* may not prevent competitors from independently developing and marketing a competing product that does not infringe our licensed patents or other intellectual property.

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

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our corporate licensees, collaborators, contract manufacturers, employees and consultants. These agreements, however, may be breached. We may not have adequate remedies for any such breaches, and our trade secrets might otherwise become known or might be independently discovered by our competitors. In addition, we cannot be certain that others will not independently develop substantially equivalent or superseding proprietary technology, or that an equivalent product will not be marketed in competition with *Feraheme* or *MuGard*, thereby substantially reducing the value of our proprietary rights. Our inability to protect *Feraheme* or *MuGard* through our patents and other intellectual property rights prior to their expiration could have a material adverse effect on our business, financial condition and prospects.

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

Generic ferumoxytol competitors could enter the market through approval of abbreviated new drug applications, or ANDAs, that use *Feraheme* as a reference listed drug, which would allow generic competitors to rely on *Feraheme*'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



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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.

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

In March 2010, we entered into our initial agreement with Takeda, which was amended in June 2012, under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme/Rienso* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey, or the Licensed Territories. We are highly dependent on Takeda for certain regulatory filings outside of the U.S. with respect to *Feraheme/Rienso* and the commercialization of *Feraheme/Rienso* outside of the U.S. Takeda is in the process of launching *Feraheme/Rienso* on country by country basis in its territories, for the treatment of IDA in CKD patients. To date, Takeda has launched *Feraheme/Rienso* in 11 countries (Finland, the Netherlands, Ireland, UK, Norway, Austria, Slovenia, Denmark, Sweden, Canada and Switzerland), and therefore, revenues from sales of *Feraheme/Rienso* in this territory are not currently a material part of ours or Takeda's business. In June 2013, Takeda filed an application for Type II Variation of the marketing authorization for *Rienso* in the EU with the EMA seeking marketing authorization for an additional therapeutic indication for *Rienso* for the treatment of IDA in adult patients, and in October 2013 Takeda filed a sNDS with Health Canada seeking marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients. 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 will 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 certain foreign regulatory bodies with regard to the regulatory approval of products outside of the U.S.

To receive regulatory approval outside of the U.S. for the commercial marketing and sale of

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*Feraheme/Rienso* for the broad IDA indication, Takeda will have to demonstrate that *Feraheme/Rienso* is of good quality and is safe and effective for use in the broader patient population. The ability to and the extent to which Takeda obtains regulatory approvals for *Feraheme/Rienso* for the treatment of IDA in a broad range of patients in the Licensed Territories and 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 the currently approved CKD indication is narrowed;
- If *Feraheme/Rienso* is linked to serious unexpected adverse reactions in patients;
- If Takeda experiences significant delays or setbacks in obtaining approval in the broad IDA patient population;
- If approval is granted with significant restrictions to the current or proposed package insert;
- If Takeda is required to incur significant costs as post-marketing commitments;
- If Takeda is unsuccessful in its commercialization of *Feraheme/Rienso* in the agreed-upon territories;
- If revenues fail to materialize due to market, competitive or pricing dynamics in Takeda's territories; 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.

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

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

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

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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 heading *The success of Feraheme and MuGard in the U.S. depends on our ability to maintain the proprietary nature of our technology*, our intellectual property rights may be subject to increased risk abroad, including opposition proceedings before the patent offices for other countries, such as the European Patent Office, or the EPO, or similar adversarial proceedings, regarding intellectual property rights with respect to *Feraheme/Rienso*. For example, in July 2010, Sandoz GmbH, or Sandoz, filed with the EPO an opposition to one of our previously issued patents which covers ferumoxytol in the EU. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked our European ferumoxytol patent. In December 2012, our notice of appeal was recorded with the EPO. The appeals process is costly and time-consuming and if it results in an unfavorable outcome to us, it could result in a loss of proprietary rights in the EU and may allow Sandoz or other companies to use our proprietary technology without a license from us, which may also result in a loss of future royalty or milestone payments to us, as well as the possibility that Takeda may determine that the terms of our agreement are no longer viable. We cannot predict the outcome of our appeal of the EPO decision. This or any future patent interference proceedings involving our patents may result in substantial costs to us, distract our management from day-to-day business operations and responsibilities, prevent us or Takeda from marketing and selling *Feraheme/Rienso* or increase the risk that a generic version of *Feraheme/Rienso* could enter the market to compete with *Feraheme/Rienso*. In countries where we do not have or have not applied for patents for ferumoxytol, we may be unable to prevent others from developing or selling similar products. In addition, in jurisdictions outside the U.S. where we have patent rights, we may be unable to prevent unlicensed parties from selling or importing products or technologies derived elsewhere using our proprietary technology. Any such limitation on our intellectual property rights would cause substantial harm to our competitive position and to our ability to develop and commercialize *Feraheme/Rienso*. Our inability to protect *Feraheme/Rienso* through our patents and other intellectual property rights in any territory prior to their expiration could have a material adverse effect on our business, financial condition and prospects.

***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, clinics or hospitals, which vary from quarter to quarter. In addition, our 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 customers. In the event wholesalers, distributors, clinics or hospitals with whom we do business in the U.S. determine to limit their purchases of our products, our product sales could be adversely affected. Further, in the event wholesalers, distributors, 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 cancellable at any time by our customers, often without notice, and are non-exclusive agreements within the IV iron market. While these contracts are intended to support the use of *Feraheme*, our competitors could offer better pricing, incentives, 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

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*Feraheme* sales to vary from quarter to quarter. For example, in advance of an anticipated price increase, following the publication of our quarterly average selling price, or ASP, which affects the rate at which *Feraheme* is reimbursed, or a reduction in expected rebates or discounts, customers may order *Feraheme* in larger than normal quantities which could cause *Feraheme* sales to be lower in subsequent quarters than they would have been otherwise. Further, any changes in purchasing patterns or inventory levels, changes to our contracting strategy, increases in product returns, delays in purchasing products or delays in payment for products by one of our distributors or GPOs could also have a negative impact on our revenue and results of operations.

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

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

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

- Our and Takeda's ability to demonstrate to healthcare providers, particularly hematologists, oncologists, hospitals, nephrologists, and others who may purchase or prescribe *Feraheme/Rienso*, the clinical efficacy and safety of *Feraheme/Rienso* as an alternative to currently marketed IV iron products which treat IDA in CKD patients;
- Our and Takeda's ability to convince physicians and other healthcare providers to use IV iron, and *Feraheme/Rienso* in particular, rather than oral iron, which is the current treatment of choice of most physicians for treating IDA in CKD patients;
- The actual or perceived safety and efficacy profile of *Feraheme/Rienso* as compared to alternative iron replacement therapeutic agents, particularly if unanticipated adverse reactions to *Feraheme/Rienso* result in further changes to or restrictions in the *Feraheme/Rienso* package insert, voluntary or involuntary product recalls and/or otherwise create safety concerns among potential prescribers;
- The relative price and level of reimbursement in 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;

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- The relative price and/or level of reimbursement of *Feraheme/Rienso* outside of the U.S. as compared to alternative iron replacement therapeutic agents;
- The actual or perceived convenience and ease of administration of *Feraheme/Rienso* as compared to alternative iron replacement therapeutic agents, including iron administered orally;
- The limitation on the approved indications and the patient populations for *Feraheme/Rienso*, especially in light of FDA's decision that we have not provided sufficient information to permit

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labeling of *Feraheme* for safe and effective use for this population, and the currently approved patient population in Europe; and

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

The key component of our U.S. commercialization strategy is to market and sell *Feraheme* for use in non-dialysis adult CKD patients. The current U.S. non-dialysis CKD market is comprised primarily of three sites of care where a substantial number of CKD patients are treated: 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 practices are members of GPOs, which leverage the purchasing power of a group of entities to obtain discounts based on the collective bargaining power of the group, our ability to attract customers in these sites of care also depends in part on our ability to effectively promote *Feraheme* to and enter into pricing agreements with GPOs. The GPOs can also offer opportunities for competitors to *Feraheme* that provide the ability to quickly gain market share by offering a more attractive price or contracts and incentives that encourage the members of the GPO to use or switch to the competing product. If we are not successful in capturing a significant share of the U.S. non-dialysis CKD market or if we are not successful in securing and maintaining formulary coverage for *Feraheme*, or if we cannot maintain strong relationships and offer competitive contracts to key customers and GPOs, our potential profitability as well as our long-term business prospects could be adversely affected.

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

In the U.S., we sell *Feraheme* primarily to wholesalers and specialty distributors and therefore a significant portion of our revenues is generated by a small number of customers. Four customers accounted for 93% of our total revenues during the three months ended March 31, 2014, and three customers accounted for 94% of our accounts receivable balance as of March 31, 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 28% of our end-user demand during the first quarter 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

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fluctuations.

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

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

In addition, U.S. and many foreign governments continue to propose and pass legislation designed to reduce the cost of health care for patients. In the U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the Health Care Reform Act, was enacted in March 2010 and includes certain cost containment measures including an increase to the minimum rebates for products covered by Medicaid programs, the extension of such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations and the expansion of the 340B Drug Discount Program under the Public Health Service Act. In addition, the heightened focus on the health care industry by the federal government could result in the implementation of significant federal spending cuts, including cuts in Medicare and other health related spending in the near-term. For example, recent legislation has resulted in Medicare payments being subject to a two percent reduction, referred to as sequestration, until 2023. 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, 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 January 2011, a prospective payment system for renal dialysis services provided to Medicare beneficiaries who have end-stage renal disease, or ESRD, became effective under which virtually all costs of providing renal dialysis services are reimbursed under a single prospective payment per treatment. This bundled approach to reimbursement has and will likely continue to alter the utilization of physician-administered drugs in the ESRD market as well as put downward pressure on the prices pharmaceutical companies can charge ESRD facilities for such drugs, particularly where alternative products are available. In the U.S., *Feraheme* is sold at a price that is substantially higher than alternative IV iron products in the dialysis setting, and as a result, the demand for *Feraheme* in the dialysis setting has largely disappeared. In addition, 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.

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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 average sales price, or 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, or 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 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. While Medicare is the predominant payor for treatment of patients with CKD, Medicare payment policy, in time, can also influence pricing and reimbursement in the non-Medicare markets, as private third-party payors and state Medicaid plans frequently adopt Medicare principles in setting reimbursement methodologies. 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/Rienso* may also depend, in part, upon the availability of reimbursement within existing healthcare payment systems. Generally, in Europe and other countries outside of the U.S., the government sponsored healthcare system is the primary payor of healthcare costs of patients and therefore enjoys significant market power. Some foreign countries also set prices for pharmaceutical products as part of the regulatory process, and we cannot guarantee that the prices set by such governments will be sufficient to generate substantial revenues or allow sales of *Feraheme/Rienso* to be profitable in those countries. 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/Rienso* in countries outside of the U.S. would have an adverse impact on Takeda's ability to generate product sales of *Feraheme/Rienso* in such territories, which would, in turn, limit the amount of royalties we may receive under our amended agreement with Takeda.

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

In the U.S., there have been, and we expect there will continue to be, a number of legislative and regulatory proposals aimed at changing the U.S. healthcare system. For example, the Health Care Reform Act contains a number of provisions that significantly impact the pharmaceutical industry and may negatively affect our potential 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.

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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 Health Care 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 beginning in 2011. Each individual pharmaceutical manufacturer 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* 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 program, issued proposed regulations to implement the changes to the drug rebate components of the Medicaid program under the Healthcare Reform Act but has not yet issued final regulations. CMS is currently expected to release the final regulations in 2014.

The Healthcare Reform Act also expanded the Public Health Service's 340B drug pricing discount program. The 340B pricing 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 15% in 2013. Since these institutions are granted lower prices than those offered to our other customers, any further growth in the 340B business may have a negative impact on our sales price per gram and gross margins.

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 is expected to issue a comprehensive proposed regulation in 2014 that will address many aspects of the 340B program. When that regulation is 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 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

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prices that can be charged for *Feraheme* or the amount of reimbursement rates and terms available from governmental agencies or third-party payors, limiting the profitability of *Feraheme*, increasing our rebate liability or limiting the commercial opportunity for *Feraheme*, including its acceptance by healthcare payors.

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

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

- Unexpected demand for or shortage of raw or other materials;
- Adverse financial developments at or affecting the supplier;
- Regulatory requirements or action;
- An inability to provide timely scheduling and/or sufficient capacity;
- Manufacturing difficulties;
- Changes to the specifications of the raw materials such that they no longer meet our standards;
- Labor disputes or shortages; or
- Import or export problems.

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

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

Even if we are able to obtain raw or other materials from an alternative source, if these raw or other

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materials are not available in a timely manner or on commercially reasonable terms, we would be unable to manufacture *Feraheme/Rienso*, both for commercial sale and for use in our clinical trials, on a timely and cost-effective basis, which could cause us to lose money. Any such difficulty in obtaining raw or other materials could severely hinder our ability to manufacture *Feraheme/Rienso* and could have a material adverse impact on our ability to generate additional revenues and to achieve profitability. Moreover, Access is likely subject to many of the same third party risks regarding the manufacture and supply of *MuGard*, which would impact our ability to generate revenues of *MuGard* in the U.S.

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

In addition to FDA and related regulatory requirements in the U.S. and abroad, we are subject to extensive additional federal, state and foreign healthcare regulation, which includes but is not limited to, the Federal False Claims Act, the Federal Anti-Kickback Statute, the Foreign Corrupt Practices Act, and their state analogues, and similar laws in countries outside of the U.S., laws governing sampling and distribution of products, and government price reporting laws. False claims laws prohibit anyone from knowingly presenting, or causing to be presented for payment to third-party payors, including Medicare and Medicaid, false or fraudulent claims for reimbursed drugs or services, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Anti-kickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug, that is reimbursed by a state or federal program. The Foreign Corrupt Practices Act and similar foreign anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Similar laws and regulations exist in many other countries throughout the world in which we intend to commercialize *Feraheme/Rienso* through Takeda. 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 and/or other sanctions could be imposed on us and/or Takeda, including, but not limited to, restrictions on how we and/or Takeda market and sell *Feraheme/Rienso* and how we market and sell *MuGard*, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation, or other sanctions. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition and results of operations.

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

If we fail to comply with any federal, state or foreign laws or regulations governing our industry, we could be subject to a range of regulatory actions that could adversely affect our ability to commercialize our

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products, harm or prevent sales of our products, or substantially increase the costs and expenses of commercializing and marketing our products, all of which could have a material adverse effect on our business, financial condition and results of operations.

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

As a condition of reimbursement by various U.S. federal and state healthcare programs for *Feraheme*, we are required to calculate and report certain pricing information to U.S. federal and state healthcare agencies. We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program, and we have obligations to report Average Sales Price, or 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*, 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 twelve 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 ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B drug discount program. 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 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*. This ASP information forms the basis for reimbursement for the majority of our current *Feraheme* business 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. It also requires us to make an assessment of whether these agreements are deemed to be for *bona fide* services and that the services are deemed to be at fair market value in our industry and for our products. These calculations are very complex and could involve the need for us to unbundle or reallocate discounts or rebates offered over a multiple quarters or across multiple products. Our processes for estimating amounts



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due under these governmental pricing programs involve subjective decisions and estimates. The unbundling of discounts and rebates across multiple reporting periods can 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 Health Care 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 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. 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 program. In the event that CMS terminates our rebate agreement, no federal payments would 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 equity securities, cash from sales of *Feraheme/Rienso*, cash generated by our investing activities, and payments from our licensees. As of March 31, 2014, we had an accumulated deficit of approximately \$473.4 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., 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



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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 twelve months will be from sales of *Feraheme/Rienso* as an IV iron replacement therapeutic agent for use in adult CKD patients in the U.S., royalties we may receive with respect to sales of *Feraheme/Rienso* in the EU and Canada under the Amended Takeda Agreement, and from sales of *MuGard*. We have never independently marketed or sold any products prior to *Feraheme*, and we may not be successful in marketing or selling *Feraheme* or *MuGard* in the U.S. and Takeda may not be successful in marketing or selling *Feraheme/Rienso* outside of the U.S. If we or Takeda are not successful in marketing and selling *Feraheme/Rienso*, if revenues grow more slowly than we anticipate or if our operating expenses exceed our expectations, or if we are otherwise unable to achieve, maintain or increase profitability on a quarterly or annual basis, our business, results of operations and financial condition could be materially adversely affected and the market price of our common stock may decline.

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

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

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

We are a pharmaceutical company focused on marketing commercial products and we plan to expand our 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 portfolio, we will be unlikely to achieve profitability. 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 most of our current senior executives, but such agreements do not guarantee that these executives will remain employed by us for any significant period of time, or at all. For example, in February 2014, our chief commercial officer resigned to pursue another opportunity after only one year with us, which may lead to increased turnover. There is intense competition for qualified personnel in the areas of our activities, and we may not be able to continue to attract and retain the qualified personnel necessary for the development of our business.

Previously implemented workforce reductions could residually harm our ability to attract and retain qualified personnel. In addition, any restructuring plans we may initiate in the future may be disruptive to our operations and could harm our ability to attract and retain qualified key personnel. For example, cost saving measures may distract management from our core business, harm our reputation, or yield unanticipated consequences, such as attrition beyond planned reductions in workforce, increased difficulties in our day-to-day operations, reduced employee productivity and a deterioration of employee morale. Any



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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 or otherwise, could cause significant disruption if we are unable to implement or maintain a sufficient succession plan for certain personnel or departments. Any failure to attract, retain or replace qualified personnel could prevent us from successfully commercializing and developing our products, impair our ability to maintain sales levels and/or support potential sales growth.

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

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

We do not have significant experience in managing and maintaining a supply chain and distribution network, and we are placing substantial reliance on third parties to perform product supply chain services for us. Such services include packaging, warehousing, inventory management, storage and distribution of *Feraheme/Rienso* and *MuGard*. We have contracted with Packaging Coordinators, Inc. (formerly Catalent Pharma Solutions, LLC) to provide certain labeling, packaging and storage services for final U.S., Canadian and Swiss *Feraheme/Rienso* drug product. In addition, we have contracted with Integrated Commercialization Services, Inc. to be our exclusive third-party logistics provider to perform a variety of functions related to the sale and distribution of *Feraheme* in the U.S., including services related to warehousing and inventory management, distribution, chargeback processing, accounts receivable management and customer service call center management. If these or any future third-parties are unable to provide uninterrupted labeling, packaging and storage services or supply chain services, respectively, we may incur substantial losses of sales to wholesalers or other purchasers of our products.

In addition, the packaging, storage and distribution of our products in the U.S. and abroad requires significant coordination among our, Takeda's, and Access'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 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 clinical research organizations, or 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 Access, in the conduct of our business. In addition, we have contracted and plan to continue to contract with



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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/Rienso* sales in additional indications and/or outside of the U.S.

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

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

- The magnitude of U.S. *Feraheme* and *MuGard* sales;
- The loss of a key customer or GPO;
- The impact of any pricing or contracting strategies we have implemented or may implement related to our products, including the magnitude of rebates and/or discounts we may offer, or changes in pricing by our competitors or a new entrant into the market;
- The introduction of new competitive products, such as Injectafer® or generic versions of new or currently available drug therapies;
- Any expansion or contraction of the overall size of the IV iron market, which could result from a number of factors including but not limited to changes in treatment guidelines or practices related to IDA;
- Changes in the actual or perceived safety or efficacy profile of our products, especially in light of the recent complete response letter we received from the FDA, that could cause customers to decrease or discontinue their use of our products or could affect the regulatory status of our products in the U.S. or elsewhere;

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- Changes in the actual or perceived safety or efficacy profile of products that compete with *Feraheme/Rienso* or *MuGard* that could cause our customers to decrease or discontinue their use of our products;
- The timing and magnitude of costs incurred in connection with business development activities or business development transactions into which we may enter;
- Any changes to the mix of our business;
- Changes in buying patterns, fees and inventory levels of our wholesalers, distributors, clinics or hospitals;

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- The timing and magnitude of *Feraheme/Rienso* milestone payments, product sales revenues and royalties we may receive from Takeda under the Amended Takeda Agreement;
- The initiation or outcome of any material litigation or patent challenges to which we are or become a party and the magnitude of costs associated with such litigation;
- The timing and magnitude of costs associated with the commercialization of our products in the U.S., including costs associated with pursuing a broader indication of *Feraheme*, maintaining our commercial infrastructure and executing our promotional and marketing strategies;
- Changes in accounting estimates related to reserves on revenue, returns, contingent consideration, impairment of long-lived assets or other accruals or changes in the timing and availability of government or customer discounts, rebates and incentives;
- The timing and magnitude of costs associated with the manufacture of *Feraheme/Rienso*, including costs of raw and other materials and costs associated with maintaining commercial inventory and qualifying additional manufacturing capacities and alternative suppliers;
- The timing and magnitude of costs associated with our ongoing and planned clinical studies of *Feraheme/Rienso* in connection with our pediatric program, our current or future post-marketing commitments for the EMA and other regulatory agencies, our pursuit of additional indications and our development of *Feraheme/Rienso* in countries outside of the U.S;
- The costs associated with manufacturing batch failures or inventory write-offs due to out-of-specification release testing or ongoing stability testing that results in a batch no longer meeting specifications;
- Changes in reimbursement practices and laws and regulations affecting our products from federal, state and foreign legislative and regulatory authorities, government health administration authorities, private health insurers and other third-party payors;
- The recognition of deferred tax assets during periods in which we generate taxable income; and
- The implementation of new or revised accounting or tax rules or policies.

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

*If the estimates we make, or the assumptions on which we rely, in preparing our 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

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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 about matters that are inherently uncertain. Any significant differences between our actual results and our estimates could materially affect our financial position and results of operations.

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

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

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

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

- Warning letters;
- Civil or criminal penalties;

- Variation, suspension or withdrawal of regulatory approvals;
- Changes to the package insert of our products, such as additional warnings regarding potential side

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effects or potential limitations on the current dosage and administration of *Feraheme/Rienso* or IV irons as a class;

- Requirements to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, or other issues involving our products;
- Implementation of risk mitigation programs 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, Access 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.

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

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

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

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

The market price of our common stock has been, and may continue to be, volatile, and your investment in our stock could decline in value or fluctuate significantly. Our stock price has ranged between \$16.49 and \$28.42 in the fifty-two week period through April 30, 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:

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- Our ability to successfully commercialize *Feraheme* in the U.S. and Takeda's ability to successfully commercialize *Feraheme/Rienso* in licensed territories outside of the U.S.;
- Our ability to increase or maintain sales and utilization of *Feraheme* in the current indication or 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;
- Fluctuations in our net revenue per unit of *Feraheme* 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 or products or product candidates of our competitors, including as a result of the FDA's recent complete response letter addressing our sNDA and any 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 or similar agreements by us or our competitors or the termination of any current or future material collaboration agreements;
- The timing and magnitude of product revenue and actual or anticipated fluctuations in our operating results;
- Changes in or our failure to meet financial estimates published by securities analysts or our own publicly disclosed financial guidance;
- Increases or decreases in our operating expenses or our gross margin on our products;
- Developments in patents or other proprietary rights by or for the benefit of us or our competitors, such as the recent decision by the EPO regarding our European ferumoxytol patent or an ANDA filing by a generic entrant;
- Our ability to successfully integrate *MuGard* with our business and market *MuGard* in the U.S.;

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- The availability of reimbursement coverage for our products or changes in the reimbursement policies of U.S. or foreign governmental or private payors;
- Public announcements of U.S. or foreign regulatory actions with respect to our products or products or product candidates of our competitors;
- The status or results of clinical trials for *Feraheme* or products or product candidates of our competitors;
- The acquisition, development or regulatory approvals of technologies, product candidates or products by us or our competitors;
- Cash milestones earned, if any, under the Amended Takeda Agreement;
- The initiation or outcome of any material litigation or patent challenges to which we are or may become a party;

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- 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 April 30, 2014, seven financial analysts publish reports about us and our business. We do not control these or any other analysts. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. In addition, our future operating results are subject to substantial uncertainty, and our stock price could decline significantly if we fail to meet or exceed analysts' forecasts and expectations. If any of the analysts who cover us downgrade our stock, 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.

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

In February 2014, we publicly provided 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.

***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.***

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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.

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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 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, 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;
- 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 may need additional capital to achieve our business objectives.***

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

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

- Our ability to obtain regulatory approval for *Feraheme/Rienso* to treat IDA regardless of the underlying cause both within the U.S. and outside of the U.S., particularly in the EU, 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;
- The magnitude and growth rate of U.S. *Feraheme* sales over prior periods;

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

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- The success, costs and structure of any business or corporate development initiatives to bring additional products into our portfolio;
- The outcome of and costs associated with any material litigation or patent challenges to which we are or may become a party;
- Our ability to achieve the various milestones and receive the associated payments under the Amended Takeda Agreement;
- Costs associated with the U.S. commercialization of our products, including costs associated with maintaining our commercial infrastructure, executing our promotional and marketing strategies, and conducting our required pediatric clinical studies and any post-marketing clinical studies for *Feraheme*;
- The timing and magnitude of costs associated with qualifying additional manufacturing capacities and alternative suppliers;
- Our ability to maintain successful collaborations with our licensees and/or to enter into additional alternative strategic relationships, if necessary; and
- Our ability to raise additional capital on terms and within a timeframe acceptable to us, if necessary.

We estimate that our cash resources as of March 31, 2014, combined with cash we currently expect to receive from sales of *Feraheme/Rienso* and *MuGard*, earnings on our investments, and royalty and milestone payments we may receive from Takeda will be sufficient to finance our currently planned operations for at least the next twelve months. We may require additional funds or need to establish additional alternative strategic arrangements to execute a business development transaction. We may at any time seek funding through additional arrangements with collaborators through public or private equity or debt financings. We may not be able to obtain financing or to secure alternative strategic arrangements on acceptable terms or within an acceptable timeframe, if at all.

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 March 31, 2014, we had \$200.9 million in cash and cash equivalents and \$184.6 million in investments. These investments are subject to general credit, liquidity, market and interest rate risks, which have been and may, in the future, be exacerbated by a U.S. and/or global financial crisis. We may realize losses in the fair value of certain of our investments or a complete loss of these investments if the credit markets tighten, which would have an adverse effect on our results of operations, liquidity and

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financial condition.

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.

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

We are subject to changing rules and regulations of U.S. federal and state government as well as the stock exchange on which our common stock is listed. These entities, including the Public Company Accounting Oversight Board, the NASDAQ Stock Market, or NASDAQ, and the Securities and Exchange Commission, or the SEC, have issued a significant number of new and increasingly complex requirements and regulations over the last several years and continue to develop additional regulations and requirements in response to laws enacted by Congress. Our efforts to comply with these requirements have resulted in, and are likely to continue to result in, an increase in our expenses and a diversion of management's time from other business activities.

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

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

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

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

disruptive to our business.

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***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. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, NASDAQ or other regulatory authorities.

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

A purported class action complaint was originally filed on March 18, 2010 in the U.S. District Court for the District of Massachusetts, entitled Silverstrand Investments et. al. v. AMAG Pharm., Inc., et. al., Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Chief Financial Officer, the then-members of our Board of Directors, or Board, and certain underwriters in our January 2010 offering of common stock violated certain federal securities laws, specifically Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, and that our former President and Chief Executive Officer and former Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged omissions in a registration statement filed in January 2010. The plaintiffs sought unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. On August 11 and 15, 2011, respectively, the District Court issued an Opinion and Order dismissing the SAC with prejudice for failure to state a claim upon which relief could be granted. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the U.S. Court of Appeals for the First Circuit, or the Court of Appeals. The Court of Appeals heard oral argument on May 11, 2012. On February 4, 2013, the Court of Appeals affirmed in part and reversed in part the District Court's Opinion and Order and remanded the case to the District Court. On February 19, 2013, we filed a Petition for Panel Rehearing and Rehearing *En Banc*, which was denied on March 15, 2013. On March 22, 2013, we filed a Motion to Stay the Mandate remanding the case to the District Court pending review by the U.S. Supreme Court of the Court of Appeals' February 4, 2013 decision. The Court of Appeals granted the Motion to Stay the Mandate on April 8, 2013. On June 13, 2013, we filed a Petition for a Writ of Certiorari, or the Petition, with the U.S. Supreme Court seeking review of the Court of Appeal's decision and to have that decision overturned. On October 7, 2013 the U.S. Supreme Court denied our Petition, resulting in the case's return to the District Court for further proceedings relative to the SAC's surviving claims. 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.



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brief in support of our Motion on December 27, 2013. On April 7, 2014, the District Court denied our renewed Motion to Dismiss. A status conference is scheduled for May 14, 2014. Whether or not the plaintiff's appeal is successful, this type of litigation is often expensive and diverts management's attention and resources, which could adversely affect the operation of our business. If we are ultimately required to pay significant defense costs, damages or settlement amounts, such payments could adversely affect our operations.

We may also be the target of similar litigation in the future. Any future litigation could result in substantial costs and divert our management's attention and resources, which could cause serious harm to our business, operating results and financial condition. Though we maintain liability insurance, if any costs 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/Rienso* is used over longer periods of time by a wider group of patients taking numerous other medicines or by patients with additional underlying health problems, the likelihood of adverse drug reactions or unintended side effects, including death, may increase. While these adverse events are rare, all IV irons, including *Feraheme/Rienso*, can cause patients to experience serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and/or fatal. Although we maintain product liability insurance coverage for claims arising from the use of our products in clinical trials and commercial use, coverage is expensive, and we may not be able to maintain sufficient insurance at a reasonable cost, if at all. Product liability claims, whether or not they have merit, could also decrease demand for our products, subject us to product recalls or harm our reputation, cause us to incur substantial costs, and divert management's time and attention.

***Our shareholder rights plan, certain provisions in our charter and by-laws, certain contractual relationships and certain Delaware law provisions could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove 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 become exercisable generally upon the earlier of 10 days after a person or group acquires 20% or more of our outstanding common stock or 10 business days after the announcement by a person or group of an intention to acquire 20% of our outstanding common stock via tender offer or similar transaction. The shareholder rights plan could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which stockholders might otherwise receive a premium for their shares over then-current prices.

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

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



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

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

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

## **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

The following table provides certain information with respect to our purchases of shares of our stock during the three months ended March 31, 2014:

| Period                                        | Total Number<br>of Shares<br>Purchased (1) | Average Price<br>Paid per<br>Share | Total Number of Shares Purchased<br>as Part of Publicly Announced<br>Plans or Programs (2) | Maximum Number of<br>Shares that May Yet Be<br>Purchased Under the<br>Plans or Programs (2) |
|-----------------------------------------------|--------------------------------------------|------------------------------------|--------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| January 1, 2014 through<br>January 31, 2014   |                                            |                                    |                                                                                            |                                                                                             |
| February 1, 2014 through<br>February 28, 2014 | 3,296                                      | \$ 20.12                           |                                                                                            |                                                                                             |

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|                                         |       |    |       |
|-----------------------------------------|-------|----|-------|
| March 1, 2014 through<br>March 31, 2014 | 443   | \$ | 19.36 |
| Total                                   | 3,739 | \$ | 20.03 |

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(1) Represents shares of our common stock withheld by us to satisfy the minimum tax withholding obligations in connection with the vesting of restricted stock units held by our employees.

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- (2) We do not currently have any publicly announced repurchase programs or plans.

**Item 6. Exhibits**

- (a) **List of Exhibits**

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| Exhibit Number | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4.1            | Base Indenture, dated as of February 14, 2014, by and between AMAG Pharmaceuticals, Inc. and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865).                                                                                                                                                                                                                                                      |
| 4.2            | First Supplemental Indenture, dated as of February 14, 2014, by and between AMAG Pharmaceuticals, Inc. and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865).                                                                                                                                                                                                                                        |
| 4.3            | Form of 2.50% Convertible Senior Note due 2019 (included in Exhibit 4.2)                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 4.4            | Amendment to Rights Agreement, dated as of February 11, 2014, by and between the Company and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865).                                                                                                                                                                                                                                                |
| 10.1 +         | Supply Agreement, dated February 7, 2014, by and between the Company and Takeda Pharmaceuticals International, GMBH A/S, an affiliate of Takeda Pharmaceutical Company Limited. (Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***]). This exhibit has been filed separately with the SEC without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended). |
| 10.2* +        | Form of Employment Agreement between the Company and each executive officer of the Company (other than Mr. Heiden).                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 10.3* +        | Employment Agreement dated as of February 7, 2014 between the Company and Mr. Heiden.                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 10.4           | Underwriting Agreement, dated as of February 11, 2014, among AMAG Pharmaceuticals, Inc. and J.P. Morgan Securities LLC, on its own behalf and as representative of the several underwriters named in Schedule 1 thereto (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865).                                                                                                                                                                  |
| 10.5           | Base Call Option Transaction Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865).                                                                                                                                                                                                               |
| 10.6           | Base Call Option Transaction Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865).                                                                                                                                                                                                                                                   |
| 10.7           | Base Call Option Transaction Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865).                                                                                                                                                                                                                                 |
| 10.8           | Base Warrants Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865).                                                                                                                                                                                                                              |
| 10.9           | Base Warrants Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865).                                                                                                                                                                                                                                                                  |
| 10.10          | Base Warrants Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865).                                                                                                                                                                                                                                                |
| 10.11          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

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Additional Call Option Transaction Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865).

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- 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.
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- 101 + The following materials from AMAG Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 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.

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

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

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

This exhibit includes a schedule identifying the other documents omitted and setting forth the material details in which such documents differ from the exhibit, which is a form agreement, in reliance on Instruction 2 to Item 601 of Regulation S-K.

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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: May 5, 2014

AMAG PHARMACEUTICALS, INC.

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

Date: May 5, 2014

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**EXHIBIT INDEX**

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