

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-K



13002081

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OF
SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended December 31, 2012

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SEC
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)

100 Hayden Avenue

Lexington, Massachusetts

(Address of Principal Executive Offices)

04-2742593

(I.R.S. Employer
Identification No.)

02421

(Zip Code)

(617) 498-3300

(Registrant's Telephone Number, Including Area Code)

SEC
Mail Processing
Section

APR 22 2013

Washington DC
400

Securities registered pursuant to Section 12(b) of the Act: **Common Stock, par value \$0.01 per share, NASDAQ Global Select Market**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. **Yes** **No**

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. **Yes** **No**

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

The aggregate market value of the registrant's voting stock held by non-affiliates as of June 30, 2012 was approximately \$329,200,000 based on the closing price of \$15.40 of the Common Stock of the registrant as reported on the NASDAQ Global Select Market on such date. As of February 15, 2013, there were 21,541,891 shares of the registrant's Common Stock, par value \$0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement to be filed in connection with the solicitation of proxies for the Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

AMAG PHARMACEUTICALS, INC.
FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2012
TABLE OF CONTENTS

PART I

Item 1.	Business	2
Item 1A.	Risk Factors	28
Item 1B.	Unresolved Staff Comments	55
Item 2.	Properties	55
Item 3.	Legal Proceedings	56
Item 4.	Mine Safety Disclosures	57

PART II

Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	58
Item 6.	Selected Financial Data	61
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	62
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	91
Item 8.	Financial Statements and Supplementary Data	93
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	136
Item 9A.	Controls and Procedures	136
Item 9B.	Other Information	136

PART III

Item 10.	Directors, Executive Officers and Corporate Governance	137
Item 11.	Executive Compensation	137
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	137
Item 13.	Certain Relationships and Related Transactions, and Director Independence	137
Item 14.	Principal Accountant Fees and Services	137

PART IV

Item 15.	Exhibits and Financial Statement Schedules	138
----------	--	-----

PART I

Except for the historical information contained herein, the matters discussed in this Annual Report on Form 10-K 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 Annual Report on Form 10-K, words such as “may,” “will,” “expect,” “intend,” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Examples of forward-looking statements contained in this report include statements regarding the following: our expectation to expand our portfolio through the in-license or purchase of additional specialty pharmaceutical products, our expectation that we may receive a decision from the U.S. Food and Drug Administration on our supplemental New Drug Application sometime in the fourth quarter of 2013, our expectation that Takeda Pharmaceutical Company Limited plans to file a Type II Variation with the European Medicines Agency in 2013 for the treatment of iron deficiency anemia in adult patients, our expectation that the enrollment of our ongoing pediatric studies will take several years to complete, our intention to commence a pediatric iron deficiency anemia study once the appropriate dose is determined, our plan to begin enrollment in the second quarter of 2013 for a post-approval trial to assess the safety and efficacy of repeat doses of Feraheme for the treatment of iron deficiency anemia, our expectation that 3SBio, Inc. will begin a clinical trial if approved by the Chinese State Food and Drug Administration, our expectation of costs to be incurred in connection with and revenue sources to fund our future operations, our expectation that the majority of all Feraheme utilization in the U.S. will be in the non-dialysis chronic kidney disease patient population, our expectation that final data from IDA-303 will be available in 2013, 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 intention to no longer commercially manufacture or sell GastroMARK after completion of our obligations to our licensees in the first quarter of 2013, our expectation that we will sell our Cambridge, Massachusetts manufacturing facility in the near future, our expectations regarding the manufacture of all Feraheme/Rienso drug substance and drug product at our third-party manufacturers, our expectations regarding the timing of regulatory approval by the European Medicines Agency on our new assay, our expectations regarding the validity of our European patent and timing of the appeals process, our expectation that dialysis sales will not be significant in 2013, our expectation that our reserves as a percentage of gross sales will increase slightly in 2013, our expectation that increases in the Branded Drug Fee under the Health Care Reform Act will not be material to our results of operations or financial condition, our expectation that our license fee and other collaboration revenues will decrease in 2013, our expectation that we will not achieve new milestones under the Amended Takeda Agreement in 2013, our expectation that our costs of product sales as a percentage of net product sales and royalties will decrease in 2013, our expectation that our research and development expenses will decrease in 2013, our expectations regarding the amount of external expenses we expect to incur and the timing of our planned research and development projects, our expectation that selling, general and administrative expenses will remain relatively stable in 2013, our expectation regarding our dividend and interest income, our expectations regarding our short- and long-term liquidity and capital requirements and our ability to finance our operations, our expectations regarding our future cash flows, our belief regarding the potential impact of the adoption of newly issued and future accounting guidance on our financial statements, our expectations that the aggregate of our cash, cash equivalents and investments balances will decrease in 2013, 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 I, Item 1A below under “Risk Factors” and elsewhere in this Annual Report on Form 10-K. We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the United States Securities and Exchange Commission to publicly update or revise any such statements to reflect any change in company expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

ITEM 1. BUSINESS:

Overview

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a specialty pharmaceutical company focused on the development and commercialization of *Feraheme*[®] (ferumoxytol) Injection for Intravenous, or IV, use to treat iron deficiency anemia, or IDA. 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 commercial sale of *Feraheme* in the U.S. in July 2009 through our own commercial organization, including a specialty sales force. We sell *Feraheme* to authorized wholesalers and specialty distributors, who in turn, sell *Feraheme* to healthcare providers who administer *Feraheme* primarily within hospitals, hematology and oncology centers, and nephrology clinics.

We are working to continue to grow *Feraheme* in the U.S. CKD market and to drive additional growth of *Feraheme* through both international and label expansion. To further build our business, we intend to expand our portfolio through the in-license or purchase of additional marketed specialty pharmaceutical products. 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 may also pursue more strategic transactions which complement our future market expansion goals for *Feraheme*.

International Expansion

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

Label Expansion

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. in 2012, approximately 800,000 grams of IV iron were administered for the treatment of non-dialysis patients with IDA. We believe that approximately half, or 400,000 grams, of the IV iron administered in the U.S. is for the treatment of non-dialysis patients with CKD and the other half is for non-CKD patients with IDA due to other causes, including patients with gastrointestinal diseases or disorders, abnormal uterine bleeding, or AUB, inflammatory diseases, and chemotherapy-induced anemia.

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

In December 2012, we submitted a supplemental new drug application, or sNDA, to the FDA, seeking approval for *Feraheme* for the treatment of IDA in adult patients who have failed to or could not use oral iron. The sNDA submission was primarily based on the data from IDA-301 and IDA-302. In addition, the sNDA included data from an interim analysis of IDA-303 and a previously completed post-approval clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron. We believe that approval for *Feraheme* for this expanded indication would effectively double the market opportunity for *Feraheme*, by allowing us to access the half of the IV iron market that is beyond our current approved indication. Assuming a normal review cycle, we expect a decision from the FDA on our sNDA sometime in the fourth quarter of 2013.

We expect that Takeda will file a Type II Variation, which is the EU equivalent of a U.S. sNDA, with the European Medicines Agency, or EMA, in 2013 seeking marketing approval for *Rienso* for the treatment of IDA in adult patients.

Takeda Collaboration

In March 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme/Rienso* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey. In June 2012, we entered into an amendment to the Takeda Agreement, or the Amended Takeda Agreement, which removed the Commonwealth of Independent States from the territories under which Takeda has the exclusive rights to develop and commercialize *Feraheme/Rienso*. In addition, the Amended Takeda Agreement modified the timing and pricing arrangements for a supply agreement to be entered into between us and Takeda in the future, the terms related to primary and secondary manufacturing for drug substance and drug product, certain patent related provisions, and the re-allocation of certain of the agreed-upon milestone payments. In 2012, we received a total of \$33.0 million in milestone payments from Takeda associated with the EU approval and the commercial launches of *Feraheme/Rienso* in Canada and the EU. In addition, in connection with the commercial launches of *Feraheme/Rienso* by Takeda, we recorded revenue from product sales to Takeda and royalties on sales by Takeda of \$0.1 million in 2012.

Clinical Development of Feraheme

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

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 two pediatric studies needed to meet the requirements of the Pediatric Research Equity Act in the U.S. described above, and two additional pediatric studies requested by the EMA. These studies include a rollover 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 two ongoing pediatric studies of *Feraheme* for the treatment of IDA in pediatric CKD patients, described above. The amendment to our pediatric investigation plan in 2012 was intended to increase the rate of enrollment for these studies through modifications to the patient entry criteria.

As part of our obligations under the Amended Takeda Agreement and as part of our post-approval commitments to the EMA, we are planning to initiate a multi-center clinical trial to determine the safety and efficacy of repeat doses of ferumoxytol for the treatment of IDA in patients with hemodialysis dependent CKD. As part of the post-approval commitment we made to the EMA as a condition of the approval of the MAA for ferumoxytol in the EU this study includes a treatment arm with iron sucrose as well as a magnetic resonance imaging, or MRI, study which will 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. We currently expect enrollment to begin in the second quarter of 2013. The costs related to the MRI portion of this study are subject to our established cost sharing arrangement with Takeda.

From time to time, we or our licensees may sponsor pilot clinical studies or collaborate with investigators on their research ideas to evaluate the safety and efficacy of Feraheme in new indications or alternative dosing regimens.

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

In December 2009, our licensee in China, 3SBio Inc., or 3SBio, filed an application with the Chinese State Food and Drug Administration, or the SFDA, to obtain approval to begin a clinical trial necessary to file for marketing approval of *Feraheme* in China. If approved by the SFDA, 3SBio plans to commence a multi-center randomized efficacy and safety study of *Feraheme* in China involving approximately 200 CKD patients.

Other information

Prior to the 2009 U.S. approval and commercial launch of *Feraheme*, we devoted substantially all of our resources to our research and development programs. Since then, we have incurred substantial costs related to the commercialization and development of *Feraheme*. We expect to continue to incur significant expenses as we continue to manufacture, market and sell *Feraheme/Rienso* as an IV iron replacement therapeutic for use in adult CKD patients in the U.S., to seek marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients, and to continue to obtain marketing approval for *Feraheme* in countries where *Feraheme/Rienso* has yet to receive approval. Prior to the U.S. commercial launch of *Feraheme*, we financed our operations primarily from the sale of our equity securities, cash generated by our investing activities, and payments from our licensees. Since 2009, our revenues have been primarily attributable to product sales of *Feraheme/Rienso*, along with milestone and license fee payments from Takeda. We currently expect to fund our future operations from cash from sales of *Feraheme* in the U.S., milestone payments we expect to earn from Takeda, product sales and royalties we may receive with respect to sales of *Feraheme/Rienso* outside of the U.S., cash generated by our investing activities, and the sale of our equity or debt securities, if necessary. As of December 31, 2012, we had an accumulated deficit of approximately \$456.7 million and a cash, cash equivalents and investments balance of approximately \$227.0 million.

Our common stock trades on the NASDAQ Global Select Market, or NASDAQ, under the trading symbol "AMAG."

Our Core Technology

Our core technology is based on coated superparamagnetic iron oxide particles and their characteristic properties. Our core competencies include the ability to design such particles for particular applications and to manufacture the particles in controlled sizes. Our technology and expertise enable us to synthesize, sterilize and stabilize these iron oxide particles in a manner necessary for use in pharmaceutical products such as IV iron replacement therapeutics.

Our iron oxide particles are composed of bioavailable iron that is easily utilized by the body and incorporated into the body's iron stores. As a result, our core technology is well suited for use as an IV iron replacement therapy product. Our rights to our technology are derived from and/or protected by license agreements, patents, patent applications and trade secret protections. See "Patents and Trade Secrets."

Products

The following table summarizes the uses and potential uses of ferumoxytol, the names of our principal licensees, the current U.S. and foreign regulatory status, and the primary markets for ferumoxytol.

Product	Uses/Potential Uses	Licensees	U.S. Regulatory Status	Foreign Regulatory Status
Feraheme® (ferumoxytol) Injection	IV iron replacement therapeutic agent for the treatment of IDA in adult patients with CKD.	Takeda (Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey). 3SBio (China).	Approved and marketed.	Approved and marketed as <i>Feraheme</i> in Canada. Approved and marketed as <i>Rienso</i> in the European Union and Switzerland. Filed for CKD registrational trial with the SFDA in China, December 2009.
Feraheme® (ferumoxytol) Injection	IV iron replacement therapeutic agent in patients with IDA, regardless of the underlying cause.	Takeda (Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey). 3SBio (China) (option to extend license into additional therapeutic indications).	sNDA filed in December 2012.	Type II Variation expected to be filed with the EMA by Takeda in 2013.

For a discussion of the substantive regulatory requirements applicable to the development and regulatory approval process in the U.S. and other countries, see "Government Regulation."

Feraheme for the treatment of IDA in patients with CKD

Overview

In June 2009, *Feraheme* was approved for marketing in the U.S. by the FDA for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. In July 2009, we began to market and sell *Feraheme* in the U.S. in both the dialysis and non-dialysis CKD markets, including to nephrologists, hematologists, dialysis organizations, hospitals and other end-users who treat patients with CKD. Beginning in 2010, due to changes in the way the federal government reimburses providers

for the care of dialysis patients, the utilization of *Feraheme* shifted from primarily dialysis patients to non-dialysis patients. Accordingly, we have since focused our commercial efforts entirely on building *Feraheme* utilization in non-dialysis CKD patients. We anticipate the majority of all *Feraheme* utilization in the U.S. will continue to be in the non-dialysis CKD patient population until, and if, the Company achieves a broader label to include non-CKD patients.

In December 2011, ferumoxytol was granted marketing approval in Canada, under the trade name *Feraheme*, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. In June 2012, the European Commission granted marketing authorization for ferumoxytol, under the trade name *Rienso*, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. The marketing authorization is valid in the current EU member states as well as in Iceland and Norway. In August 2012, ferumoxytol was granted marketing approval in Switzerland under the trade name *Rienso* for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. Under our amended agreement with Takeda, Takeda has an exclusive license to market and sell ferumoxytol in Canada, the EU and Switzerland, as well as certain other geographic territories.

Chronic kidney disease, anemia, and iron deficiency

Based on data contained in a 2007 publication in the *Journal of the American Medical Association*, it is estimated that approximately 10 to 15% of the U.S. adult population is affected by CKD, a condition generally characterized by damaged kidneys, or a reduction in kidney function below 50% of normal. Anemia, a common condition among CKD patients, is associated with cardiovascular complications, decreased quality of life, hospitalizations, and increased mortality. Anemia develops early during the course of CKD and worsens with advancing kidney disease. Iron deficiency is a common cause of anemia in CKD patients and can result from multiple blood draws, hospitalizations and interventional procedures, gastrointestinal bleeding, or poor nutritional intake. Regardless of the cause of anemia, iron replacement therapy is essential to increase iron stores and raise hemoglobin levels. Iron is also essential for effective treatment with erythropoiesis stimulating agents, or ESAs, which are commonly used in anemic patients to stimulate red blood cell production. Based on data contained in a 2009 publication in the *Journal of the American Society of Nephrology*, we estimate there are approximately 1.6 million adults in the U.S. with IDA and stages 3 through 5 CKD, who are patients in the later stages of CKD but not yet on dialysis and could therefore benefit from receiving iron.

Currently there are two methods used to treat IDA in CKD patients: oral iron supplements and IV iron. Oral iron is currently the first line iron replacement therapy of choice of most physicians in both the U.S. and abroad. However, oral iron supplements are often not absorbed well by the gastrointestinal tract and frequently have unpleasant side effects, such as constipation, diarrhea, and cramping, which can cause patients to stop taking their medication. In addition, it can take an extended time for hemoglobin levels to improve following the initiation of oral iron treatment, and even then may not reach the targeted hemoglobin levels. Conversely, iron given intravenously allows larger amounts of iron to be provided to patients while avoiding many of the side effects and treatment compliance issues associated with oral iron, and can result in faster rises in hemoglobin levels. The administration of IV iron has been shown to be effective in treating anemia either when used alone and also in combination with an ESA. Current U.S. treatment guidelines indicate that treating first with iron alone may delay, reduce or eliminate the need for ESA therapy. We believe that a small fraction of non-dialysis CKD patients in the U.S. with IDA are currently being treated with IV iron, and thus a significant opportunity remains to grow the market for IV iron in this patient population.

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

IDA not associated with CKD is widely prevalent in many different patient populations. For many of these patients, treatment with oral iron is unsatisfactory. These patients include patients with

gastrointestinal diseases or disorders, women with AUB, patients with inflammatory diseases, and cancer patients. It is estimated that more than 4 million patients in the U.S. have IDA (CKD and non-CKD). Currently, we estimate that approximately 5 to 10% of these patients are treated with IV iron.

In December 2012, we submitted a sNDA to the FDA for *Feraheme* to expand the approved indication for ferumoxytol beyond the current indication for treatment of IDA in adult patients with CKD to adult IDA patients who have failed or could not use oral iron. The sNDA included data from two controlled, multi-center phase III clinical trials, IDA-301 and IDA-302, including more than 1,400 patients, which served as the primary data supporting the safety and efficacy of ferumoxytol for the treatment of IDA in this target patient population. In addition, the sNDA included data from an interim analysis of the IDA open-label extension study, IDA-303, and a previously completed post-approval clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron. Assuming a standard review cycle, we expect a decision from the FDA on our sNDA sometime in the fourth quarter of 2013.

We expect that Takeda will file a Type II Variation, which is the EU equivalent of a U.S. sNDA, with the EMA in 2013 seeking marketing approval for *Rienso* for the treatment of IDA in adult patients.

IDA-301 was a double-blind, placebo-controlled trial designed to compare the safety and efficacy of two doses of 510 milligrams each of *Feraheme* to that of placebo in a total of 808 patients with IDA at 136 sites in the U.S., Canada, India, Latvia, Hungary, and Poland. The patients enrolled in this study had a history of unsatisfactory response to, or could otherwise not use, oral iron and had IDA associated with various conditions including gastrointestinal diseases or disorders, AUB, inflammatory diseases, and chemotherapy-induced anemia.

Patients in this study were randomized to receive a one gram IV course of either *Feraheme* or saline as placebo and the study was designed to demonstrate superiority on efficacy. Of the 808 patients enrolled in this study, 608 patients were randomly assigned to receive *Feraheme* and 200 were randomly assigned to receive placebo. The demographics and all baseline parameters of patients who participated in this study were well balanced between the two treatment groups. The primary efficacy endpoint of the study for the FDA was the proportion of patients who achieved an increase in hemoglobin of greater than 2.0 grams per deciliter at any time from the date of determination of their baseline hemoglobin level, or baseline, to the fifth week following administration of the study drug, or week five. The primary efficacy endpoint of the study for the EU regulatory authorities was the mean change in hemoglobin from baseline to week five. Patients enrolled in this study were eligible to enter IDA-303, a recently completed open-label extension study to evaluate repeat dosing with *Feraheme*. We have closed enrollment in this extension study with 637 patients. These patients were followed for six months and were eligible to receive two doses of 510 milligrams each of *Feraheme* whenever they met treatment criteria. Final data from IDA-303 is expected to be available in 2013.

In the IDA-301 study, *Feraheme* achieved both primary efficacy endpoints evaluated. Patients treated with *Feraheme* in the IDA-301 trial achieved a statistically significant mean increase in hemoglobin at week five of 2.7 grams per deciliter, as compared to a mean increase of 0.1 grams per deciliter in patients who received placebo. In addition, a greater than 2.0 grams per deciliter increase in hemoglobin at any time from baseline to week five was achieved in a statistically significantly greater proportion of patients treated with *Feraheme* in this study, 81.1%, as compared with 5.5% of patients who received placebo. Further, data from IDA-301 also showed a direct correlation between a rise in hemoglobin and improvement in fatigue, as assessed by patient reported outcome measures.

No new safety signals were observed with *Feraheme* in the IDA-301 trial and the types of reported AEs were consistent with those seen in our previous studies and those contained in the approved U.S. package insert for *Feraheme*. Overall, AEs were reported in 49.2% of *Feraheme*-treated patients as

compared to 43.0% of patients who received placebo. Patients in both treatment groups experienced protocol-defined AEs of special interest, including mild to severe hypotension or hypersensitivity reactions, ranging from fever alone to an anaphylactoid reaction. Of the *Feraheme*-treated patients, 3.6% experienced protocol-defined AEs of special interest as compared to 1.0% of patients who received placebo. Cardiovascular AEs were reported in 0.8% of *Feraheme*-treated patients, all of which were considered unrelated to study drug by the investigators, and none were reported in the placebo group. Serious adverse events, or SAEs, were reported at a comparable frequency in both treatment groups, with SAEs reported in 2.6% of *Feraheme*-treated patients and 3.0% of patients who received placebo. Four of the SAEs in *Feraheme*-treated patients, or 0.7%, were reported as related to study drug by investigators.

IDA-302 was a multi-center, open-label, active-controlled international clinical trial designed to compare treatment with *Feraheme* to treatment with IV iron sucrose in a total of 605 patients with IDA at 74 sites in Europe, Asia Pacific and Australia. The patients enrolled in the study had a history of unsatisfactory response to, or could not otherwise use, oral iron therapy and had IDA associated with various conditions including gastrointestinal diseases or disorders, AUB, inflammatory diseases, and chemotherapy-induced anemia.

Patients in IDA-302 were randomized to receive a one gram IV course of either *Feraheme* or iron sucrose and the study was designed to demonstrate non-inferiority on efficacy. Of the 605 patients enrolled in the study, 406 patients were randomly assigned to receive *Feraheme* and 199 were randomly assigned to receive iron sucrose. The demographics and all baseline parameters of patients who participated in this study were well balanced between the two treatment groups. The primary efficacy endpoint of the study for the FDA was the proportion of patients who achieved a greater than or equal to 2.0 grams per deciliter increase in hemoglobin at any time from baseline to week five. The primary efficacy endpoint of the study for EU regulatory authorities was the mean change in hemoglobin from baseline to week five.

In the IDA-302 study, *Feraheme* achieved both primary efficacy endpoints evaluated. Patients treated with *Feraheme* in the IDA-302 trial achieved a mean increase in hemoglobin at week five of 2.7 grams per deciliter as compared to a mean increase of 2.4 grams per deciliter in patients treated with IV iron sucrose. In addition, an increase of 2.0 grams per deciliter or more in hemoglobin at any time from baseline to week five was achieved in 84% of patients treated with *Feraheme* as compared to 81% of patients treated with IV iron sucrose.

No new safety signals were observed with *Feraheme* in the IDA-302 trial and the types of reported AEs were consistent with those seen in our previous studies and those contained in the approved U.S. package insert for *Feraheme*. Overall, AEs experienced by patients in the two treatment groups were comparable, with AEs reported in 41.4% of *Feraheme*-treated patients as compared to 44.2% of patients treated with IV iron sucrose. Patients in both treatment groups experienced protocol-defined AEs of special interest, including moderate to severe hypotension or hypersensitivity reactions, ranging from fever alone to an anaphylactoid reaction. Of the *Feraheme*-treated patients, 2.7% experienced protocol-defined AEs of special interest as compared to 5.0% of patients who received IV iron sucrose. Cardiovascular AEs were comparable between the two treatment groups, with cardiovascular AEs reported in 1.0% of both the *Feraheme*-treated patients and the patients in the IV iron sucrose group. SAEs were reported in 4.2% of *Feraheme*-treated patients as compared to 2.5% of patients treated with IV iron sucrose. Two of the SAEs in *Feraheme*-treated patients, or 0.5%, were reported as related to study drug by the investigators.

Multiple underlying conditions are associated with the development of IDA including gastrointestinal diseases or disorders, AUB, inflammatory diseases, and chemotherapy-induced anemia. IDA in patients with gastrointestinal diseases or disorders is likely caused by blood loss and/or the inadequate intake or absorption of iron due primarily to bariatric surgeries, inflammatory bowel disease, chronic gastrointestinal bleeding and certain malabsorption disorders. Based on market research, we estimate that more than 500,000 patients who have gastrointestinal diseases or disorders in the U.S. also have IDA. Oral iron has been used to treat IDA in patients with gastrointestinal diseases or disorders, but its efficacy is variable due to inconsistent bioavailability and absorption, the high incidence of gastrointestinal side effects and patient noncompliance.

AUB is defined as chronic, heavy, or prolonged uterine bleeding that can result from multiple causes, including uterine abnormalities, blood disorders, pregnancy, intrauterine devices, medications, and heavy menstrual bleeding. IDA is commonly associated with AUB, and based on market research, we estimate that approximately 1 million women in the U.S. have both IDA and AUB and are treated with a variety of surgical and/or medical management techniques. IDA in patients with AUB, regardless of the cause, requires treatment with iron supplementation, either by oral or IV administration.

IDA is also common in patients with cancer, and based on market research, we estimate that nearly 400,000 cancer patients in the U.S. have IDA. Iron supplementation through both oral and IV administration plays an important role in treating anemia in cancer patients. While there may be some differences in the underlying causes of anemia and iron deficiency in cancer patients who are receiving chemotherapy and those who are not, patients in both categories may develop IDA due to blood loss and/or the inadequate intake or absorption of iron. Oral iron has been used to treat IDA in cancer patients, but its efficacy is variable due to inconsistent bioavailability and poor absorption, a high incidence of gastrointestinal side effects, potential interactions with other treatments, and patient noncompliance. IV iron has been shown in small clinical trials to be well tolerated in the cancer patient population in both patients who are receiving chemotherapy and those who are not.

Currently, only INFeD® and Dexferrum® are approved in the U.S. for the treatment of a broader group of patients with IDA in whom oral iron is unsatisfactory or impossible. All of the other currently marketed IV iron products, including *Feraheme*, are only approved in the U.S. for either the treatment of IDA in CKD patients or CKD patients on hemodialysis. We believe that a new entrant into the broader IDA U.S. market could significantly increase the number of patients who will be treated with IV iron.

GastroMARK

GastroMARK®, which is marketed and sold under the trade name Lumirem® outside of the U.S., is our oral contrast agent used for delineating the bowel during MRI and is approved and marketed in the U.S., Europe and other countries through our licensees. In the second quarter of 2012, we terminated our commercial license agreements for *GastroMARK*. Following the completion of our obligations under these agreements in the first quarter of 2013, we intend to cease commercially manufacturing or selling *GastroMARK*. Pursuant to the terms of the respective termination agreements, in June 2012, we paid our licensees aggregate termination fees of \$1.6 million, which we recorded in selling, general and administrative expenses in our consolidated statement of operations.

Licensing, Marketing and Distribution Arrangements

Although we are commercializing *Feraheme* in the U.S. through our own commercial organization, our commercial strategy also includes the formation of collaborations with other companies to facilitate

the development, manufacture, sale and distribution of our products in the U.S. and abroad. At present we are parties to the following collaborations:

Takeda

In March 2010, we entered into the Takeda Agreement, under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme/Rienso* as a therapeutic agent in certain agreed-upon territories. In June 2012, we entered into the Amended Takeda Agreement, which removed the Commonwealth of Independent States from the territories under which Takeda has the exclusive rights to develop and commercialize *Feraheme/Rienso*. In addition, the Amended Takeda Agreement modified the timing and pricing arrangements for a supply agreement to be entered into between us and Takeda in the future, the terms related to primary and secondary manufacturing for drug substance and drug product, certain patent related provisions, and the re-allocation of certain of the agreed-upon milestone payments.

In December 2011, ferumoxytol was granted marketing approval in Canada, under the trade name *Feraheme*, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. In June 2012, the European Commission granted marketing authorization for ferumoxytol under the trade name *Rienso* for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. The marketing authorization is valid in the current EU member states as well as in Iceland and Norway. In August 2012, ferumoxytol was granted marketing approval in Switzerland under the trade name *Rienso* for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. During 2012, we received \$33.0 million in milestone payments related to the EU regulatory approval and the commercial launches of *Feraheme/Rienso* in Canada and the EU. In addition, in connection with the commercial launches of *Feraheme/Rienso* by Takeda, we recorded revenue from product sales to Takeda and royalties on sales by Takeda of \$0.1 million in 2012.

Under the Amended Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme/Rienso* and, accordingly, are responsible for supply of *Feraheme/Rienso* to Takeda at a fixed price per unit, which is capped for a certain period of time. We are also responsible for conducting, and bearing the costs related to, certain pre-defined clinical studies with the costs of future modifications or additional studies to be allocated between the parties according to an agreed-upon cost-sharing mechanism. In connection with the execution of the original Takeda Agreement, we received a \$60.0 million upfront payment from Takeda in April 2010. We have received and may also receive additional regulatory approval and performance-based milestone payments, reimbursement of certain out-of-pocket regulatory and clinical supply costs, defined payments for supply of *Feraheme/Rienso*, and tiered double-digit royalties on net product sales in the agreed-upon territories. The remaining milestone payments we may be entitled to receive under the agreement could over time equal up to \$186.0 million. We can make no assurances as to the amount of milestone payments, if any, we will actually receive under the agreement.

Packaging Coordinators, Inc.

In May 2009, we entered into a commercial packaging services agreement with Packaging Coordinators, Inc. (formerly Catalent Pharma Solutions, LLC), or PCI, as amended in January 2013, or the PCI Agreement. Under the provisions of the PCI Agreement, PCI provides certain labeling, packaging and storage services for final U.S. *Feraheme* drug product and storage services for Canadian and Swiss *Feraheme/Rienso* drug product. This agreement will renew automatically for successive established time periods unless either party provides written notice of its desire not to renew within certain time constraints. In addition, either party has the right to immediately terminate the agreement based on certain bankruptcy-related conditions or if the other party materially breaches any provision of this agreement and such breach is not cured within a certain period of time. Further, we may terminate the PCI Agreement for any reason or no reason with ninety days' written notice to PCI. PCI

has two qualified facilities in the U.S., which we can utilize for our labeling, packaging and storage needs. *Rienso* labeling and packaging for sale in the EU and Switzerland is currently conducted in Italy and is the responsibility of Takeda.

Integrated Commercialization Services, Inc.

In October 2008, we entered into a commercial outsourcing services agreement with Integrated Commercialization Services, Inc., or ICS, as amended, or the ICS Agreement. Under the provisions of the ICS Agreement, ICS agreed 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. This agreement, as amended, will continue in effect until January 31, 2014, unless terminated earlier. The term of the agreement may be extended upon written mutual agreement of the parties six months prior to the expiration of the term. In addition, the ICS Agreement may be terminated under certain conditions such as non-payment of amounts due, failure to perform any material obligations under the agreement, or upon the occurrence of certain bankruptcy-related events.

3SBio

In 2008, we entered into a Collaboration and Exclusive License Agreement, or the 3SBio License Agreement, and a Supply Agreement, or the 3SBio Supply Agreement, with 3SBio for the development and commercialization of *Feraheme* as an IV iron replacement therapeutic agent in China. The 3SBio License Agreement grants 3SBio an exclusive license for an initial term of thirteen years to develop and commercialize *Feraheme* as a therapeutic agent in China for an initial indication for the treatment of IDA in patients with CKD and an option to expand into additional therapeutic indications. In consideration of the grant of the license, we received an upfront payment of \$1.0 million. We are eligible to receive certain other specified milestone payments upon regulatory approval of *Feraheme* in China for CKD and other indications. We are also entitled to receive tiered royalties of up to 25% based on net sales of *Feraheme* by 3SBio in China. We retained all manufacturing rights for *Feraheme* under these agreements. In addition, pursuant to the 3SBio Supply Agreement, 3SBio has agreed to purchase from us, and we have agreed to supply to 3SBio, *Feraheme* at a predetermined per unit price for use in connection with 3SBio's development and commercialization obligations for so long as the 3SBio License Agreement is in effect. If approved by the SFDA, 3SBio currently plans to begin a clinical trial necessary to file for marketing approval of *Feraheme* in China.

Manufacturing

In the third quarter of 2012, we ceased our manufacturing operations at our Cambridge, Massachusetts manufacturing facility, where we previously manufactured *Feraheme* for U.S. commercial sale and for use in human clinical trials. We currently rely solely on third parties for the manufacture of *Feraheme/Rienso* for our commercial and clinical requirements of ferumoxytol in the U.S., the EU and Switzerland. Our third-party contract manufacturing facilities are subject to current good manufacturing practices, or cGMP, regulations enforced by the FDA and equivalent foreign regulatory agencies through periodic inspections to confirm such compliance. Although we and Takeda are currently working to establish and qualify alternative manufacturing facilities for both drug substance and finished drug product of *Feraheme/Rienso*, we do not currently have an alternative manufacturer for our *Feraheme/Rienso* drug substance and finished drug product. We target to maintain sufficient inventory levels of our projected U.S. near-term demand of *Feraheme* drug product in order to minimize risks of supply disruption at points in our single source supply chain. We intend to continue to outsource the manufacture and distribution of *Feraheme/Rienso* for the foreseeable future, and we

believe this manufacturing strategy will enable us to direct our financial resources to the commercialization of *Feraheme*.

Prior to ceasing our manufacturing operations in 2012, we manufactured *Feraheme* drug substance and drug product for use in the Canadian market at our Cambridge facility. Although we and Takeda are working to obtain regulatory approval of the manufacturing facilities at our current third-party contract manufacturers to produce *Feraheme* for sale in Canada, we do not currently have manufacturing facilities for this geography. Prior to closing our Cambridge manufacturing facility, we produced what we believe to be sufficient inventory to satisfy Takeda's Canadian supply needs until we have obtained regulatory approval at our third-party manufacturing facilities.

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. 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. In late 2012, we produced a batch of *Rienso* which did not meet our release specifications in the EU. As a result, we are incurring additional costs associated with the development, validation and technology transfer to Takeda of a more accurate assay in order to be able to release this batch and any future batches produced for sale in the EU. This new assay will require review and approval by the EMA, which we expect will occur in the first half of 2013.

Sigma-Aldrich, Inc.

In August 2012, we entered into a Commercial Supply Agreement, or the SAFC Agreement, with Sigma-Aldrich, Inc., or SAFC, pursuant to which SAFC agreed to manufacture and we agreed to purchase from SAFC, the active pharmaceutical ingredient, or API, or the drug product intermediate, or DPI, for use in the finished product of ferumoxytol for U.S. commercial sale, for sale outside of the U.S. by Takeda, as well as for use in clinical trials. Subject to certain conditions, the SAFC Agreement provides that we purchase from SAFC certain minimum quantities of API or DPI each year, but we are not obligated to use SAFC as our sole supplier of API or DPI. In addition, the prices for each batch will decline as batches are produced in greater quantities throughout each year of the agreement. The SAFC Agreement will continue in force until June 22, 2015 and may be extended thereafter for additional two year periods, unless cancelled by us or SAFC within an agreed-upon notice period. The SAFC Agreement may also be terminated by either party at any time in the event of a material breach of the agreement by the other party provided that the breaching party fails to cure such breach within an agreed-upon notice period.

DSM Pharmaceuticals, Inc.

In January 2010, we entered into a Pharmaceutical Manufacturing and Supply Agreement, or the DSM Agreement, with DSM Pharmaceuticals, Inc., or DSM, pursuant to which DSM agreed to manufacture ferumoxytol finished drug product for U.S. commercial sale, for sale outside of the U.S., as well as for use in clinical trials at a fixed price per vial. The DSM Agreement will continue in force until January 13, 2015. The DSM Agreement may be terminated at any time upon mutual written agreement by us and DSM or at any time by us subject to certain notice requirements and early termination fees. In addition, the DSM Agreement may be terminated by either us or DSM in the event of a material breach of the agreement by the other party provided that the breaching party fails to cure such breach within an agreed-upon notice period.

To support the global commercialization of *Feraheme/Rienso*, we have developed a fully integrated manufacturing support system, including quality assurance, quality control, regulatory affairs and inventory control policies and procedures. These support systems are intended to enable us to maintain high standards of quality for our products.

Raw Materials

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 any long-term supply contracts with these third parties. Although certain of our raw or other materials are readily available, others may be obtained only from qualified suppliers. Certain materials used in *Feraheme/Rienso* may from time to time be procured from a single source without a qualified alternative supplier. The qualification of an alternative source may require repeated testing of the new materials and generate greater expenses to us or our third-party manufacturers if materials that we or they 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 or our third-party manufacturers 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 and other materials used to manufacture *Feraheme/Rienso*, 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.

Patents and Trade Secrets

We consider the protection of our technology to be material to our business. Because of the substantial length of time and expense associated with bringing new products through development and regulatory approval to the marketplace, we place considerable importance on obtaining patent and trade secret protection for our products. Our success depends, in large part, on our ability to maintain the proprietary nature of our technology and other trade secrets. To do so, we must prosecute and maintain existing patents, obtain new patents and ensure trade secret protection. We must also operate without infringing the proprietary rights of third parties or allowing third parties to infringe our rights.

Our policy is to aggressively protect our competitive technology position by a variety of means, including applying for patents in the U.S. and in appropriate foreign countries. We currently hold a number of U.S. and foreign patents, which expire at various times through 2020. 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 foreign patents may also be eligible for extension in accordance with applicable law in certain countries.

We also have patent applications pending in the U.S. and have filed counterpart patent applications in certain foreign countries. Although further patents may be issued on pending applications, we cannot be sure that any such patents will be issued on a timely basis, if at all. In addition, any issued patents may not provide us with competitive advantages or may be challenged by others, and the existing or future patents of third parties may limit our ability to commercialize *Feraheme/Rienso*. For example, in July 2010, Sandoz GmbH, or Sandoz, filed with the European Patent Office, or the EPO, an opposition to our previously issued patent that covers ferumoxytol in the EU. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked our European ferumoxytol patent. In December 2012, our notice of appeal was recorded with the EPO, which suspends the revocation of our patent. We will continue to defend the validity of this patent throughout the appeals process, which we expect to take two to three years. In the event the appeals process is unfavorable to us, it could result in a loss of proprietary rights in the EU and may allow other companies in the EU to use our proprietary technology without a license from us, and may also result in a loss of future royalty or milestone payments to us from Takeda. We cannot predict the outcome of our appeal of the EPO decision. 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.

We also rely on the benefits of market exclusivity in protecting our intellectual property rights for *Feraheme* in the U.S. The FDA previously determined that ferumoxytol did not qualify as a new chemical entity, or NCE, and instead granted *Feraheme* a three-year “new use” market exclusivity, which expired in June 2012. In March 2010 and December 2012, we formally requested that the FDA reconsider its determination with respect to *Feraheme*’s NCE status, which, if granted, would provide *Feraheme* with exclusivity until June 2014, or five years from the date of *Feraheme*’s U.S. approval. We cannot give any assurances as to whether the FDA will accept our most recent request for reconsideration, that the FDA will make this reconsideration in a timely manner, or that *Feraheme* will be granted NCE exclusivity. The regulatory approval process for NCE status is discussed in more detail below under the heading “U.S. Approval Process—Marketing Exclusivity” and the associated risks are discussed in more detail in Part I, Item 1A below under “Risk Factors” under the heading, “Competitors could file applications seeking a path to U.S. approval of a generic ferumoxytol.”

Frequently, the unpredictable nature and significant costs of patent litigation leads the parties to settle to remove any uncertainty related to the status of their patents. 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.

Competition

The pharmaceutical and biopharmaceutical industry is intensely competitive and subject to rapid technological change. We and Takeda compete in the marketing and sale of *Feraheme/Rienso* and many of our competitors are large, well-known pharmaceutical companies. One or more of our competitors 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 iron replacement therapy market is highly sensitive to several factors including, but not limited to, the actual or perceived safety and efficacy profile of the available products, the ability to obtain appropriate insurance coverage and reimbursement rates and terms, price competitiveness, and product characteristics such as convenience of administration and dosing regimens.

Although *Feraheme* is approved in the U.S. for the treatment of IDA in adult patients with CKD, including both dialysis and non-dialysis CKD patients, our U.S. commercial strategy is now entirely focused on growing the utilization of *Feraheme* in non-dialysis dependent adult CKD patients with IDA. We believe there is a significant opportunity in the U.S. for *Feraheme* for the treatment of IDA in CKD patients not yet on dialysis. The U.S. non-dialysis IV iron market is comprised primarily of three sites of care where a substantial number of CKD patients are treated: hematology and oncology centers, hospitals, and nephrology clinics.

There are currently two iron replacement options for treating IDA in CKD patients: oral iron supplements and IV iron. The National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative guidelines recommend either oral or IV iron for peritoneal dialysis patients and non-dialysis patients with stages 1 through 5 CKD. Oral iron is currently the first-line iron replacement therapy of choice of most physicians in both the U.S. and abroad. However, oral iron supplements are poorly absorbed by many patients, which may adversely impact their effectiveness, and are associated with certain side effects that may adversely affect patient compliance in using such products. The alternative to oral iron for the treatment of IDA is IV iron.

Feraheme currently competes with the following IV iron replacement therapies in the U.S. for the treatment of IDA in CKD patients:

- Venofer®, an iron sucrose complex, which is approved for use in hemodialysis, peritoneal dialysis, non-dialysis dependent CKD patients and pediatric CKD patients and is marketed in the U.S. by Fresenius Medical Care North America and American Regent Laboratories, Inc., or American Regent, a subsidiary of Luitpold Pharmaceuticals, Inc., or Luitpold;
- Ferrlecit®, a sodium ferric gluconate, which is marketed by Sanofi-Aventis U.S. LLC, is approved for use only in hemodialysis patients;
- A generic version of Ferrlecit® marketed by Watson Pharmaceuticals, Inc., or Watson;
- INFeD®, an iron dextran product marketed by Watson, which is approved in the U.S. for the treatment of patients with documented iron deficiency in whom oral iron administration is unsatisfactory or impossible; and
- Dexferrum®, an iron dextran product marketed by American Regent, which is approved in the U.S. for the treatment of patients with documented iron deficiency in whom oral iron administration is unsatisfactory or impossible.

In addition to the currently marketed products described above, *Feraheme* may also compete in the U.S. with Injectafer®, which is known as Ferinject® in Europe and which is discussed below, which is in development in the U.S. for the treatment of IDA. In September 2011, Luitpold submitted an NDA to the FDA seeking marketing approval for Injectafer® for the treatment of IDA. In July 2012, Luitpold received a Complete Response letter from the FDA withholding approval of Injectafer®. If approved in the U.S., Injectafer® is expected to be marketed by American Regent, the current distributor of Venofer®. Pharmacosmos A/S, or Pharmacosmos, the producer of another IV iron, Monofer® (iron isomaltoside 1000), which is approved in Europe, is also conducting clinical trials in the U.S. and may try to gain regulatory approval in the U.S. for Monofer®.

Outside of the U.S., *Feraheme/Rienso* also competes with a number of branded IV iron replacement products, including Venofer®, Ferrlecit®, Monofer®, Ferinject® (ferric carboxymaltose injection) (the brand name for Injectafer® outside the U.S.) and certain other iron dextran and iron sucrose products. Monofer® is an injectable iron preparation developed by Pharmacosmos, which is currently approved for marketing in approximately 23 countries for the treatment of IDA. Ferinject® is an IV iron replacement therapy developed by Vifor Pharma, the pharmaceuticals business unit of the Galenica Group, and is currently approved for marketing in approximately 43 countries worldwide, including 29 countries within Europe, for the treatment of iron deficiency where oral iron is ineffective or cannot be used. In December 2010, Vifor Pharma and Fresenius Medical Care North America announced that they had created a new company which will hold the commercialization rights to Venofer® and Ferinject® outside of the U.S. Venofer® and Ferrlecit® have been marketed in many countries throughout the world, including most of Europe and Canada, for many years. *Feraheme/Rienso* competes primarily with Venofer®, Ferinject® and Ferrlecit® in both the Canadian and European markets. Currently, all other IV iron products currently approved and marketed in the EU are approved for marketing to a broader group of patients with IDA. *Feraheme/Rienso* was approved only for use in 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.

The market opportunity for *Feraheme/Rienso* in the U.S. and abroad could also be negatively affected by approved generic IV iron replacement therapy products that achieve commercial success. For example, in 2011, Watson launched a generic version of Ferrlecit® in the U.S. which is approved for marketing in the U.S. for the treatment of IDA in adult patients and in pediatric patients age six years and older undergoing chronic hemodialysis who are receiving supplemental epoetin therapy. Sagent Pharmaceuticals, Inc. has also indicated its intention to introduce a generic iron sucrose in the

U.S. in the future. There are also a number of approved generic IV iron products in countries outside the U.S. which directly compete with *Feraheme/Rienso*, including a generic version of Venofer®.

The Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Act, requires an applicant whose subject drug is a drug with an FDA listed patent to notify the patent-holder of their application and potential infringement of their patent rights. If an applicant for ferumoxytol notifies us of such application, we would have 45 days upon receipt of that notice to bring a patent infringement suit in federal district court against the applicant seeking approval of a product. If such a suit is commenced, the FDA is generally prohibited from granting approval of an application until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic's favor, or expiration of the patent(s). If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the applicable standards for approval.

A generic version of *Feraheme* can be marketed only with the approval of the FDA of the respective application for such generic version. In December 2012, the FDA issued draft guidance making recommendations regarding establishing bioequivalence with *Feraheme*, pursuant to which a party could seek approval of a generic version of that product through an abbreviated new drug application, or ANDA. 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 ANDA process is discussed in more detail below under the heading "U.S. Approval Process—Marketing Exclusivity."

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 we may receive from Takeda on sales outside of the U.S. Please see the discussion in Part I, Item 1A below under "Risk Factors" under the heading, "*Competitors could file applications seeking a path to U.S. approval of a generic ferumoxytol.*"

For IV iron replacement therapy in patients with CKD, the total therapeutic course of iron typically used in clinical practice is 1,000 milligrams, or one gram. Venofer® is typically administered as a slow intravenous injection over two to five minutes in doses of 100 to 200 milligrams, thus requiring five to ten physician visits to reach a standard one gram therapeutic course. The recommended dose of Ferrlecit® and the generic version of Ferrlecit® is 125 milligrams administered by intravenous infusion over one hour per dialysis session or undiluted as a slow intravenous injection per dialysis session, thus requiring eight physician visits to reach a standard one gram therapeutic course. The recommended dose of INFED® and Dexferrum® is a slow push in 100 milligram doses and require up to ten physician visits to receive a standard one gram therapeutic course. *Feraheme/Rienso* is administered as a 510 milligram injection followed by a second 510 milligram injection three to eight days later, each of which can be administered in less than one minute at a regular office visit without the use of infusion equipment or prolonged medical intervention. In 2011, the FDA required changes to the product labels of Venofer®, Ferrlecit® and *Feraheme*, to include a 30 minute observation period to monitor patients for signs and symptoms of hypersensitivity during and following the administration of these products. There is no observation period for the iron dextran products.

We believe that our and Takeda's ability to successfully compete with other IV iron products in the U.S. and internationally depends on a number of factors, including the actual or perceived safety and efficacy profile of *Feraheme/Rienso* as compared to alternative iron replacement therapeutics, our ability to obtain and maintain favorable pricing, insurance coverage and reimbursement rates and terms for

Feraheme/Rienso, the timing and scope of regulatory approval of *Feraheme/Rienso* for the broad IDA indication and of products or additional indications by our competitors, our ability to implement effective marketing campaigns, the effectiveness of our sales force, our ability to maintain favorable patent protection for *Feraheme/Rienso*, market acceptance of *Feraheme/Rienso*, and our ability to manufacture sufficient quantities of *Feraheme/Rienso* at commercially acceptable costs. In addition, our ability to effectively compete with these products in the U.S. non-dialysis CKD market depends in part upon our ability to gain formulary access in hospitals and effectively promote *Feraheme* within group purchasing organizations, or GPOs, and to physicians who treat non-dialysis CKD patients.

Based on sales data provided to us in February 2013 by IMS Health Incorporated, or IMS, we estimate that the size of the total 2012 U.S. non-dialysis IV iron replacement therapy market was approximately 806,000 grams, which represented an increase of approximately 2% over 2011. Based on this IMS data, the following represents the 2012 and 2011 U.S. market share allocation of the total non-dialysis IV iron market based on the volume of IV iron administered:

	2012 U.S. Non-dialysis IV Iron Market (806,000 grams)	2011 U.S. Non-dialysis IV Iron Market (792,000 grams)
Venofer®	46%	48%
INFeD®	20%	20%
<i>Feraheme</i>	14%	12%
Generic sodium ferric gluconate	10%	5%
Ferrlecit®	7%	11%
Dexferrum®	3%	4%

The market share data listed in the table above is not necessarily indicative of the market shares in dollars due to the variations in prices among the IV iron products.

Sales, Marketing and Distribution

In July 2009, we began U.S. commercial sale of *Feraheme*, which is being marketed and sold in the U.S. 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. 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, we also routinely enter into pricing agreements with GPOs in these markets so the members of the GPOs have access to *Feraheme* and the related discounts. In addition, we outsource a number of our product supply chain services to ICS, our third-party logistics provider, including services related to warehousing and inventory management, distribution, chargeback processing, accounts receivable management and customer service call center management.

Our sales and marketing teams use a variety of common pharmaceutical marketing strategies to promote *Feraheme* including sales calls to purchasing entities, such as hospitals, hematology and oncology centers and nephrology practices in addition to individual physicians or other healthcare professionals, medical education symposia, personal and non-personal promotional materials, local and national educational programs, scientific meetings and conferences and informational websites. In addition, we provide customer service and other related programs for *Feraheme* including physician reimbursement support services, a patient assistance program for uninsured or under-insured patients and a customer service call center.

Our commercial strategy currently focuses on the non-dialysis dependent CKD market in the U.S. Based on data contained in a 2009 publication in the *Journal of the American Society of Nephrology*, we estimate there are 1.6 million adults in the U.S. with stages 3 through 5 CKD and IDA, and we believe

that a small fraction of those patients are currently being treated with IV iron. We believe there is a significant opportunity in this market to provide IV iron to non-dialysis CKD patients, and our sales team has been working to educate physicians who treat CKD patients on the benefits of IV iron and the dosing profile of *Feraheme* in order to change existing treatment paradigms and expand the IV iron use in physicians' offices, clinics, and hospitals where CKD patients are treated for IDA.

Feraheme/Rienso has been granted marketing approval in Canada, the EU, Iceland, Norway and Switzerland for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD and was commercially launched in Canada, Switzerland and the EU in late 2012. Under our amended agreement with Takeda, Takeda is solely responsible for *Feraheme/Rienso* commercialization efforts in these areas including the deployment of a specialized sales force, pricing and reimbursement negotiations with national, provincial or local health authorities and customers, and development of market access strategies.

The following table sets forth customers who represented 10% or more of our total revenues for the years ended December 31, 2012, 2011, and 2010. Revenues from Takeda include collaboration revenue recognized in connection with the Amended Takeda Agreement, milestone payments we received in 2012 and revenues from product sales to Takeda and royalties received from Takeda in 2012.

	Years Ended December 31,		
	2012	2011	2010
AmerisourceBergen Drug Corporation	34%	41%	36%
Takeda Pharmaceuticals Company Limited	31%	13%	<10%
McKesson Corporation	17%	21%	<10%
Cardinal Health, Inc.	12%	13%	<10%
Metro Medical Supply, Inc.	<10%	<10%	21%

Government Regulation

Overview

The development, manufacture and commercialization of pharmaceutical products are subject to extensive regulation by numerous governmental authorities in the U.S. and abroad. In the U.S., the Federal Food, Drug and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations govern, among other things, the research and development, manufacturing, quality control (testing), labeling, record-keeping, approval, storage, distribution, and advertising and promotion of pharmaceutical products. In addition, many of our activities in the U.S. are subject to the jurisdiction of various other federal regulatory and enforcement departments and agencies, such as the Department of Health and Human Services, the Federal Trade Commission and the Department of Justice. Individual states, acting through their attorneys general, have become active as well, seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws. A number of states, along with the federal government, have also enacted, or are considering enacting, legislation to control pharmaceutical marketing activities, such as the federal Physician Payment Sunshine Act, or the Sunshine Act.

Our activities outside of the U.S. are also subject to regulatory requirements governing the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of *Feraheme/Rienso*. These regulatory requirements vary from country to country. The approval process may be more or less rigorous from country to country and the time required for approval may also vary from country to country. In Europe, Canada and some other international markets, the government provides healthcare at low direct cost to consumers and regulates pharmaceutical prices or patient reimbursement levels to control costs for the government-sponsored healthcare system.

Failure to comply with any of the applicable U.S. or foreign regulatory requirements may result in a variety of administrative or judicially imposed sanctions including, among other things, the regulatory agency's refusal to approve pending applications, withdrawals of approval, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of operations, injunctions, fines, civil penalties or criminal prosecution.

The development and approval of a product candidate requires a significant number of years of work and the expenditure of substantial resources, and is often subject to unanticipated delays and may be subject to new legislation or regulations. In addition to complying with requirements as they currently exist, a sponsor could be negatively impacted by changes in the regulatory framework. From time to time, legislation is introduced that could significantly alter laws pertaining to the approval, manufacturing, pricing, and/or marketing of drug products. Even without changes to relevant laws, U.S. and foreign regulatory agencies could release new guidance or revise its implementation of current regulations in a manner that significantly affects us and our products, including our ability to receive marketing approval for new indications for *Feraheme/Rienso*. It is impossible to predict whether legislative changes will be enacted, or whether regulations or guidance will be amended or supplemented, or the potential impact of such changes.

U.S. Approval Process

Clinical Development

Before new human pharmaceutical products may be marketed or sold commercially in the U.S., the FDA requires the following steps: (a) pre-clinical laboratory tests, pre-clinical safety and efficacy studies and formulation studies; (b) the submission to the FDA of an Investigational New Drug Application, or IND, for human clinical testing, which must become effective before human clinical trials may commence; (c) adequate and well-controlled human clinical trials under current good clinical practices to establish the safety and efficacy of the drug for its intended use; (d) submission of an NDA to the FDA; (e) approval and validation of manufacturing facilities used in production of the pharmaceutical product under cGMP; and (f) review and approval of the NDA by the FDA.

Pre-clinical studies include the laboratory evaluation of product chemistry and animal studies to assess the potential safety and efficacy of a product and its formulation. The results of such laboratory tests and animal studies are submitted to the FDA as a part of an IND and are reviewed by the FDA prior to and during human clinical trials. If there are no objections from the FDA within 30 days of filing an IND, a sponsor may proceed with initial studies in human volunteers, also known as clinical trials.

Clinical trials are typically conducted in the following three sequential phases, which may overlap in some instances:

- *Phase I:* Clinical trials which involve the initial administration of the study drug to a small group of healthy human volunteers (or, more rarely, to a group of selected patients with the targeted disease or disorder) under the supervision of a principal investigator selected by the sponsor. These Phase I trials are designed to test for safety, dosage tolerance, absorption, distribution, metabolism, excretion and clinical pharmacology and, if possible, early indications of effectiveness.
- *Phase II:* Clinical trials which involve a small sample of the actual intended patient population and aim to: (a) provide a preliminary assessment of the efficacy of the investigational drug for a specific clinical indication; (b) ascertain dose tolerance and optimal dose range; and (c) collect additional clinical information relating to safety and potential adverse effects.
- *Phase III:* If an investigational drug is found through Phase I and Phase II studies to have some efficacy and an acceptable clinical safety profile in the targeted patient population, Phase III

studies can be initiated. Phase III studies are well-controlled comparative studies designed to gather additional information within an expanded patient population in geographically dispersed clinical trial sites in order to further establish safety and efficacy in conditions that the drug will be used if approved for marketing.

The FDA may suspend clinical trials at any point in this process if it concludes that patients are being exposed to an unacceptable health risk. In addition, clinical trial results are frequently susceptible to varying interpretations by scientists, medical personnel, regulatory personnel, statisticians and others, which may delay, limit or prevent further clinical development or regulatory approvals of a product candidate.

Submission and FDA Review of an NDA

Following the successful completion of adequate and well-controlled human clinical trials, the results of the trials, together with the results of pre-clinical tests and studies, are submitted to the FDA as part of an NDA. The NDA must also include information related to the preparation and manufacturing of the new drug, analytical methods, and proposed product packaging and labeling. When the NDA is submitted, the FDA has 60 days from receipt to determine whether the application is sufficiently complete to merit a substantive review and should therefore be “filed.” If the FDA determines that the application is incomplete, it must notify the sponsor through a “refusal-to-file” letter, and the sponsor then has the option to resubmit the NDA after addressing the concerns raised by the FDA. If the FDA accepts the NDA for filing, the NDA undergoes a series of reviews intended to confirm and validate the sponsor’s conclusion that the drug is safe and effective for its proposed use.

Under the Food and Drug Administration Modernization Act, an NDA is designated for either Standard Review or Priority Review. A Priority Review designation may be given if a new drug offers major advancements in treatment or provides a treatment where no adequate therapy exists. In July 2012, the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, was enacted. The FDASIA includes the reauthorization of the Prescription Drug User Fee Act, or PDUFA, that provides FDA with the necessary resources to maintain a predictable and efficient review process for human drug and biologic products. The FDA has, pursuant to PDUFA, as reauthorized by FDASIA, set a goal that it review and act upon 90% of NDAs with a Standard Review designation within ten months of the FDA’s acceptance of the filing and 90% of NDAs with a Priority Review designation within six months of the filing date. However, whether an NDA is designated for a Standard or Priority Review, there is no guarantee that any single submission will be acted on within these time frames, and the FDA’s goals are subject to change from time to time. In addition, FDA review of a drug development program may proceed under its “Fast Track” programs, which are intended for a combination of a product and a claim that addresses an unmet medical need. Fast Track is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life threatening conditions and demonstrate the potential to address unmet medical needs. A Fast Track designation provides the sponsor the benefits of scheduling meetings when needed to receive FDA input into development plans, the option of submitting an NDA in sections rather than all components simultaneously, or a rolling review, and the option of requesting evaluation of studies using surrogate endpoints. Fast Track status does not, however, necessarily lead to a Priority Review, as described above, or Accelerated Approval designation, which provides earlier approval of drugs to treat serious diseases and that fill an unmet medical need.

If the FDA's evaluations of the NDA and the sponsor's manufacturing facilities are favorable, the FDA will issue an approval letter, and the sponsor may begin marketing the drug in the U.S. for the approved indications, subject to certain universal post-approval requirements described further below. The FDA may also impose drug-specific conditions on its approval, such as requirements for additional post-marketing testing or surveillance. If the FDA determines that it cannot approve the NDA in its current form, it will issue a complete response letter to indicate that the review cycle for an application is complete and that the application will not be approved in its current form. The complete response letter usually describes the specific deficiencies that the FDA identified in the application and may require additional clinical or other data or impose other conditions that must be met in order to obtain final approval of the NDA. Addressing the deficiencies noted by the FDA could be impractical or costly and may result in significant delays prior to final approval.

Adverse Event Reporting

The FDA requires a sponsor to submit reports of certain information on side effects and AEs associated with its products that occur either during clinical trials or after marketing approval. These requirements include specific and timely notification of certain serious, unexpected and/or frequent AEs, as well as regular periodic reports summarizing adverse drug experiences. Failure to comply with these FDA safety reporting requirements may result in FDA regulatory action that may include civil action or criminal penalties. In addition, as a result of these reports, the FDA could create a Tracked Safety Issue for a product in the FDA's Document Archiving, Reporting and Regulatory Tracking System, place additional limitations on an approved product's use, such as through labeling changes, or, potentially, could require withdrawal or suspension of the product from the market.

FDA Post-Approval Requirements

Even if initial approval of an NDA is granted, such approval is subject to a wide-range of regulatory requirements, any or all of which may adversely impact a sponsor's ability to effectively market and sell the approved product. Furthermore, the FDA may require the sponsor to conduct Phase IV clinical trials, also known as post-marketing requirements or post-marketing commitments, to provide additional information on safety and efficacy. The results of such post-market studies may be negative and could lead to limitations on the further marketing of a product. Also, under the Pediatric Research Equity Act, the FDA may require pediatric assessment of certain drugs unless waived or deferred due to the fact that necessary studies are impossible or highly impractical to conduct or where there is strong evidence that suggests the drug would be ineffective or unsafe or that the drug does not represent a meaningful therapeutic benefit over existing therapies and is not likely to be used in a substantial number of pediatric patients. In addition, the FDA may require a sponsor to implement a Risk Evaluation Mitigation Strategy, or REMS, a strategy to manage a known or potential serious risk associated with the product. The FDA may, either prior to approval or subsequent to approval if new safety data arises, require a REMS if it determines that a REMS is necessary to ensure that the benefits of the product outweigh its risks. A REMS may include a medication guide, patient package insert, a plan for communication with healthcare providers, elements to ensure safe use of the product, and an implementation system. A REMS must also include a timetable for submission of assessments of the strategy at specified time intervals. Failure to comply with a REMS, including submission of a required assessment, may result in substantial civil penalties.

Where a sponsor wishes to expand the originally approved prescribing information, such as adding a new indication, it must submit and obtain approval of a sNDA. Changes to an indication generally require additional clinical studies, which can be time-consuming and require the expenditure of substantial additional resources. Under PDUFA, the target timeframe for the review of a sNDA to add a new clinical indication is ten months from the date of filing.

Marketing Exclusivity

Market exclusivity provisions under the FDC Act can delay the submission or the approval of certain applications. Under Sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the FDC Act, as amended by the Hatch-Waxman Act, an NCE that is granted regulatory approval may be eligible for five years of marketing exclusivity in the U.S. following regulatory approval. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a Section 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an ANDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement, or the Paragraph IV certification. An ANDA differs from the typical NDA described above in that it is an application containing information to demonstrate that the proposed product is identical to a previously approved product. ANDA applicants are not required to conduct costly and time-consuming clinical trials to establish the safety and efficacy of their products; rather, they are permitted to rely on the innovator's data regarding safety and efficacy, and an applicant usually needs to only submit data demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product, in addition to any data necessary to establish that any difference in strength, dosage form, inactive ingredients, or delivery mechanism does not result in different safety or efficacy profiles, as compared to the reference drug. Likewise, a Section 505(b)(2) NDA differs from the typical NDA in that it allows a sponsor to rely, at least in part, on the FDA's findings of safety and/or effectiveness for a previously approved drug. Thus, generic manufacturers can sell their products at prices much lower than those charged by the innovative pharmaceutical or biotechnology companies which have incurred substantial expenses associated with the research and development of a new drug.

The FDC Act also provides three years of marketing exclusivity for an NDA, Section 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application (for example, for new indications, dosages, or strengths of an existing drug). This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or tentative approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

FDA Regulation of Product Marketing and Promotion

The FDA also regulates all advertising and promotional activities for products, both prior to and after approval, including but not limited to direct-to-consumer advertising, sales representative communications to healthcare professionals, promotional programming, and promotional activities involving the internet, publications, radio and TV as well as other media. Approved drug products must be promoted in a manner consistent with their terms and conditions of approval, including the scope of their approved use. The FDA may take enforcement action against a company for promoting unapproved uses of a product, or off-label promotion, or for other violations of its advertising and labeling laws and regulations. Failure to comply with these requirements could lead to, among other things, adverse publicity, product seizures, civil or criminal penalties, or regulatory letters, which may include warnings and require corrective advertising or other corrective communications to healthcare professionals.

FDA Regulation of Manufacturing Facilities

Manufacturing procedures and quality control for approved drugs must conform to cGMP, which practices are described in the FDC Act and FDA guidance. cGMP requirements must be followed at all times, and domestic manufacturing establishments are subject to periodic inspections by the FDA in order to assess, among other things, cGMP compliance. In addition, prior to approval of an NDA or sNDA, the FDA will perform a pre-approval inspection of the sponsor's manufacturing facility, including its equipment, facilities, laboratories and processes, to determine the facility's compliance with cGMP and other rules and regulations. Vendors that supply finished products or components to the sponsor that are used to manufacture, package and label products are subject to similar regulation and periodic inspections. If the FDA identifies deficiencies during an inspection, it may issue notices on FDA Form 483, which may be followed by warning letters if observations are not addressed satisfactorily listing conditions the FDA investigators believe may violate cGMP or other FDA regulations. FDA guidelines specify that a warning letter be issued only for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

Product approval may be delayed or denied due to cGMP non-compliance or other issues at the sponsor's manufacturing facilities or contractor sites or suppliers included in the NDA or sNDA, and the complete resolution of these inspectional findings may be beyond the sponsor's control. If after a successful completion of an FDA inspection of a sponsor's manufacturing facilities, the sponsor makes a material change in manufacturing equipment, location or process, additional regulatory review may be required. Re-inspection of the sponsor's manufacturing facilities or contractor sites or suppliers may also occur. If the FDA determines that the sponsor's equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may seek civil, criminal or administrative sanctions and/or remedies against the sponsor, including suspension of its manufacturing operations.

To supply products for use outside of the U.S., our third-party manufacturers must comply with cGMP and are subject to periodic inspection by the FDA or by regulatory authorities in certain other countries. In complying with these requirements, manufacturers, including a drug sponsor's third-party contract manufacturers, must continue to expend time, money and effort in the area of production and quality to ensure compliance. Failure to maintain compliance with cGMP regulations and other applicable manufacturing requirements of various regulatory agencies could result in fines, unanticipated compliance expenditures, recall, total or partial suspension of production, suspension of the FDA's review of future sNDAs, enforcement actions, injunctions or criminal prosecution.

Fraud and abuse regulation

Our general operations, and the research, development, manufacture, sale and marketing of our products, are subject to extensive federal and state regulation, including but not limited to FDA regulations, the Federal Anti-Kickback Statute, the Federal False Claims Act, and the Foreign Corrupt Practices Act, and their state analogues. 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. False claims laws prohibit anyone from knowingly presenting, or causing to be presented for payment to third-party payers, 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. 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. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. If we or our representatives fail to comply with any of these laws or regulations, a range of fines, penalties and/or other sanctions could be imposed on

us, including, but not limited to, restrictions on how we market and sell *Feraheme*, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation, or other sanctions.

Other U.S. Regulatory Requirements

We are also subject to regulation under local, state and federal law regarding occupational safety, laboratory practices, handling of chemicals, environmental protection and hazardous substances control. We possess a Byproduct Materials License from the Commonwealth of Massachusetts for receipt, possession, manufacturing and distribution of radioactive materials and Registration Certificates from the federal Drug Enforcement Agency and the Commonwealth of Massachusetts Department of Public Health for handling controlled substances. We are also registered with the federal Environmental Protection Agency, or EPA, as a generator of hazardous waste. All hazardous waste disposals must be made in accordance with EPA and Commonwealth of Massachusetts requirements. We are subject to the regulations of the Occupational Safety and Health Act and have a safety program in effect to assure compliance with all of these regulations. We believe our procedures for handling and disposing of hazardous materials used in our research and development activities comply with all applicable federal, state and local requirements. Nevertheless, the risk of accidental contamination or injury from these materials cannot be completely eliminated and, in the event of an accident or injury, we could be held liable for any damages that result.

Certain states also require that we obtain licenses or permits as an out-of-state distributor or manufacturer in order to market, sell and/or ship our pharmaceutical products into their state. We have obtained licenses and permits in some states and, depending on our future activities, may also need to obtain additional licenses or permits in other areas where we decide to manufacture, market or sell our products. New laws, regulations or judicial decisions, or new interpretations of existing laws and regulations, may require us to modify our development programs, revise the way we manufacture, market and sell our products, require additional clinical trials or post-approval safety studies, or limit coverage or reimbursement rates and terms for our products.

In recent years, several states have enacted legislation requiring pharmaceutical companies operating within the state to establish marketing and promotional compliance programs or codes of conduct and/or file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities. Similar legislation is being considered by additional states and by Congress. In addition, as part of The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the Health Care Reform Act, the federal government has enacted the Sunshine Act provisions. Beginning in August 2013, manufacturers of drugs are required to publicly report gifts and payments made to physicians and teaching hospitals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Failure to comply with any of these laws could result in a range of fines, penalties and/or other sanctions.

Foreign Regulatory Process

In our efforts to market and sell *Feraheme/Rienso* outside of the U.S., we and our licensees are subject to foreign regulatory requirements. Approval of a drug by applicable regulatory agencies of foreign countries must be secured prior to the marketing of such drug in those countries. The regulatory approval process in countries outside of the U.S. vary widely from country to country and may in some cases be more rigorous than requirements in the U.S. Certain foreign regulatory authorities may require additional studies or studies designed with different clinical endpoints and/or comparators than those which we are conducting or have already completed. In addition, any adverse regulatory action taken by the FDA with respect to an approved product in the U.S. may 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 obtain regulatory approval of a drug in the EU, marketing authorizations may be submitted under a centralized, mutual recognition or decentralized procedure or national procedure (single country). Under the centralized procedure, the sponsor can submit a single application to the EMA which, if approved, permits the marketing of a product in all EU Member States and certain non-member states, including Iceland and Norway. Under the mutual recognition procedure, the sponsor applies for national marketing authorization in one state, and upon approval can then seek simultaneous approval in all other EU Member States. Under the decentralized procedure, the sponsor can file simultaneously to several EU Member States, identifying a single reference member state to act as the primary reviewer of the application. Upon approval, the product will be licensed only in the reference member state and the other countries to which it applied. Once an applicant receives marketing authorization in an EU Member State, through any application route, the applicant is then required to engage in pricing discussions and negotiations with a separate pricing authority in that country. In certain countries, commercial sales are only able to commence once pricing approval has been received. In addition, all products, irrespective of the method of filing, are afforded 10 years of market exclusivity and eight years of data protection upon approval. In June 2012, *Rienso* was granted marketing approval in the EU for the treatment of IDA in CKD patients and commercially launched in late 2012.

The Canadian pharmaceutical industry is subject to federal regulation by Health Canada, the public health department of the Canadian government charged with overseeing healthcare-related regulatory matters, pursuant to the Canadian federal Food and Drugs Act. Health Canada's criteria for obtaining and maintaining marketing approval is generally similar to that of the FDA. In December 2011, *Feraheme* was granted marketing approval by Health Canada for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD and commercially launched in late 2012.

The pharmaceutical industry in Switzerland is subject to federal regulation by Swissmedic, the Swiss Agency for Therapeutic Products. In August 2012, *Rienso* was granted marketing approval by Swissmedic and commercially launched in late 2012.

Reimbursement

In both the U.S. and foreign markets, our and Takeda's ability to successfully commercialize *Feraheme/Rienso* is dependent, in significant part, on the availability and extent of reimbursement to end-users from third-party payors for the use of *Feraheme/Rienso*, including governmental payors, managed care organizations, and private health insurers. Reimbursement by third-party payors may depend 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. For example, to reduce expenditures associated with pharmaceutical products, many third-party payors use cost containment methods, including: (a) formularies, which limit coverage for drugs not included on a predetermined list; (b) variable co-payments, which may make a certain drug more expensive for patients as compared with a competing drug; (c) utilization management controls, such as requirements for prior authorization before the payor will cover the drug; and (d) other coverage policies that limit access to certain drugs for certain uses based on the payor-specific coverage policy.

In addition, U.S. and many foreign governments continue to attempt to curb health care costs through legislation, including legislation aimed at reducing the pricing and reimbursement of pharmaceutical products. 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, 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, such as a potential 2% across the board sequestration of Medicare expenditures. 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. These and any future changes in government regulation or private third-party payors' reimbursement policies may reduce the extent of reimbursement for *Feraheme/Rienso* and adversely affect our future operating results.

Currently, in U.S. physician clinic settings, Medicare Part B generally reimburses for physician-administered drugs at a rate of 106% of the drug's average selling 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 confirms 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. 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 January 2011, a prospective payment system for dialysis services provided to Medicare beneficiaries who have end-stage renal disease, or ESRD, became effective under which all costs of providing dialysis services are bundled together into a single prospective payment per treatment. This bundled approach to reimbursement has and will likely continue to alter the utilization of physician-administered drugs in the ESRD market as well as put downward pressure on the prices pharmaceutical companies can charge ESRD facilities for such drugs, particularly where alternative products are available. In the U.S., *Feraheme* is sold at a price that is substantially higher than alternative IV iron products in the dialysis setting, and as a result, the demand for *Feraheme* in the dialysis setting has largely disappeared. In addition, it is also possible that this "bundled" approach may be applied to specific disease states other than ESRD. For example, one large insurer in the U.S. has attempted to bundle certain costs related to the treatment of cancer patients.

In addition, in the U.S. hospital in-patient setting, *Feraheme* is reimbursed by Medicare under a diagnosis related group payment system, which provides a per discharge reimbursement based on the diagnosis and/or procedure rather than actual costs incurred in patient treatments, thereby increasing the incentive for a hospital to limit or control expenditures. As a result, *Feraheme* has not been nor do we expect it to be broadly used in the hospital in-patient setting.

In countries outside of the U.S., market acceptance 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.

If adequate reimbursement levels are not maintained by government and other third-party payors for *Feraheme/Rienso*, our and Takeda's ability to sell *Feraheme/Rienso* may be limited and/or our and Takeda's ability to establish acceptable pricing levels for *Feraheme/Rienso* may be impaired, thereby reducing anticipated revenues and our prospects of achieving profitability.

Backlog

We had a \$1.7 million and \$0.1 million product sales backlog as of December 31, 2012 and 2011, respectively. The \$1.7 million backlog as of December 31, 2012 was largely due to increased orders from certain of our licensees and to the timing of orders received from our third-party logistics provider. Generally, product orders from our customers are fulfilled within a relatively short time of receipt of a customer order.

Employees

As of February 15, 2013, we had 129 employees. We also utilize consultants and independent contractors on a regular basis to assist in the development and commercialization of *Feraheme*. Our success depends in part on our ability to attract, retain and motivate qualified executive, sales, technical operations, managerial, scientific and medical personnel. Although we believe we have been relatively successful to date in obtaining and retaining such personnel, we may not be successful in the future.

None of our employees is represented by a labor union, and we consider our relationship with our employees to be good.

Foreign Operations

We have no foreign operations. Revenues from customers outside of the U.S. amounted to approximately 32%, 14% and 10% of our total revenues for the years ended December 31, 2012, 2011 and 2010, respectively, and were principally related to collaboration revenues recognized in connection with our agreement with Takeda, which is based in Japan. During 2012, our revenues from customers outside of the U.S included approximately \$20.0 million related to milestone payments we received from Takeda.

Research and Development

We have dedicated a significant portion of our resources to our efforts to develop our products and product candidates, particularly *Feraheme*. We incurred research and development expenses of \$33.3 million, \$58.1 million and \$54.5 million during the years ended December 31, 2012, 2011 and 2010, respectively. We expect our research and development expenses to decrease in 2013 due to the completion in 2012 of our Phase III clinical program for *Feraheme* in patients with IDA regardless of the underlying cause. However, we will continue to incur significant expenses in 2013 and beyond related to our pediatric clinical studies and our clinical trial to determine the safety and efficacy of repeat doses of *Feraheme* for the treatment of IDA in patients with hemodialysis dependent CKD.

Code of Ethics

Our Board of Directors has adopted a code of ethics that applies to our officers, directors and employees. We have posted the text of our code of ethics on our website at <http://www.amagpharma.com> in the "Investors" section. In addition, should any changes be made to our code of ethics, we intend to disclose within four business days, on our website (or in any other medium required by law or the NASDAQ): (1) the date and nature of any amendment to our code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver,

from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver, and the date of the waiver.

Available Information

Our internet website address is <http://www.amagpharma.com>. Through our website, we make available, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy and registration statements, and all of our insider Section 16 reports (and any amendments to such filings), as soon as reasonably practicable after such material is electronically filed with, or furnished to, the U.S. Securities and Exchange Commission, or the SEC. These SEC reports can be accessed through the “Investors” section of our website. The information found on our website is not part of this or any other report we file with, or furnish to, the SEC. Paper copies of our SEC reports are available free of charge upon request in writing to Investor Relations, AMAG Pharmaceuticals, Inc., 100 Hayden Avenue, Lexington, MA 02421. The content on any website referred to in this Form 10-K is not incorporated by reference into this Form 10-K unless expressly noted.

For additional information regarding our segments, refer to Note L of the Notes to Financial Statements included in Part II, Item 8 “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS:

The following information sets forth material risks and uncertainties that may affect our business, including our future financial and operational results and could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and elsewhere as discussed in the introduction to Part I above. You should carefully consider the risks described below, in addition to the other information in this Annual Report on Form 10-K, before making an investment decision. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present material risks to our business at this time also may impair our business operations.

We are solely 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 solely dependent on our and our licensees’ successful commercialization and development of *Feraheme/Rienso*. Accordingly, if we are unable to generate sufficient revenues from sales of *Feraheme/Rienso*, or from milestone payments and royalties we may receive related to *Feraheme/Rienso*, we may never be profitable, our financial condition will be materially adversely affected, and our business prospects will be limited.

We intend to continue to dedicate significant resources to the development and commercialization of *Feraheme/Rienso*. However, we or Takeda may not be successful in our efforts to successfully commercialize *Feraheme/Rienso* in its current chronic kidney disease, or CKD, indication or to expand the approved indication of *Feraheme/Rienso* to include additional indications. Although we filed a supplemental New Drug Application, or sNDA, in the U.S. for our global registration program for *Feraheme* in patients with iron deficiency anemia, or IDA, who had failed to or could not use oral iron, the U.S. Food and Drug Administration, or the FDA, may not accept or approve our sNDA, or may require that we narrow the scope of our proposed indication. In addition, we expect that Takeda will file a Type II Variation, which is the European Union, or EU, equivalent of a U.S. sNDA, with the European Medicines Agency, or EMA, in 2013 seeking marketing approval for *Rienso* for the treatment of IDA in adult patients. However, we have no control over Takeda’s process, timeline or interactions

with the European regulatory agencies, Takeda may not be successful in filing a Type II Variation in a timely manner, or at all, and we cannot be assured that the EMA will accept and approve the filing. We are not currently conducting or sponsoring research to expand our product development pipeline beyond *Feraheme*. Therefore, our revenues and operations will not be as diversified as some of our competitors which have multiple products or product candidates. Any failure by us or Takeda to gain marketing approval for *Feraheme/Rienso* for the treatment of IDA regardless of the underlying cause could limit long-term shareholder value and adversely affect the future prospects of our business.

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

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

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

In addition, in December 2012, the FDA published draft guidance regarding new draft product-specific bioequivalence for drug products containing ferumoxytol. The FDA generally publishes product-specific bioequivalence guidance after it has received an inquiry from a generic drug manufacturer about submitting an ANDA for the product in question; thus, it is possible that a generic drug manufacturer has approached the FDA requesting guidance about submitting an ANDA for ferumoxytol, the active ingredient in *Feraheme*, and that such an ANDA may be filed in the near future. Because the FDA may deny our request for reconsideration of NCE status for *Feraheme* and because the published bioequivalence guidance could encourage a generic entrant seeking a path to approval of a generic ferumoxytol to file an ANDA, we could face generic competition in the near-term or have to engage in extensive litigation with a generic competitor to protect our patent rights, either

of which could adversely affect our business and results of operations. 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 intravenous, or IV, iron products could limit our U.S. sales and any royalties we may receive from Takeda, which would have an adverse impact on our business and results of operations.

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

In the third quarter of 2012, we ceased our manufacturing operations at our Cambridge, Massachusetts manufacturing facility. Consequently, we currently rely solely on our third-party contract manufacturers to manufacture *Feraheme/Rienso* for our commercial and clinical use in the U.S., the EU and Switzerland. 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 manufacturers whose facilities and procedures comply with current good manufacturing practices, or cGMP, regulations and other regulatory requirements on terms that are favorable to us, if at all. Prior to ceasing our manufacturing operations in 2012, we manufactured *Feraheme* drug substance and drug product for use in the Canadian market at our Cambridge facility. Although we and Takeda are working to obtain regulatory approval of the manufacturing facilities at our current third-party contract manufacturers to produce *Feraheme* for sale in Canada, we do not currently have manufacturing facilities for this geography.

Our ability to have *Feraheme/Rienso* manufactured in sufficient quantities and at acceptable costs to meet our commercial demand and clinical development needs is dependent on the uninterrupted and efficient operation of our third-party contract manufacturing facilities. Any difficulties, disruptions or delays in the *Feraheme/Rienso* manufacturing process could result in product defects or shipment delays, recall or withdrawal of product previously shipped for commercial or clinical purposes, inventory write-offs or the inability to meet commercial demand for *Feraheme/Rienso* in a timely and cost-effective manner. Our current third-party manufacturer does not manufacture for us exclusively and may exhaust some or all of its resources meeting the demand of other customers. 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 potential manufacturing delays resulting from our efforts to gain regulatory approval of a new assay for the production of *Rienso* for sale in the EU, could result in our inability to meet our commercial demand for *Feraheme/Rienso*.

In addition, the transition of the manufacturing processes to third-party contract manufacturers and the oversight of such third parties could take a significant amount of time and may increase the risk of certain problems, including cost overruns, process reproducibility, stability issues, the inability to deliver required quantities of product that conform to specifications in a timely manner, or the inability to manufacture *Feraheme/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 fixed price at which we are required to supply *Feraheme/Rienso* to Takeda under our License, Development and Commercialization Agreement, as most recently amended in June 2012, or the Amended Takeda Agreement. As a result, we may lose sales, fail to generate increased revenues, suffer regulatory setbacks and/or we may lose money on our supply of *Feraheme/Rienso* to Takeda, any of which could have an adverse impact on our potential profitability and future business prospects.

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

Significant safety or drug interaction problems could arise with respect to *Feraheme/Rienso*, including an increase in the severity or frequency of known problems or the discovery of previously unknown problems, and may result in a variety of adverse regulatory actions. In the U.S., under the Food and Drug Administration Amendments Act of 2007, the FDA has broad authority to force drug manufacturers to take any number of actions if safety or drug interaction problems arise, including, but not limited to the following:

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

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

For example, in November 2010, following discussions with the FDA, we revised the *Feraheme* package insert, which includes essential information regarding the FDA-approved use of *Feraheme*, including, among other things, the approved indication, side effects, and dosage instructions, to include bolded warnings and precautions that describe events that have been reported during post-marketing review after *Feraheme* administration, including life-threatening hypersensitivity reactions and clinically significant hypotension. We directly alerted healthcare providers of the changes to the *Feraheme* package insert. During June 2011, we made further changes to the *Feraheme* package insert based on additional post-marketing data. These or any future changes to the *Feraheme* package insert could adversely impact our or Takeda's ability to successfully compete in the IV iron market and could have an adverse impact on potential sales of *Feraheme* and our future business prospects.

The data submitted to both the FDA as part of our NDA and to the EMA as part of the Marketing Authorization Application for *Feraheme/Rienso* in the CKD indication was obtained in controlled clinical trials of limited duration. New safety or drug interaction issues may arise as *Feraheme/Rienso* is used over longer periods of time by a wider group of patients, some of whom may be taking numerous other medicines or by patients with additional underlying health problems. In addition, as we conduct and complete other clinical trials for *Feraheme*, new safety issues may be identified which could negatively impact our ability to successfully complete these studies, the use and/or regulatory status of *Feraheme/Rienso* for the treatment of IDA in patients with CKD in the U.S., EU or other territories, and the prospects for approval of future sNDAs, such as our December 2012 sNDA submission for *Feraheme* for the treatment of IDA regardless of the underlying cause. For example, the FDA may determine that our sNDA for our IDA global registrational program does not establish a sufficiently acceptable safety profile for the approval of a broader *Feraheme* label.

As more data become available and an increased number of patients are treated with *Feraheme/Rienso*, new safety or drug interaction issues may arise and 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., directly alert 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.

Our and Takeda's ability to grow revenues from sales of Feraheme/Rienso could be limited if we or Takeda do not obtain approval, or if we or Takeda experience significant delays in our or Takeda's efforts to obtain approval to market and sell Feraheme/Rienso for the treatment of IDA in a broad range of patients.

In December 2012, we submitted a sNDA to the FDA for *Feraheme* for the treatment of IDA in a broad range of patients. In addition, we expect that Takeda will file a Type II Variation, which is the EU equivalent of a U.S. sNDA, with the EMA in 2013 seeking marketing approval for *Feraheme/Rienso* for the treatment of IDA in adult patients. Before applying for regulatory approval in the U.S. or foreign countries for the commercial marketing and sale of *Feraheme/Rienso* for the broad IDA indication, we have to demonstrate, through extensive human clinical trials, that *Feraheme/Rienso* is safe and effective for use in this broader patient population. Conducting these and other clinical trials is a complex, time-consuming and expensive process that requires adherence to a wide range of regulatory requirements. The FDA and foreign regulatory agencies have substantial discretion in the approval process and may decide that the results of our recently completed clinical trials are insufficient for approval or that *Feraheme/Rienso* is not effective or safe in indications other than IDA in adult patients with CKD. For example, in our Phase III clinical trial in the broader patient population, *Feraheme*-treated patients experienced a 0.6% rate of related serious adverse events, or SAEs, as compared to a 0.2% rate of related SAEs from our current *Feraheme* label for treatment of IDA patients with CKD. Clinical and other data is often susceptible to varying interpretations, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain FDA or EMA approval for their products. There is no guarantee that the FDA or EMA will determine that the results of our clinical trials in our global registrational program for *Feraheme/Rienso* in a broad range of patients with IDA will adequately demonstrate that *Feraheme/Rienso* is safe and effective in such a patient population to grant approval.

The FDA or EMA could also determine that our clinical trials and/or our manufacturing processes were not properly designed, 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 our study sites fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may disqualify certain data generated from those sites or require us to perform additional clinical trials before approving our marketing application, which could adversely impact our ability to obtain marketing approval in the U.S. for *Feraheme/Rienso* in the broad IDA indication. Any such deficiency in the design, implementation or oversight of our clinical development programs could cause us to incur significant additional costs, experience significant delays or prevent us from obtaining marketing approval for *Feraheme/Rienso* for the broad IDA indication. In addition, any failure by us or Takeda to obtain approval for the broad IDA indication could adversely affect the commercialization of *Feraheme/Rienso* in its current indication. If, for any of these or other reasons, we or Takeda do not obtain approval, or if we or Takeda experience significant delays in our or Takeda's efforts to obtain approval to market and sell *Feraheme/Rienso* for the treatment of IDA in a broad range of patients, 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.

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

As part of our business strategy to expand our product portfolio and achieve profitability, we are seeking to acquire or in-license other products that we believe would be complementary to our existing business. 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. We may not be successful in acquiring or in-licensing a product or product candidate that will provide us with commercial, development and/or financial synergies with *Feraheme* and our current organization such that we will be able to eliminate expenses either from our existing operations or from the cost structure of the acquired product.

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

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

We rely on a combination of patents, trademarks and copyrights in the conduct of our business. The patent positions of pharmaceutical and biopharmaceutical firms are generally uncertain and involve complex legal and factual questions. We may not be successful or timely in obtaining any patents for which we submit applications. The breadth of the claims obtained in our patents may not provide sufficient protection for our technology. The degree of protection afforded by patents for proprietary or licensed technologies or for future discoveries may not be adequate to preserve our ability to protect or commercially exploit those technologies or discoveries. The patents issued to us may provide us with little or no competitive advantage. In addition, there is a risk that others will independently develop or duplicate similar technology or products or circumvent the patents issued to us.

Our U.S. feromoxytol patents are currently scheduled to expire in 2020. 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.

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.

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*, thereby substantially reducing the value of our proprietary rights. Our inability to protect *Feraheme* through our patents and other intellectual property rights prior to their expiration could have a material adverse effect on our business, financial condition and prospects.

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

The laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S. and therefore, in addition to similar risks to those describe above under the heading "*The success of Feraheme 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, such as in China, where we license certain development

and commercial rights to *Feraheme* to 3SBio, Inc., we may be unable to prevent others from developing or selling similar products. In addition, in jurisdictions outside the U.S. where we have patent rights, we may be unable to prevent unlicensed parties from selling or importing products or technologies derived elsewhere using our proprietary technology. Any such limitation on our intellectual property rights would cause substantial harm to our competitive position and to our ability to develop and commercialize *Feraheme/Rienso*. Our inability to protect *Feraheme/Rienso* through our patents and other intellectual property rights in any territory prior to their expiration could have a material adverse effect on our business, financial condition and prospects.

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

The pharmaceutical and biopharmaceutical industry is intensely competitive and subject to rapid technological change. We and Takeda compete in the marketing and sale of *Feraheme/Rienso* and many of our competitors are large, well-known pharmaceutical companies. One or more of our competitors 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 iron replacement therapy market is 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 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* that would be, or are perceived to be, more efficacious, safer, cheaper, easier to administer, or 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, certain of the IV iron products that we compete with are approved for the treatment of IDA in a broader group of patients than *Feraheme/Rienso*. We or Takeda may not be able to convince physicians and other healthcare providers or payers to switch from using the other IV iron therapeutic products to *Feraheme/Rienso*. If we or Takeda are not able to differentiate *Feraheme/Rienso* from other marketed IV iron products, our ability to maintain a premium price, our ability to generate revenues and achieve and maintain profitability, and our long-term business prospects could be adversely affected.

Feraheme currently competes with several IV iron replacement therapies in the U.S., If these or other iron replacement products are approved for marketing and sale in the U.S. or are approved for a broader IDA indication than *Feraheme*, our efforts to market and sell *Feraheme* in the U.S. and our ability to generate additional revenues and achieve profitability could be adversely affected.

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. If Takeda is unable to convince physicians and other healthcare providers to switch from using the competing IV iron products to *Feraheme/Rienso*, our ability to generate revenues from royalties we may receive from Takeda will be limited and our operating results will be negatively affected. In addition, all other IV iron products currently

approved and marketed and sold in the EU are approved for marketing to a broader group of patients with IDA. *Feraheme/Rienso* was approved only for use in adult CKD patients, which could put *Feraheme/Rienso* at a competitive disadvantage unless and until it receives approval for a broader indication outside of the U.S.

Feraheme/Rienso 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 *Feraheme/Rienso* in the U.S. and in other territories depends upon its level of market adoption by physicians, hospitals, patients, and healthcare payors, including managed care organizations and group purchasing organizations, or GPOs. If *Feraheme/Rienso* does not achieve or maintain an adequate level of market adoption for any reason, our potential profitability and our future business prospects will be severely adversely impacted. *Feraheme/Rienso* represents an alternative to other products 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 for *Feraheme/Rienso* may not be viewed as advantageous to potential prescribers and payors as the pricing and/or reimbursement rates and terms of alternative IV iron 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 and/or otherwise create safety concerns among potential prescribers;
- The relative level of available reimbursement in the U.S. for *Feraheme* from payors, including government payors, such as Medicare and Medicaid, and private payors as compared to the level of available reimbursement for alternative IV iron products;
- The relative price and/or level of reimbursement of *Feraheme/Rienso* outside of the U.S. as compared to alternative iron replacement therapeutic agents;
- The actual or perceived convenience and ease of administration of *Feraheme/Rienso* as compared to alternative iron replacement therapeutic agents, including iron administered orally; and
- The effectiveness of our and Takeda's commercial organizations and distribution networks in marketing, selling and supplying *Feraheme/Rienso*.

The key component of our U.S. commercialization strategy is to market and sell *Feraheme* for use in non-dialysis adult CKD patients. The current U.S. non-dialysis CKD market is comprised primarily of three sites of care where a substantial number of CKD patients are treated: hematology and oncology centers, hospitals, and nephrology clinics. IV iron therapeutic products are not currently widely used by certain physicians who treat non-dialysis CKD patients in the U.S., particularly nephrologists, due to safety concerns and the inconvenience and often impracticability of administering IV iron therapeutic products in their offices. It is often difficult to change physicians' existing treatment paradigms even when supportive clinical data is available. In addition, our ability to effectively market

and sell *Feraheme* in the U.S. hospital market depends in part upon our ability to achieve acceptance of *Feraheme* onto hospital formularies. Since many hospitals and hematology, oncology and nephrology practices are members of GPOs, which leverage the purchasing power of a group of entities to obtain discounts based on the collective bargaining power of the group, our ability to attract customers in these sites of care also depends in part on our ability to effectively promote *Feraheme* to and enter into pricing agreements with GPOs. 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*, our potential profitability as well as our long-term business prospects could be adversely affected.

We derive a substantial amount of our revenue from a limited number of customers and the loss of one or more of these customers 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 94% of our total revenues during the year ended December 31, 2012, and three customers accounted for 94% of our accounts receivable balance as of December 31, 2012. 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 32% of our end-user demand in the year ended December 31, 2012 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 loss of, material reduction in sales volume to, or a significant adverse change in our relationship with any of our key wholesalers, distributors or GPOs could have a material adverse effect on our revenue in any given period and may result in significant annual or quarterly revenue fluctuations.

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

In both the U.S. and foreign markets, our and Takeda's ability to successfully commercialize *Feraheme/Rienso* is dependent, in significant part, on the availability and extent of reimbursement to end-users from third-party payors for the use of *Feraheme/Rienso*, 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 *Feraheme/Rienso* or provide an insufficient level of coverage and reimbursement, physicians and other healthcare providers may choose to use alternative IV iron replacement products, which would have an adverse effect on our ability to generate revenues.

In addition, U.S. and many foreign governments continue to propose and pass legislation designed to reduce the cost of health care for patients. In the U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the Health Care Reform Act, was enacted in March 2010 and includes certain cost containment measures including an increase to the minimum rebates for products covered by Medicaid programs, the extension of such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations and the expansion of the 340B Drug Discount Program under the Public Health Service Act. In addition, the heightened focus on the health care industry by the federal government could result in the implementation of significant federal spending cuts, including cuts in Medicare and other health related spending in the near-term, such as a potential 2% across-the-board sequestration of Medicare expenditures. The full impact of these laws on our business is uncertain. In recent years some states have also passed legislation to control the prices of drugs as well as begun a move toward managed care to relieve some of their Medicaid cost burden. While Medicare is the predominant payor for treatment of patients with CKD, Medicare payment policy, in time, can also influence pricing and reimbursement in the non-Medicare markets, as private third-party payors and state Medicaid plans frequently adopt Medicare principles in setting reimbursement methodologies. These and any future changes in government regulation or private third-party payors' reimbursement policies may reduce the extent of reimbursement for *Feraheme/Rienso* and adversely affect our future operating results.

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

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

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

In March 2010, we entered into our initial agreement with Takeda, which was amended in June 2012, under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme/Rienso* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey. We are highly dependent on Takeda for certain regulatory filings outside of the U.S. with respect to *Feraheme/Rienso* and the commercialization of *Feraheme/Rienso* outside of the U.S., including in Canada, Switzerland and the EU. If Takeda fails to perform its obligations under the Amended Takeda Agreement or is ineffective in its commercialization of *Feraheme/Rienso* in the agreed-upon territories, or if we fail to effectively manage our relationship with Takeda, our ability to and the extent to which we obtain regulatory approvals for *Feraheme/Rienso* and our *Feraheme/Rienso* commercialization efforts outside of the U.S. would be significantly harmed, which would have an adverse effect on milestone payments and royalties we may receive under the Amended Takeda Agreement. Further, if we fail to fulfill certain of our obligations under the Amended Takeda Agreement, Takeda has the right to assume the responsibility of clinical development and manufacturing of *Feraheme/Rienso* in the agreed-upon territories, which would increase the cost of and delay the *Feraheme/Rienso* development program outside of the U.S.

Takeda has the unilateral right to terminate the Amended Takeda Agreement under certain conditions, including without cause. 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, or to increase our internal infrastructure, both of which would likely result in significant additional expense and the disruption or failure of commercial efforts outside of the U.S. In addition, such a termination would prevent us from receiving the milestone payments and royalties we may receive under the Amended Takeda Agreement.

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

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

We have also established certain testing and release specifications with the FDA and other foreign regulatory agencies. This release testing must be performed in order to allow the finished product to be used for commercial sale. If our finished product does not meet these release specifications or if the release testing is variable, we may not be able to supply product to meet our projected demand. In addition, variations in the regulatory approval of *Feraheme/Rienso* in the currently approved territories require that our third-party manufacturers follow different manufacturing processes and analytical testing methods. For example, in late 2012, we produced a batch of *Rienso* which did not meet our release specifications in the EU. As a result, we are incurring additional costs associated with the development, validation and technology transfer to Takeda of a more accurate assay in order to be able to release this batch and any future batches produced for sale in the EU. This new assay will require review and approval by the EMA. 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.

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 any long-term supply contracts with these third parties. These third-party suppliers may cease to produce the raw or other materials used in *Feraheme/Rienso* or otherwise fail to supply these materials to us or our third-party manufacturers or fail to supply sufficient quantities of these materials to us or our third-party manufacturers in a timely manner for a number of reasons, including but not limited to the following:

- Unexpected demand for or shortage of raw or other materials;
- Adverse financial developments at or affecting the supplier;
- Regulatory requirements or action;
- An inability to provide timely scheduling and/or sufficient capacity;
- Manufacturing difficulties;
- Labor disputes or shortages; or
- Import or export problems.

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

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

materials of the quality required to manufacture *Feraheme/Rienso* from an alternative source on commercially reasonable terms, or in a timely manner, if at all.

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

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 December 31, 2012, we had an accumulated deficit of approximately \$456.7 million. Our losses were primarily the result of costs incurred in our efforts to manufacture, market and sell *Feraheme/Rienso*, including costs associated with maintaining our commercial infrastructure and marketing and promotion costs, research and development costs, such as costs associated with our clinical trials, and selling, general and administrative costs. We expect to continue to incur significant expenses as we continue to manufacture, market and sell *Feraheme* as an IV iron replacement therapeutic for use in adult CKD patients in the U.S., and as we further develop and seek marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients. As a result, we will need to generate sufficient revenues in future periods to achieve and maintain profitability. 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. and royalties we may receive with respect to sales of *Feraheme/Rienso* in Canada and the EU under the Amended Takeda Agreement, which we originally entered into with Takeda in 2010. We have never independently marketed or sold any products prior to *Feraheme*, and we or Takeda may not be successful in marketing or selling *Feraheme/Rienso*. If we or Takeda are not successful in marketing and selling *Feraheme/Rienso*, if revenues grow more slowly than we anticipate or if our operating expenses exceed our expectations, or if we are otherwise unable to achieve, maintain or increase profitability on a quarterly or annual basis, our business, results of operations and financial condition could be materially adversely affected and the market price of our common stock may decline.

We have limited experience independently commercializing a pharmaceutical product, and any failure on our part to effectively execute our Feraheme 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 drug 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* in the U.S., and if we are unsuccessful in maintaining an effective commercial function or experience a high level of employee turnover, then the commercialization of *Feraheme* could be severely impaired. For example, we reduced our workforce in 2011 as part of an overall corporate restructuring, including certain positions within our commercial function, with further restructuring occurring in 2012. These workforce reductions or any future reductions or departures, could harm our ability to attract and retain qualified personnel, which could prevent us from successfully commercializing *Feraheme* in the U.S., impair our ability to maintain sales levels and/or impair our ability to support potential sales growth and sales of *Feraheme* for any additional indications we may commercialize in the future. Any failure by us to

successfully commercialize *Feraheme* in the U.S. could have a material adverse impact on our ability to generate revenues, our ability to achieve profitability, and the future prospects for our business.

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

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

Previously implemented workforce reductions could residually harm our ability to attract and retain qualified personnel. In addition, any restructuring plans we may initiate in the future may be disruptive to our operations and could harm our ability to attract and retain qualified key personnel. For example, cost saving measures may distract management from our core business, harm our reputation, or yield unanticipated consequences, such as attrition beyond planned reductions in workforce, increased difficulties in our day-to-day operations, reduced employee productivity and a deterioration of employee morale. Any workforce reductions could also harm our ability to attract and retain qualified executive, sales, technical operations, managerial, scientific, and medical personnel who are critical to our business. Furthermore, because we are currently operating with fewer employees and service providers, any further turnover, whether occurring as part of a restructuring plan or otherwise, could cause significant disruption if we are unable to implement or maintain a sufficient succession plan for certain personnel or departments. Any failure to attract, retain or replace qualified personnel could prevent us from successfully commercializing and developing *Feraheme*, impair our ability to maintain sales levels and/or support potential sales growth.

Moreover, although we believe it is necessary to reduce the cost of our operations to improve our performance, these initiatives may preclude us from making potentially significant expenditures that could improve our competitiveness over the longer term. We cannot guarantee that 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 Feraheme/Rienso 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*. We have contracted with Packaging Coordinators, Inc. (formerly Catalent Pharma Solutions, LLC), or PCI, to provide certain labeling, packaging and storage services for final U.S. and Canadian *Feraheme* drug product. In addition, we have contracted with Integrated Commercialization Services, Inc., or ICS, 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 ICS or PCI are unable to provide uninterrupted supply chain services or labeling, packaging and storage services, respectively, we may incur substantial losses of sales to wholesalers or other purchasers of *Feraheme*.

In addition, the packaging, storage and distribution of *Feraheme/Rienso* in the U.S. and abroad requires significant coordination among our and Takeda's manufacturing, sales, marketing and finance organizations and multiple third parties including our third-party logistics provider, 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 *Feraheme/Rienso* 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 *Feraheme/Rienso* to be delayed or interrupted, which would have an adverse effect on our business, financial condition and results of operations.

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

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

In addition, we have contracted and plan to continue to contract with certain third parties to provide certain services, including site selection, enrollment, monitoring, data management and other services, in connection with the conduct of our clinical trials and the preparation and filing of our regulatory applications. We have limited experience conducting clinical trials outside the U.S., and, therefore, we are also largely relying on third parties such as clinical research organizations to manage, monitor and carry out these clinical trials. Although we depend heavily on these parties, we do not control them and, therefore, we cannot be assured that these third parties will adequately perform all of their contractual obligations to us. If our third-party service providers cannot adequately fulfill their obligations to us in a timely and satisfactory manner, if the quality and accuracy of our clinical trial data or our regulatory submissions are compromised due to poor quality or failure to adhere to our protocols or regulatory requirements or if such third parties otherwise fail to adequately discharge their responsibilities or meet deadlines, our development plans and planned regulatory submissions both in and outside of the U.S may be delayed or terminated, which would adversely impact our ability to generate revenues from *Feraheme/Rienso* sales in additional indications and/or outside of the U.S.

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* sales;
- The loss of a key customer or GPO;

- The impact of any pricing strategies we have implemented or may implement related to *Feraheme*, 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 in the iron replacement therapeutic market, such as Injectafer®, if approved 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;
- Any changes to the mix of our business;
- Changes in buying patterns and inventory levels of our wholesalers or distributors;
- The timing and magnitude of 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 *Feraheme* in the U.S., including costs associated with maintaining our commercial infrastructure and executing our promotional and marketing strategy;
- The magnitude of costs incurred in connection with business development activities or business development transactions into which we enter;
- Changes in accounting estimates related to reserves on revenue, returns, or other accruals or changes in the timing and availability of government or customer discounts, rebates and incentives;
- Changes in the actual or perceived safety or efficacy profile of *Feraheme/Rienso*, or products that compete with *Feraheme/Rienso* that could cause customers to increase, reduce or discontinue their use of *Feraheme/Rienso*;
- The timing and magnitude of costs associated with commercial-scale manufacturing 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 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 *Feraheme/Rienso* from federal, state and foreign legislative and regulatory authorities, government health administration authorities, private health insurers and other third-party payors; and
- The implementation of new or revised accounting or tax rules or policies.

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

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 Feraheme profitably.

In the U.S., there have been, and we expect there will continue to be, a number of legislative and regulatory proposals aimed at changing the U.S. healthcare system. For example, the Health Care Reform Act contains a number of provisions that significantly impact the pharmaceutical industry and may negatively affect our potential *Feraheme* revenues. Among other things, the Health Care Reform Act increased the minimum Medicaid drug rebates for pharmaceutical companies, extended the rebate provisions to Medicaid managed care organizations, and expanded the 340B Drug Discount Program under the Public Health Service Act. For example, the percentage of *Feraheme* business sold to 340B institutions has grown from 5% in 2010 to 14% in 2012. 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. 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.

In addition, various healthcare reform proposals have emerged at the state level in the U.S. We cannot predict the impact that newly enacted laws or any future legislation or regulation will have on us. We expect that there will continue to be a number of U.S. federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs. These efforts could adversely affect our business by, among other things, limiting the prices that can be charged for *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.

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

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

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

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us, and the related disclosure of contingent assets and liabilities. On an ongoing basis, our management evaluates our critical and other significant estimates and judgments, including among others those associated with revenue recognition related to product sales and collaboration agreements, product sales allowances and accruals, assessing investments for potential other-than-temporary impairment and determining the values of investments, estimates used to measure the fair value of our held for sale assets, accrued expenses, income taxes and equity-based compensation expense. We base our estimates on market data, our observance of trends in our industry, and various other assumptions that we believe to be reasonable under the circumstances. If actual results differ from these estimates, there could be a material adverse effect on our financial results and the performance of our stock.

As part of our revenue recognition policy, our estimates of product returns, rebates and chargebacks, fees and other discounts require subjective and complex judgments due to the need to make estimates about matters that are inherently uncertain. Any significant differences between our actual results and our estimates could materially affect our financial position and results of operations. For example during the years ended December 31, 2012 and 2011, we revised our estimated Medicaid reserve rate, which resulted in a reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales of \$0.6 million and \$2.5 million, respectively. Further, during the year ended December 31, 2012, we reduced our reserve for product returns by approximately \$2.2 million due to a lower than expected actual returns rate since the 2009 launch of *Feraheme* as well as a reduction in our expected rate of product returns in the future.

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

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

The market price of our common stock has been, and may continue to be, volatile, and your investment in our stock could decline in value or fluctuate significantly. Our stock price has ranged between \$12.43 and \$18.50 in the fifty-two week period through February 15, 2013. The stock market has from time to time experienced extreme price and volume fluctuations, particularly in the biotechnology and pharmaceuticals sectors, which have often been unrelated to the operating performance of particular companies. Various factors and events, many of which are beyond our control, may have a significant impact on the market price of our common stock. Factors which may affect the market price of our common stock include, among others:

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

- The timing and magnitude of *Feraheme/Rienso* 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 *Feraheme/Rienso*;
- Developments in patents or other proprietary rights by or for the benefit of us or our competitors, such as the recent decision by the EPO regarding our European ferumoxytol patent or decisions regarding *Feraheme's* NCE status or an ANDA filing by a generic entrant;
- The availability of reimbursement coverage for *Feraheme/Rienso* 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 *Feraheme/Rienso* or products or product candidates of our competitors;
- Actual or perceived safety concerns related to *Feraheme/Rienso* or products or product candidates of our competitors, including any actions taken by U.S. or foreign regulatory authorities in connection with such concerns;
- 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;
- Significant collaboration, product or business acquisitions, joint venture or similar agreements by us or our competitors;
- Shareholder activism and attempts to disrupt our strategy by activist investors;
- General market conditions; and
- Sales of large blocks of our common stock.

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

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

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

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

In 2013, we publicly provided financial guidance, including expected 2013 *Feraheme/Rienso* product revenue, total revenue, estimated operating expenses, estimated cost of goods sold as a percent of sales, quarterly cash flow trajectory throughout 2013 and estimated year-end cash and cash equivalents balance. If, for any reason, we are unable to realize our expected revenue growth in 2013 and beyond, including as the result of a lower-than-anticipated impact of our 2013 price increases, we may fail to realize our publicly announced revenue and year-end cash and cash equivalents balance guidance. If we fail to realize or if we change or update any element of our publicly disclosed financial guidance or other expectations about our business, our stock price could decline in value.

We may need additional capital to achieve our business objectives.

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

- Our ability to successfully commercialize *Feraheme* in the U.S. and Takeda's ability to successfully commercialize *Feraheme/Rienso* in its licensed territories outside of the U.S.;
- The magnitude of U.S. *Feraheme* sales;
- The magnitude of *Feraheme/Rienso* sales and royalties we may receive from Takeda outside of the U.S.;
- Our ability to obtain regulatory approval for *Feraheme/Rienso* to treat IDA regardless of the underlying cause both within the U.S. and outside of the U.S., particularly in the EU;
- The success, costs and structure of any business or corporate development initiatives to bring additional products into our portfolio;
- The outcome of and costs associated with any material litigation or patent challenges to which we are or may become a party;
- Our ability to achieve the various milestones and receive the associated payments under the Amended Takeda Agreement;
- Costs associated with the U.S. commercialization of *Feraheme*, including costs associated with maintaining our commercial infrastructure, executing our promotional and marketing strategy for *Feraheme*, and conducting our required pediatric clinical studies and any post-marketing clinical studies;
- The timing and magnitude of costs associated with qualifying additional manufacturing capacities and alternative suppliers;
- Costs associated with our development of *Feraheme* for the treatment of IDA in a broad range of patients in the U.S.;
- 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 December 31, 2012, combined with cash we currently expect to receive from sales of *Feraheme/Rienso*, from earnings on our investments, and potential royalty payments we may receive from Takeda will be sufficient to finance our currently planned

operations for at least the next twelve months. We may require additional funds or need to establish additional alternative strategic arrangements to execute a business development transaction. We may at any time seek funding through additional arrangements with collaborators through public or private equity or debt financings. We may not be able to obtain financing or to secure alternative strategic arrangements on acceptable terms or within an acceptable timeframe, if at all.

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

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

As of December 31, 2012, we had \$46.3 million in cash and cash equivalents and \$180.8 million in short-term investments. These investments are subject to general credit, liquidity, market and interest rate risks, which have been and may, in the future, be exacerbated by a U.S. and/or global financial crisis. We may realize losses in the fair value of certain of our investments or a complete loss of these investments if the credit markets tighten, which would have an adverse effect on our results of operations, liquidity and financial condition.

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

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 U.S. 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.

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

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

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

We and/or Takeda are subject to ongoing regulatory requirements and review both in the U.S. and in foreign jurisdictions pertaining to *Feraheme/Rienso*'s manufacture, labeling, packaging, adverse event reporting, storage, marketing, promotion and record keeping. Failure to comply with such regulatory requirements or the later discovery of previously unknown problems with *Feraheme/Rienso* or our third-party contract manufacturing facilities or processes by which we manufacture *Feraheme/Rienso* may result in restrictions on our ability to manufacture, market or sell *Feraheme/Rienso*, including its withdrawal from the market. Any such restrictions could result in a decrease in *Feraheme/Rienso* sales, damage to our reputation or the initiation of lawsuits against us, Takeda, or our third-party contract

manufacturers. We and/or Takeda may also be subject to additional sanctions, including but not limited to:

- Warning letters;
- Civil or criminal penalties;
- Suspension or withdrawal of regulatory approvals;
- Temporary or permanent closing of the facilities of our third-party contract manufacturers;
- Requirements to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, or other issues involving *Feraheme/Rienso*;
- Changes to the *Feraheme/Rienso* package insert, such as potential limitations on the current dosage and administration of *Feraheme/Rienso* or IV irons as a class;
- Implementation of risk mitigation programs;
- Restrictions on our continued manufacturing, marketing or sale of *Feraheme/Rienso*; 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.

If we or Takeda market or distribute Feraheme/Rienso 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., and government price reporting laws. False claims laws prohibit anyone from knowingly presenting, or causing to be presented for payment to third-party payors, including Medicare and Medicaid, false or fraudulent claims for reimbursed drugs or services, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Anti-kickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug, that is reimbursed by a state or federal program. The Foreign Corrupt Practices Act and similar foreign anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Similar laws and regulations exist in many other countries throughout the world in which we intend to commercialize *Feraheme/Rienso* through Takeda and our other licensees. We have developed and implemented a corporate compliance program based on what we believe are current best practices in the pharmaceutical industry, but we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all federal, state and foreign regulations. If we, our representatives, or our licensees, including Takeda, fail to comply with any of these laws or regulations, a range of fines, penalties and/or other sanctions could be imposed on us and/or Takeda, including, but not limited to, restrictions on how we and/or Takeda market and sell *Feraheme/Rienso*, 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 publicly report gifts and payments made to physicians and teaching hospitals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Compliance with these laws is difficult, time consuming and costly, and if we are found to not be in full compliance with these laws, we may face enforcement actions, fines and other penalties, and we could receive adverse publicity which could have an adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Any system of internal controls, however 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 United States District Court for the District of Massachusetts, entitled *Silverstrand Investments et. al. v. AMAG Pharm., Inc., et. al.*, Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Executive Vice President and Chief Financial Officer, 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 by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff sought unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. On August 11, 2011, the District Court issued an Opinion and Order dismissing the SAC in its entirety for failure to state a claim upon which relief could be granted. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the United States Court of Appeals for the First Circuit, or the Court of Appeals. After briefing was completed by all parties, the Court of Appeals heard oral argument on May 11, 2012, and took the matter under advisement. 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 18, 2013, we filed a Petition for Panel Hearing or Rehearing *En Banc*, asking the Court of Appeals to reconsider its decision. 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 Feraheme/Rienso.

The administration of *Feraheme/Rienso* to humans, whether in clinical trials or after approval for commercial use, may expose us to liability claims, whether or not *Feraheme/Rienso* is 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. Although we maintain product liability insurance coverage for claims arising from the use of our products in clinical trials and commercial use, coverage is expensive, and we may not be able to maintain sufficient insurance at a reasonable cost, if at all. Product liability claims, whether or not they have merit, could also decrease demand for *Feraheme/Rienso*, subject us to product recalls or harm our reputation, cause us to incur substantial costs, and divert management's time and attention.

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

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

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

- The ability of our Board to increase or decrease the size of the Board without stockholder approval;
- Advance notice requirements for the nomination of candidates for election to our Board and for proposals to be brought before our annual meeting of stockholders;
- The authority of our Board to designate the terms of and issue new series of preferred stock without stockholder approval;
- Non-cumulative voting for directors; and
- 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 Second Amended and Restated 2007 Equity Incentive Plan generally permits our Board to provide for the acceleration of vesting of options granted under that plan in the event of certain transactions that result in a change of control.

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS:

None.

ITEM 2. PROPERTIES:

In May 2008, we entered into a lease agreement for certain real property located at 100 Hayden Avenue, Lexington, Massachusetts for use as our principal executive offices. The term of the lease began on May 22, 2008 and will continue until August 31, 2016 with two successive five year extension terms at our option. The aggregate size of rentable floor area for the offices is 55,924 square feet, and the rent for the initial term commenced in February 2009.

During any extension term, the base rent will be an amount agreed upon by us and the landlord. In addition to base rent, we are also required to pay a proportionate share of the landlord's annual operating costs. On May 20, 2008, in connection with our facility lease, we delivered to the landlord a security deposit of approximately \$0.5 million in the form of an irrevocable letter of credit. The cash securing this letter of credit is classified on our balance sheet as a long-term asset and is restricted in its use.

Our manufacturing and quality operations were located in a building we own comprised of approximately 25,000 square feet located at 61 Mooney Street, Cambridge, Massachusetts. In the third quarter of 2012, we ceased our manufacturing operations at our Cambridge, Massachusetts facility and

moved to a fully outsourced manufacturing supply chain and intend to sell the land and building in the near future. Employees who manage the contract manufacturers and quality operations were moved to our headquarters in Lexington, Massachusetts.

ITEM 3. 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 United States District Court for the District of Massachusetts, entitled *Silverstrand Investments et. al. v. AMAG Pharm., Inc., et. al.*, Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Executive Vice President and Chief Financial Officer, the then members of our Board of Directors, and certain underwriters in our January 2010 offering of common stock violated certain federal securities laws, specifically Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, and that our former President and Chief Executive Officer and former Executive Vice President and Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff sought unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. On August 11, 2011, the District Court issued an Opinion and Order dismissing the SAC in its entirety for failure to state a claim upon which relief could be granted. A separate Order of Dismissal was filed on August 15, 2011. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the United States Court of Appeals for the First Circuit, or the Court of Appeals. After briefing was completed by all parties, the Court of Appeals heard oral argument on May 11, 2012, and took the matter under advisement. 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 18, 2013, we filed a Petition for Panel Hearing or Rehearing *En Banc*, asking the Court of Appeals to reconsider its decision. 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 our previously issued patent which covers ferumoxytol in the EU. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked our European ferumoxytol patent. In December 2012, our notice of appeal was recorded with the EPO, which suspends the revocation of our patent. 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 year ended December 31, 2012. However, any future unfavorable outcome in this matter could negatively affect the magnitude and timing of future revenues, including royalties and milestone payments we may receive from Takeda pursuant to our collaboration agreement with Takeda. We continue to believe the patent is valid and intend to vigorously appeal the decision.

We may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which we are focused. Other than the above actions, we are not aware of any material claims against us as of December 31, 2012.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES:

Market Information

Our common stock trades on the NASDAQ Global Select Market, or NASDAQ, under the trading symbol "AMAG." On February 15, 2013, the closing price of our common stock, as reported on the NASDAQ, was \$16.91 per share. The following table sets forth, for the periods indicated, the high and low sale prices per share for our common stock as reported on the NASDAQ.

	<u>High</u>	<u>Low</u>
Year Ended December 31, 2012		
First quarter	\$19.24	\$14.98
Second quarter	\$16.45	\$12.43
Third quarter	\$17.95	\$14.11
Fourth quarter	\$18.50	\$13.85
Year Ended December 31, 2011		
First quarter	\$19.47	\$15.93
Second quarter	\$19.40	\$15.18
Third quarter	\$19.48	\$12.65
Fourth quarter	\$19.62	\$13.05

Stockholders

On February 15, 2013, we had approximately 100 stockholders of record of our common stock, and we believe that the number of beneficial holders of our common stock was approximately 23,000 based on responses from brokers to a search conducted by Broadridge Financial Solutions, Inc. on our behalf.

Dividends

We have never declared or paid a cash dividend on our common stock. We currently anticipate that we will retain all of our earnings for use in the development of our business and do not anticipate paying any cash dividends in the foreseeable future.

Repurchases of Equity Securities

The following table provides certain information with respect to our purchases of shares of our stock during the fourth quarter of 2012.

<u>Period</u>	<u>Total Number of Shares Purchased(1)</u>	<u>Average Price Paid per Share</u>	<u>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs(2)</u>	<u>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs(2)</u>
October 1, 2012 through October 31, 2012	—	—	—	—
November 1, 2012 through November 30, 2012	628	\$14.34	—	—
December 1, 2012 through December 31, 2012	<u>2,426</u>	<u>\$15.03</u>	—	—
Total	3,054	\$14.89	—	—

(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.

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

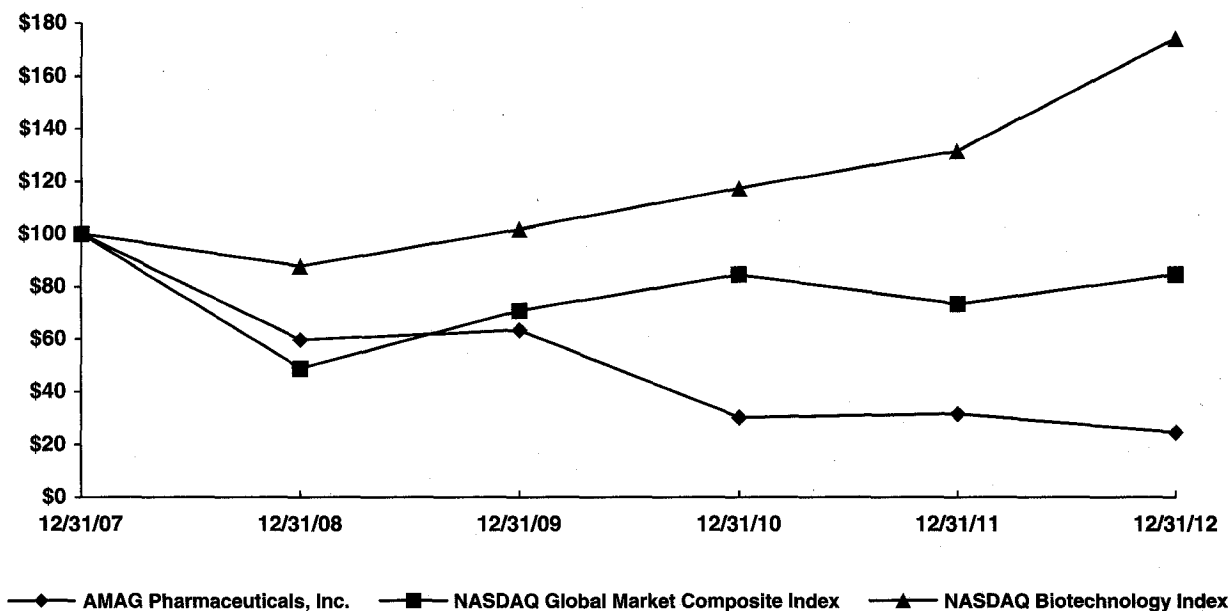
Securities Authorized for Issuance Under Equity Compensation Plans

See Part III, Item 12 for information regarding securities authorized for issuance under our equity compensation plans. Such information is incorporated by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the U.S. Securities and Exchange Commission, or the SEC, not later than 120 days after the close of our year ended December 31, 2012.

Five-Year Comparative Stock Performance Graph

The following graph compares the yearly percentage change in the cumulative total stockholder return on our common stock with the cumulative total return on the NASDAQ Global Market Composite Index and NASDAQ Biotechnology Index over the past five years. The comparisons assume

\$100 was invested on December 31, 2007 in our common stock, in the NASDAQ Global Market and the NASDAQ Biotechnology Index, and assumes reinvestment of dividends, if any.



	12/31/2007	12/31/2008	12/31/2009	12/31/2010	12/31/2011	12/31/2012
AMAG Pharmaceuticals, Inc.	100.00	59.62	63.25	30.10	31.45	24.46
NASDAQ Global Market Composite Index . .	100.00	48.80	70.67	84.51	73.26	84.64
NASDAQ Biotechnology Index	100.00	87.70	101.70	117.18	131.34	173.75

The stock price performance shown in this performance graph is not necessarily indicative of future price performance. Information used in the graph was obtained from Zach's Investment Research, Inc., a source we believe is reliable. However, we are not responsible for any errors or omissions in such information.

The material in this section is being furnished and shall not be deemed "filed" with the SEC for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall the material in this section be deemed to be incorporated by reference in any registration statement or other document filed with the SEC under the Securities Act of 1933, except to the extent we specifically and expressly incorporate it by reference into such filing.

ITEM 6. SELECTED FINANCIAL DATA:

The following table sets forth selected financial data as of and for the years ended December 31, 2012, 2011, 2010, 2009 and 2008. The selected financial data set forth below has been derived from our audited financial statements. This information should be read in conjunction with the financial statements and the related notes thereto included in Part II, Item 8 of this Annual Report on Form 10-K and Management's Discussion and Analysis of Financial Condition and Results of Operations included in Part II, Item 7 of this Annual Report on Form 10-K.

	Years Ended December 31,				
	2012	2011	2010	2009	2008
	(in thousands, except per share data)				
Statement of Operations Data					
Revenues:					
U.S. product sales, net	\$ 58,287	\$ 52,097	\$ 59,339	\$ 15,774	\$ —
International product sales and royalties	120	—	—	—	—
License fee and other collaboration revenues	26,475	8,321	6,132	516	959
Other product sales and royalties	496	831	774	888	979
Total revenues	<u>85,378</u>	<u>61,249</u>	<u>66,245</u>	<u>17,178</u>	<u>1,938</u>
Costs and expenses:					
Cost of product sales	14,220	10,531	7,606	1,013	292
Research and development expenses	33,296	58,140	54,462	36,273	31,716
Selling, general and administrative expenses	53,071	68,863	84,939	77,829	49,536
Restructuring expenses	2,215	3,508	2,224	—	—
Total costs and expenses	<u>102,802</u>	<u>141,042</u>	<u>149,231</u>	<u>115,115</u>	<u>81,544</u>
Other income (expense):					
Interest and dividend income, net	1,286	1,747	1,741	3,154	9,139
(Losses) gains on investments, net	(1,466)	(193)	408	942	(3,024)
Fair value adjustment of settlement rights	—	—	(788)	(778)	1,566
Total other income (expense)	<u>(180)</u>	<u>1,554</u>	<u>1,361</u>	<u>3,318</u>	<u>7,681</u>
Net loss before income taxes	(17,604)	(78,239)	(81,625)	(94,619)	(71,925)
Income tax benefit	854	1,170	472	1,268	278
Net loss	<u>\$(16,750)</u>	<u>\$(77,069)</u>	<u>\$(81,153)</u>	<u>\$(93,351)</u>	<u>\$(71,647)</u>
Net loss per share—basic and diluted:	<u>\$ (0.78)</u>	<u>\$ (3.64)</u>	<u>\$ (3.90)</u>	<u>\$ (5.46)</u>	<u>\$ (4.22)</u>
Weighted average shares outstanding used to compute net loss per share:					
Basic and diluted	21,392	21,189	20,806	17,109	16,993
	December 31,				
	2012	2011	2010	2009	2008
	(in thousands)				
Balance Sheet Data					
Working capital (current assets less current liabilities)	\$221,423	\$201,037	\$254,073	\$ 85,168	\$149,918
Total assets	\$258,137	\$267,224	\$336,076	\$184,619	\$231,955
Long-term liabilities	\$ 52,383	\$ 47,634	\$ 54,079	\$ 4,081	\$ 4,149
Stockholders' equity	\$172,797	\$180,596	\$245,286	\$142,977	\$213,414

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS:

Overview

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a specialty pharmaceutical company focused on the development and commercialization of *Feraheme*[®] (ferumoxytol) Injection for Intravenous, or IV, use to treat iron deficiency anemia, or IDA. 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 commercial sale of *Feraheme* in the U.S. in July 2009 through our own commercial organization, including a specialty sales force. We sell *Feraheme* to authorized wholesalers and specialty distributors, who in turn, sell *Feraheme* to healthcare providers who administer *Feraheme* primarily within hospitals, hematology and oncology centers, and nephrology clinics.

We are working to continue to grow *Feraheme* in the U.S. CKD market and to drive additional growth of *Feraheme* through both international and label expansion. To further build our business, we intend to expand our portfolio through the in-license or purchase of additional marketed specialty pharmaceutical products. We are seeking complementary products that will leverage our commercial infrastructure and focus on hematology and oncology centers, hospital infusion centers or other sites of care where IV iron is administered or where IDA patients are diagnosed or treated. We are also looking at the potential addition of products outside of our current sales force's call points, which could be synergistic with our *Feraheme* goal of expanding the IV iron market through increased referrals from certain physician specialties, such as gastroenterologists.

International Expansion

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

Label Expansion

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

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

package insert for *Feraheme*. In addition, patients from IDA-301 were eligible to enroll in an open-label extension study, or IDA-303, and receive treatment with *Feraheme*, as defined in the protocol.

In December 2012, we submitted a supplemental new drug application, or sNDA, to the FDA, seeking approval for *Feraheme* for the treatment of IDA in adult patients who have failed to or could not use oral iron. The sNDA submission was primarily based on the data from IDA-301 and IDA-302. In addition, the sNDA included data from an interim analysis of IDA-303 and a previously completed post-approval clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron. We believe that approval for *Feraheme* for this expanded indication would effectively double the market opportunity for *Feraheme*, by allowing us to access the half of the IV iron market outside of dialysis that is beyond our current approved indication. Assuming a standard review cycle, we expect a decision from the FDA on our sNDA sometime in the fourth quarter of 2013.

We expect that Takeda will file a Type II Variation, which is the EU equivalent of a U.S. sNDA, with the European Medicines Agency, or EMA, in 2013 seeking marketing approval for *Rienso* for the treatment of IDA in adult patients.

Takeda Collaboration

In March 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme/Rienso* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey. In June 2012, we entered into an amendment to the Takeda Agreement, or the Amended Takeda Agreement, which removed the Commonwealth of Independent States from the territories under which Takeda has the exclusive rights to develop and commercialize *Feraheme/Rienso*. In addition, the Amended Takeda Agreement modified the timing and pricing arrangements for a supply agreement to be entered into between us and Takeda in the future, the terms related to primary and secondary manufacturing for drug substance and drug product, certain patent related provisions, and the re-allocation of certain of the agreed-upon milestone payments. In 2012, we received a total of \$33.0 million in milestone payments from Takeda associated with the EU approval and the commercial launches of *Feraheme/Rienso* in Canada and the EU. In addition, in connection with the commercial launches of *Feraheme/Rienso* by Takeda, we recorded revenue from product sales to Takeda and royalties on sales by Takeda of \$0.1 million in 2012.

Clinical Development of Feraheme

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

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 two pediatric studies needed to meet the requirements of the Pediatric Research Equity Act in the U.S. described above, and two additional pediatric studies requested by the EMA. These studies include a rollover 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 two ongoing pediatric studies of *Feraheme* for the

treatment of IDA in pediatric CKD patients, described above. The amendment to our pediatric investigation plan in 2012 was intended to increase the rate of enrollment for these studies through modifications to the patient entry criteria.

As part of our obligations under the Amended Takeda Agreement and as part of our post-approval commitments to the EMA, we are planning to initiate a multi-center clinical trial to determine the safety and efficacy of repeat doses of ferumoxytol for the treatment of IDA in patients with hemodialysis dependent CKD. As part of the post-approval commitment we made to the EMA as a condition of the approval of the MAA for ferumoxytol in the EU this study includes a treatment arm with iron sucrose as well as a magnetic resonance imaging, or MRI, study which will 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. We currently expect enrollment to begin in the second quarter of 2013. The costs related to the MRI portion of this study are subject to our established cost sharing arrangement with Takeda.

From time to time, we or our licensees may sponsor pilot clinical studies or collaborate with investigators on their research ideas to evaluate the safety and efficacy of *Feraheme* in new indications or alternative dosing regimens.

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

In December 2009, our licensee in China, 3SBio Inc., or 3SBio, filed an application with the Chinese State Food and Drug Administration, or the SFDA, to obtain approval to begin a clinical trial necessary to file for marketing approval of *Feraheme* in China. If approved by the SFDA, 3SBio plans to commence a multi-center randomized efficacy and safety study of *Feraheme* in China involving approximately 200 CKD patients with IDA.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make certain estimates and assumptions that affect the reported amount of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The most significant estimates and assumptions are used in, but are not limited to, revenue recognition related to product sales and collaboration agreements, product sales allowances and accruals, assessing investments for potential other-than-temporary impairment and determining values of investments, estimates used to measure the fair value of our held for sale assets, accrued expenses, income taxes and equity-based compensation expense. Actual results could differ materially from those estimates. In making these estimates and assumptions, management employs critical accounting policies. Our critical accounting policies include revenue recognition and related sales allowances and accruals, valuation of investments and equity-based compensation.

1. Revenue Recognition and Related Sales Allowances and Accruals

We recognize revenue from the sale of *Feraheme/Rienso* as well as license fee and other collaboration revenues, including milestone payments, other product sale revenues, and royalties we receive from our licensees. We recognize revenue in accordance with current accounting guidance related to the recognition, presentation and disclosure of revenue in financial statements, which

outlines the basic criteria that must be met to recognize revenue and provides guidance for disclosure of revenue in financial statements. We recognize revenue when:

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

U.S. Product Sales, Net

We record product sales allowances and accruals related to prompt payment discounts, chargebacks, government and other rebates, distributor, wholesaler and group purchasing organization, or GPO, fees, and product returns as a reduction of revenue in our consolidated statement of operations at the time product sales are recorded. Calculating these gross-to-net sales adjustments involves estimates and judgments based primarily on actual *Feraheme* sales data, forecasted customer buying patterns and market research data related to utilization rates by various end-users. In addition, we also monitor our distribution channel to determine whether additional allowances or accruals are required based on inventory in our sales channel.

Classification of U.S. Product Sales Allowances and Accruals

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

Allowances against receivable balances primarily relate to prompt payment discounts, provider chargebacks and certain government agency rebates and are recorded at the time of sale, resulting in a reduction in product sales revenue and the reporting of product sales receivables net of allowances. Accruals related to Medicaid and provider volume rebates, wholesaler and distributor fees, GPO fees, other discounts to healthcare providers and product returns are recorded at the time of sale, resulting in a reduction in product sales revenue and the recording of an increase in accrued expenses.

Discounts

We typically offer a 2% prompt payment discount to our customers as an incentive to remit payment in accordance with the stated terms of the invoice, generally thirty days. Because we anticipate that those customers who are offered this discount will take advantage of the discount, we accrue 100% of the prompt payment discount, at the time of sale, based on the gross amount of each invoice. We adjust the accrual quarterly to reflect actual experience.

Chargebacks

Chargeback reserves represent our estimated obligations resulting from the difference between the prices at which we sell *Feraheme* to wholesalers and the sales price ultimately paid to wholesalers under fixed price contracts by third-party payors, including governmental agencies. We determine our chargeback estimates based on actual *Feraheme* sales data and forecasted customer buying patterns. Actual chargeback amounts are determined at the time of resale to the qualified healthcare provider, and we generally issue credits for such amounts within several weeks of receiving notification from the wholesaler. Estimated chargeback amounts are recorded at the time of sale, and we adjust the allowance quarterly to reflect actual experience.

Government and Other Rebates

Government and other rebate reserves relate to our reimbursement arrangements with state Medicaid programs or performance rebate agreements with certain classes of trade. We determine our estimates for Medicaid rebates based on actual *Feraheme* sales data, forecasted customer buying patterns and market research data related to utilization rates by various end-users blended with historical experience of products similar to *Feraheme* sold by others. We currently have limited actual claims payment data, and therefore are not able to solely rely on our actual *Feraheme* claims experience. In estimating these reserves, we provide for a Medicaid rebate associated with both those expected instances where Medicaid will act as the primary insurer as well as in those instances where we expect Medicaid will act as the secondary insurer. For rebates associated with reaching defined performance goals, we determine our estimates using actual *Feraheme* sales data and forecasted customer buying patterns. Rebate amounts generally are invoiced quarterly and are paid in arrears, and we expect to pay such amounts within several weeks of notification by the Medicaid or provider entity. Estimated government and other rebates are recorded at the time of sale and, with the exception of Medicaid as discussed below, we adjust the accrual quarterly to reflect actual experience.

During 2012, we revised our estimated Medicaid utilization rate based on actual rebate claims received since the 2009 launch of *Feraheme*, our expectations of state level activity, and estimated rebate claims not yet submitted, which resulted in a \$0.6 million reduction of our estimated Medicaid rebate reserve related to prior period *Feraheme* sales. This change in estimate was reflected as an increase in our net product sales in 2012. As a result, our gross to net percentage for 2012 was slightly lower than it otherwise would have been had we not reduced our Medicaid rebate reserve. We regularly assess our Medicaid reserve balance and the rate at which we accrue for claims against product sales. If we determine in future periods that our actual rebate experience is not indicative of expected claims or if other factors affect estimated claims rates, we may be required to change our estimated Medicaid reserve and/or the current rate at which we estimate our Medicaid claims, which would affect our earnings in the period of the change in estimate and such change could be significant. A 1.0% increase in our estimate of our Medicaid utilization rate for the year ended December 31, 2012 would have resulted in approximately a \$0.2 million decrease in net product sales.

Distributor/Wholesaler and Group Purchasing Organization Fees

Fees under our arrangements with distributors and wholesalers are usually based upon units of *Feraheme* purchased during the prior month or quarter and are usually paid by us within several weeks of our receipt of an invoice from the wholesaler or distributor, as the case may be. Fees under our arrangements with GPOs are usually based upon member purchases during the prior quarter and are generally billed by the GPO within 30 days after period end. Current accounting standards related to consideration given by a vendor to a customer, including a reseller of a vendor's products, specify that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling price of the vendor's products or services and therefore should be characterized as a reduction of revenue. Consideration should be characterized as a cost incurred if we receive, or will receive, an identifiable benefit (goods or services) in exchange for the consideration and we can reasonably estimate the fair value of the benefit received. Because the fees we pay to wholesalers do not meet the foregoing conditions to be characterized as a cost, we have characterized these fees as a reduction of revenue. We generally pay such amounts within several weeks of our receipt of an invoice from the distributor, wholesaler, or GPO. Accordingly, we accrue the estimated fee due at the time of sale, based on the contracted price invoiced to the customer. We adjust the accrual quarterly to reflect actual experience.

Product Returns

Consistent with industry practice, we generally offer our distributors and wholesaler customers a limited right to return product purchased directly from us principally based upon the product's expiration date which, once packaged, is currently four or five years in the U.S. We estimate product returns based upon historical experience since the 2009 launch of *Feraheme* and trends of products similar to *Feraheme* sold by others. 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 *Feraheme's* cost and expense to store. Based on the level of inventory in the wholesale distribution channel, 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. During 2012, we reduced our reserve for product returns by approximately \$2.2 million, primarily as a result of a lower than expected rate of product returns as well as the lapse of the product return period on certain manufactured *Feraheme* lots that carried a two year expiration. As a result, the product returns provision applied to gross product sales for the year ended December 31, 2012 was a credit of \$1.5 million, resulting in an increase to net product sales for the year. The reduction of our estimated product returns reserve had a positive impact of \$0.10 per basic and diluted share for year ended December 31, 2012. We did not significantly adjust our reserve for product returns during 2011 or 2010. *Feraheme* is still early in its product lifecycle and returns experience may change over time. A future revision to our product returns estimate would result in a corresponding change to our net product sales in the period in which the change is made and could be significant. A 1.0% increase in our returns as a percentage of gross sales for the year ended December 31, 2012 would have resulted in approximately a \$0.8 million decrease in net product sales.

International Product Sales and Royalties

We record all international product sales and royalties for *Feraheme/Rienso* sold to Takeda in deferred revenues in our consolidated balance sheet. We recognize these deferred revenues, and the associated cost of product sales, in our consolidated statement of operations at the time Takeda reports to us that sales have been made to its customers.

Milestone Payments under Multiple Element Arrangements

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

We evaluate revenue from arrangements that have multiple elements to determine whether the components of the arrangement represent separate units of accounting as defined in the accounting guidance related to revenue arrangements with multiple deliverables. Under current accounting guidance, which governs any agreements that contain multiple elements that are either entered into or materially modified subsequent to January 1, 2011, companies are required to establish the fair value of undelivered products and services based on a separate revenue recognition process using management's best estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. Agreements entered into prior to January 1, 2011, that have not been materially modified, including our agreements with Takeda and 3SBio, are accounted for under previous accounting guidance, which provides that an element of a contract can be accounted for separately if the delivered elements have standalone value and the fair value of all undelivered elements is determinable. If an element is considered to have standalone value but the fair value of any of the undelivered items cannot be determined, all elements of the arrangement are recognized as revenue as a single unit of accounting over the period of performance for such undelivered items or services. Significant management judgment is required in determining what elements constitute deliverables and what deliverables or combination of deliverables should be considered units of accounting.

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

Our collaboration agreements may entitle us to additional payments upon the achievement of performance-based milestones. If a milestone involves substantive effort on our part and its achievement is not considered probable at the inception of the collaboration, we recognize the milestone consideration as revenue in the period in which the milestone is achieved only if it meets the following additional criteria: (1) the milestone consideration received is commensurate with either the level of effort required to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone; (2) the milestone is related solely to past performance; and (3) the milestone consideration is reasonable

relative to all deliverables and payment terms in the arrangement. There is significant judgment involved in determining whether a milestone meets all of these criteria. For milestones that do not meet the above criteria and are therefore not considered substantive milestones, we recognize that portion of the milestone payment equal to the percentage of the performance period completed at the time the milestone is achieved and the above conditions are met. The remaining portion of the milestone will be recognized over the remaining performance period using a proportional performance or straight-line method.

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

Takeda Agreement

In March 2010, we entered into the Takeda Agreement which, as discussed above, was amended in June 2012 to, among other things, modify the timing and pricing arrangements for a supply agreement to be entered into between us and Takeda in the future, the terms related to primary and secondary manufacturing for drug substance and drug product, certain patent related provisions, and the re-allocation of certain of the agreed-upon milestone payments. We analyzed the Amended Takeda Agreement and determined that the amended terms did not result in a material modification of the original Takeda Agreement based on the fact that there were no changes to the deliverables under the original Takeda Agreement as a result of the amendment, and the change in arrangement consideration as a result of the amendment was not quantitatively material in relation to the total arrangement consideration.

Under the Amended Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme/Rienso* and, accordingly, are responsible for supply of *Feraheme/Rienso* to Takeda at a fixed price per unit, which is capped for a certain period of time. We are also responsible for conducting, and bearing the costs related to, certain pre-defined clinical studies with the costs of future modifications or additional studies to be allocated between the parties according to an agreed-upon cost-sharing mechanism. We have determined that our obligations under the Amended Takeda Agreement have not changed from those under the original Takeda Agreement and include the following four deliverables: the license, access to future know-how and improvements to the *Feraheme/Rienso* technology, regulatory and clinical research activities, and the manufacturing and supply of product. Pursuant to the accounting guidance in effect in 2010, when we signed the original Takeda Agreement and which governed revenue recognition on multiple element arrangements, we evaluated the four deliverables under the original Takeda Agreement and determined that our obligation to provide manufacturing supply of product meets the criteria for separation and is therefore treated as a single unit of accounting, which we refer to as the supply unit of accounting. Further, we concluded that the license is not separable from the undelivered future know-how and technological improvements or the undelivered regulatory and clinical research activities. Accordingly, these deliverables are being combined and also treated as a single unit of accounting, which we refer to as the combined unit of accounting.

With respect to the combined unit of accounting, our obligation to provide access to our future know-how and technological improvements is the final deliverable and is an obligation which exists throughout the term of the Amended Takeda Agreement. In connection with the execution of the original Takeda Agreement, we received a \$60.0 million upfront payment from Takeda in April 2010, which we recorded as deferred revenue, as well as approximately \$1.0 million reimbursed to us during 2010 for certain expenses incurred prior to entering the agreement, which we considered an additional upfront payment. Because we cannot reasonably estimate the total level of effort required to complete the obligations under the combined deliverable, we are recognizing the entire \$60.0 million upfront payment, the \$1.0 million reimbursed to us in 2010, as well as any non-substantive milestone payments

that are achieved into revenues on a straight-line basis over a period of ten years from March 31, 2010, the date on which we originally entered the Takeda Agreement, which represented the then current patent life of *Feraheme/Rienso* and our best estimate of the period over which we will substantively perform our obligations. We continue to believe that the then current patent life of *Feraheme/Rienso* is our best estimate of the period over which we will substantively perform our obligations under this agreement. 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 will be recorded in license fee and other collaboration revenues in our consolidated statement of operations to match the costs that we incur during the period in which we perform those services.

2. Valuation of investments

We generally invest in corporate debt securities, U.S. treasury and government agency securities, commercial paper and, in 2011, auction rate securities, or ARS. All of our investments are classified as "available-for-sale" and are recorded at their estimated fair value. The fair value of our investments is generally determined from quoted market prices received from independent pricing services based upon market transactions. Independent pricing services normally derive security prices from recently reported trades for identical or similar securities, making adjustments based upon other significant observable market transactions. At the end of each reporting period, we perform quantitative and qualitative analyses of prices received from third parties to determine whether prices are reasonable estimates of fair value.

We also analyze when the volume and level of activity for an asset or liability have significantly decreased and when circumstances indicate that a transaction may not be considered orderly. In order to determine whether the volume and level of activity for an asset or liability have significantly decreased, we assess current activity as compared to normal market activity for the asset or liability. We rely on many factors such as trading volume, trading frequency, the levels at which market participants indicate their willingness to buy and sell our securities, as reported by market participants, and current market conditions. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if there has been a significant decrease in the volume and level of activity for an asset, group of similar assets or liabilities. Similarly, in order to identify transactions that are not orderly, we take into consideration the activity in the market which can influence the determination and occurrence of an orderly transaction. Also, we inquire as to whether there may have been restrictions on the marketing of the security to a single or limited number of participants. Where possible, we assess the financial condition of the seller to determine whether observed transactions may have been forced. If there is a significant disparity between the trading price for a security held by us as compared to the trading prices of similar recent transactions, we consider whether this disparity is an indicator of a disorderly trade. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if the evidence suggests that a transaction or group of similar transactions is not orderly. Based upon these procedures, we determined that market activity for our non-ARS assets appeared normal and that transactions did not appear disorderly as of December 31, 2012 and 2011.

In order to assess whether our investments in debt securities which experience a decline in fair value below amortized cost basis are other-than-temporarily impaired, we evaluate whether (i) we have the intent to sell the security or (ii) it is more likely than not that we will be required to sell the security prior to recovery of its amortized cost basis. If either of these conditions is met, we recognize the difference between the amortized cost of the security and its fair value at the impairment

measurement date in our consolidated statement of operations. If neither of these conditions is met, we must perform additional analyses to evaluate whether there could be a credit loss associated with the security. Factors we consider in making this judgment include, but are not limited to:

- The extent to which the market value is less than the cost basis;
- The length of time that the market value has been less than the cost basis;
- Whether the unrealized loss is event-driven, credit-driven or a result of changes in market interest rates or risk premium;
- The investment's rating and whether the investment is investment-grade and/or has been downgraded since its purchase;
- Whether the issuer is current on all payments in accordance with the contractual terms of the investment and is expected to meet all of its obligations under the terms of the investment;
- Any underlying collateral and the extent to which the recoverability of the carrying value of our investment may be affected by changes in such collateral;
- Whether we have a favorable history in redeeming similar securities at prices at or above fair value;
- Unfavorable changes in expected cash flows; and
- Other subjective factors.

If we determine from this analysis that we do not expect to receive cash flows sufficient to recover the entire amortized cost of the security, a credit loss exists, and the impairment is considered other-than-temporary and is recognized in our consolidated statement of operations. Our assessment of whether unrealized losses are other-than-temporary requires significant judgment.

3. Equity-Based Compensation

Under the fair value recognition guidance of equity-based compensation accounting rules, equity-based compensation cost is generally required to be measured at the grant date (based upon an estimate of the fair value of the compensation granted) and recorded to expense over the requisite service period, which generally is the vesting period. Because equity-based compensation expense is based on awards ultimately expected to vest, we must make certain judgments about whether employees and directors will complete the requisite service period. Accordingly, we have reduced the compensation expense being recognized for estimated 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. Forfeitures are estimated based upon historical experience, adjusted for unusual events such as the corporate restructurings in 2012, 2011 and 2010, which resulted in higher than expected turnover and forfeitures in those years. If factors change and we employ different assumptions in future periods, the compensation expense that we record in the future may differ significantly from what we have recorded in the current period.

We estimate the fair value of equity-based compensation involving stock options based on the Black-Scholes option pricing model. We estimate the fair value of our restricted stock units whose vesting is contingent upon market conditions using the Monte-Carlo simulation method. These models require the input of several factors such as the expected option term, the expected risk-free interest rate over the expected option term, the expected volatility of our stock price over the expected option term, and the expected dividend yield over the expected option term and are subject to various assumptions. The fair value of awards whose fair values are calculated using the Black-Scholes option pricing model is generally being amortized on a straight-line basis over the requisite service period and is recognized based on the proportionate amount of the requisite service period that has been rendered

during each reporting period. The fair value of awards with market conditions is being amortized based upon the estimated derived service period. We believe our valuation methodologies are appropriate for estimating the fair value of the equity awards we grant to our employees and directors. Our equity award valuations are estimates and thus may not be reflective of actual future results or amounts ultimately realized by recipients of these grants. These amounts, and the amounts applicable to future quarters, are also subject to future quarterly adjustments based upon a variety of factors, which include, but are not limited to, changes in estimated forfeiture rates and the issuance of new equity-based awards. The fair value of restricted stock units granted to our employees and directors is determined based upon the quoted closing market price per share on the date of grant, adjusted for estimated forfeitures. As with any accounting policy that applies judgments and estimates, actual results could significantly differ from those estimates or our estimates could change in the future.

Impact of Recently Issued and Proposed Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board, or FASB, issued amended guidance on the presentation of comprehensive income in financial statements. This amendment provides companies the option to present the components of net income and other comprehensive income either as one continuous statement of comprehensive income or as two separate but consecutive statements. This guidance eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. The provisions of this guidance became effective in 2012. We have adopted all provisions of this pronouncement by including other comprehensive income as part of our consolidated statements of comprehensive loss and such adoption did not have a significant impact on our consolidated financial statements.

In May 2011, the FASB issued an amendment to the accounting guidance for fair value measurements and related disclosures. This amendment clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable inputs, or Level 3 measurements. This guidance became effective for interim and annual periods beginning after December 15, 2011. We have adopted all provisions of this pronouncement and such adoption did not have a significant impact on our consolidated financial statements.

Results of Operations—Years Ended December 31, 2012, 2011 and 2010

Revenues

Our total revenues for the years ended December 31, 2012, 2011 and 2010 consisted of the following (in thousands):

	Years Ended December 31,			2012 to 2011 change		2011 to 2010 change	
	2012	2011	2010	\$ Change	% Change	\$ Change	% Change
U.S. product sales, net	\$58,287	\$52,097	\$59,339	\$ 6,190	12%	\$(7,242)	-12%
International product sales and royalties	120	—	—	120	N/A	—	—
License fee and other collaboration revenues	26,475	8,321	6,132	18,154	>100%	2,189	36%
Other product sales and royalties	496	831	774	(335)	-40%	57	7%
Total	<u>\$85,378</u>	<u>\$61,249</u>	<u>\$66,245</u>	<u>\$24,129</u>	<u>39%</u>	<u>\$(4,996)</u>	<u>-8%</u>

Our total revenues in 2012 increased by \$24.1 million as compared to 2011, primarily as the result of a \$6.2 million increase in U.S. net product sales and a \$18.2 million increase in our license fee and other collaboration revenues associated with our collaboration agreement with Takeda, as described in further detail below.

The \$5.0 million decrease in our total revenues in 2011 as compared to 2010 was primarily attributable to a \$7.2 million decrease in U.S. net product sales, partially offset by a \$2.2 million increase in our license fee and other collaboration revenues associated with our collaboration agreement with Takeda, as described in further detail below.

The following table sets forth customers who represented 10% or more of our total revenues for the years ended December 31, 2012, 2011 and 2010.

	Years Ended December 31,		
	2012	2011	2010
AmerisourceBergen Drug Corporation	34%	41%	36%
Takeda Pharmaceuticals Company Limited	31%	13%	<10%
McKesson Corporation	17%	21%	<10%
Cardinal Health, Inc.	12%	13%	<10%
Metro Medical Supply, Inc.	<10%	<10%	21%

U.S. Product Sales, Net

Net U.S. product sales for the years ended December 31, 2012, 2011 and 2010 consisted of the following (in thousands):

	Years Ended December 31,			2012 to 2011 change		2011 to 2010 change	
	2012	2011	2010	\$ Change	% Change	\$ Change	% Change
<i>Feraheme</i>	\$58,287	\$52,097	\$59,339	\$6,190	12%	\$(7,242)	-12%
Total	\$58,287	\$52,097	\$59,339	\$6,190	12%	\$(7,242)	-12%

Our total net U.S. product sales increased by \$6.2 million, or 12%, during 2012 as compared to 2011 primarily as the result of an increase in *Feraheme* provider demand in 2012 and to a lesser extent, the impact of our 2012 *Feraheme* price increases, and changes in our estimated reserves, described below. The \$6.2 million increase in our net U.S. product sales was the result of a \$15.5 million increase in our gross U.S. product sales in 2012 as compared to 2011, partially offset by higher allowances related to customer discounts and chargebacks in 2012. During 2012, we recorded allowances of \$33.2 million as compared to \$23.6 million in 2011. These allowances do not include the aggregate of changes in estimated Medicaid and product return reserves of \$2.8 million and \$2.5 million, as described below, that we recorded during the years ended December 31, 2012 and 2011, respectively.

During 2012 and 2011, we revised our estimated Medicaid reserve rate based on actual rebate claims received since the 2009 launch of *Feraheme*, our expectations of state level activity, and estimated rebate claims not yet submitted, which resulted in a reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales of \$0.6 million and \$2.5 million, respectively. Further, during 2012, we reduced our reserve for product returns by approximately \$2.2 million primarily as a result of a lower than expected rate of product returns as well as the lapse of the product return period on certain manufactured *Feraheme* lots that carried a two year expiration. There was no significant adjustment of our reserve for product returns in 2011. These changes in estimates were reflected as an increase in our net product sales for the years ended December 31, 2012 and 2011 and resulted in reductions to our gross to net percentage in these respective periods. We regularly assess our Medicaid and product return reserve balances and accrual rates. If we determine in future periods that our actual

rebate or returns experience is not indicative of expected claims or returns, if our actual claims or returns experience changes, or if other factors affect estimated claims or returns rates, we may be required to change our Medicaid reserve or product return reserve estimates and/or the current rates at which we estimate Medicaid reserves or returns, which would affect our earnings in the period of the change and could be significant.

Our total net U.S. product sales decreased by \$7.2 million, or 12%, in 2011 as compared to 2010. The \$7.2 million decrease was primarily due to decreased sales of *Feraheme* to dialysis providers during 2011 as compared to 2010, including a decrease of \$6.8 million in net sales related to a launch incentive program which we initiated in 2009 and under which we recognized revenues of \$7.0 million during 2010 as compared to \$0.2 million during 2011. Our *Feraheme* net product sales to dialysis customers in 2011 were de minimis relative to our dialysis sales during 2010 principally as a result of the January 2011 implementation of the Medicare prospective payment system, which made it unlikely that dialysis providers would choose to use *Feraheme*. The decreased *Feraheme* net product sales in the dialysis market was only partially offset by increased *Feraheme* net product sales in the non-dialysis market in 2011 as compared to 2010. In addition, during 2011, we revised our estimated Medicaid utilization rate based on actual rebate claims received since the 2009 launch of *Feraheme*, our expectations of state level activity, and estimated rebate claims not yet submitted, which resulted in a \$2.5 million reduction of our 2011 estimated Medicaid rebate reserve related to prior year *Feraheme* sales as compared to a \$0.6 million reduction in our 2010 estimated Medicaid rebate reserve. We also offered higher average customer discounts, chargebacks and rebates to our end-users during 2011 as compared to 2010. During 2011, we reduced our gross product sales by recording allowances of \$23.6 million, excluding the \$2.5 million Medicaid rebate reserve reduction, as compared to allowances of \$22.8 million recorded during 2010, excluding the \$0.6 million Medicaid rebate reserve reduction.

Our U.S. net product sales may fluctuate from period to period due to the enactment of or changes in legislation that impact third-party reimbursement coverage and pricing. For example, in January 2011, the implementation of the Medicare prospective payment system had the effect of significantly diminishing the utilization of *Feraheme* in the dialysis market and as a result, beginning in 2010, *Feraheme* sales in the dialysis setting began to significantly decline and were de minimis in 2012 and 2011. We expect that dialysis sales will continue to be insignificant in 2013 and beyond.

An analysis of our product sales allowances and accruals for the years ended December 31, 2012, 2011 and 2010 is as follows (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Provision for U.S. product sales allowances and accruals			
Discounts and chargebacks	\$26,517	\$13,851	\$ 5,113
Government and other rebates	6,058	8,544	16,374
Medicaid rebate reserve adjustment	(621)	(2,532)	(599)
Returns	(1,516)	1,259	1,334
Total provision for U.S. product sales allowances and accruals	\$30,438	\$21,122	\$22,222
Total gross U.S. product sales	\$88,725	\$73,219	\$81,561
Total provision for U.S. product sales allowances and accruals as a percent of total gross U.S. product sales	34%	29%	27%

Total discounts and chargebacks for 2012 were \$26.5 million, or 30% of total gross product sales, as compared to \$13.9 million, or 19% of total gross product sales, in 2011. The 11% increase in total discounts and chargebacks as a percentage of total gross product sales in 2012 as compared to 2011 was primarily due to higher discounts offered to customers off the gross sales price as well as a change in pricing strategy from offering rebates for purchases of *Feraheme* above a certain minimum volume

threshold to entering into commercial contracts which provide increased upfront discounts on the purchase price of *Feraheme*. Total government and other rebates (excluding any changes in estimates related to Medicaid rebate reserves) were \$6.1 million, or 7% of total gross product sales, in 2012 as compared to \$8.5 million, or 12% of gross product sales, in 2011. The decrease in total government and other rebates as a percentage of gross product sales was related primarily to lower volume rebates offered in 2012 as compared to 2011.

Total discounts and chargebacks for 2011 were \$13.9 million, or 19% of total gross product sales, as compared to \$5.1 million, or 6% of total gross sales in 2010. Total government and other rebates (excluding any changes in estimates related to Medicaid rebate reserves) were \$8.5 million, or 12% of gross product sales, in 2011 as compared to \$16.4 million, or 20% of gross product sales, in 2010. The increase in total discounts and chargebacks as a percentage of total gross product sales and the corresponding decrease in government and other rebates as a percentage of total gross product sales were primarily due to a change in our customer mix and pricing strategy. Beginning in January 2011, with the implementation of the Medicare prospective payment system, the utilization of *Feraheme* in the dialysis market significantly decreased. As a result, our U.S. commercial strategy shifted to focus on growing the utilization of *Feraheme* in non-dialysis CKD patients with IDA, specifically in hematology, oncology, nephrology, and hospital sites of care, many of which are members of GPOs, which leverage the purchasing power of a group of customers to obtain lower prices based on the collective bargaining power of the group. These lower prices are typically obtained through contractually arranged discounting programs. Additionally, as end user experience with *Feraheme* became more established, particularly in these non-dialysis sites of care, during 2011, we entered into commercial contracts which provided discounts on the purchase price of *Feraheme* and gradually decreased our volume rebate programs. These changes resulted in a decrease to our net selling price per unit of *Feraheme* in 2011 as compared to 2010.

We are subject to reimbursement arrangements with state Medicaid programs for which we estimate and record rebate reserves. We determine our estimates for Medicaid rebates based on actual *Feraheme* sales data, forecasted customer buying patterns and market research data related to utilization rates by various end-users blended with historical experience of products similar to *Feraheme* sold by others. During 2012, 2011 and 2010, we revised our estimated Medicaid reserve rate based on actual rebate claims received since the launch of *Feraheme* in July 2009, our expectations of state level activity, and estimated rebate claims not yet submitted, which resulted in a reduction of our estimated Medicaid rebate reserve related to prior period *Feraheme* sales of \$0.6 million, \$2.5 million and \$0.6 million, respectively. These changes in estimates were reflected as an increase in our net product sales for the years ended December 31, 2012, 2011 and 2010 and resulted in reductions to our gross to net percentage in these respective periods. Actual claims to date have been limited. In future periods, we may be required to adjust our estimates based on additional experience or other changes in expectations, and such adjustments may be significant. Any such adjustments would be reflected as a change to our sales allowances and, accordingly, an increase or decrease to net product sales in that period. If actual future results vary from any of our estimates, we may need to adjust our previous estimates, which would also affect our earnings in the period of the adjustment.

We generally offer our wholesalers, specialty distributors and other customers a limited right to return product purchased directly from us, principally based on the product's expiration date which, once packaged, is currently four or five years in the U.S. Reserves for product returns for U.S. sales are recorded in the period the related revenue is recognized, resulting in a reduction to product sales. Currently, sales to our licensees are recognized as revenue when product is sold to our licensees' customers and therefore no return reserve is required at the time of sale to our licensees. We evaluate our estimated product returns rate each period based on the historical return patterns and known or expected changes in the marketplace. During 2012, we reduced our reserve for product returns by approximately \$2.2 million, primarily as a result of a lower than expected rate of product returns as

well as the lapse of the product return period on certain manufactured *Feraheme* lots that carried a two year expiration. As a result, the product returns provision applied to gross product sales for 2012 was a credit of \$1.5 million, resulting in an increase to product sales, as compared to a \$1.3 million charge in both 2011 and 2010, resulting in decreases to product sales. Actual returns to date have been limited. In future periods, we may be required to adjust our estimates based on additional experience or other changes in expectations, which would result in a corresponding change to our net product sales in the period in which the change is made and could be significant. If actual future results vary from any of our estimates, we may need to adjust our previous estimates, which would also affect our earnings in the period of the adjustment.

An analysis of the amount of, and change in, reserves for the years ended December 31, 2012, 2011 and 2010 is as follows (in thousands):

	Discounts and Chargebacks	Government and Other Rebates	Returns	Total
Balance at January 1, 2010	\$ 499	\$ 5,194	\$ 463	\$ 6,156
Current provisions relating to sales in current year	5,113	16,374	1,405	22,892
Other provisions relating to deferred revenue	—	(1,085)	—	(1,085)
Adjustments relating to sales in prior year	—	(599)	(71)	(670)
Payments/returns relating to sales in current year	(3,965)	(8,540)	—	(12,505)
Payments/returns relating to sales in prior year	(499)	(3,126)	—	(3,625)
Balance at December 31, 2010	<u>\$ 1,148</u>	<u>\$ 8,218</u>	<u>\$ 1,797</u>	<u>\$ 11,163</u>
Current provisions relating to sales in current year	14,074	8,605	1,259	23,938
Other provisions relating to deferred revenue	—	(18)	—	(18)
Adjustments relating to sales in prior years	(223)	(2,593)	—	(2,816)
Payments/returns relating to sales in current year	(12,251)	(6,195)	(55)	(18,501)
Payments/returns relating to sales in prior years	(926)	(4,916)	(159)	(6,001)
Balance at December 31, 2011	<u>\$ 1,822</u>	<u>\$ 3,101</u>	<u>\$ 2,842</u>	<u>\$ 7,765</u>
Current provisions relating to sales in current year	26,517	6,152	577	33,246
Adjustments relating to sales in prior years	—	(715)	(2,093)	(2,808)
Payments/returns relating to sales in current year	(24,739)	(4,511)	—	(29,250)
Payments/returns relating to sales in prior years	(1,859)	(1,597)	(308)	(3,764)
Balance at December 31, 2012	<u>\$ 1,741</u>	<u>\$ 2,430</u>	<u>\$ 1,018</u>	<u>\$ 5,189</u>

During 2012, 2011 and 2010, we decreased our product sales allowances and accruals by approximately \$2.8 million, \$2.8 million and \$0.7 million, respectively, for changes in estimates relating to sales in prior years. The \$2.8 million adjustments made during 2012 were primarily due to a net reduction of our reserve for product returns of \$2.2 million as a result of a lower than expected rate of product returns as well as the lapse of the return period on certain manufactured *Feraheme* lots that carried a two year expiration and a \$0.6 million change to our estimated Medicaid rebate reserve. The adjustments made during 2011 and 2010 were primarily due to changes in our estimated Medicaid utilization rate based on actual rebate claims received since the 2009 launch of *Feraheme*, our expectations of state level activity, and estimated rebate claims not yet submitted. This resulted in \$2.5 million and \$0.6 million reductions of our estimated Medicaid rebate reserve for 2011 and 2010, respectively.

Overall, we expect that our reserves as a percentage of gross sales will increase slightly during 2013 as compared to 2012 due primarily to our efforts to continue to increase adoption and utilization of *Feraheme*, our efforts to address continuing reimbursement and competitive pricing pressures, the expected customer mix and utilization rates, and the fact that our reserves as percentage of gross

product sales were positively impacted by changes in our estimated Medicaid rebate and product return reserves during 2012. During 2012, we implemented gross price increases for *Feraheme*, some of which was discounted back to customers under performance-based contracts. We anticipate that the effect of these price increases will offset the impact of the widening gross to net adjustment and that the average net revenue per gram of *Feraheme* will increase in future periods.

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

- The magnitude and timing of adoption of *Feraheme* by physicians, hospitals and other healthcare payors and providers;
- 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 Injectafer®, if approved or generic versions of new or currently available drug therapies;
- The effect of federal and other legislation such as the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the Health Care Reform Act, and the Budget Control Act of 2011;
- The inventory levels maintained by *Feraheme* wholesalers, distributors and other customers;
- The frequency of re-orders by existing customers;
- The impact of any actual or perceived safety or efficacy issues with *Feraheme*; and
- The impact of and any actions taken by us or our competitors to address pricing and reimbursement considerations related to *Feraheme* or products that compete with *Feraheme*.

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

Recent Healthcare Reform Legislation

The Health Care Reform Act was enacted in the U.S. in March 2010 and includes certain cost containment measures including an increase to the minimum rebates for products covered by Medicaid programs and the extension of such rebates to drugs dispensed to Medicaid beneficiaries enrolled in 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. In the first quarter of 2010, an increase from 15.1% to 23.1% in the minimum statutory Medicaid rebate to states participating in the Medicaid program became effective. Given the relatively small portion of our sales that are subject to Medicaid claims, this increase in the minimum Medicaid rebate did not materially reduce our product revenues in 2012, 2011 and 2010.

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 2012 was \$0.1 million and was non-deductible for income tax purposes. We have included this amount in selling, general and administrative expense in our consolidated statement of operations. We were not assessed and therefore did not record any Branded Drug Fee in any period during 2011 or 2010. 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 entities covered by the 340B Drug Discount Program under the Public Health Service Act, which provides drugs at reduced rates, was expanded by the Health Care Reform Act to include additional hospitals. The expansion of 340B eligible entities did not materially impact our discounts and chargebacks as a percentage of gross product sales in 2012 as compared to 2011 or in 2011 as compared to 2010. However, the amount of *Feraheme* business in 340B eligible entities is growing faster than other customers to which we sell. Because of the federal pricing discounts granted to these 340B institutions, the revenue realized per unit of *Feraheme* sold to 340B institutions is lower than from other customers and this change in the mix of our business contributed to our increase in discounts in 2012 as compared to 2011.

We were not materially impacted by recent healthcare reform legislation during 2012, 2011 or 2010. Presently, we have not identified any provisions that could materially impact our business but we will continue to monitor future developments related to this legislation. The potential long-term impact on our business is inherently difficult to predict as many details regarding the implementation of this legislation have not yet been determined.

International Product Sales and Royalties

We record all international product sales and royalties for *Feraheme/Rienso* sold to Takeda in deferred revenues in our consolidated balance sheet. We recognize these deferred revenues, and the associated cost of product sales, in our consolidated statement of operations at the time Takeda reports to us that sales have been made its customers. During 2012, we recognized \$0.1 million in product sales and royalty revenue related to the Amended Takeda Agreement and we have included this revenue in international product sales and royalties in our consolidated statement of income. Takeda launched *Feraheme/Rienso* in Canada, Switzerland and the EU in the fourth quarter of 2012. As of December 31, 2012, we have \$1.0 million in deferred revenue related to product shipped to Takeda, but not yet sold through to Takeda's customers.

License Fee and Other Collaboration Revenues

License fee and other collaboration revenues for the years ended December 31, 2012, 2011 and 2010 consisted of the following (in thousands):

	Years Ended December 31,			2012 to 2011 change		2011 to 2010 change	
	2012	2011	2010	\$ Change	% Change	\$ Change	% Change
Milestone revenues recognized from							
Takeda	\$19,950	\$ —	\$ —	\$19,950	N/A	\$ —	—
Deferred license fee revenues recognized							
from Takeda	6,096	6,096	4,572	—	—	1,524	33%
Reimbursement revenues primarily from							
Takeda	429	2,225	1,560	(1,796)	-81%	665	43%
Total	<u>\$26,475</u>	<u>\$8,321</u>	<u>\$6,132</u>	<u>\$18,154</u>	<u>>100%</u>	<u>\$2,189</u>	<u>36%</u>

Our license fee and other collaboration revenues in 2012 increased by \$18.2 million as compared to 2011 and increased by \$2.2 million in 2011 as compared to 2010. During 2012, we received a \$15.0 million milestone payment from Takeda associated with the regulatory approval of *Rienso* in the EU, which we deemed a substantive milestone and recorded in its entirety in revenues in our license fee and other collaboration revenues in our consolidated statement of operations. In addition, during 2012, we received an aggregate of \$18.0 million of milestone payments related to the commercial launches of *Feraheme/Rienso* in Canada and the EU, which we deemed non-substantive milestones and are amortizing into revenue on a cumulative catch up basis using the proportional performance method extended over the original life of the Takeda Agreement. As a result, we have included \$5.0 million of the \$18.0 million in our license fee and other collaboration revenues in 2012. We did not receive any milestone payments in 2011 or 2010.

In addition, during 2012, 2011 and 2010 we recorded \$6.1 million, \$6.1 million, and \$4.6 million, respectively, of revenues associated with the amortization of \$61.0 million of deferred revenues recorded in connection with the original Takeda Agreement. The \$1.5 million increase in 2011 as compared to 2010 was the result of recognizing a full year of the upfront payment from Takeda during 2011 as compared to nine months during 2010. The \$61.0 million of deferred revenues was comprised of a \$60.0 million upfront payment which we received from Takeda in April 2010, as well as approximately \$1.0 million reimbursed to us during 2010 for certain expenses incurred prior to entering the agreement, which we considered an additional upfront payment. As of December 31, 2012, we had approximately \$44.2 million remaining in deferred revenues related to the \$61.0 million upfront payments received from Takeda.

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 we incur in the conduct of certain regulatory and clinical research 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 in our consolidated statement of operations and offset the costs that we incur during the period in which we perform those services. During 2012, 2011 and 2010, we recorded \$0.4 million, \$2.0 million, and \$1.6 million, respectively, of revenues associated with the reimbursement of out-of-pocket regulatory and clinical supply costs in connection with the Amended Takeda Agreement.

We anticipate that our license fee and other collaboration revenues will decrease in 2013 as compared to 2012 given the non-recurring \$15.0 million substantive milestone payment and the \$5.0 million cumulative catch up associated with the \$18.0 million non-substantive milestone payments we received from Takeda in 2012 and recognized in our 2012 revenues, as discussed above. We do not expect any new milestones to be achieved under the Amended Takeda Agreement in 2013.

Other Product Sales and Royalties

Our other product sales and royalties include product sales of *GastroMARK* to our licensees as well as royalties received from our licensees' sales of *GastroMARK*. The \$0.3 million decrease in our other product sales and royalties in 2012 as compared to 2011 was due to decreased sales as a result of our 2012 terminations of our agreements with our *GastroMARK* licensees.

Costs and Expenses

Cost of Product Sales

Cost of product sales for the years ended December 31, 2012, 2011 and 2010 consisted of the following (in thousands):

	Years Ended December 31,			2012 to 2011 change		2011 to 2010 change	
	2012	2011	2010	\$ Change	% Change	\$ Change	% Change
Cost of Product Sales	\$14,220	\$10,531	\$7,606	\$3,689	35%	\$2,925	38%
Percentage of Net Product Sales and Royalties	24%	20%	13%				

Our cost of product sales are primarily comprised of manufacturing costs, costs of managing our contract manufacturers, and costs for quality assurance and quality control associated with our sales of *Feraheme* in the U.S., international sales of *Feraheme/Rienso*, and *GastroMARK* sales to our licensees. During 2012, our cost of product sales increased by \$3.7 million, or 35%, as compared to 2011. Included in our cost of product sales for 2012 was \$2.3 million in accelerated depreciation and impairment costs associated with our ongoing divestiture of our Cambridge, Massachusetts manufacturing facility. During the third quarter of 2012, we determined that our manufacturing facility and related assets were considered held for sale, based on an analysis of current accounting guidance. This \$2.3 million charge during 2012 reflects an adjustment to reduce the carrying value of these assets to fair value less the cost to sell based on what we believe is the best estimate of the net realizable value of the assets upon divestiture. In addition, the increase in our cost of product sales during 2012 as compared to 2011 was due to \$0.9 million of additional *Feraheme* vials sold and a \$0.6 million write-off of commercial inventory deemed no longer saleable.

Our cost of product sales increased by \$2.9 million, or 38%, during 2011 as compared to 2010 primarily due to higher idle capacity costs at our Cambridge, Massachusetts manufacturing facility. The high idle capacity costs resulted from reduced production activity due to our alignment of production volumes and inventory with our then current and expected *Feraheme* sales. Idle capacity costs are included in cost of product sales in the period incurred.

We expect our cost of product sales as a percentage of net product sales and royalties to decrease during 2013 as compared to 2012 because we do not expect to record any significant costs related to our manufacturing facility during 2013.

Research and Development Expenses

Research and development expenses include external expenses, such as costs of clinical trials, contract research and development expenses, certain manufacturing research and development costs, regulatory filing fees, consulting and professional fees and expenses, and internal expenses, such as compensation of employees engaged in research and development activities, the manufacture of product needed to support research and development efforts, related costs of facilities, and other general costs related to research and development. Where possible, we track our external costs by major project. To the extent that external costs are not attributable to a specific project or activity, they are included in other external costs. Prior to the initial regulatory approval of our products or development of new manufacturing processes, costs associated with manufacturing process development and the manufacture of drug product are recorded as research and development expenses. Subsequent to initial regulatory approval, costs associated with the manufacture of our products for commercial sale are capitalized in inventory and recorded as cost of product sales when sold.

Research and development expenses for the years ended December 31, 2012, 2011 and 2010 consisted of the following (in thousands):

	Years Ended December 31,			2012 to 2011 change		2011 to 2010 change	
	2012	2011	2010	\$ Change	% Change	\$ Change	% Change
External Research and Development Expenses							
<i>Feraheme</i> to treat IDA regardless of the underlying cause	\$12,357	\$27,405	\$17,132	\$(15,048)	-55%	\$10,273	60%
<i>Feraheme</i> to treat IDA in CKD patients	3,226	9,385	11,003	(6,159)	-66%	(1,618)	-15%
<i>Feraheme</i> as a therapeutic agent, general	1,033	917	799	116	13%	118	15%
<i>Feraheme</i> manufacturing process development and materials	2,297	2,752	3,059	(455)	-17%	(307)	-10%
<i>Feraheme</i> as an imaging agent	—	—	2,483	—	—	(2,483)	-100%
Other external costs	152	263	763	(111)	-42%	(500)	-66%
Total	\$19,065	\$40,722	\$35,239	\$(21,657)	-53%	\$ 5,483	16%
Internal Research and Development Expenses							
Compensation, payroll taxes, benefits and other expenses	12,237	15,544	15,715	(3,307)	-21%	(171)	-1%
Equity-based compensation expense	1,994	1,874	3,508	120	6%	(1,634)	-47%
Total	\$14,231	\$17,418	\$19,223	\$ (3,187)	-18%	\$(1,805)	-9%
Total Research and Development Expenses	\$33,296	\$58,140	\$54,462	\$(24,844)	-43%	\$ 3,678	7%

Total research and development expenses incurred in 2012 decreased by \$24.8 million, or 43%, as compared to 2011. The decrease was primarily due to reduced external research and development costs of \$21.7 million in 2012. In addition, 2012 internal research and development costs decreased by \$3.2 million as compared to 2011.

The \$21.7 million, or 53%, decrease in our external research and development expenses in 2012 as compared to 2011, was due primarily to a \$15.0 million decrease in costs incurred in connection with our Phase III clinical development program for *Feraheme* to treat IDA regardless of the underlying cause, which was completed in 2012. In addition, costs associated with our global clinical program to support the MAA in the EU for the treatment of IDA in CKD patients, which was completed in 2012, our post-approval clinical study evaluating *Feraheme* treatment as compared to treatment with another IV iron, which was completed in 2011, and the current pace of enrollment in our on-going pediatric studies of *Feraheme*, decreased by \$6.2 million.

The \$3.2 million, or 18%, decrease in our internal research and development expenses in 2012 as compared to 2011 was primarily attributable to the decrease in compensation and related benefits following our 2012 and 2011 corporate restructurings, which resulted in lower headcount in our research and development departments.

Total research and development expenses incurred in 2011 increased by \$3.7 million, or 7%, from 2010 due to increased external research and development expenses of \$5.5 million in 2011, partially offset by a \$1.8 million decrease in our internal research and development costs in 2011 as compared to 2010.

The \$5.5 million, or 16%, increase in our external research and development expenses in 2011 as compared to 2010, was due primarily to an increase of \$10.3 million in costs incurred in connection with our Phase III clinical development program for *Feraheme* to treat IDA regardless of the underlying cause, which was initiated in June 2010, and costs incurred related to certain of our pediatric studies of *Feraheme*. This increase was partially offset by a \$1.6 million reduction in costs associated with our global clinical program to support the MAA in the EU for the treatment of IDA in CKD patients, which was completed in 2012, as well as \$2.5 million in certain costs incurred in 2010 in connection with a clinical trial for *Feraheme* as an imaging agent, which was discontinued in 2010.

The \$1.8 million, or 9%, decrease in our internal research and development expenses in 2011 as compared to 2010, was primarily attributable to a \$1.6 million reduction of equity-based compensation expense and the net decrease in compensation and related benefits principally due to restructurings that took place in 2011 and 2010, which resulted in lower headcount in our research and development departments during 2011.

Research and Development Activities

We expect research and development expenses to decrease in 2013 as compared to 2012 primarily due to the completion of our clinical development program of *Feraheme* for the treatment of IDA regardless of the underlying cause and the reduction of costs related to the preparation and the related December 2012 submission of our U.S. *Feraheme* sNDA to treat IDA regardless of the underlying cause, partially offset by costs associated with certain *Feraheme* clinical studies we have committed to conduct as a condition of approval of the *Rienso* MAA by the EMA, such as our post-approval commitment discussed above, as well as other miscellaneous research and development related activities in support of our *Feraheme/Rienso* development programs.

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

- *Feraheme to treat IDA regardless of the underlying cause.* This project currently includes: (1) a completed Phase III clinical study evaluating *Feraheme* treatment as compared to treatment with placebo; (2) a completed Phase III clinical study evaluating *Feraheme* treatment as compared to treatment with another IV iron; and (3) a completed extension study.
- *Feraheme to treat IDA in CKD patients.* This project currently includes: (1) a completed clinical study evaluating *Feraheme* treatment as compared to treatment to another IV iron to support the MAA submission; (2) two ongoing pediatric studies that are being conducted as part of our post-approval Pediatric Research Equity Act requirement to support pediatric CKD labeling of *Feraheme*; (3) two additional pediatric studies to be completed in accordance with our approved pediatric investigation plan to support the MAA submission; and (4) a 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 as well as a MRI study to evaluate the potential for iron to accumulate in the body following repeated IV iron administration for the treatment of IDA in patients with CKD over a two year period.

Through December 31, 2012, we have incurred aggregate external research and development expenses of approximately \$57.7 million related to our current program for the development of *Feraheme* to treat IDA regardless of the underlying cause. We currently estimate that the total

remaining external costs associated with the efforts needed to complete this development project will be less than \$3.0 million, which will be incurred in 2013.

Through December 31, 2012, we have incurred aggregate external research and development expenses of approximately \$23.9 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 \$23.0 to \$33.0 million over the next several years.

Conducting clinical trials involves a number of uncertainties, many of which are out of our control. Our estimates of external costs associated with our research and development projects could therefore vary from our current estimates for a variety of reasons including but not limited to the following:

- Delays in our clinical trials due to slow enrollment;
- Unexpected results from our clinical sites that affect our ability to complete the studies in a timely manner;
- Unanticipated adverse reactions to *Feraheme* either in commercial use or in a clinical trial setting;
- Inadequate performance or errors by third-party service providers;
- Any deficiencies in the design or oversight of these studies by us;
- The need to conduct additional clinical trials; or
- Any adverse regulatory action or delay in the submission of any applicable regulatory filing.

As a result, we are unable to reasonably estimate the specific timing of any expected net cash inflows resulting from these projects, provided however, as the result of recent regulatory decisions on our marketing applications in the EU and the respective commercial launches for *Feraheme/Rienso* in the CKD indication in the EU and Canada, we have received \$33.0 million in milestone payments and we have begun receiving product sales revenues and royalty payments in accordance with the Amended Takeda Agreement.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses include costs related to our commercial personnel, including our specialty sales force, medical education professionals, pharmacovigilance and safety monitoring and other commercial support personnel, costs related to our administrative personnel, including our legal, finance, business development and executive personnel, external and facilities costs required to support the marketing and sale of *Feraheme* and other costs associated with our corporate activities.

Selling, general and administrative expenses for the years ended December 31, 2012, 2011 and 2010 consisted of the following (in thousands):

	Years Ended December 31,			2012 to 2011 change		2011 to 2010 change	
	2012	2011	2010	\$ Change	% Change	\$ Change	% Change
Compensation, payroll taxes and benefits	\$23,273	\$29,553	\$35,274	\$ (6,280)	-21%	\$ (5,721)	-16%
Sales and marketing consulting, professional fees, and other expenses	12,133	16,859	27,593	(4,726)	-28%	(10,734)	-39%
General and administrative consulting, professional fees and other expenses	12,860	14,903	11,498	(2,043)	-14%	3,405	30%
Equity-based compensation expense . . .	4,805	7,548	10,574	(2,743)	-36%	(3,026)	-29%
Total	<u>\$53,071</u>	<u>\$68,863</u>	<u>\$84,939</u>	<u>\$(15,792)</u>	<u>-23%</u>	<u>\$(16,076)</u>	<u>-19%</u>

Total selling, general and administrative expenses incurred in 2012 decreased by \$15.8 million, or 23%, as compared to 2011 for the following reasons:

- A \$6.3 million decrease in compensation, payroll taxes and benefits during 2012 as compared to 2011 due primarily to reduced headcount resulting from our 2012 and 2011 corporate restructurings;
- A \$4.7 million decrease in sales and marketing consulting, professional fees, and other expenses during 2012 as compared to 2011 primarily due to reduced costs related to advertising and marketing materials, and certain other general marketing costs;
- A \$2.0 million decrease in general and administrative consulting, professional fees and other expenses during 2012 as compared to 2011 primarily due to a decrease in our professional fees, specifically \$4.5 million of costs incurred in 2011 in connection with our then proposed merger with Allos Therapeutics, Inc., or Allos, including a \$2.0 million expense reimbursement fee paid to Allos in connection with the termination of the merger agreement. These increased costs were partially offset by \$1.6 million in termination fee payments made in 2012 to our *GastroMARK* licensees in connection with the termination of our commercial license agreements with them, costs incurred in 2012 in connection with our intention to expand our product portfolio and the 2012 closure of our Cambridge, Massachusetts manufacturing facility; and
- A \$2.7 million decrease in equity-based compensation expenses for 2012 due primarily to a \$3.3 million reduction of equity-based compensation expense associated with the 2011 departures of certain of our executive officers, including our former chief financial officer, our chief executive officer and our chief commercial officer, and the impact of our 2012 and 2011 corporate workforce reductions, partially offset by the expense associated with equity awards to new employees in 2012, including our current chief executive officer, and additional equity awards to existing employees.

Total selling, general and administrative expenses incurred in 2011 decreased by \$16.1 million, or 19%, as compared to 2010 for the following reasons:

- A \$5.7 million decrease in compensation, payroll taxes and benefits during 2011 as compared to 2010 primarily as a result of reduced headcount resulting from our 2010 restructuring;
- A \$10.7 million decrease in sales and marketing consulting, professional fees, and other expenses during 2011 as compared to 2010 due to reduced costs related to the reduction or elimination of field-based contract nurses, advertising and marketing materials, and certain other general marketing costs;
- A \$3.4 million increase in our general and administrative consulting, professional fees and other expenses during 2011 as compared to 2010 primarily due to \$4.5 million of costs incurred in connection with our then proposed merger with Allos; and
- A \$3.0 million decrease in equity-based compensation expense during 2011 as compared to 2010 due primarily to a \$1.6 million reduction of equity-based compensation expense associated with the 2011 departures of certain of our executive officers, and the expected impact on our equity compensation forfeitures resulting from our 2011 corporate workforce reduction, partially offset by the expense associated with equity awards to new employees and additional equity awards to existing employees. This \$1.6 million includes a reduction of expense of approximately \$0.7 million previously recorded for certain of our former chief executive officer's outstanding equity awards as the result of the modification of the terms of such awards pursuant to his November 2011 separation agreement.

We expect total selling, general and administrative expenses will remain relatively stable during 2013 as compared to 2012.

Restructuring Expense

During 2012, we initiated a corporate restructuring, including a workforce reduction plan. The majority of the workforce reduction plan was associated with our manufacturing and development infrastructure, including our decision to divest our Cambridge, Massachusetts manufacturing facility. As a result of the restructuring, we recorded charges of approximately \$2.2 million in 2012. Of the \$2.2 million in restructuring expense, approximately \$1.5 million was related to employee severance and benefits, and approximately \$0.7 million was related to the write-down of primarily raw material inventory that was no longer usable due to the closure of the facility. The workforce reduction was substantially completed by the end of 2012, and the majority of the related expenses were paid by the end of 2012.

During 2011, we initiated a corporate restructuring, including a workforce reduction plan for which we recorded \$3.5 million of restructuring related costs, primarily related to employee severance and benefits. The workforce reduction was substantially completed by the end of 2011 and the majority of the related expenses were paid by the end of 2012.

During 2010, we also initiated a corporate restructuring, including a workforce reduction plan, for which we recorded \$2.2 million of restructuring related costs, primarily related to employee severance and benefits. These expenses were substantially paid by the end of 2011. The majority of the workforce reduction was completed during 2010 and the remaining positions were eliminated by the end of 2011.

Other Income (Expense)

Other income (expense) for the years ended December 31, 2012, 2011 and 2010 consisted of the following (in thousands):

	<u>Years Ended December 31,</u>			<u>2012 to 2011 change</u>		<u>2011 to 2010 change</u>	
	<u>2012</u>	<u>2011</u>	<u>2010</u>	<u>\$ Change</u>	<u>% Change</u>	<u>\$ Change</u>	<u>% Change</u>
Interest and dividend income, net	\$ 1,286	\$1,747	\$1,741	\$ (461)	-26%	\$ 6	—
(Losses) gains on investments, net	(1,466)	(193)	408	(1,273)	>100%	(601)	<(100%)
Fair value adjustment of settlement rights	—	—	(788)	—	—	788	-100%
Total	<u>\$ (180)</u>	<u>\$1,554</u>	<u>\$1,361</u>	<u>\$(1,734)</u>	<u><(100%)</u>	<u>\$ 193</u>	<u>14%</u>

Other income (expense) for 2012 decreased by \$1.7 million as compared to 2011 primarily due to the \$1.5 million loss we realized on the June 2012 sale of our then remaining ARS portfolio. In addition, there was a \$0.5 million decrease in our interest and dividend income as the result of lower average cash balances in 2012 as compared to 2011.

Other income (expense) in 2011 remained relatively constant as compared to 2010 and we expect interest and dividend income to remain relatively constant in 2013 as compared to 2012.

Income Tax Benefit

We recognized an income tax benefit of \$0.9 million, \$1.2 million and \$0.5 million during the years ended December 31, 2012, 2011 and 2010, respectively, as the result of our recognition of a corresponding income tax expense associated with the increase in value of certain securities as a result of their redemption at prices higher than the fair market value at which they were recorded. This income tax expense was recorded in other comprehensive income.

Net Loss

For the reasons stated above, we incurred a net loss of \$16.8 million, \$77.1 million and \$81.2 million, or \$0.78, \$3.64 and \$3.90 per basic and diluted share, for the years ended December 31, 2012, 2011 and 2010, respectively.

Liquidity and Capital Resources

General

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

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

- Our ability to successfully commercialize *Feraheme* in the U.S. and Takeda's ability to successfully commercialize *Feraheme/Rienso* in its licensed territories outside of the U.S.;
- The magnitude of U.S. *Feraheme* sales;
- Our ability to obtain U.S. and EU regulatory approval for ferumoxytol to treat IDA regardless of the underlying cause;
- Our ability to achieve the various milestones and receive the associated payments under the Amended Takeda Agreement;
- The magnitude of *Feraheme/Rienso* product sales and royalties we may receive from Takeda outside of the U.S.;
- Costs associated with the U.S. commercialization of *Feraheme*, including costs associated with maintaining our commercial infrastructure, executing our promotional and marketing strategy for *Feraheme* and conducting our required pediatric clinical trials and our post-marketing clinical studies;
- Costs associated with qualifying additional manufacturing capacities and alternative suppliers;
- The outcome of and costs associated with any material litigation or patent challenges to which we are or may become a party;
- The success, costs and structure of any business or corporate development initiatives to bring additional products into our portfolio;
- Our ability to maintain successful collaborations with our licensees and/or to enter into additional strategic relationships or acquisitions, if necessary; and
- Our ability to raise additional capital on terms and within a timeframe acceptable to us, if necessary.

As of December 31, 2012, our investments consisted of corporate debt securities, U.S. treasury and government agency securities and commercial paper. We place our cash, cash equivalents and investments in instruments that meet high credit quality and diversification standards, as specified in our investment policy. Our investment policy also limits the amount of our credit exposure to any one issue or issuer, excluding U.S. government entities, and seeks to manage these assets to achieve our goals of preserving principal, maintaining adequate liquidity at all times, and maximizing returns.

Cash, cash equivalents and investments as of December 31, 2012 and 2011 consisted of the following (in thousands):

	December 31,		\$ Change	% Change
	2012	2011		
Cash and cash equivalents	\$ 46,293	\$ 63,474	\$(17,181)	-27%
Short-term investments	180,750	148,703	32,047	22%
Long-term investments	—	17,527	(17,527)	-100%
Total	<u>\$227,043</u>	<u>\$229,704</u>	<u>\$ (2,661)</u>	<u>-1%</u>

The \$2.7 million decrease in cash, cash equivalents and investments as of December 31, 2012 as compared to December 31, 2011 was primarily due to cash expended to fund our operations and working capital, partially offset by cash received from *Feraheme* sales, milestone payments, and product sales and royalty payments from Takeda and interest income.

We expect that our cash, cash equivalents and investments balances, in the aggregate, will decrease in 2013. Our expectation assumes our continued investment in the development and commercialization of *Feraheme*, and the continued realignment of our cost structure following our 2012 and 2011 corporate restructurings. We believe that our cash, cash equivalents and investments as of December 31, 2012 and the cash we currently expect to receive from sales of *Feraheme*, earnings on our investments, and potential product sales and royalty payments from Takeda will be sufficient to satisfy our cash flow needs for at least the next twelve months, including projected operating expenses related to our ongoing development and commercialization programs for *Feraheme*.

During 2012, we initiated a corporate restructuring, including a workforce reduction plan. The majority of the workforce reduction plan was associated with our manufacturing and development infrastructure, including our decision to divest our Cambridge, Massachusetts manufacturing facility. As a result of the restructuring, we recorded charges of approximately \$2.2 million in 2012. Of the \$2.2 million in restructuring expense, approximately \$1.5 million was related to employee severance and benefits, and approximately \$0.7 million was related to the write-down of primarily raw material inventory that was no longer usable due to the closure of the facility. The workforce reduction was substantially completed by the end of 2012, and the majority of the related expenses were paid by the end of 2012.

During 2011, we initiated a corporate restructuring, including a workforce reduction plan for which we recorded \$3.5 million of restructuring related costs, primarily related to employee severance and benefits. The workforce reduction was substantially completed by the end of 2011 and the related expenses were substantially paid by the end of 2012.

In June 2012, we sold our remaining ARS portfolio, with a par value of \$19.8 million, for proceeds of \$18.3 million and recognized a loss of approximately \$1.5 million in other income (expense) in our 2012 consolidated statement of income. All of the ARS we held consisted of municipal bonds with an auction reset feature and were classified as available-for-sale.

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

Year Ended December 31, 2012

Cash flows from operating activities

During 2012, our use of \$1.2 million in cash in operations was attributable principally to our net loss of approximately \$16.8 million, adjusted for the following:

- Non-cash operating items of \$14.6 million including equity-based compensation expense, depreciation, amortization of premium/discount on purchased securities, net losses (gains) on investments, and other non-cash items;
- An increase in deferred revenues and other long-term liabilities of \$7.5 million, primarily from the deferral of a portion of the milestones received from Takeda in 2012;
- A combined decrease of \$5.6 million in accounts receivable, prepaid assets and inventories; and
- A decrease of \$12.1 million in accounts payable and accrued expenses.

Our net loss of \$16.8 million was primarily the result of compensation and other expenses, 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 and collaboration revenues, including the recognition of approximately \$20.0 million in milestone payments from Takeda.

Cash flows from investing activities

Cash used in investing activities in 2012 was \$16.4 million and was primarily attributable to the purchases of investments, partially offset by proceeds from the sales and maturities of our investments, including the June 2012 sale of our remaining ARS portfolio.

Year Ended December 31, 2011

Cash flows from operating activities

During 2011, our use of \$63.8 million of cash in operations was attributable principally to our net loss of approximately \$77.1 million, adjusted for the following:

- Non-cash operating items of \$15.2 million including equity-based compensation expense, depreciation, income tax benefit, and other non-cash items;
- A decrease in deferred revenues and other long-term liabilities of \$6.7 million, which reflects timing differences between the receipt and payment of cash associated with certain transactions and the recognition of such amounts in our results of operations;
- A combined decrease of \$3.1 million in accounts receivable, prepaid assets and inventories; and
- An increase of \$1.7 million in accounts payable and accrued expenses.

Our net loss of \$77.1 million in 2011 was primarily the result of commercialization expenses, including marketing and promotion costs, compensation and other expenses, research and development costs, including costs associated with our clinical trials, and general and administrative costs, partially offset by net product and collaboration revenues.

Cash flows from investing activities

Cash provided by investing activities in 2011 was \$14.0 million during 2011 and was primarily attributable to proceeds from the sales and maturities of our investments partially offset by purchases of investments.

Contractual Obligations

We currently have no long-term debt obligations or capital lease obligations. Our contractual obligations primarily consist of our obligations under non-cancellable operating leases and other purchase obligations. Future lease obligations and purchase commitments, as of December 31, 2012, are as follows (in thousands):

	Payment due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Facility lease obligations	\$ 7,945	\$2,080	\$4,309	\$1,556	\$—
Purchase commitments	3,710	3,550	100	60	—
Operating lease obligations, excluding facility lease	161	101	60	—	—
Total	<u>\$11,816</u>	<u>\$5,731</u>	<u>\$4,469</u>	<u>\$1,616</u>	<u>\$—</u>

Operating and Facility Lease Obligations

We have entered into certain operating leases, including leases of certain automobiles and certain office equipment which expire through 2014. We lease approximately 76 automobiles for our field-based employees. These leases require an initial minimum lease commitment of 12 months per automobile, after which we are responsible for certain disposal costs in the event of termination of the lease. As of December 31, 2012, all of our leased automobiles have been held beyond the initial 12 month commitment period.

In May 2008, we entered into a lease agreement for certain real property located at 100 Hayden Avenue, Lexington, Massachusetts for use as our principal executive offices. The term of the lease began on May 22, 2008 and will continue until August 31, 2016 with two successive five year extension terms at our option. The aggregate size of rentable floor area for the offices is 55,924 square feet, and the rent for the initial term commenced in February 2009. The lease requires us to pay rent as follows (in thousands):

Period	Minimum Lease Payments
Year Ended December 31, 2013	\$2,071
Year Ended December 31, 2014	2,127
Year Ended December 31, 2015	2,183
Year Ended December 31, 2016	1,556
Total	<u>\$7,937</u>

During any extension term, the base rent will be an amount agreed upon by us and the landlord. In addition to base rent, we are also required to pay a proportionate share of the landlord's annual operating costs.

Purchase Commitments

During 2012, we entered into various agreements with third parties for which we had remaining purchase commitments of approximately \$3.7 million as of December 31, 2012. These agreements principally related to certain purchase orders for the production of *Feraheme/Rienso*, outsourced commercial activities, manufacturing commitments, our information technology infrastructure and other operational activities.

Other Funding Commitments

As of December 31, 2012, we had several ongoing clinical studies in various clinical trial stages. Our most significant clinical trial expenditures were to clinical research organizations, or CROs. The contracts with CROs are generally cancellable, with notice, at our option. We have recorded accrued expenses in our consolidated balance sheet of approximately \$0.7 million representing expenses incurred with these organizations as of December 31, 2012, net of any amounts prepaid to these CROs. As a result of our cancellation rights, we have not included these CRO contracts in the contractual obligations table above.

Severance Arrangements

We have entered into employment agreements or other arrangements with most of our executive officers and certain other employees, which provide for salary continuation payments and, in certain instances, the acceleration of the vesting of certain equity awards to such individuals in the event that the individual is terminated other than for cause, as defined in the applicable employment agreements or arrangements.

Indemnification Agreements

In the course of operating our business, we have entered into a number of indemnification arrangements under which we may be required to make payments to or on behalf of certain third parties including our directors, officers, and certain employees as well as certain other third parties with whom we enter into agreements. For further discussion of how this may affect our business, refer to Note M of the Notes to Financial Statements included in Part II, Item 8 "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

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 United States District Court for the District of Massachusetts, entitled *Silverstrand Investments et. al. v. AMAG Pharm., Inc., et. al.*, Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Executive Vice President and Chief Financial Officer, the then members of our Board of Directors, and certain underwriters in our January 2010 offering of common stock violated certain federal securities laws, specifically Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, and that our former President and Chief Executive Officer and former Executive Vice President and Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff sought unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering

on or about January 21, 2010. On August 11, 2011, the District Court issued an Opinion and Order dismissing the SAC in its entirety for failure to state a claim upon which relief could be granted. A separate Order of Dismissal was filed on August 15, 2011. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the United States Court of Appeals for the First Circuit, or the Court of Appeals. After briefing was completed by all parties, the Court of Appeals heard oral argument on May 11, 2012, and took the matter under advisement. 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 18, 2013, we filed a Petition for Panel Hearing or Rehearing *En Banc*, asking the Court of Appeals to reconsider its decision.

In July 2010, Sandoz GmbH, or Sandoz, filed with the European Patent Office, or the EPO, an opposition to our previously issued patent which covers ferumoxytol in the EU. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked our European ferumoxytol patent. In December 2012, our notice of appeal was recorded with the EPO, which suspends the revocation of our patent. 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 year ended December 31, 2012. However, any future unfavorable outcome in this matter could negatively affect the magnitude and timing of future revenues, including royalties and milestone payments we may receive from Takeda pursuant to our collaboration agreement with Takeda. We continue to believe the patent is valid and intend to vigorously appeal the decision.

For additional information on our Legal Proceedings, please see the discussion under Part I, Item 3—Legal Proceedings.

Off-Balance Sheet Arrangements

As of December 31, 2012, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK:

As of December 31, 2012 and 2011, our investments equaled \$180.8 million and \$166.2 million, respectively, and were invested in corporate debt securities, U.S. treasury and government agency securities, commercial paper and, as of December 31, 2011, the amount also included auction rate securities, or ARS. Our investments 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. These investments are subject to interest rate risk. The modeling technique used measures the change in fair values arising from an immediate hypothetical shift in market interest rates and assumes that ending fair values include principal plus accrued interest. If market interest rates for comparable investments were to increase immediately and uniformly by 50 basis points, or one-half of a percentage point, from levels as of December 31, 2012 and 2011, this would have resulted in a hypothetical decline in fair value of our investments, excluding our ARS, of approximately \$1.0 million and \$0.6 million, respectively, and if market interest rates for comparable investments were to decrease immediately and uniformly by 50 basis points, or one-half of a percentage point, from levels as of December 31, 2012 and 2011, this would have resulted in a hypothetical increase in fair value of our investments, excluding our ARS, of approximately \$0.9 million and \$0.5 million, respectively. These amounts are determined by considering the impact of the hypothetical interest rate movements on our available-for-sale

investment portfolios. This analysis does not consider the effect of credit risk as a result of the changes in overall economic activity that could exist in such an environment.

As of December 31, 2011, we held a total of \$17.5 million in fair market value of ARS, reflecting an impairment of approximately \$2.4 million as compared to the par value of these securities of \$19.9 million. These securities were sold in 2012 for \$18.3 million and we recognized a loss of \$1.5 million on the sale.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA:

Index To Consolidated Financial Statements

Management's Annual Report on Internal Control over Financial Reporting	94
Report of Independent Registered Public Accounting Firm	95
Consolidated Balance Sheets—as of December 31, 2012 and 2011	96
Consolidated Statements of Operations—for the years ended December 31, 2012, 2011 and 2010 ..	97
Consolidated Statements of Comprehensive Loss—for the years ended December 31, 2012, 2011 and 2010	98
Consolidated Statements of Stockholders' Equity—as of December 31, 2012, 2011 and 2010	99
Consolidated Statements of Cash Flows—for the years ended December 31, 2012, 2011 and 2010 ..	100
Notes to Consolidated Financial Statements	101

MANAGEMENT'S ANNUAL REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management is responsible for establishing and maintaining adequate internal controls over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities and Exchange Act of 1934, as amended. Our internal control over financial reporting is a process designed under the supervision of our principal executive officer and principal financial officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we assessed the effectiveness of our internal control over financial reporting as of December 31, 2012 based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2012.

The effectiveness of our internal control over financial reporting as of December 31, 2012 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of AMAG Pharmaceuticals, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows present fairly, in all material respects, the financial position of AMAG Pharmaceuticals, Inc. and its subsidiaries at December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.



Boston, Massachusetts
March 1, 2013

AMAG Pharmaceuticals, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	As of December 31,	
	2012	2011
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 46,293	\$ 63,474
Short-term investments	180,750	148,703
Accounts receivable, net	6,410	5,932
Inventories	12,451	15,206
Receivable from collaboration	263	428
Assets held for sale	2,000	—
Prepaid and other current assets	6,213	6,288
Total current assets	254,380	240,031
Property, plant and equipment, net	3,297	9,206
Long-term investments	—	17,527
Restricted cash	460	460
Total assets	\$ 258,137	\$ 267,224
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,515	\$ 3,732
Accrued expenses	20,338	28,916
Deferred revenues	9,104	6,346
Total current liabilities	32,957	38,994
Long-term liabilities:		
Deferred revenues	50,350	45,196
Other long-term liabilities	2,033	2,438
Total liabilities	85,340	86,628
Commitments and contingencies (Notes M & N)		
Stockholders' equity:		
Preferred stock, par value \$0.01 per share, 2,000,000 shares authorized; none issued	—	—
Common stock, par value \$0.01 per share, 58,750,000 shares authorized; 21,506,754 and 21,306,413 shares issued and outstanding at December 31, 2012 and 2011, respectively	215	213
Additional paid-in capital	632,487	625,133
Accumulated other comprehensive loss	(3,247)	(4,842)
Accumulated deficit	(456,658)	(439,908)
Total stockholders' equity	172,797	180,596
Total liabilities and stockholders' equity	\$ 258,137	\$ 267,224

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

AMAG Pharmaceuticals, Inc.
Consolidated Statements of Operations
(in thousands, except per share data)

	Years Ended December 31,		
	2012	2011	2010
Revenues:			
U.S. product sales, net	\$ 58,287	\$ 52,097	\$ 59,339
International product sales and royalties	120	—	—
License fee and other collaboration revenues	26,475	8,321	6,132
Other product sales and royalties	496	831	774
Total revenues	85,378	61,249	66,245
Costs and expenses:			
Cost of product sales	14,220	10,531	7,606
Research and development expenses	33,296	58,140	54,462
Selling, general and administrative expenses	53,071	68,863	84,939
Restructuring expenses	2,215	3,508	2,224
Total costs and expenses	102,802	141,042	149,231
Other income (expense):			
Interest and dividend income, net	1,286	1,747	1,741
(Losses) gains on investments, net	(1,466)	(193)	408
Fair value adjustment of settlement rights	—	—	(788)
Total other income (expense)	(180)	1,554	1,361
Net loss before income taxes	(17,604)	(78,239)	(81,625)
Income tax benefit	854	1,170	472
Net loss	<u>\$(16,750)</u>	<u>\$(77,069)</u>	<u>\$(81,153)</u>
Net loss per share:			
Basic and diluted	\$ (0.78)	\$ (3.64)	\$ (3.90)
Weighted average shares outstanding used to compute net loss per share:			
Basic and diluted	21,392	21,189	20,806

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

AMAG Pharmaceuticals, Inc.
Consolidated Statements of Comprehensive Loss
(in thousands)

	<u>Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Net loss	<u>\$(16,750)</u>	<u>\$(77,069)</u>	<u>\$(81,153)</u>
Other comprehensive income (loss):			
Unrealized gains (losses) on securities:			
Holding gains (losses) arising during period, net of tax	129	1,980	497
Reclassification adjustment for (gains) losses included in net loss .	<u>1,466</u>	<u>206</u>	<u>400</u>
Net unrealized gains (losses) on securities	<u>1,595</u>	<u>2,186</u>	<u>897</u>
Total comprehensive loss	<u>\$(15,155)</u>	<u>\$(74,883)</u>	<u>\$(80,256)</u>

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

AMAG Pharmaceuticals, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2009	17,363	\$174	\$432,414	\$(281,686)	\$(7,925)	\$142,977
Net shares issued in connection with the exercise of stock options and restricted stock units	132	1	1,336	—	—	1,337
Shares issued in connection with employee stock purchase plan	42	—	892	—	—	892
Non-cash equity-based compensation	—	—	14,777	—	—	14,777
Unrealized gains on securities, net of tax of \$0.5 million	—	—	—	—	897	897
Shares issued in connection with financing, net of financing costs of \$8.1 million	3,600	36	165,523	—	—	165,559
Net loss	—	—	—	(81,153)	—	(81,153)
Balance at December 31, 2010	21,137	211	614,942	(362,839)	(7,028)	245,286
Net shares issued in connection with the exercise of stock options and restricted stock units	132	1	120	—	—	121
Shares issued in connection with employee stock purchase plan	37	1	507	—	—	508
Non-cash equity-based compensation	—	—	9,564	—	—	9,564
Unrealized gains on securities, net of tax of \$1.2 million	—	—	—	—	2,186	2,186
Net loss	—	—	—	(77,069)	—	(77,069)
Balance at December 31, 2011	21,306	213	625,133	(439,908)	(4,842)	180,596
Net shares issued in connection with the exercise of stock options and restricted stock units	178	2	98	—	—	100
Shares issued in connection with employee stock purchase plan	23	—	270	—	—	270
Non-cash equity-based compensation	—	—	6,986	—	—	6,986
Unrealized gains on securities, net of tax of \$0.9 million	—	—	—	—	1,595	1,595
Net loss	—	—	—	(16,750)	—	(16,750)
Balance at December 31, 2012	21,507	\$215	\$632,487	\$(456,658)	\$(3,247)	\$172,797

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

AMAG Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2012	2011	2010
Cash flows from operating activities:			
Net loss	\$ (16,750)	\$ (77,069)	\$ (81,153)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	3,084	2,536	2,405
Impairment loss on assets held for sale	1,100	—	—
Non-cash equity-based compensation expense	7,024	10,038	14,523
Non-cash income tax benefit	(854)	(1,170)	(481)
Amortization of premium/discount on purchased securities	2,808	3,639	1,679
Fair value adjustment of settlement rights	—	—	788
Losses (gains) on investments, net	1,466	193	(408)
Changes in operating assets and liabilities:			
Accounts receivable, net	(478)	(147)	21,565
Inventories	5,891	1,506	(6,675)
Receivable from collaboration	165	13	(441)
Prepaid and other current assets	75	1,661	(2,477)
Accounts payable and accrued expenses	(12,195)	1,698	2,745
Deferred revenues	7,912	(6,353)	46,697
Other long-term liabilities	(405)	(349)	(294)
Total adjustments	15,593	13,265	79,626
Net cash used in operating activities	(1,157)	(63,804)	(1,527)
Cash flows from investing activities:			
Proceeds from sales or maturities of investments	133,061	141,095	160,079
Purchase of investments	(149,406)	(126,585)	(262,597)
Capital expenditures	(47)	(507)	(1,223)
Net cash (used in) provided by investing activities	(16,392)	14,003	(103,741)
Cash flows from financing activities:			
Proceeds from the exercise of stock options	98	121	1,337
Proceeds from the issuance of common stock, net of underwriting discounts and other expenses	—	—	165,559
Proceeds from the issuance of common stock under ESPP	270	508	892
Net cash provided by financing activities	368	629	167,788
Net (decrease) increase in cash and cash equivalents	(17,181)	(49,172)	62,520
Cash and cash equivalents at beginning of the year	63,474	112,646	50,126
Cash and cash equivalents at end of the year	<u>\$ 46,293</u>	<u>\$ 63,474</u>	<u>\$ 112,646</u>
Supplemental data:			
Non-cash investing activities:			
Accrued construction in progress	\$ 228	\$ —	\$ —

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

Notes to Consolidated Financial Statements

A. Description of Business

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a specialty pharmaceutical company focused on the development and commercialization of *Feraheme*[®] (ferumoxytol) Injection for Intravenous, or IV, use to treat iron deficiency anemia, or IDA. 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 commercial sale of *Feraheme* in the U.S. in July 2009 through our own commercial organization, including a specialty sales force. We sell *Feraheme* to authorized wholesalers and specialty distributors, who in turn, sell *Feraheme* to healthcare providers who administer *Feraheme* primarily within hospitals, hematology and oncology centers, and nephrology clinics.

Outside of the U.S., ferumoxytol has been granted marketing approval in Canada, Switzerland and the European Union, or EU, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. The European marketing authorization is valid in the current EU member states as well as in Iceland and Norway. Under our amended agreement with Takeda Pharmaceutical Company Limited, or Takeda, Takeda has an exclusive license to market and sell ferumoxytol in Canada, the EU and Switzerland, as well as certain other geographic territories. In Canada, Takeda promotes ferumoxytol under the trade name *Feraheme* and in the EU and Switzerland, Takeda promotes ferumoxytol under the trade name *Rienso*[®] 30mg/ml solution for Injection. In 2012, we received a total of \$33.0 million in milestone payments from Takeda associated with the EU approval and the commercial launches of *Feraheme/Rienso* in Canada and the EU. In addition, in connection with the commercial launches of *Feraheme/Rienso* by Takeda, we recorded revenue from product sales to Takeda and royalties on sales by Takeda of \$0.1 million in 2012.

GastroMARK[®], which is marketed and sold under the trade name *Lumirem*[®] outside of the U.S, is our oral contrast agent used for delineating the bowel during magnetic resonance imaging and is approved and marketed in the U.S., Europe and other countries through our licensees. In the second quarter of 2012, we terminated our commercial license agreements for *GastroMARK*. Following the completion of our obligations under these agreements in the first quarter of 2013, we intend to cease commercially manufacturing or selling *GastroMARK*. Pursuant to the terms of the respective termination agreements, in June 2012, we paid our licensees aggregate termination fees of \$1.6 million, which we recorded in selling, general and administrative expenses in our consolidated statement of operations.

We are subject to risks common to companies in the pharmaceutical industry including, but not limited to, our sole dependence on the success of *Feraheme/Rienso*, uncertainties related to the protection of our proprietary technology, our dependence on third parties to manufacture *Feraheme/Rienso*, the potential development of significant safety or drug interaction problems with respect to *Feraheme/Rienso*, uncertainty of the regulatory approval process for the broader *Feraheme/Rienso* indication or for potential alternative manufacturing facilities and processes, uncertainties related to potential collaborations, in-licensing arrangements or acquisition agreements, competition in our industry, uncertainties regarding market acceptance of *Feraheme/Rienso*, our reliance on a limited number of customers, uncertainties related to patient insurance coverage and third-party reimbursement rates and terms for *Feraheme/Rienso*, our reliance on Takeda to commercialize *Feraheme/Rienso* in certain territories outside of the U.S., the potential inability of our third-party manufacturers to operate their facilities in compliance with current good manufacturing practices and manufacture sufficient quantities of *Feraheme/Rienso*, our or our third-party manufacturers' potential inability to obtain raw or other materials, our potential inability to become profitable in the future, our limited experience commercializing and distributing a pharmaceutical product, our dependence on key personnel, the potential fluctuation of our operating results, uncertainties related to the impact of

current and future healthcare initiatives and legislation, potential differences between actual future results and the estimates or assumptions used by us in preparation of our consolidated financial statements, the volatility of our stock price, our potential inadvertent failure to comply with reporting and payment obligations under government pricing programs, our potential inadvertent failure to comply with the regulations of the FDA or other federal, state or foreign government agencies, uncertainties related to the actions of activist stockholders, potential product liability, potential legislative and regulatory changes, and potential costs and liabilities associated with pending or future litigation or patent challenges.

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

B. Summary of Significant Accounting Policies

Use of Estimates and Assumptions

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

Principles of Consolidation

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

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. At December 31, 2012, substantially all of our cash and cash equivalents were held in either commercial bank accounts or money market funds.

Investments

We account for and classify our investments as either “available-for-sale,” “trading,” or “held-to-maturity,” in accordance with current guidance related to the accounting and classification of certain investments in debt and equity securities. The determination of the appropriate classification by us is based on a variety of factors, including management’s intent at the time of purchase. As of December 31, 2012 and 2011, all of our investments were classified as available-for-sale securities.

Available-for-sale securities are those securities which we view as available for use in current operations, if needed. We generally classify our available-for-sale securities as short-term investments, even though the stated maturity date may be one year or more beyond the current balance sheet date. Available-for-sale investments are stated at fair value with their unrealized gains and losses included as a separate component of stockholders’ equity entitled “Accumulated other comprehensive loss,” until such gains and losses are realized or until an unrealized loss is considered other-than-temporary.

We recognize and report other-than-temporary impairments of our debt securities in accordance with current accounting guidance, which requires that for debt securities with a decline in fair value below amortized cost basis, an other-than-temporary impairment exists if (i) we have the intent to sell the security or (ii) it is more likely than not that we will be required to sell the security prior to recovery of its amortized cost basis. If either of these conditions is met, we recognize the difference between the amortized cost of the security and its fair value at the impairment measurement date in our consolidated statement of operations. If neither of these conditions is met, we must perform additional analyses to evaluate whether the unrealized loss is associated with the creditworthiness of the security rather than other factors, such as interest rates or market factors. These factors include evaluation of the security, issuer and other factors such as the duration of the period that, and extent to which, the fair value was less than cost basis, the financial health of and business outlook for the issuer, including industry and sector performance, operational and financing cash flow factors, overall market conditions and trends, underlying collateral, whether we have a favorable history in redeeming similar securities at prices at or above fair value, and credit ratings with respect to our investments provided by investments ratings agencies. If we determine from this analysis that we do not expect to receive cash flows sufficient to recover the entire amortized cost of the security, a credit loss exists. In this situation, the impairment is considered other-than-temporary and is recognized in our consolidated statement of operations.

Fair Value of Financial Instruments

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

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.

Assets Measured at Fair Value on a Recurring Basis

We hold certain assets that are required to be measured at fair value on a recurring basis, including our cash equivalents and short- and long-term investments. The following tables represent the

fair value hierarchy as of December 31, 2012 and 2011 for those assets that we measure at fair value on a recurring basis (in thousands):

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

Fair Value Measurements at December 31, 2011 Using:				
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	\$ 55,995	\$55,995	\$ —	\$ —
Corporate debt securities	94,626	—	94,626	—
U.S. treasury and government agency securities	48,086	—	48,086	—
Commercial paper	5,991	—	5,991	—
Auction rate securities	17,527	—	—	17,527
	<u>\$222,225</u>	<u>\$55,995</u>	<u>\$148,703</u>	<u>\$17,527</u>

With the exception of our money market funds, and previously, our auction rate securities, or ARS, which we sold in June 2012, and which were valued using Level 3 inputs, the fair value of our investments is primarily determined from independent pricing services which use Level 2 inputs to determine fair value. Independent pricing services normally derive security prices from recently reported trades for identical or similar securities, making adjustments based upon other significant observable market transactions. At the end of each reporting period, we perform quantitative and qualitative analyses of prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analyses, we did not adjust or override any fair value measurements provided by our pricing services as of either December 31, 2012 or 2011. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during either of the years ended December 31, 2012 or 2011.

We also analyze when the volume and level of activity for an asset or liability have significantly decreased and when circumstances indicate that a transaction may not be considered orderly. In order to determine whether the volume and level of activity for an asset or liability have significantly decreased, we assess current activity as compared to normal market activity for the asset or liability. We rely on many factors such as trading volume, trading frequency, the levels at which market participants indicate their willingness to buy and sell our securities, as reported by market participants, and current market conditions. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if there has been a significant decrease in the volume and level of activity for an asset, group of similar assets or liabilities. Similarly, in order to identify transactions that are not orderly, we take into consideration the activity in the market which can influence the determination and occurrence of an orderly transaction. Also, we inquire as to whether there may have been restrictions on the marketing of the security to a single or limited

number of participants. Where possible, we assess the financial condition of the seller to determine whether observed transactions may have been forced. If there is a significant disparity between the trading price for a security held by us as compared to the trading prices of similar recent transactions, we consider whether this disparity is an indicator of a disorderly trade. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if the evidence suggests that a transaction or group of similar transactions is not orderly. Based upon these procedures, we determined that market activity for our non-ARS assets appeared normal and that transactions did not appear disorderly as of December 31, 2012 and 2011.

In June 2012, we sold our remaining ARS portfolio, with a par value of \$19.8 million, for proceeds of \$18.3 million.

The following table provides a rollforward of Level 3 assets for the years ended December 31, 2012 and 2011 (in thousands):

	<u>December 31, 2012</u>	<u>December 31, 2011</u>
Balance at beginning of period	\$ 17,527	\$ 33,597
Transfers to Level 3	—	—
Total gains (losses) (realized or unrealized):		
Included in earnings	(1,471)	(210)
Included in other comprehensive income (loss)	2,373	3,790
Purchases, issuances, sales and settlements:		
Purchases	—	—
Issuances	—	—
Sales	(18,329)	—
Settlements	<u>(100)</u>	<u>(19,650)</u>
Balance at end of period	<u>\$ —</u>	<u>\$ 17,527</u>
The amount of total gains (losses) for the period included in earnings attributable to the change in unrealized gains (losses) relating to assets still held at end of period	<u>\$ —</u>	<u>\$ —</u>

Assets Held for Sale

During 2012, we determined that certain assets related to our Cambridge, Massachusetts manufacturing facility, including the related land, building and certain equipment, met the criteria established by current accounting guidance for classifying assets as held for sale. As a result, in 2012, we reclassified these assets from property, plant and equipment to assets held for sale in our consolidated balance sheet. In anticipation of a future sale, we have valued these assets at the lower of their carrying amount or fair value less cost to sell to arrive at the estimated fair value of \$2.0 million as of December 31, 2012. Prior to our determination that our Cambridge, Massachusetts manufacturing facility and related assets met the requirements to be classified as assets held for sale, we accelerated the depreciation on such assets to reflect our then estimated fair value. In doing so, we recorded \$1.4 million of accelerated depreciation in our consolidated statement of operations for the year ended December 31, 2012. Upon determination that these assets met the criteria for held for sale, we recognized an impairment loss to decrease the carrying value of the assets to our best estimate of fair value and continue to evaluate the estimate of fair value on an ongoing basis. As a result, we have recognized an aggregate impairment loss of \$1.1 million to decrease the carrying value of the assets to our best estimate of fair value as of December 31, 2012. Of these \$2.5 million of non-cash charges, we recorded \$2.3 million in cost of product sales and \$0.2 million in research and development expenses in our 2012 consolidated statement of operations. The fair values of the land, building, and equipment were estimated using offers received from potential purchasers, real estate appraisals and other estimates from third-parties and accordingly, these assets have been classified as Level 3 assets.

Inventories

Inventories are stated at the lower of cost or market (net realizable value), with approximate cost being determined on a first-in, first-out basis.

Prior to initial approval from the FDA or other regulatory agencies, we expense costs relating to the production of inventory in the period incurred. After such time as the product receives initial regulatory approval, we begin to capitalize the inventory costs related to the product. Prior to the June 2009 FDA approval of *Feraheme* for commercial sale in the U.S., all production costs related to *Feraheme* were expensed to research and development. Subsequent to receiving FDA approval, costs related to the production of *Feraheme* are capitalized to inventory, including the costs of converting previously existing raw or other materials to inventory and vialing, labeling, and packaging inventory manufactured prior to approval whose costs had already been recorded as research and development expense. We continue to expense costs associated with clinical trial material as research and development expense.

Property, Plant and Equipment

Property, plant and equipment are recorded at cost and depreciated when placed into service using the straight-line method, based on the following estimated useful lives: buildings—40 years; building improvements—over the shorter of the remaining useful life of the building or the life of the improvement; laboratory and production equipment—5 years; and furniture and fixtures—5 years. The furniture, fixtures, and leasehold improvements associated with our facility lease are being depreciated over the shorter of their useful lives or the remaining life of the original lease (excluding optional lease renewal terms).

Costs for capital assets not yet placed in service are capitalized on our balance sheets, and the cost of maintenance and repairs is expensed as incurred. Upon sale or other disposition of property and equipment, the cost and related depreciation are removed from the accounts and any resulting gain or loss is charged to our consolidated statement of operations. Currently, our long-lived assets consist entirely of property and equipment. Long-lived assets to be held and used are evaluated for impairment whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset (asset group) and its eventual disposition. In the event such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values. Assets classified as held for sale are no longer subject to depreciation and are recorded at the lower of carrying value or estimated net realizable value.

Patents

We expense all patent-related costs as incurred.

Research and Development Expenses

Research and development expenses include external expenses, such as costs of clinical trials, contract research and development expenses, certain manufacturing research and development costs, regulatory filing fees, consulting and professional fees and expenses, and internal expenses, such as compensation of employees engaged in research and development activities, the manufacture of product needed to support research and development efforts, related costs of facilities, and other general costs related to research and development. Manufacturing costs are expensed as incurred until a product has received the necessary initial regulatory approval.

Advertising Costs

Advertising costs are expensed as incurred and are included in selling, general and administrative expenses in our consolidated statement of operations. Advertising costs, including promotional expenses and costs related to trade shows were \$1.8 million, \$3.1 million and \$7.4 million for the years 2012, 2011 and 2010, respectively.

Revenue Recognition and Related Sales Allowances and Accruals

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

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

U.S. Product Sales, Net

We record product sales allowances and accruals related to prompt payment discounts, chargebacks, government and other rebates, distributor, wholesaler and group purchasing organization, or GPO, fees, and product returns as a reduction of revenue in our consolidated statement of operations at the time product sales are recorded. Calculating these gross-to-net sales adjustments involves estimates and judgments based primarily on actual *Feraheme* sales data, forecasted customer buying patterns, and market research data related to utilization rates by various end-users. In addition, we also monitor our distribution channel to determine whether additional allowances or accruals are required based on inventory in our sales channel. An analysis of our product sales allowances and accruals for the years ended December 31, 2012, 2011 and 2010 is as follows (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Provision for U.S. product sales allowances and accruals			
Discounts and chargebacks	\$26,517	\$13,851	\$ 5,113
Government and other rebates	6,058	8,544	16,374
Medicaid rebate reserve adjustment	(621)	(2,532)	(599)
Returns	(1,516)	1,259	1,334
Total provision for U.S. product sales allowances and accruals	\$30,438	\$21,122	\$22,222
Total gross U.S. product sales	\$88,725	\$73,219	\$81,561
Total provision for U.S. product sales allowances and accruals as a percent of total gross U.S. product sales	34%	29%	27%

Classification of U.S. Product Sales Allowances and Accruals

Product sales allowances and accruals are primarily comprised of both direct and indirect fees, discounts and rebates and provisions for estimated product returns. Direct fees, discounts and rebates are contractual fees and price adjustments payable to wholesalers, specialty distributors and other customers that purchase products directly from us. Indirect fees, discounts and rebates are contractual

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

Allowances against receivable balances primarily relate to prompt payment discounts, provider chargebacks and certain government agency rebates and are recorded at the time of sale, resulting in a reduction in product sales revenue and the reporting of product sales receivables net of allowances. Accruals related to Medicaid and provider volume rebates, wholesaler and distributor fees, GPO fees, other discounts to healthcare providers and product returns are recorded at the time of sale, resulting in a reduction in product sales revenue and the recording of an increase in accrued expenses.

Discounts

We typically offer a 2% prompt payment discount to our customers as an incentive to remit payment in accordance with the stated terms of the invoice, generally thirty days. Because we anticipate that those customers who are offered this discount will take advantage of the discount, we accrue 100% of the prompt payment discount, at the time of sale, based on the gross amount of each invoice. We adjust the accrual quarterly to reflect actual experience.

Chargebacks

Chargeback reserves represent our estimated obligations resulting from the difference between the prices at which we sell *Feraheme* to wholesalers and the sales price ultimately paid to wholesalers under fixed price contracts by third-party payors, including governmental agencies. We determine our chargeback estimates based on actual *Feraheme* sales data and forecasted customer buying patterns. Actual chargeback amounts are determined at the time of resale to the qualified healthcare provider, and we generally issue credits for such amounts within several weeks of receiving notification from the wholesaler. Estimated chargeback amounts are recorded at the time of sale, and we adjust the allowance quarterly to reflect actual experience.

Government and Other Rebates

Government and other rebate reserves relate to our reimbursement arrangements with state Medicaid programs or performance rebate agreements with certain classes of trade. We determine our estimates for Medicaid rebates based on actual *Feraheme* sales data, forecasted customer buying patterns and market research data related to utilization rates by various end-users blended with historical experience of products similar to *Feraheme* sold by others. We currently have limited actual claims payment data, and therefore are not able to solely rely on our actual *Feraheme* claims

experience. In estimating these reserves, we provide for a Medicaid rebate associated with both those expected instances where Medicaid will act as the primary insurer as well as in those instances where we expect Medicaid will act as the secondary insurer. For rebates associated with reaching defined performance goals, we determine our estimates using actual *Feraheme* sales data and forecasted customer buying patterns. Rebate amounts generally are invoiced quarterly and are paid in arrears, and we expect to pay such amounts within several weeks of notification by the Medicaid or provider entity. Estimated government and other rebates are recorded at the time of sale and, with the exception of Medicaid as discussed below, we adjust the accrual quarterly to reflect actual experience.

During the years ended December 31, 2012, 2011 and 2010, we revised our estimated Medicaid utilization rate based on actual rebate claims received since the 2009 launch of *Feraheme*, our expectations of state level activity, and estimated rebate claims not yet submitted, which resulted in a reduction of our estimated Medicaid rebate reserve related to prior period *Feraheme* sales of \$0.6 million, \$2.5 million and \$0.6 million, respectively. These changes in estimates were reflected as an increase in our net product sales for the years ended December 31, 2012, 2011 and 2010. As a result, our gross to net percentages for 2012, 2011 and 2010 were lower than they otherwise would have been had we not reduced our Medicaid rebate reserve. The reduction of our estimated Medicaid rebate reserve had an impact of \$0.03, \$0.12 and \$0.03 per basic and diluted share for the years ended December 31, 2012, 2011 and 2010, respectively. We regularly assess our Medicaid reserve balance and the rate at which we accrue for claims against product sales. If we determine in future periods that our actual rebate experience is not indicative of expected claims, or if other factors affect estimated claims rates, we may be required to change our estimated Medicaid reserve and/or the current rate at which we estimate our Medicaid claims, which would affect our earnings in the period of the change in estimate and such change could be significant.

Distributor/Wholesaler and Group Purchasing Organization Fees

Fees under our arrangements with distributors and wholesalers are usually based upon units of *Feraheme* purchased during the prior month or quarter and are usually paid by us within several weeks of our receipt of an invoice from the wholesaler or distributor, as the case may be. Fees under our arrangements with GPOs are usually based upon member purchases during the prior quarter and are generally billed by the GPO within 30 days after period end. Current accounting standards related to consideration given by a vendor to a customer, including a reseller of a vendor's products, specify that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling price of the vendor's products or services and therefore should be characterized as a reduction of revenue. Consideration should be characterized as a cost incurred if we receive, or will receive, an identifiable benefit (goods or services) in exchange for the consideration and we can reasonably estimate the fair value of the benefit received. Because the fees we pay to wholesalers do not meet the foregoing conditions to be characterized as a cost, we have characterized these fees as a reduction of revenue and have included them in government and other rebates in the table above. We generally pay such amounts within several weeks of our receipt of an invoice from the distributor, wholesaler, or GPO. Accordingly, we accrue the estimated fee due at the time of sale, based on the contracted price invoiced to the customer. We adjust the accrual quarterly to reflect actual experience.

Product Returns

Consistent with industry practice, we generally offer our distributors and wholesaler customers a limited right to return product purchased directly from us principally based upon the product's expiration date which, once packaged, is currently four or five years in the U.S. We estimate product returns based upon historical experience since the 2009 launch of *Feraheme* and trends of products similar to *Feraheme* sold by others. 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 *Feraheme's* cost and expense to store. Based on the level of inventory in the wholesale distribution channel, 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. During 2012, we reduced our reserve for product returns by approximately \$2.2 million primarily as a result of a lower than expected rate of product returns as well as the lapse of the product return period on certain manufactured *Feraheme* lots that carried a two year expiration. As a result, the product returns provision applied to gross product sales for the year ended December 31, 2012 was a credit of \$1.5 million, resulting in an increase to net product sales for the year. The reduction of our estimated product returns reserve had a positive impact of \$0.10 per basic and diluted share for year ended December 31, 2012. We did not significantly adjust our reserve for product returns during 2011 or 2010. *Feraheme* is still early in its product lifecycle and returns experience may change over time. A future revision to our product returns estimate would result in a corresponding change to our net product sales in the period in which the change is made and could be significant.

International Product Sales and Royalties

We record all international product sales for *Feraheme/Rienso* sold to Takeda in deferred revenues in our consolidated balance sheet. We recognize these deferred revenues, and the associated cost of product sales, in our consolidated statement of operations at the time Takeda reports to us that sales have been made to its customers.

License Fee and Other Collaboration Revenues

The terms of product development and commercialization agreements entered into between us and our collaborative licensees may include non-refundable license fees, payments based on the achievement of certain milestones and performance goals, reimbursement of certain out-of-pocket costs, payment for manufacturing services, and royalties on product sales. We recognize license fee and research and development revenue under collaborative arrangements over the term of the applicable agreements using a proportional performance model, if practical. Otherwise, we recognize such revenue on a straight-line basis. Under this model, revenue is generally recognized in an amount equal to the lesser of the amount due under the agreements or an amount based on the proportional performance to date. In cases where project costs or other performance metrics are not estimable but there is an established contract period, revenues are recognized on a straight-line basis over the term of the relevant agreement. In cases where we are reimbursed for certain research and development costs associated with our collaboration agreements and where we are acting as the principal in carrying out these services, any reimbursement payments are recorded in license fee and other collaboration revenues in our consolidated statement of operations to match the costs that we incur during the period in which we perform those services. Nonrefundable payments and fees are recorded as deferred revenue upon receipt and may require deferral of revenue recognition to future periods.

Multiple Element Arrangements and Milestone Payments

We evaluate revenue from arrangements that have multiple elements to determine whether the components of the arrangement represent separate units of accounting as defined in the accounting

guidance related to revenue arrangements with multiple deliverables. Under current accounting guidance, which governs any agreements that contain multiple elements that are either entered into or materially modified subsequent to January 1, 2011, companies are required to establish the fair value of undelivered products and services based on a separate revenue recognition process using management's best estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. Agreements entered into prior to January 1, 2011, that have not been materially modified, including our agreements with Takeda and 3SBio, Inc., or 3SBio, are accounted for under previous accounting guidance, which provides that an element of a contract can be accounted for separately if the delivered elements have standalone value and the fair value of all undelivered elements is determinable. If an element is considered to have standalone value but the fair value of any of the undelivered items cannot be determined, all elements of the arrangement are recognized as revenue as a single unit of accounting over the period of performance for such undelivered items or services. Significant management judgment is required in determining what elements constitute deliverables and what deliverables or combination of deliverables should be considered units of accounting.

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

Our collaboration agreements may entitle us to additional payments upon the achievement of performance-based milestones. If a milestone involves substantive effort on our part and its achievement is not considered probable at the inception of the collaboration, we recognize the milestone consideration as revenue in the period in which the milestone is achieved only if it meets the following additional criteria:

- The milestone consideration received is commensurate with either the level of effort required to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone;
- The milestone is related solely to past performance; and
- The milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement.

There is significant judgment involved in determining whether a milestone meets all of these criteria. For milestones that do not meet the above criteria and are therefore not considered substantive milestones, we recognize that portion of the milestone payment equal to the percentage of the performance period completed at the time the milestone is achieved and the above conditions are met. The remaining portion of the milestone will be recognized over the remaining performance period using a proportional performance or straight-line method.

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

Shipping and Handling Costs

We utilize a third-party logistics provider, which is a subsidiary of one of our distribution customers, to provide us with various shipping and handling services related to sales of *Feraheme*. Current accounting standards related to consideration given by a vendor to a customer, including a reseller of a vendor's products, specify that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling price of the vendor's products or services and therefore should be characterized as a reduction of revenue. However, that presumption is overcome and the consideration should be characterized as a cost incurred if both of the following conditions are met:

- We receive, or will receive, an identifiable benefit (goods or services) in exchange for the consideration; and
- We can reasonably estimate the fair value of the benefit received.

Since both of the above conditions were met with respect to the costs we incurred for shipping and handling services incurred with our third-party logistics provider, we have recorded \$0.2 million, \$0.1 million and \$0.2 million as a selling, general and administrative expense during the years ended December 31, 2012, 2011 and 2010, respectively.

Equity-Based Compensation

Under the fair value recognition guidance of equity-based compensation accounting rules, equity-based compensation cost is generally required to be measured at the grant date (based upon an estimate of the fair value of the compensation granted) and recorded to expense over the requisite service period, which generally is the vesting period. Because equity-based compensation expense is based on awards ultimately expected to vest, we must make certain judgments about whether employees and directors will complete the requisite service period. Accordingly, we have reduced the compensation expense being recognized for estimated 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. Forfeitures are estimated based upon historical experience, adjusted for unusual events such as the corporate restructurings in 2012, 2011 and 2010, which resulted in higher than expected turnover and forfeitures in those years. If factors change and we employ different assumptions in future periods, the compensation expense that we record in the future may differ significantly from what we have recorded in the current period.

We estimate the fair value of equity-based compensation involving stock options based on the Black-Scholes option pricing model. We estimate the fair value of our restricted stock units whose vesting is contingent upon market conditions using the Monte-Carlo simulation model. These models require the input of several factors such as the expected option term, the expected risk-free interest rate over the expected option term, the expected volatility of our stock price over the expected option term, and the expected dividend yield over the expected option term and are subject to various assumptions. The fair value of awards whose fair values are calculated using the Black-Scholes option pricing model is generally being amortized on a straight-line basis over the requisite service period and is recognized based on the proportionate amount of the requisite service period that has been rendered during each reporting period. The fair value of awards with market conditions is being amortized based upon the estimated derived service period. We believe our valuation methodologies are appropriate for estimating the fair value of the equity awards we grant to our employees and directors. Our equity award valuations are estimates and thus may not be reflective of actual future results or amounts ultimately realized by recipients of these grants. These amounts, and the amounts applicable to future quarters, are also subject to future quarterly adjustments based upon a variety of factors, which include, but are not limited to, changes in estimated forfeiture rates and the issuance of new equity-based awards. The fair value of restricted stock units granted to our employees and directors is determined based upon the quoted closing market price per share on the date of grant, adjusted for estimated

forfeitures. As with any accounting policy that applies judgments and estimates, actual results could significantly differ from those estimates which could result in a material adverse impact to our financial results.

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 our deferred tax assets will not be realized.

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 December 31, 2012, our cash, cash equivalents and investments amounted to approximately \$227.0 million. We currently invest our excess cash primarily in U.S. government and agency money market funds, and investments in corporate debt securities, U.S. treasury and government agency securities and commercial paper. As of December 31, 2012 we had approximately \$24.1 million of our total \$46.3 million cash and cash equivalents balance invested in institutional money market funds, of which \$16.3 million was invested in a single fund, which is collateralized solely by U.S. treasury and government agency securities.

Our operations are located solely within the U.S. We are focused principally on developing, manufacturing, and commercializing *Feraheme/Rienso*. 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 years ended December 31, 2012, 2011 and 2010.

	<u>Years Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
AmerisourceBergen Drug Corporation	34%	41%	36%
Takeda Pharmaceuticals Company Limited	31%	13%	<10%
McKesson Corporation	17%	21%	<10%
Cardinal Health, Inc.	12%	13%	<10%
Metro Medical Supply, Inc.	<10%	<10%	21%

In addition, approximately 32% of our end-user demand in 2012 was generated by members of a single GPO with which we have contracted. Revenues from customers outside of the U.S. amounted to approximately 32%, 14% and 10% of our total revenues for the years ended December 31, 2012, 2011 and 2010, respectively, and were principally related to collaboration revenue recognized in connection with our collaboration agreement with Takeda, which is based in Japan.

Comprehensive Income (Loss)

The current accounting guidance related to comprehensive income (loss) requires us to display comprehensive loss and its components as part of our consolidated financial statements. Our comprehensive loss consists of net loss and other comprehensive income (loss). Other comprehensive income (loss) includes changes in equity that are excluded from net loss, which for all periods presented related to unrealized holding gains and losses on available-for-sale investments, net of tax.

Net Loss per Share

We compute basic net loss per share by dividing net loss by the weighted average number of common shares outstanding during the relevant period. The components of basic and diluted net loss per share were as follows (in thousands, except per share data):

	Years Ended December 31,		
	2012	2011	2010
Net loss	\$(16,750)	\$(77,069)	\$(81,153)
Weighted average common shares outstanding	21,392	21,189	20,806
Net loss per share:			
Basic and diluted	\$ (0.78)	\$ (3.64)	\$ (3.90)

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

	Years Ended December 31,		
	2012	2011	2010
Options to purchase shares of common stock	2,190	1,817	2,411
Shares of common stock issuable upon the vesting of restricted stock units	374	669	385
Total	<u>2,564</u>	<u>2,486</u>	<u>2,796</u>

Reclassifications

Certain amounts in prior periods have been reclassified in order to conform to the current period presentation.

C. Investments

As of December 31, 2012 and 2011, our investments equaled \$180.8 million and \$166.2 million, respectively, and consisted of securities classified as available-for-sale in accordance with accounting standards which provide guidance related to accounting and classification of certain investments in debt and equity securities.

The following is a summary of our investments as of December 31, 2012 and 2011 (in thousands):

	December 31, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	\$ 52,332	\$ 88	\$ (6)	\$ 52,414
Due in one to three years	59,176	137	(37)	59,276
U.S. treasury and government agency securities				
Due in one year or less	24,795	86	—	24,881
Due in one to three years	34,606	84	(2)	34,688
Commercial paper				
Due in one year or less	9,494	1	(4)	9,491
Total investments	<u>\$180,403</u>	<u>\$396</u>	<u>\$(49)</u>	<u>\$180,750</u>
	December 31, 2011			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	\$ 74,687	\$ 81	\$ (115)	\$ 74,653
Due in one to three years	19,950	73	(50)	19,973
U.S. treasury and government agency securities				
Due in one year or less	26,770	67	(7)	26,830
Due in one to three years	21,028	228	—	21,256
Commercial paper				
Due in one year or less	5,997	—	(6)	5,991
Total short-term investments	<u>\$148,432</u>	<u>\$449</u>	<u>\$(178)</u>	<u>\$148,703</u>
Long-term investments:				
Auction rate securities				
Due after five years	19,900	—	(2,373)	17,527
Total long-term investments	<u>\$ 19,900</u>	<u>\$ —</u>	<u>\$(2,373)</u>	<u>\$ 17,527</u>
Total investments	<u>\$168,332</u>	<u>\$449</u>	<u>\$(2,551)</u>	<u>\$166,230</u>

Auction Rate Securities

In June 2012, we sold our remaining ARS portfolio, with a par value of \$19.8 million, for proceeds of \$18.3 million and recognized a loss of approximately \$1.5 million in other income (expense) in our consolidated statement of operations for the year ended December 31, 2012.

Impairments and Unrealized Gains and Losses on Investments

The following is a summary of the fair value of our investments with unrealized losses that are deemed to be temporarily impaired and their respective gross unrealized losses aggregated by

investment category and length of time that individual securities have been in a continuous unrealized loss position as of December 31, 2012 and 2011 (in thousands):

	December 31, 2012					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	\$37,036	\$(43)	\$—	\$—	\$37,036	\$(43)
U.S. treasury and government agency securities	6,271	(2)	—	—	6,271	(2)
Commercial paper	3,992	(4)	—	—	3,992	(4)
	<u>\$47,299</u>	<u>\$(49)</u>	<u>\$—</u>	<u>\$—</u>	<u>\$47,299</u>	<u>\$(49)</u>

	December 31, 2011					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	\$34,097	\$(161)	\$ 4,124	\$ (4)	\$38,221	\$ (165)
U.S. treasury and government agency securities	8,841	(7)	—	—	8,841	(7)
Commercial paper	5,991	(6)	—	—	5,991	(6)
Auction rate securities	—	—	19,900	(2,373)	19,900	(2,373)
	<u>\$48,929</u>	<u>\$(174)</u>	<u>\$24,024</u>	<u>\$(2,377)</u>	<u>\$72,953</u>	<u>\$(2,551)</u>

We did not recognize any unrealized other-than-temporary impairment losses in our consolidated statements of operations related to our securities during either of the years ended December 31, 2012 or 2011. Future events may occur, or additional information may become available, which may cause us to identify credit losses where we do not expect to receive cash flows sufficient to recover the entire amortized cost basis of a security and which may necessitate the recording of future realized losses on securities in our portfolio. Significant losses in the estimated fair values of our investments could have a material adverse effect on our earnings in future periods.

Realized Gains and Losses on Investments

Gains and losses are determined on the specific identification method. During 2012, we recorded realized losses of \$1.5 million to our consolidated statement of operations related to the sale of our then remaining ARS portfolio, as discussed above.

D. Accounts Receivable, Net

Our net accounts receivable were \$6.4 million and \$5.9 million as of December 31, 2012 and 2011, respectively, and primarily represented amounts due from wholesalers and distributors to whom we sell *Feraheme* directly. Accounts receivable are recorded net of reserves for estimated chargeback obligations, prompt payment discounts and any allowance for doubtful accounts. Reserves for other sales-related allowances such as rebates, distribution and other fees, and product returns are included in accrued expenses in our consolidated balance sheets.

As part of our credit management policy, we perform ongoing credit evaluations of our customers, and we have not required collateral from any customer. To date, we have not experienced significant bad debts. Accordingly, we have not established an allowance for doubtful accounts at either December 31, 2012 or 2011. If the financial condition of any of our significant customers was to

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

Customers which represented greater than 10% of our accounts receivable balances as of December 31, 2012 and 2011 were as follows:

	December 31,	
	2012	2011
AmerisourceBergen Drug Corporation	48%	44%
McKesson Corporation	28%	33%
Cardinal Health, Inc.	18%	15%

E. Inventories

Our major classes of inventories were as follows as of December 31, 2012 and 2011 (in thousands):

	December 31,	
	2012	2011
Raw materials	\$ 2,652	\$ 1,892
Work in process	2,524	3,696
Finished goods	7,275	9,618
Total inventories	<u>\$12,451</u>	<u>\$15,206</u>

During 2012, we wrote-off \$0.6 million of inventory which was initially produced to validate the manufacturing process at third-party suppliers and which we no longer believed was suitable for sale. We have recorded the \$0.6 million write-off in research and development expenses. In addition, during 2012, we wrote-off \$0.6 million of commercial inventory deemed no longer saleable, which we recorded in cost of goods sold. We reserved \$0.7 million of additional inventory related to our ongoing divestiture of our Cambridge, Massachusetts manufacturing facility and have recorded the reserve in restructuring costs.

On a quarterly basis, we analyze our inventory levels to determine whether we have any obsolete, expired, or excess inventory. If any inventory is expected to expire prior to being sold, has a cost basis in excess of its net realizable value, is in excess of expected sales requirements as determined by internal sales forecasts, or fails to meet commercial sale specifications, the inventory is written-down through a charge to cost of goods sold. The determination of whether inventory costs will be realizable requires estimates by management. A critical input in this determination is future expected inventory requirements, based on internal sales forecasts and forecasts received from Takeda. Once packaged, *Feraheme/Rienso* currently has a shelf-life of four or five years in the U.S. and between two and three years outside of the U.S., and as a result of comparison to internal sales forecasts, we expect to fully realize the carrying value of our current *Feraheme/Rienso* finished goods inventory. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. Charges for inventory write-downs are not reversed if it is later determined that the product is saleable.

F. Property, Plant and Equipment, Net

Property, plant and equipment consisted of the following as of December 31, 2012 and 2011, respectively (in thousands):

	December 31,	
	2012	2011
Land	\$ —	\$ 360
Buildings and improvements	5,373	11,308
Laboratory and production equipment	115	7,662
Furniture and fixtures	5,326	5,382
Construction in process	228	86
	<u>11,042</u>	<u>24,798</u>
Less—accumulated depreciation	(7,745)	(15,592)
Property, plant and equipment, net	<u>\$ 3,297</u>	<u>\$ 9,206</u>

During the third quarter of 2012, we determined that certain assets related to our Cambridge, Massachusetts manufacturing facility, including the related land, building and certain equipment, met the criteria established by current accounting guidance for classifying assets as held for sale. As a result, we reclassified these assets from property, plant and equipment to assets held for sale in our consolidated balance sheet during 2012. We have classified these assets as current as we expect to complete the sale within one year. Current accounting guidance requires us to record assets held for sale at the lower of the carrying amount or fair value less cost to sell and discontinue the recognition of depreciation. Based on such guidance, we recorded the value of these assets at \$2.0 million, their estimated fair market value as of December 31, 2012. Prior to our determination that our Cambridge manufacturing facility and related assets met the requirements to be classified as assets held for sale, we accelerated the depreciation on such assets to reflect our then estimated fair value. In doing so, we recorded \$1.4 million of accelerated depreciation in our consolidated statements of operations in 2012. Upon determination that these assets met the criteria for held for sale, we recognized an impairment loss to decrease the carrying value of the assets to our best estimate of fair value, and continue to evaluate the estimate of fair value on an ongoing basis. As a result, we have recognized an aggregate impairment loss of \$1.1 million to decrease the carrying value of the assets to our best estimate of fair value as of December 31, 2012. The fair values of the land, building and equipment were estimated using offers received from potential purchasers, real estate appraisals and other estimates from third parties.

G. Current and Long-Term Liabilities

Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2012 and 2011 (in thousands):

	December 31,	
	2012	2011
Clinical, manufacturing and regulatory consulting fees and expenses	\$ 7,737	\$11,468
Salaries, bonuses, and other compensation	5,236	5,924
Commercial rebates, fees and returns	3,448	5,943
Professional, license, and other fees and expenses	1,719	1,966
Restructuring expense	1,383	2,366
Commercial consulting fees and expenses	815	1,249
Total accrued expenses	<u>\$20,338</u>	<u>\$28,916</u>

Deferred Revenues

Deferred revenues consisted of the following as of December 31, 2012 and 2011 (in thousands):

	December 31,	
	2012	2011
Short-term deferred revenues:		
Takeda	\$ 8,854	\$ 6,096
Other short-term deferred revenues	250	250
Total	<u>\$ 9,104</u>	<u>\$ 6,346</u>
Long-term deferred revenues:		
Takeda	\$49,350	\$44,196
3SBio	1,000	1,000
Total	<u>\$50,350</u>	<u>\$45,196</u>

During 2010, under the terms of our License, Development and Commercialization Agreement, or the Takeda Agreement, we received certain payments, including a \$60.0 million upfront fee and \$1.0 million reimbursed to us for certain expenses incurred prior to entering the agreement. We have recorded such payments as deferred revenue which we are recognizing on a straight-line basis over a period of 10 years, which represents the current patent life of *Feraheme/Rienso* and our best estimate of the period over which we will substantially perform our obligations. In addition, during 2012, we received an aggregate of \$18.0 million in milestone payments from Takeda associated with the commercial launches of *Feraheme/Rienso* in Canada and the EU. These milestone payments were considered non-substantive milestone payments and accounted for in accordance with our revenue attribution method, as described in more detail below in Note N. Therefore, we are amortizing the \$18.0 million using the proportional performance method over the original life of the Takeda Agreement. During 2012, we recorded \$5.0 million of the \$18.0 million to license fee and other collaboration revenues in our consolidated statement of operations and have included the remaining \$13.0 million in our deferred revenues in our consolidated balance sheet.

In consideration of the grant of the license to 3SBio in 2008, we received an upfront payment of \$1.0 million, the recognition of which has been deferred and will be recognized under the proportional performance methodology over the remaining portion of the thirteen year initial term of the agreement once we begin to supply *Feraheme* to 3SBio.

Other Long-Term Liabilities

Other long-term liabilities at both December 31, 2012 and 2011 consisted solely of deferred rent related to the lease of our principal executive offices in Lexington, Massachusetts.

H. Income Taxes

For the years ended December 31, 2012, 2011 and 2010, we recognized \$0.9 million, \$1.2 million and \$0.5 million in current federal income tax benefits, respectively. These federal income tax benefits were the result of the recognition of corresponding income tax expense associated with the decrease in the unrealized loss on our investments, primarily related to our ARS, which we carried at fair market value during these respective periods. The corresponding income tax expense was recorded in other comprehensive income (loss). 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 reconciliation of the statutory U.S. federal income tax rate to our effective income tax rate is as follows:

	Years Ended December 31,		
	2012	2011	2010
Statutory U.S. federal tax rate	(34.0)%	(34.0)%	(34.0)%
State taxes, net of federal benefit	4.2%	(3.4)%	(5.8)%
Equity-based compensation expense	42.4%	2.4%	1.7%
Permanent items, net	1.2%	0.4%	0.5%
Tax credits	0.8%	(1.6)%	(2.2)%
Valuation allowance	(19.5)%	34.7%	39.2%
Total tax (benefit) expense	<u>(4.9)%</u>	<u>(1.5)%</u>	<u>(0.6)%</u>

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. The components of our deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2012	2011
Assets		
Net operating loss carryforwards	\$ 75,740	\$ 75,738
Tax credit carryforwards	12,403	12,560
Deferred revenue	22,315	19,321
Equity-based compensation expense	3,681	10,331
Capitalized research & development	45,137	43,463
Other	4,239	6,406
Property, Plant, and Equipment Depreciation	1,393	—
Liabilities		
Property, Plant, and Equipment Depreciation	—	(130)
	<u>164,908</u>	<u>167,689</u>
Valuation allowance	<u>(164,908)</u>	<u>(167,689)</u>
Net deferred taxes	<u>\$ —</u>	<u>\$ —</u>

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 valuation allowance decreased by approximately \$2.8 million for the year ended December 31, 2012, primarily due to an increase in our net operating loss, or NOL, carryforwards, capitalized research and development expense, and offset by a decrease in our equity-based compensation expense. The valuation allowance increased by approximately \$26.8 million and \$27.9 million for the years ended December 31, 2011 and 2010, respectively, primarily due to an increase in our NOL carryforwards, capitalized research and development expense, and equity based compensation expense.

At December 31, 2012, we had federal NOL carryforwards of approximately \$203.5 million and state NOL carryforwards of up to \$132.7 million. We also had federal capital loss carryforwards of \$3.3 million to offset future capital gains and an additional \$24.4 million and \$5.6 million of federal and state NOLs, respectively, not reflected above which were attributable to deductions from the exercise of equity awards. The benefit from these deductions will be recorded as a credit to additional paid-in capital if and when realized through a reduction of taxes paid in cash. Our federal NOLs and our most significant state NOLs expire at various dates through 2032. Our capital loss carryforwards will expire

through 2017. In addition, we have federal and state tax credits of approximately \$9.2 million and \$4.9 million, respectively, to offset future tax liabilities. Our tax credits will expire periodically through 2032 if not utilized.

Utilization of our NOLs and research and development, or R&D, credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986, or Section 382, as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change as defined by Section 382 results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since our formation, we have raised capital through the issuance of capital stock on several occasions. These financings, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in a change of control as defined by Section 382 or could result in a change of control in the future upon subsequent disposition. In May 2011, we conducted an analysis under Section 382 to determine if historical changes in ownership through December 31, 2010 would limit or otherwise restrict our ability to utilize these NOL and R&D credit carryforwards. As a result of this analysis, we do not believe there are any significant limitations on our ability to utilize these carryforwards. However, changes in ownership after December 31, 2010 could affect the limitation in future years. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization.

At December 31, 2012 and 2011, we had no unrecognized tax benefits. We have not, as yet, conducted a study of our R&D credit carryforwards. Such a study could result in an adjustment to our R&D credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against our R&D credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or statement of operations if an adjustment were required.

We would recognize both accrued interest and penalties related to unrecognized benefits in income tax expense. We have not recorded any interest or penalties on any unrecognized benefits since inception.

The statute of limitations for assessment by the Internal Revenue Service, or the IRS, and state tax authorities is closed for tax years prior to December 31, 2009, although carryforward attributes that were generated prior to tax year 2009 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period. We file income tax returns in the U.S. federal and various state jurisdictions. There are currently no federal or state audits in progress.

On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which reinstated, retroactive to January 1, 2012, certain tax benefits that had previously expired. In accordance with the financial accounting standards for income taxes, we are required to account for the effects of changes in tax law and rates on deferred tax balances in the period the legislation is enacted. As this legislation was enacted in January 2013, our 2012 financial statements were not affected by this legislation.

I. Equity-Based Compensation

We currently maintain several equity compensation plans, including our Second Amended and Restated 2007 Equity Incentive Plan, or the 2007 Plan, our Amended and Restated 2000 Stock Plan, or the 2000 Plan, and our 2010 Employee Stock Purchase Plan, or the 2010 ESPP. During 2012, we also granted equity to our chief executive officer through an inducement grant that was outside of these plans.

Second Amended and Restated 2007 Equity Incentive Plan

Our 2007 Plan was originally approved by our stockholders in November 2007. In each of May 2009 and May 2010, our stockholders approved proposals to amend and restate our 2007 Plan to, among other things, increase the number of shares authorized for issuance thereunder by 600,000 and 800,000 shares, respectively. In addition, the amendment approved by our stockholders in May 2009 replaced a limitation on the number of shares in the aggregate which could be issued under the 2007 Plan with respect to restricted stock units, restricted stock, stock and similar equity interests in our company with a fungible share reserve whereby the number of shares available for issuance under the 2007 Plan is reduced by one share of our common stock issued pursuant to an option or stock appreciation right and by 1.5 shares for each share of our common stock issued pursuant to a restricted stock unit award or other similar equity-based award.

The 2007 Plan provides for the grant of stock options, restricted stock units, restricted stock, stock, and other equity interests in our company to employees, officers, directors, consultants, and advisors of our company and our subsidiaries. We generally issue common stock from previously authorized but unissued shares to satisfy option exercises and restricted stock awards. 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, are determined by our Board of Directors, or Board, or the Compensation Committee of our Board. Our Board may award stock options in the form of nonqualified stock options or incentive stock options, or ISOs. ISOs may be granted at an exercise price no less than fair market value of a share of our common stock on the date of grant, as determined by our Board or the Compensation Committee of our Board, subject to certain limitations.

Our Board establishes the vesting schedule for stock options and the method of payment for the exercise price. In general, our equity-based awards are subject to three or four year vesting. Our standard stock option agreement allows for payment of the exercise price for vested stock options either through cash remittance of the exercise price to us in exchange for newly issued shares, or through a non-cash exchange of previously issued shares held by the recipient equal in value to the exercise price in exchange for newly issued shares. The latter method results in no cash being received by us, but also results in a lower number of total shares subsequently being outstanding (as compared to a cash exercise), as a direct result of previously issued shares being exchanged in return for the issuance of new shares. Shares returned to us in this manner are retired. In addition, under the 2007 Plan, participants may satisfy their tax obligations related to restricted stock unit vesting in whole or in part by transferring shares of common stock to us. Shares returned to us in this manner are retired.

As of December 31, 2012, we have granted options and restricted stock units covering 5,283,775 shares of common stock under our 2007 Plan, of which 2,273,686 stock options and 615,430 restricted stock units have expired or terminated, and of which 38,338 options have been exercised and 347,725 shares of common stock have been issued pursuant to restricted stock units that became fully vested. The number of options and restricted stock units outstanding under this plan as of December 31, 2012 was 1,734,920 and 273,676, respectively. The remaining number of shares available for future grants as of December 31, 2012 was 1,513,918, 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 December 31, 2012, we have granted stock options and restricted stock units covering 2,182,700 shares of common stock under the 2000 Plan, of which 946,977 stock options and 1,500 restricted stock units have expired or terminated, and of which 1,036,570 stock options have been exercised and 42,500 shares of common stock have been issued pursuant to restricted stock units that became fully vested. The remaining number of shares underlying outstanding stock options which were issued pursuant to our 2000 Plan as of December 31, 2012 was 155,153. There were no remaining restricted stock units which were issued pursuant to our 2000 Plan as of December 31, 2012. All outstanding stock options granted under the 2000 Plan have an exercise price equal to the closing price of our common stock on the grant date and have a ten year term. In November 2007, the 2000 Plan was succeeded by our 2007 Plan and, accordingly, no further grants may be made under this plan. Any shares that remained available for issuance under the 2000 Plan as of the date of adoption of the 2007 Plan are included in the number of shares that may be issued under the 2007 Plan. Any shares subject to outstanding awards granted under the 2000 Plan that expire or terminate for any reason prior to exercise will be added to the total number of shares available for issuance under the 2007 Plan.

Other Equity Compensation Grants

In May 2012, in connection with his entry into an employment agreement as our President and Chief Executive Officer, our Board granted William Heiden an option to purchase 300,000 shares of our common stock at an exercise price equal to the fair market value of a share of our common stock on the date of grant. The option will be exercisable in four equal annual installments beginning on the first anniversary of the grant date. Mr. Heiden was also granted 100,000 restricted stock units, which will vest in four equal annual installments beginning on the first anniversary of the grant date. The foregoing grants were made pursuant to an inducement grant outside of our 2007 Plan as permitted under the NASDAQ Global Market rules. We assessed the terms of these awards to Mr. Heiden and determined there was no possibility that we would have to settle these awards in cash and therefore, equity accounting was applied. In July 2012, we filed a Form S-8 registration statement with the Securities and Exchange Commission with respect to these equity compensation grants.

Equity-based compensation expense

Equity-based compensation expense, excluding amounts that have been capitalized into inventory, for the years ended December 31, 2012, 2011 and 2010 consisted of the following (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Cost of product sales	\$ 225	\$ 616	\$ 441
Research and development	1,994	1,874	3,508
Selling, general and administrative	4,805	7,548	10,574
Total equity-based compensation expense	<u>\$7,024</u>	<u>\$10,038</u>	<u>\$14,523</u>

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 the corporate restructurings in 2012, 2011 and 2010, which resulted in higher than expected turnover and forfeitures in those years. 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.

In addition, during 2011, we reduced our equity-based compensation expense by approximately \$0.7 million to reflect the modification of the terms of certain of our former chief executive officer's outstanding equity awards pursuant to his November 2011 separation agreement.

Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns associated with operating losses we incurred in the past, we have not recognized any excess tax benefits from the exercise of options. Accordingly, there was no impact recorded in cash flows from financing activities or cash flows from operating activities as reported in the accompanying consolidated statements of cash flows.

The following table summarizes the weighted average assumptions we utilized for purposes of valuing grants of options to our employees and non-employee directors:

	Years Ended December 31,					
	2012		2011		2010	
	Employees	Non-Employee Directors	Employees	Non-Employee Directors	Employees	Non-Employee Directors
Risk free interest rate (%)	0.66	0.68	1.67	1.36	2.47	1.61
Expected volatility (%)	57	56	51	51	58	53
Expected option term (years)	4.66	4.00	5.50	4.00	5.50	4.00
Dividend yield	none	none	none	none	none	none

Risk free interest rates utilized are based upon published U.S. Treasury yields at the date of the grant for the expected option term. We estimate our expected stock price volatility by basing it on a blend of the historical volatility of our own common stock price and the historical volatility of other similar companies over the prior period equivalent to our expected option term to better reflect expected future volatility. To compute the expected option term, we estimate the calculated historical term of stock options.

The following table summarizes details regarding our stock option plans and any grants outside of the plans under an inducement grant for the year ended December 31, 2012 (excluding restricted stock units, which are presented separately below):

	December 31, 2012			
	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (\$ in millions)
Outstanding at beginning of year	1,817,027	\$35.16		
Granted	1,500,800	14.72		
Exercised	(9,188)	10.65		
Expired and/or forfeited	(1,118,566)	31.60		
Outstanding at end of year	<u>2,190,073</u>	<u>\$23.07</u>	<u>6.7</u>	<u>\$0.6</u>
Outstanding at end of year—vested and unvested expected to vest	<u>1,981,028</u>	<u>\$23.82</u>	<u>6.7</u>	<u>\$0.6</u>
Exercisable at end of year	<u>729,294</u>	<u>\$36.59</u>	<u>6.0</u>	<u>\$0.1</u>

The weighted average grant date fair value of stock options granted during the years ended December 31, 2012, 2011 and 2010 was \$6.90, \$7.40, and \$18.57, respectively. A total of 336,443 stock options vested during the year ended December 31, 2012. The total grant date fair value of options that vested during the years ended December 31, 2012, 2011 and 2010 was \$5.5 million, \$9.8 million, and \$12.0 million, respectively. The aggregate intrinsic value of options exercised during the years ended December 31, 2012, 2011 and 2010, excluding purchases made pursuant to our employee stock purchase plans, measured as of the exercise date, was approximately \$0.1 million, \$0.1 million, and \$1.1 million, respectively. The intrinsic value of a stock option is the amount by which the fair market value

of the underlying stock exceeds the exercise price of the common stock option on the last trading day of each year.

In the year ended December 31, 2012, we issued an aggregate of 247,050 restricted stock units to our employees and directors. In general, these grants vest on an annual basis over a three or four year period. The estimated fair value of restricted stock units granted was determined at the grant date based upon the quoted market price per share on the date of the grant. The estimated fair value of restricted stock unit awards issued during 2012 was approximately \$3.9 million.

The following table summarizes details regarding restricted stock units granted under our equity incentive plans for the year ended December 31, 2012 and our May 2012 grant to our chief executive officer:

	December 31, 2012	
	Unvested Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at beginning of year	669,009	\$21.16
Granted	247,050	15.64
Vested	(171,182)	20.59
Forfeited	(371,201)	21.91
Outstanding at end of year	<u>373,676</u>	<u>\$17.02</u>
Outstanding at end of year and expected to vest	<u>295,916</u>	<u>\$16.54</u>

At December 31, 2012, the amount of unrecorded equity-based compensation expense, net of forfeitures, attributable to future periods was approximately \$11.9 million. Of this amount, \$8.2 million was associated with stock options and is expected to be amortized on a straight-line basis to expense over a weighted average period of approximately 3.1 years, and \$3.7 million was associated with restricted stock units and is expected to be amortized to on a straight-line basis to expense over a weighted average period of approximately 2.9 years. Such amounts will be amortized primarily to research and development or selling, general and administrative expense. These future estimates are subject to change based upon a variety of future events, which include, but are not limited to, changes in estimated forfeiture rates, employee turnover, and the issuance of new stock options and other equity-based awards.

2010 Employee Stock Purchase Plan

In May 2010, our stockholders approved our 2010 ESPP as the successor to and continuation of the 2006 Employee Stock Purchase Plan, or 2006 ESPP. The 2010 ESPP authorizes the issuance of up to 100,000 shares of our common stock to eligible employees. Currently, eligible employees may purchase shares (subject to certain plan and/or income tax limitations) in semi-annual offerings through payroll deductions of up to an annual maximum of 10% of the employee's total compensation, as defined by our Board. The purchase price per share is the lesser of 85% of the fair market value of our common stock on the first or last day of the plan period. During 2012, we issued 23,025 shares under our 2010 ESPP.

The assumptions used for awards granted under our employee stock purchase plans were as follows:

	Years Ended December 31,		
	2012	2011	2010
Risk free interest rate (%)	0.12	0.09	0.22
Expected volatility (%)	43	37	42
Expected option term (years)	0.5	0.5	0.5
Dividend yield	none	none	none

The weighted average fair value for purchase rights granted under our 2010 ESPP and our 2006 ESPP, during the years ended December 31, 2012, 2011 and 2010 was \$4.48, \$5.01, and \$13.66, respectively, and was estimated using the Black-Scholes option-pricing model.

J. Employee Savings Plan

We provide a 401(k) Plan to our employees by which they may defer compensation for income tax purposes under Section 401(k) of the Internal Revenue Code. Each employee may elect to defer a percentage of his or her salary up to a specified maximum. Our 401(k) Plan provides, among other things, for a company contribution of 3% of each employee's combined salary and certain other compensation for the plan year. Salary deferred by employees and contributions by us to the 401(k) Plan are not taxable to employees until withdrawn from the 401(k) Plan and contributions are deductible by us when made. The amount of our company contribution for the 401(k) Plan was \$0.8 million, \$1.0 million, and \$1.3 million for the years ended December 31, 2012, 2011 and 2010, respectively.

K. Stockholders' Equity

Preferred Stock

Our certificate of incorporation authorizes our Board to issue preferred stock from time to time in one or more series. The rights, preferences, restrictions, qualifications and limitations of such stock are determined by our Board. In September 2009, our Board adopted a shareholder rights plan, or Rights Plan. The terms of the Rights Plan provide for a dividend distribution of one preferred share purchase right, or Right, for each outstanding share of our common stock, par value \$0.01 per share, to shareholders of record as of September 17, 2009, and for one such Right to attach to each newly issued share of common stock thereafter. Each Right entitles shareholders to purchase one one-thousandth of a share of Series A Junior Participating Preferred Stock for each outstanding share of our common stock. The Rights issued pursuant to our Rights Plan become exercisable generally upon the earlier of 10 days after a person or group, or an Acquiring Person, 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. In that event, each holder of a Right, other than the Acquiring Person, would for a period of 60 days be entitled to purchase, at the exercise price of the Right, such number of shares of our common stock having a current value of twice the exercise price of the Right. Once a person becomes an Acquiring Person, until such Acquiring Person acquires 50% or more of our common stock, our Board can exchange the Rights, in part or in whole, for our common stock at an exchange ratio of one share of common stock per Right. If we are acquired in a merger or other business combination transaction, each holder of a Right, other than the Acquiring Person, would then be entitled to purchase, at the exercise price of the Right, such number of shares of the acquiring company's common stock having a current value of twice the exercise price of the Right. The Board may redeem the Rights or terminate the Rights Plan at any time before a person or group becomes an Acquiring Person. The Rights will expire on September 17, 2019 unless the Rights are earlier redeemed or exchanged by us. In May 2012, we amended the

definition of an Acquiring Person in the Rights Plan to provide that Adage Capital Management, L.P., or Adage, would not be deemed an "Acquiring Person" unless Adage, together with its affiliates and associates, have acquired beneficial ownership of 25% or more of our outstanding common stock (other than solely from repurchases of stock by us which increases Adage's percentage ownership above 25%). Pursuant to the terms of the amendment, this provision terminated in the third quarter of 2012 and Adage returned to being subject to the 20% limit applied to our other stockholders.

Common Stock Transactions

In January 2010, we sold 3,600,000 shares of our common stock, \$0.01 par value per share, in an underwritten public offering at a price to the public of \$48.25 per common share, resulting in gross proceeds of approximately \$173.7 million. Net proceeds to us after deducting fees, commissions and other expenses related to the offering were approximately \$165.6 million. The shares were issued pursuant to a shelf registration statement on Form S-3 which became effective upon filing.

L. Business Segments

We have determined that we conduct our operations in one business segment: the manufacture, development and commercialization of products derived from our proprietary technology for use in treating human diseases. Long-lived assets consist entirely of property and equipment and are located in the U.S. for all periods presented.

M. Commitments and Contingencies

Commitments

Operating and Facility Lease Obligations

We have entered into certain operating leases, including leases of certain automobiles, and certain office equipment which expire through 2014. Expense associated with these operating leases amounted to approximately \$0.9 million, \$0.8 million, and \$1.0 million for the years ended December 31, 2012, 2011 and 2010, respectively. Future minimum lease payments associated with all noncancellable automobile, equipment, service and lease agreements, excluding facility-related leases are approximately \$0.1 million for 2013. We lease 76 automobiles for our field-based employees. These leases require an initial minimum lease commitment of 12 months per automobile, after which we are responsible for certain disposal costs in the event of termination of the lease. As of December 31, 2012, all of our leased automobiles have been held beyond the initial 12 month commitment period.

In May 2008, we entered into a lease agreement for certain real property located at 100 Hayden Avenue, Lexington, Massachusetts for use as our principal executive offices. The term of the lease began on May 22, 2008 and will continue until August 31, 2016 with two successive five year extension terms at our option. In accordance with accounting guidance related to accounting for operating leases with scheduled rent increases, we recognize rent expense on this facility on a straight-line basis over the initial term of the lease. In addition, as provided for under the lease, we received approximately \$2.2 million of tenant improvement reimbursements from the landlord. These reimbursements are being recorded as a deferred rent liability in our consolidated balance sheets and are amortized on a straight-line basis as a reduction to rent expense over the term of the lease. We have recorded all tenant improvements as leasehold improvements and are amortizing these improvements over the shorter of the estimated useful life of the improvement or the remaining life of the initial lease term. Amortization of leasehold improvements is included in depreciation expense.

The lease requires us to pay rent as follows (in thousands):

<u>Period</u>	<u>Minimum Lease Payments</u>
Year Ended December 31, 2013	\$2,071
Year Ended December 31, 2014	2,127
Year Ended December 31, 2015	2,183
Year Ended December 31, 2016	<u>1,556</u>
Total	<u>\$7,937</u>

During any extension term, the base rent will be an amount agreed upon by us and the landlord. In addition to base rent, we are also required to pay a proportionate share of the landlord's annual operating costs.

Facility-related rent expense was \$1.7 million for each of the years ended December 31, 2012, 2011, and 2010.

In addition, in connection with our facility lease, in May 2008 we delivered to the landlord a security deposit of approximately \$0.5 million in the form of an irrevocable letter of credit. The cash securing this letter of credit is classified on our balance sheets as a long-term asset and is restricted in its use.

Purchase Commitments

During 2012, we entered into various agreements with third parties for which we had remaining purchase commitments of approximately \$3.7 million as of December 31, 2012. These agreements principally related to certain purchase orders for the production of *Feraheme/Rienso*, certain outsourced commercial activities, manufacturing commitments, our information technology infrastructure, and other operational activities.

Severance Arrangements

We have entered into employment agreements or other arrangements with most of our executive officers and certain other employees, which provide for salary continuation payments and, in certain instances, the acceleration of the vesting of certain equity awards to such individuals in the event that the individual is terminated other than for cause, as defined in the applicable employment agreements or arrangements.

Indemnification Obligations

As permitted under Delaware law, pursuant to our certificate of incorporation, by-laws and agreements with all of our current directors, executive officers, and certain of our employees, we are obligated to indemnify such individuals for certain events or occurrences while the officer, director or employee is, or was, serving at our request in such capacity. The maximum potential amount of future payments we could be required to make under these indemnification obligations is not capped. Our director and officer insurance policy limits our initial exposure to \$1.0 million and our policy provides significant coverage. As a result, we believe the estimated fair value of these indemnification obligations is likely to be immaterial.

We are also a party to a number of other agreements entered into in the ordinary course of business, which contain typical provisions and which obligate us to indemnify the other parties to such agreements upon the occurrence of certain events. Such indemnification obligations are usually in effect from the date of execution of the applicable agreement for a period equal to the applicable statute of limitations. Our aggregate maximum potential future liability under such indemnification provisions is uncertain. Except for expenses we incurred related to the ongoing class action lawsuit filed against us in March 2010, we have not incurred any expenses as a result of such indemnification provisions. Accordingly, we have determined that the estimated aggregate fair value of our potential liabilities under such indemnification provisions is not significant, and we have not recorded any liability related to such indemnification.

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 United States District Court for the District of Massachusetts, entitled *Silverstrand Investments et. al. v. AMAG Pharm., Inc., et. al.*, Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Executive Vice President and Chief Financial Officer, 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 Executive Vice President and Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff sought unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. On August 11, 2011, the District Court issued an Opinion and Order dismissing the SAC in its entirety for failure to state a claim upon which relief could be granted. A separate Order of Dismissal was filed on August 15, 2011. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the United States Court of Appeals for the First Circuit, or the Court of Appeals. After briefing was completed by all parties, the Court of Appeals heard oral argument on May 11, 2012, and took the matter under advisement. 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 18, 2013, we filed a Petition for Panel Hearing or Rehearing *En Banc*, asking the Court of Appeals to reconsider its decision. 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 our previously issued patent which covers ferumoxytol in the EU. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked our European ferumoxytol patent. In December 2012, our notice of appeal was recorded with the EPO, which suspends the revocation of our patent. 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 year ended December 31, 2012. 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 December 31, 2012. 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 December 31, 2012. We expense legal costs as they are incurred.

N. Collaborative Agreements

Our commercial strategy includes the formation of collaborations with other pharmaceutical companies to facilitate the sale and distribution of *Feraheme/Rienso*, primarily outside of the U.S. As of December 31, 2012, we were a party to the following collaborations:

Takeda

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

Under the Amended Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme/Rienso* and, accordingly, are responsible for supply of *Feraheme/Rienso* to Takeda at a fixed price per unit, which is capped for a certain period of time. We are also responsible for conducting, and bearing the costs related to, certain pre-defined clinical studies with the costs of future modifications or additional studies to be allocated between the parties according to an

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

In connection with the execution of the original Takeda Agreement, we received a \$60.0 million upfront payment from Takeda in April 2010, which we recorded as deferred revenue, as well as approximately \$1.0 million reimbursed to us during 2010 for certain expenses incurred prior to entering the agreement, which we considered an additional upfront payment. Because we cannot reasonably estimate the total level of effort required to complete the obligations under the combined deliverable, we are recognizing the entire \$60.0 million upfront payment, the \$1.0 million reimbursed to us in 2010, as well as any non-substantive milestone payments that are achieved into revenues on a straight-line basis over a period of ten years from March 31, 2010, the date on which we originally entered the Takeda Agreement, which represented the then current patent life of *Feraheme/Rienso* and our best estimate of the period over which we will substantively perform our obligations. We continue to believe that the then current patent life of *Feraheme/Rienso* is our best estimate of the period over which we will substantively perform our obligations under this agreement. Revenues related to the combined unit of accounting and any reimbursement revenues are recorded in license fee and other collaboration revenues in our consolidated statement of operations. During the years ended December 31, 2012, 2011 and 2010, we recorded \$6.1 million, \$6.1 million and \$4.6 million in revenues associated with the upfront payments. Any potential non-substantive milestone payments that may be received in the future will be recognized as revenue on a cumulative catch up basis when they become due and payable.

We have received and may also receive additional regulatory approval and performance-based milestone payments, reimbursement of certain out-of-pocket regulatory and clinical supply costs, defined payments for supply of *Feraheme/Rienso*, and tiered double-digit royalties on net product sales in the agreed-upon territories under the Amended Takeda Agreement. During 2012, we received \$33.0 million in milestone payments from Takeda associated with the EU approval and the commercial launches of *Feraheme/Rienso* in Canada and the EU. The remaining milestone payments we may be entitled to receive under the agreement could over time equal approximately \$186.0 million.

We have determined that any milestone payments which may become due upon approval by certain regulatory agencies will be deemed substantive milestones and, therefore, will be accounted for as revenue in the period in which they are achieved. In June 2012, we earned a \$15.0 million milestone payment from Takeda based on the European Commission marketing authorization for ferumoxytol. We deemed this milestone payment to be a substantive milestone based on our analysis that the milestone consideration received was commensurate with our performance to achieve the milestone, was solely related to past performance, and was reasonable relative to all of the deliverables and payment terms, including other milestones, within the arrangement. Therefore, we recognized the \$15.0 million milestone payment as revenue in the second quarter of 2012 in our consolidated statement of operations.

Additionally, we have 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. In the fourth quarter of 2012, we received an aggregate of \$18.0 million in milestone payments from Takeda associated with the commercial launches of *Feraheme/Rienso* in Canada and the EU. We deemed these milestone payments to be non-substantive milestone payments and accordingly, we recognized approximately \$5.0 million of the \$18.0 million on a cumulative catch up basis in the fourth quarter of 2012 in our consolidated statement of operations.

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 will be recorded in license fee and other collaboration revenues in our consolidated statement of operations to match the costs that we incur during the period in which we perform those services. We recorded \$0.4 million, \$2.0 million and \$1.6 million for the years ended December 31, 2012, 2011 and 2010, respectively, associated with other reimbursement revenues received from Takeda.

In accordance with current accounting guidance related to the recognition, presentation, and disclosure of revenue in the financial statements, we record all revenue for *Feraheme/Rienso* sold to our licensees in deferred revenues in our consolidated balance sheets. We will recognize revenues from product sales to our licensees, the related cost of goods sold, as well as any royalty revenues due from our licensees, in our consolidated statement of operations at the time our licensees report to us that sales have been made to its customers.

3SBio

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

O. Restructuring

During 2012, we initiated a corporate restructuring, including a workforce reduction plan. The majority of the workforce reduction plan was associated with our manufacturing and development infrastructure, including our decision to divest our Cambridge, Massachusetts manufacturing facility. As a result of the restructuring, we recorded charges of approximately \$2.2 million in 2012. Of the \$2.2 million in restructuring expense, approximately \$1.5 million was related to employee severance and benefits, and approximately \$0.7 million was related to the write-down of primarily raw material inventory that was no longer usable due to the closure of the facility. The workforce reduction was

substantially completed by the end of 2012, and the majority of the related expenses were paid by the end of 2012.

During 2011, we initiated a corporate restructuring, including a workforce reduction plan for which we recorded \$3.5 million of restructuring related costs, primarily related to employee severance and benefits. The workforce reduction was substantially completed by the end of 2011 and the majority of the related expenses were paid by the end of 2012.

The following table outlines the components of our restructuring expenses which were recorded in operating expenses and current liabilities for the years ended December 31, 2012 and 2011 (in thousands):

	December 31,	
	2012	2011
Accrued restructuring, beginning of period	\$ 2,366	\$ 1,324
Employee severance, benefits and related costs	1,624	3,697
Payments	(2,674)	(2,523)
Inventory and other adjustments	67	(132)
Accrued restructuring, end of period	<u>\$ 1,383</u>	<u>\$ 2,366</u>

P Consolidated Quarterly Financial Data—Unaudited

The following tables provide unaudited consolidated quarterly financial data for the years ended December 31, 2012 and 2011 (in thousands, except per share data):

	March 31, 2012	June 30, 2012	September 30, 2012	December 31, 2012
U.S. product sales, net(a)	\$ 13,626	\$14,094	\$16,186	\$14,381
International product sales and royalties	—	168	(168)	120
License fee and other collaboration revenues(b)	1,753	16,592	1,566	6,564
Other product sales and royalties	101	158	158	79
Total revenues	15,480	31,012	17,742	21,144
Cost of product sales	2,646	3,224	4,323	4,027
Operating expenses	25,643	22,772	17,420	20,532
Restructuring expenses(c)	—	1,058	562	595
Interest and dividend income, net	393	338	295	260
(Losses) gains on investments, net(d)	—	(1,471)	2	3
Income tax benefit	—	494	299	61
Net income (loss)	<u>\$(12,416)</u>	<u>\$ 3,319</u>	<u>\$(3,967)</u>	<u>\$(3,686)</u>
Net income (loss) per share—basic	\$ (0.58)	\$ 0.16	\$ (0.19)	\$ (0.17)
Net income (loss) per share—diluted	\$ (0.58)	\$ 0.15	\$ (0.19)	\$ (0.17)

	March 31, 2011	June 30, 2011	September 30, 2011	December 31, 2011
U.S. product sales, net(a)	\$ 10,861	\$ 12,846	\$ 15,560	\$ 12,830
License fee and other collaboration revenues	2,327	2,288	1,707	1,999
Other product sales and royalties	197	268	288	78
Total revenues	13,385	15,402	17,555	14,907
Cost of product sales	3,041	2,082	2,669	2,739
Operating expenses	33,200	33,521	32,124	28,158
Restructuring expenses(c)	—	—	—	3,508
Interest and dividend income, net	560	452	378	357
Gains (losses) on investments, net	1	(209)	14	1
Income tax benefit	—	396	215	559
Net loss	<u>\$(22,295)</u>	<u>\$(19,562)</u>	<u>\$(16,631)</u>	<u>\$(18,581)</u>
Net loss per share—basic and diluted	\$ (1.05)	\$ (0.92)	\$ (0.78)	\$ (0.87)

Quarterly loss per share totals differ from annual loss per share totals due to rounding.

(a) In the quarters ended September 30, 2012 and 2011, we revised our estimated Medicaid utilization rate, which resulted in a reduction of our estimated Medicaid rebate reserve related to prior year *Feraheme* sales of \$0.6 million and \$2.5 million, respectively. In addition, in the first three quarters of 2012 we reduced our reserve for product returns by \$2.2 million.

(b) During the quarters ended June 30, 2012 and December 31, 2012, we recognized \$15.0 million and \$5.0 million related to certain milestone payments we received from Takeda upon the EU marketing authorization of *Rienso* and the commercial launches of *Feraheme/Rienso* in Canada and the EU, respectively.

(c) In 2012 and 2011 we carried out corporate restructurings pursuant to which we reduced our workforce and incurred charges related to employee severance and other related costs.

(d) In June 2012, we sold our then remaining ARS portfolio and recognized a loss of approximately \$1.5 million.

Q. Valuation and Qualifying Accounts (in thousands)

	Balance at Beginning of Period	Additions(a)	Deductions Charged to Reserves	Balance at End of Period
Year ended December 31, 2012:				
Accounts receivable allowances(b)	\$ 1,822	\$26,517	\$(26,598)	\$ 1,741
Rebates, fees and returns reserves	\$ 5,943	\$ 6,729	\$(9,224)	\$ 3,448
Year ended December 31, 2011:				
Accounts receivable allowances(b)	\$ 1,148	\$14,074	\$(13,400)	\$ 1,822
Rebates, fees and returns reserves	\$10,015	\$ 9,864	\$(13,936)	\$ 5,943
Year ended December 31, 2010:				
Accounts receivable allowances(b)	\$ 499	\$ 5,113	\$(4,464)	\$ 1,148
Rebates, fees and returns reserves	\$ 5,657	\$17,779	\$(13,421)	\$10,015

(a) Additions to sales discounts, rebates, fees and returns reserves are recorded as a reduction of revenues.

(b) We have not recorded an allowance for doubtful accounts in any of the years presented above. These accounts receivable allowances represent discounts and other chargebacks related to the provision for U.S. product sales.

R. Recently Issued and Proposed Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board, or FASB, issued amended guidance on the presentation of comprehensive income in financial statements. This amendment provides companies the option to present the components of net income and other comprehensive income either as one continuous statement of comprehensive income or as two separate but consecutive statements. This guidance eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. The provisions of this guidance became effective in 2012. We have adopted all provisions of this pronouncement by including other comprehensive income as part of our consolidated statements of comprehensive loss and such adoption did not have a significant impact on our consolidated financial statements.

In May 2011, the FASB issued an amendment to the accounting guidance for fair value measurements and related disclosures. This amendment clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable inputs, or Level 3 measurements. This guidance became effective for interim and annual periods beginning after December 15, 2011. We have adopted all provisions of this pronouncement and such adoption did not have a significant impact on our consolidated financial statements.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE:

None.

ITEM 9A. 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 December 31, 2012, the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were designed and were effective to provide reasonable assurance 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 recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. 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.

Management's Annual Report on Internal Control Over Financial Reporting

Management's Report on Internal Control over Financial Reporting is contained in Part II, Item 8 "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K for the year ended December 31, 2012 and is incorporated herein by reference.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth quarter of the year ended December 31, 2012 that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION:

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE:

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Securities and Exchange Commission, or the SEC, not later than 120 days after the close of our year ended December 31, 2012.

ITEM 11. EXECUTIVE COMPENSATION:

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the SEC not later than 120 days after the close of our year ended December 31, 2012.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS:

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the SEC not later than 120 days after the close of our year ended December 31, 2012.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE:

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the SEC not later than 120 days after the close of our year ended December 31, 2012.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES:

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the SEC not later than 120 days after the close of our year ended December 31, 2012.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES:

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements.

Management's Annual Report on Internal Control over Financial Reporting

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets—as of December 31, 2012 and 2011

Consolidated Statements of Operations—for the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Comprehensive Loss—for the years ended December 31, 2012, 2011 and 2010

Consolidated Statements of Stockholders' Equity—as of December 31, 2012, 2011 and 2010

Consolidated Statements of Cash Flows—for the years ended December 31, 2012, 2011 and 2010

Notes to Consolidated Financial Statements

2. Financial Statement Schedules. No financial statement schedules have been submitted because they are not required, not applicable, or because the information required is included in the financial statements or the notes thereto.

3. Exhibit Index.

Exhibit Number	Description
3.1, 4.1	Certificate of Incorporation of the Company, as restated (incorporated herein by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, File No. 001-10865).
3.2, 4.2	By-Laws of the Company, as amended (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed November 28, 2008, File No. 0-14732).
3.3, 4.3	Certificate of Designation of Series A Junior Participating Preferred Stock (incorporated herein by reference to Exhibit 3.1 and 4.1 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732).
4.4	Specimen certificate representing the Company's Common Stock (incorporated herein by reference to Exhibit 4.3 to the Current Report on Form 8-K filed September 4, 2009, File No. 0-14732).
4.5	Rights Agreement dated as of September 4, 2009 by and among AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732).
4.6	Amendment to Rights Agreement, dated May 10, 2012, by and between the Company and American Stock Transfer & Trust Company LLC (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed May 10, 2012).
4.7	Form of Rights Certificate (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732).

Exhibit Number	Description
10.1*	Representative Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009, File No. 001-10865).
10.2*	Summary of the Company's Change of Control Policy applicable to executive officers (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed February 13, 2006, File No. 0-14732).
10.3*	AMAG Pharmaceuticals, Inc. 2010 Employee Stock Purchase Plan (incorporated herein by reference to Appendix B to the Company's Definitive Proxy Statement on Schedule 14A, filed April 19, 2010, File No. 001-10865).
10.4*	AMAG Pharmaceuticals, Inc.'s Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K filed March 8, 2012, File No. 001-10865).
10.5*	Employment Agreement, dated as of May 6, 2012, by and between the Company and William K. Heiden (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 10, 2012).
10.6*	Employment Agreement dated as of August 1, 2011 between the Company and Frank E. Thomas. (incorporated herein by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K filed March 8, 2012, File No. 001-10865).
10.7*	Second Amendment to Employment Agreement dated as of November 30, 2011 between the Company and Frank E. Thomas (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 2, 2011, File No. 001-10865).
10.8*	Letter Agreement, dated as of May 9, 2012, by and between the Company and Frank E. Thomas (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed May 10, 2012).
10.9*	Retention Agreement between the Company and Scott A. Holmes dated as of December 2, 2011 (incorporated herein by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K filed March 8, 2012, File No. 001-10865).
10.10*+	Second Amended and Restated Employment Agreement dated as of December 15, 2009, as amended February 1, 2011 and November 3, 2011 between the Company and Lee F. Allen, M.D., Ph.D.
10.11*	Retention Agreement dated as of August 27, 2012 between the Company and Lee F. Allen, M.D., Ph.D. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 31, 2012, File No. 001-10865).
10.12*+	Second Amended and Restated Employment Agreement dated as of December 15, 2009, as amended February 1, 2011 and November 3, 2011 between the Company and Christopher White.
10.13*+	Employment Agreement dated as of August 15, 2012 between the Company and Scott B. Townsend.
10.14*+	Employment Agreement dated as of January 1, 2013 between the Company and Greg Madison.
10.15*	Stockholder Agreement, May 9, 2012, by and between the Company and Adage Capital Management, L.P. (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed May 10, 2012).
10.16*	Advanced Magnetics, Inc. Amended and Restated 2000 Stock Plan (incorporated herein by reference to Appendix A to the Company's definitive proxy statement for the year ended September 30, 2005, File No. 0-14732).
10.17*	Form of Stock Option Grant under the Company's 2000 Stock Plan (employees) (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, File No. 0-14732).

Exhibit Number	Description
10.18*	Form of Stock Option Grant under the Company's 2000 Stock Plan (non-employees) (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, File No. 0-14732).
10.19*	AMAG Pharmaceuticals, Inc. Second Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A, filed April 19, 2010, File No. 001-10865).
10.20*	Form of Option Agreement (ISO) under the Company's 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed November 30, 2007, File No. 0-14732).
10.21*	Form of Option Agreement (Nonqualified Option) under the Company's 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed November 30, 2007, File No. 0-14732).
10.22*	Form of Restricted Stock Unit Agreement under the Company's 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed November 30, 2007, File No. 0-14732).
10.23*	Form of Option Agreement (Nonqualified Option) for Annual Director Grants under the Company's Second Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, File No. 001-10865).
10.24*	Form of Restricted Stock Unit Agreement for Annual Director Grants under the Company's Second Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, File No. 001-10865).
10.25*	Form of November 2011 Restricted Stock Unit Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and the Company's executive officers (incorporated herein by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K filed March 8, 2012, File No. 001-10865).
10.26*	Form of November 2011 Restricted Stock Unit Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and each non-executive employee of the Company (incorporated herein by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K filed March 8, 2012, File No. 001-10865).
10.27*	Form of Non-Plan Restricted Stock Unit Agreement, by and between the Company and William K. Heiden (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 10, 2012).
10.28*	Form of Non-Plan Stock Option Agreement, by and between the Company and William K. Heiden (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed May 10, 2012).
10.29*	Option Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and Lee F. Allen, dated as of June 25, 2012 (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 29, 2012).
10.30*	Option Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and Christopher G. White, dated as of June 25, 2012 (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed June 29, 2012).

Exhibit Number	Description
10.31	Lease Agreement, dated as of May 27, 2008, by and between AMAG Pharmaceuticals, Inc. and Mortimer B. Zuckerman and Edward H. Linde, trustees of 92 Hayden Avenue Trust under Declaration of Trust dated August 18, 1983 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 29, 2008, File No. 0-14732).
10.32	Collaboration and Exclusive License Agreement between the Company and 3SBio Inc., dated as of May 25, 2008 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, File No. 0-14732) (confidential treatment previously granted).
10.33	Supply Agreement between the Company and 3SBio Inc., dated as of May 25, 2008 (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, File No. 0-14732) (confidential treatment previously granted).
10.34	Commercial Outsourcing Services Agreement, dated October 2008, by and between the Company and Integrated Commercialization Services, Inc. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 1, 2009, File No. 0-14732) (confidential treatment previously granted).
10.35	First Amendment to Commercial Outsourcing Services Agreement, dated April 14, 2011, by and between the Company and Integrated Commercialization Services, Inc. (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, File No. 001-10865).
10.36	Second Amendment to Commercial Outsourcing Services Agreement, dated effective as of December 1, 2011, by and between the Company and Integrated Commercialization Services, Inc. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 22, 2011, File No. 001-10865) (confidential treatment previously granted).
10.37	Third Amendment to Commercial Outsourcing Services Agreement, dated effective as of August 1, 2012, by and between the Company and Integrated Commercialization Services, Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed November 7, 2012, File No. 001-10865) (confidential treatment previously granted).
10.38	Commercial Packaging Services Agreement, dated May 29, 2009, by and between the Company and Packaging Coordinators, LLC (formerly Catalent Pharma Solutions LLC) (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 1, 2009, File No. 0-14732) (confidential treatment previously granted).
10.39+	Amendment No. 1 to Commercial Packaging Services Agreement, dated January 29, 2013, by and between the Company and Packaging Coordinators, LLC (formerly Catalent Pharma Solutions LLC) (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 the redaction pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities Exchange Act of 1934, as amended).
10.40	License, Development and Commercialization Agreement by and between the Company and Takeda Pharmaceutical Company Limited, dated March 31, 2010 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, File No. 001-10865) (confidential treatment previously granted).

Exhibit Number	Description
10.41	Amendment to the License, Development and Commercialization Agreement, dated June 25, 2012, by and between the Company and Takeda Pharmaceutical Company Limited (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 29, 2012, File No. 001-10865) (confidential treatment previously granted).
10.42	Commercial Supply Agreement, dated effective as of August 29, 2012, by and between the Company and Sigma-Aldrich, Inc. (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed November 7, 2012, File No. 001-10865) (confidential treatment previously granted).
10.43	Pharmaceutical Manufacturing and Supply Agreement, dated effective as of January 8, 2010, by and between the Company and DSM Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed November 7, 2012, File No. 001-10865) (confidential treatment previously granted).
21.1+	Subsidiaries of the Company.
23.1+	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page(s) hereto)
31.1+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101++	The following materials from AMAG Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2012, 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 Stockholders' Equity, (v) Consolidated Statements of Cash, and (vi) Notes to Consolidated Financial Statements.

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

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

* Exhibits marked with a single asterisk reference management contracts, compensatory plans or arrangements, filed in response to Item 15(a)(3) of the instructions to Form 10-K.

The other exhibits listed have previously been filed with the SEC and are incorporated herein by reference, as indicated.

(b) *Exhibits.* We hereby file or furnish as exhibits, as the case may be, to this Form 10-K those exhibits listed in Part IV, Item 15(a)(3) above.

(c) *Financial Statement Schedules.* No financial statement schedules have been submitted because they are not required, not applicable, or because the information required is included in the financial statements or the notes thereto.

Exhibit Number	Description
3.1, 4.1	Certificate of Incorporation of the Company, as restated (incorporated herein by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, File No. 001-10865).
3.2, 4.2	By-Laws of the Company, as amended (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed November 28, 2008, File No. 0-14732).
3.3, 4.3	Certificate of Designation of Series A Junior Participating Preferred Stock (incorporated herein by reference to Exhibit 3.1 and 4.1 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732).
4.4	Specimen certificate representing the Company's Common Stock (incorporated herein by reference to Exhibit 4.3 to the Current Report on Form 8-K filed September 4, 2009, File No. 0-14732).
4.5	Rights Agreement dated as of September 4, 2009 by and among AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732).
4.6	Amendment to Rights Agreement, dated May 10, 2012, by and between the Company and American Stock Transfer & Trust Company LLC (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed May 10, 2012).
4.7	Form of Rights Certificate (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732).
10.1*	Representative Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009, File No. 001-10865).
10.2*	Summary of the Company's Change of Control Policy applicable to executive officers (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed February 13, 2006, File No. 0-14732).
10.3*	AMAG Pharmaceuticals, Inc. 2010 Employee Stock Purchase Plan (incorporated herein by reference to Appendix B to the Company's Definitive Proxy Statement on Schedule 14A, filed April 19, 2010, File No. 001-10865).
10.4*	AMAG Pharmaceuticals, Inc.'s Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K filed March 8, 2012, File No. 001-10865).
10.5*	Employment Agreement, dated as of May 6, 2012, by and between the Company and William K. Heiden (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 10, 2012).
10.6*	Employment Agreement dated as of August 1, 2011 between the Company and Frank E. Thomas. (incorporated herein by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K filed March 8, 2012, File No. 001-10865).
10.7*	Second Amendment to Employment Agreement dated as of November 30, 2011 between the Company and Frank E. Thomas (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 2, 2011, File No. 001-10865).
10.8*	Letter Agreement, dated as of May 9, 2012, by and between the Company and Frank E. Thomas (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed May 10, 2012).
10.9*	Retention Agreement between the Company and Scott A. Holmes dated as of December 2, 2011 (incorporated herein by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K filed March 8, 2012, File No. 001-10865).
10.10*+	Second Amended and Restated Employment Agreement dated as of December 15, 2009, as amended February 1, 2011 and November 3, 2011 between the Company and Lee F. Allen, M.D., Ph.D.

Exhibit Number	Description
10.11*	Retention Agreement dated as of August 27, 2012 between the Company and Lee F. Allen, M.D., Ph.D. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 31, 2012, File No. 001-10865).
10.12* +	Second Amended and Restated Employment Agreement dated as of December 15, 2009, as amended February 1, 2011 and November 3, 2011 between the Company and Christopher White.
10.13* +	Employment Agreement dated as of August 15, 2012 between the Company and Scott B. Townsend.
10.14* +	Employment Agreement dated as of January 1, 2013 between the Company and Greg Madison.
10.15*	Stockholder Agreement, May 9, 2012, by and between the Company and Adage Capital Management, L.P. (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed May 10, 2012).
10.16*	Advanced Magnetics, Inc. Amended and Restated 2000 Stock Plan (incorporated herein by reference to Appendix A to the Company's definitive proxy statement for the year ended September 30, 2005, File No. 0-14732).
10.17*	Form of Stock Option Grant under the Company's 2000 Stock Plan (employees) (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, File No. 0-14732).
10.18*	Form of Stock Option Grant under the Company's 2000 Stock Plan (non-employees) (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, File No. 0-14732).
10.19*	AMAG Pharmaceuticals, Inc. Second Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A, filed April 19, 2010, File No. 001-10865).
10.20*	Form of Option Agreement (ISO) under the Company's 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed November 30, 2007, File No. 0-14732).
10.21*	Form of Option Agreement (Nonqualified Option) under the Company's 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed November 30, 2007, File No. 0-14732).
10.22*	Form of Restricted Stock Unit Agreement under the Company's 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed November 30, 2007, File No. 0-14732).
10.23*	Form of Option Agreement (Nonqualified Option) for Annual Director Grants under the Company's Second Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, File No. 001-10865).
10.24*	Form of Restricted Stock Unit Agreement for Annual Director Grants under the Company's Second Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, File No. 001-10865).
10.25*	Form of November 2011 Restricted Stock Unit Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and the Company's executive officers (incorporated herein by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K filed March 8, 2012, File No. 001-10865).
10.26*	Form of November 2011 Restricted Stock Unit Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and each non-executive employee of the Company (incorporated herein by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K filed March 8, 2012, File No. 001-10865).

Exhibit Number	Description
10.27*	Form of Non-Plan Restricted Stock Unit Agreement, by and between the Company and William K. Heiden (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 10, 2012).
10.28*	Form of Non-Plan Stock Option Agreement, by and between the Company and William K. Heiden (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed May 10, 2012).
10.29*	Option Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and Lee F. Allen, dated as of June 25, 2012 (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 29, 2012).
10.30*	Option Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and Christopher G. White, dated as of June 25, 2012 (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed June 29, 2012).
10.31	Lease Agreement, dated as of May 27, 2008, by and between AMAG Pharmaceuticals, Inc. and Mortimer B. Zuckerman and Edward H. Linde, trustees of 92 Hayden Avenue Trust under Declaration of Trust dated August 18, 1983 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 29, 2008, File No. 0-14732).
10.32	Collaboration and Exclusive License Agreement between the Company and 3SBio Inc., dated as of May 25, 2008 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, File No. 0-14732) (confidential treatment previously granted).
10.33	Supply Agreement between the Company and 3SBio Inc., dated as of May 25, 2008 (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, File No. 0-14732) (confidential treatment previously granted).
10.34	Commercial Outsourcing Services Agreement, dated October 2008, by and between the Company and Integrated Commercialization Services, Inc. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 1, 2009, File No. 0-14732) (confidential treatment previously granted).
10.35	First Amendment to Commercial Outsourcing Services Agreement, dated April 14, 2011, by and between the Company and Integrated Commercialization Services, Inc. (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, File No. 001-10865).
10.36	Second Amendment to Commercial Outsourcing Services Agreement, dated effective as of December 1, 2011, by and between the Company and Integrated Commercialization Services, Inc. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 22, 2011, File No. 001-10865) (confidential treatment previously granted).
10.37	Third Amendment to Commercial Outsourcing Services Agreement, dated effective as of August 1, 2012, by and between the Company and Integrated Commercialization Services, Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed November 7, 2012, File No. 001-10865) (confidential treatment previously granted).
10.38	Commercial Packaging Services Agreement, dated May 29, 2009, by and between the Company and Packaging Coordinators, LLC (formerly Catalent Pharma Solutions LLC) (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 1, 2009, File No. 0-14732) (confidential treatment previously granted).

Exhibit Number	Description
10.39+	Amendment No. 1 to Commercial Packaging Services Agreement, dated January 29, 2013, by and between the Company and Packaging Coordinators, LLC (formerly Catalent Pharma Solutions LLC) (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 the redaction pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities Exchange Act of 1934, as amended).
10.40	License, Development and Commercialization Agreement by and between the Company and Takeda Pharmaceutical Company Limited, dated March 31, 2010 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, File No. 001-10865) (confidential treatment previously granted).
10.41	Amendment to the License, Development and Commercialization Agreement, dated June 25, 2012, by and between the Company and Takeda Pharmaceutical Company Limited (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 29, 2012, File No. 001-10865) (confidential treatment previously granted).
10.42	Commercial Supply Agreement, dated effective as of August 29, 2012, by and between the Company and Sigma-Aldrich, Inc. (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed November 7, 2012, File No. 001-10865) (confidential treatment previously granted).
10.43	Pharmaceutical Manufacturing and Supply Agreement, dated effective as of January 8, 2010, by and between the Company and DSM Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed November 7, 2012, File No. 001-10865) (confidential treatment previously granted).
21.1+	Subsidiaries of the Company.
23.1+	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page(s) hereto)
31.1+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101++	The following materials from AMAG Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2012, 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 Stockholders' Equity, (v) Consolidated Statements of Cash, and (vi) Notes to Consolidated Financial Statements.

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

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

* Exhibits marked with a single asterisk reference management contracts, compensatory plans or arrangements, filed in response to Item 15(a)(3) of the instructions to Form 10-K.

The other exhibits listed have previously been filed with the SEC and are incorporated herein by reference, as indicated.

AMAG PHARMACEUTICALS, INC.

100 Hayden Avenue
Lexington, Massachusetts 02421

NOTICE OF ANNUAL MEETING OF STOCKHOLDERS

To Be Held On May 23, 2013

SEC
Mail Processing
Section

APR 27 2013

Washington DC
400

An Annual Meeting of Stockholders of AMAG Pharmaceuticals, Inc., or the Annual Meeting, will be held at Goodwin Procter LLP, 53 State St., Boston, Massachusetts 02109 on Thursday, May 23, 2013 at 9:00 a.m., local time, to consider and act upon the following matters:

- (1) To elect the six nominees named herein to the Board of Directors to serve until the next Annual Meeting and until their successors have been elected and qualified;
- (2) To approve, on an advisory basis, the compensation of our named executive officers, as disclosed in this proxy statement;
- (3) To approve the Third Amended and Restated 2007 Equity Incentive Plan to, among other things, increase the number of shares of our common stock available for issuance thereunder by 1,100,000 shares;
- (4) To ratify the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the year ending December 31, 2013; and
- (5) To transact such other business as may properly come before the Annual Meeting or any adjournments or postponements thereof.

Only stockholders of record at the close of business on March 28, 2013, or the Record Date, are entitled to notice of, and will be entitled to vote at, the Annual Meeting or any adjournments or postponements thereof. A list of the stockholders of record entitled to vote will be available for inspection at our principal executive offices at 100 Hayden Avenue, Lexington, Massachusetts 02421 during the ten days prior to the Annual Meeting. Our stock transfer books will remain open between the Record Date and the date of the Annual Meeting.

All stockholders are cordially invited to attend the Annual Meeting in person. To assure your representation at the Annual Meeting, we urge you to vote via the Internet at www.proxyvote.com or by telephone by following the instructions on the enclosed proxy card, or by signing, voting and returning your proxy card to Broadridge Financial Solutions, 51 Mercedes Way, Edgewood, New York 11717.

By Order of the Board of Directors,



Scott B. Townsend
Secretary

Lexington, Massachusetts
April 19, 2013

Whether or not you expect to attend the Annual Meeting, please promptly complete your proxy as indicated above in order to assure representation of your shares. No postage need be affixed if the proxy is mailed in the United States. Do not send any certificates with your proxy. Even if you have voted by proxy, you may still vote in person if you attend the Annual Meeting. Please note, however, that if your shares are held of record by a broker, bank or other nominee and you wish to vote at the Annual Meeting, you must obtain a proxy issued in your name from that record holder. Please refer to the enclosed form for instructions.

Important Notice Regarding the Availability of Proxy Materials for the Annual Meeting to Be Held on May 23, 2013 at 9:00 a.m. at Goodwin Procter LLP, 53 State St., Boston, Massachusetts 02109.

This Proxy Statement, the Proxy Card, and the Company's 2012 Annual Report to Stockholders and any other proxy materials are available free of charge at www.amagpharma.com.

AMAG PHARMACEUTICALS, INC.
PROXY STATEMENT
FOR THE ANNUAL MEETING OF STOCKHOLDERS
TABLE OF CONTENTS

Questions and Answers About This Proxy Material and Voting	1
Security Ownership of Certain Beneficial Owners and Management	6
Certain Relationships and Related Transactions	9
Proposal 1: Election of Directors	10
Information Regarding the Board of Directors and Corporate Governance	14
Independence of the Board of Directors	14
Meetings of the Board of Directors	14
Committees of the Board of Directors	14
Stockholder Communication with the Board of Directors	19
Board Leadership Structure	20
The Board's Role in Risk Oversight	20
Risk Considerations in our Compensation Policies and Practices	21
Code of Ethics	22
Director Compensation	22
Proposal 2: Advisory Vote on Executive Compensation	30
Executive Officers and Compensation	31
Executive Officers	31
Compensation Discussion and Analysis	33
Regulatory Requirements	56
Summary Compensation Table for Fiscal 2012	57
Grants of Plan-Based Awards in Fiscal 2012	59
Outstanding Equity Awards at December 31, 2012	61
Option Exercises and Stock Vested in Fiscal 2012	63
Change of Control and Severance Compensation	64
Potential Payments Upon Termination or Change of Control	66
401(k) Plan	70
Compensation Committee Interlocks And Insider Participation	70
Section 16(a) Beneficial Ownership Reporting Compliance	71
Proposal 3: Approval of the Third Amended and Restated 2007 Equity Incentive Plan	72
Proposal 4: Ratification of Appointment of Independent Registered Public Accounting Firm	81

AMAG PHARMACEUTICALS, INC.

100 Hayden Avenue
Lexington, Massachusetts 02421

PROXY STATEMENT FOR THE ANNUAL MEETING OF STOCKHOLDERS TO BE HELD ON MAY 23, 2013

QUESTIONS AND ANSWERS ABOUT THIS PROXY MATERIAL AND VOTING

The Annual Meeting

Our Board of Directors, or the Board, is soliciting your proxy to vote at our Annual Meeting to be held at Goodwin Procter LLP, 53 State St., Boston, Massachusetts 02109 on Thursday, May 23, 2013 at 9:00 a.m., local time, and at any adjournments or postponements of the Annual Meeting. Directions to the meeting location are available at the website of Goodwin Procter LLP at www.goodwinprocter.com/offices. Goodwin Procter's website and the information contained therein are not incorporated into this Proxy Statement. This Proxy Statement explains the agenda, voting information and procedures for the Annual Meeting. Please read it carefully. This Proxy Statement and accompanying form of proxy were first mailed to our stockholders on or about April 19, 2013.

At the Annual Meeting, the following proposals will be subject to a vote of our stockholders: (i) a proposal to elect William K. Heiden, Michael Narachi, Robert J. Perez, Lesley Russell, MB.Ch.B., MRCP, Gino Santini and Davey S. Scoon as directors; (ii) an advisory vote on the compensation of our named executive officers; (iii) a proposal to approve our Third Amended and Restated 2007 Equity Incentive Plan, or the Restated Plan, to, among other things, increase the number of shares of our common stock available for issuance thereunder by 1,100,000 shares; and (iv) a proposal to ratify the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the year ending December 31, 2013.

In this Proxy Statement, references to "Company," "AMAG," "we," "us," or "our" mean AMAG Pharmaceuticals, Inc. Any reference in this Proxy Statement to information found on our website, www.amagpharma.com, does not incorporate such information by reference into this Proxy Statement.

Who Is Entitled To Attend And Vote At The Annual Meeting?

Only stockholders of record at the close of business on March 28, 2013, or the Record Date, are entitled to attend and vote at the Annual Meeting. On the Record Date, there were 21,554,391 shares of common stock outstanding and entitled to vote.

Stockholder of Record: Shares Registered in Your Name

If on the Record Date your shares were registered directly in your name with our transfer agent/ registrar, American Stock Transfer and Trust Company, then you are a stockholder of record. As a stockholder of record, you may vote in person at the meeting or by proxy. If you wish to vote by proxy, you may complete, sign and date the enclosed proxy card and return it by mail in the enclosed, self-addressed envelope which has postage prepaid. Instead of submitting your vote by mail, you may vote by telephone or Internet as instructed on the enclosed proxy card. Whether or not you plan to attend the meeting, we urge you to fill out and return the enclosed proxy card to ensure your vote is counted.

In order to vote by telephone or Internet, please have the enclosed proxy card with you and call the number or go to the website listed on the proxy card and follow the instructions. The telephone and Internet voting procedures are designed to authenticate stockholders' identities, to allow

stockholders to give their voting instructions and to confirm that stockholders' instructions have been recorded properly.

Beneficial Owner: Shares Registered in the Name of a Broker or Bank

If on the Record Date your shares were held, not in your name, but rather in an account at a brokerage firm, bank, dealer or similar organization, then you are the beneficial owner of shares held in "street name" and these proxy materials are being forwarded to you by that organization. The organization holding your account is considered to be the stockholder of record for purposes of voting at the Annual Meeting. As a beneficial owner, you have the right to direct your broker or other agent regarding how to vote the shares in your account and should follow the instructions for voting by proxy provided by your broker, bank or similar nominee. You are also invited to attend the Annual Meeting.

How Many Votes Do I Have?

Each stockholder is entitled to one vote for each share of common stock held by such stockholder on the Record Date.

How Do I Vote?

If you are a stockholder of record, you may vote in person at the Annual Meeting or by proxy using the enclosed proxy card. Whether or not you plan to attend the Annual Meeting, we urge you to vote by telephone or Internet as instructed in the enclosed proxy card or by completing, signing and dating the enclosed proxy card and returning it in the envelope provided. No postage is required if your proxy card is mailed in the United States. You may still attend the Annual Meeting and vote in person even if you have already voted by proxy. If you plan to attend the Annual Meeting and vote in person, we will give you a ballot or a new proxy card when you arrive. Positive identification will be required to vote your shares in person.

If you are a beneficial owner of shares registered in the name of your broker, bank, or other agent, you should have received a proxy card and voting instructions with these proxy materials from that organization. Simply follow the instructions for voting provided by your broker, bank or other agent to complete and mail the proxy card to ensure that your vote is counted. You may still attend the Annual Meeting and vote in person even if you have already voted by proxy. However, if your shares are held in the name of your broker, bank or other agent, you must bring an account statement or letter from the agent indicating that you were the beneficial owner of the shares on the Record Date for voting at the Annual Meeting. Positive identification will be required to vote your shares in person.

You may either vote "For" all the nominees to the Board or you may "Withhold" your vote for any nominee you specify. For each of the other matters to be voted on, you may vote "For" or "Against" or abstain from voting.

The persons named as attorneys-in-fact in the enclosed proxy card, William K. Heiden, Frank E. Thomas and Scott B. Townsend, were selected by the Board and are officers of the Company. All properly executed proxies submitted in time to be counted at the Annual Meeting will be voted by such persons at the Annual Meeting. Where a choice has been specified on the proxy with respect to the foregoing matters, the shares represented by the proxy will be voted in accordance with the specifications. **If no such specifications are indicated, such proxies will be voted FOR Proposal 1 (the election of the director nominees), FOR Proposal 2 (the advisory vote on the compensation of our named executive officers), FOR Proposal 3 (the approval of the Third Amended and Restated Equity Incentive Plan) and FOR Proposal 4 (the ratification of the appointment of PricewaterhouseCoopers LLP).**

If any other matter should be presented at the Annual Meeting upon which a vote properly may be taken, your shares will be voted in accordance with the judgment of the persons named in your proxy. At present, the Board knows of no other matters to be presented at the Annual Meeting.

What Does It Mean If I Receive More Than One Proxy Card?

If you receive more than one proxy card, your shares may be registered in more than one name or are registered in different accounts. Please complete, sign, date, and return all proxy cards or vote by Internet or telephone as instructed on such proxy cards to be sure that all of your shares are voted.

Can I Change My Vote After I Deliver My Proxy?

Yes. You may change your vote at any time before the final vote at the Annual Meeting. If you are the record holder of your shares, you may revoke your proxy in any one of four ways:

- Submitting another properly completed proxy card with a later date before the taking of the vote at the Annual Meeting.
- Properly casting a new vote via the Internet or by telephone at any time before the closure of the Internet or telephone voting facilities.
- Delivering written notice to us before the taking of the vote at the Annual Meeting that you are revoking your proxy. Such notice should be sent to our principal executive offices at 100 Hayden Avenue, Lexington, Massachusetts 02421, attention: Secretary.
- Attending the Annual Meeting and voting in person. Simply attending the meeting will not, in itself, revoke your proxy.

If you wish to revoke a delivered proxy and your shares are held by your broker or bank as a nominee or agent, you should follow the revocation instructions provided by your broker or bank.

What Are “Broker Non-Votes” And What Discretion Does My Broker Have To Vote My Shares Held In “Street Name?”

Broker non-votes occur when a beneficial owner of shares held in street name does not give instructions to the broker or nominee holding the shares as to how to vote on matters deemed “non-routine.” Generally, if shares are held in street name, the beneficial owner of the shares is entitled to give voting instructions to the broker or nominee holding the shares. If the beneficial owner does not provide voting instructions, the broker or nominee can still vote the shares with respect to matters that are considered to be “routine,” but not with respect to “non-routine” matters. Under the rules and interpretations of the New York Stock Exchange, which govern this issue regardless of the exchange on which the company is listed, brokers have the discretion to vote those shares on routine matters. The only routine matter included in this Proxy Statement is the ratification of our appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the year ending December 31, 2013. Pursuant to New York Stock Exchange rules, the election of directors, the advisory vote on compensation paid to our named executive officers and the approval of our Restated Plan are considered non-routine matters. For non-routine matters, brokers do not have authority, discretionary or otherwise, to vote your shares unless they receive proper instructions to do so from you in a timely manner. We strongly encourage you to submit your proxy and exercise your right to vote as a stockholder as promptly as possible.

What Constitutes A Quorum At The Annual Meeting?

A quorum of stockholders is necessary to hold a valid meeting. A quorum will be present if the holders of at least a majority of the shares of common stock issued and outstanding and entitled to

vote on the Record Date are present at the Annual Meeting in person or represented by proxy. On the Record Date, there were 21,554,391 shares of our common stock outstanding and entitled to vote.

Abstentions and broker non-votes are counted as present or represented for purposes of determining the presence or absence of a quorum for the Annual Meeting. If there is no quorum, the holders of a majority of shares present at the Annual Meeting in person or represented by proxy may adjourn the meeting to another date.

How Many Votes Are Required To Approve Each Proposal?

Our directors are elected by a plurality of the votes cast by stockholders entitled to vote at the Annual Meeting. Abstentions, broker non-votes and votes withheld will not be treated as votes cast for this Proposal 1 and will not affect the outcome of the election.

For each of Proposal 2 (the advisory vote on the compensation of our named executive officers), Proposal 3 (the approval of the Third Amended and Restated Equity Incentive Plan) and Proposal 4 (the ratification of the appointment of PricewaterhouseCoopers LLP), an affirmative vote of the holders of a majority of shares of common stock present or represented and voting at the Annual Meeting is required for approval. For non-routine matters, broker non-votes are not considered to have been voted "for" or "against" a particular proposal and therefore have no effect on Proposals 2 and 3. Proposal 4 is considered a routine matter and nominees therefore have discretionary voting power as to Proposal 4. Like broker non-votes, abstentions, are not counted as voting on a matter and thus will have no effect on Proposals 2, 3 and 4.

When a quorum is present at any meeting of stockholders, the holders of a majority of the stock present or represented and voting on a matter shall decide any matter to be voted upon by the stockholders at such meeting, except when a different vote is required by express provision of law, our charter or our by-laws. At present, the Board knows of no other matters to be presented for stockholder action at the Annual Meeting.

How Are We Soliciting Proxies And Tabulating Votes?

We will bear all costs of solicitation of proxies. In addition to these proxy materials, our directors, officers and employees, without additional remuneration, may also solicit proxies through telephone and in-person conversations. We have agreed to pay approximately \$13,000, plus out-of-pocket expenses, to Georgeson to solicit proxies on our behalf, if necessary. We will also reimburse brokerage firms, banks and other agents for the cost of forwarding proxy materials to beneficial owners.

Votes will be tabulated by Broadridge Investor Communications Solutions, Inc., or Broadridge.

How Can I Find Out The Results Of The Voting At The Annual Meeting?

Preliminary voting results will be announced at the Annual Meeting. In addition, final voting results will be published in a current report on Form 8-K that we expect to file within four business days after the Annual Meeting. If final voting results are not available to us in time to file a Form 8-K within four business days after the Annual Meeting, we intend to file a Form 8-K to publish preliminary results and, within four business days after the final results are known to us, file an amended Form 8-K to publish the final results.

When Are Stockholder Proposals And Director Nominations Due For Next Year's Annual Meeting?

To be considered for inclusion in next year's proxy materials, your proposal must be submitted in writing to our principal executive offices at 100 Hayden Avenue, Lexington, Massachusetts 02421, attention: Secretary and must be received by us no later than December 20, 2013. Proposals must

satisfy the requirements and procedures set forth in Rule 14a-8 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

If you wish to submit a proposal that is not to be included in next year's proxy materials or wish to nominate a director, you must submit such proposal or nomination in writing to our principal executive offices at 100 Hayden Avenue, Lexington, Massachusetts 02421, attention: Secretary. Such proposal or nomination must be received by us no earlier than January 23, 2014 and no later than February 22, 2014 and must satisfy the requirements described below under "*Stockholder Recommendations For Nominees As Directors And The Proposal Of Other Business.*" If the date of next year's annual meeting of stockholders is advanced by more than 30 days or delayed by more than 30 days from the anniversary of our 2013 Annual Meeting, any stockholder recommendation or proposal must be received by us no earlier than the close of business on the 120th day prior to such advanced or delayed annual meeting date and no later than the close of business on the later of (i) the 90th day prior to such advanced or delayed annual meeting date and (ii) the 10th day following the first public announcement of the meeting date.

In order to curtail controversy as to the date on which a proposal was received by us, we suggest that you submit your proposals by registered mail, return receipt requested.

You are also advised to review our by-laws, which contain additional requirements about advance notice of stockholder proposals and director nominations.

What Materials Should I Be Receiving In Connection With The Annual Meeting?

Our Annual Report, including audited financial statements for the year ended December 31, 2012, is being mailed to you along with this Proxy Statement. This Proxy Statement and the accompanying form of proxy were first mailed to our stockholders on or about April 19, 2013.

In order to reduce printing and postage costs, Broadridge, which handles the mailing of our Annual Report and proxy materials to all of our stockholders, participates in the practice of "householding" proxy statements and annual reports, which is the delivery of a single set of Annual Meeting materials to two or more stockholders sharing the same address. This means that unless contrary instructions are received from one or more of such stockholders, only one copy of the Proxy Statement and Annual Report is sent to multiple beneficial stockholders who share the same address. Each stockholder will continue to receive a separate proxy card.

Once you have received notice from your broker that they will be householding communications to your address, householding will continue until you are notified otherwise or until you revoke your consent. If, at any time, you no longer wish to participate in householding and would prefer to receive a separate set of Annual Meeting materials, you should contact Broadridge, your bank or your broker or contact our Investor Relations Department at (617) 498-3300 or 100 Hayden Avenue, Lexington, Massachusetts 02421. We will undertake to deliver promptly upon written or oral request a separate copy of the Proxy Statement and Annual Report, as applicable, to a security holder at a shared address to which a single copy of the documents was delivered. Stockholders who currently receive multiple copies of our Annual Meeting materials at their address and would like to request householding of their communications should contact their broker.

We do not provide for householding for stockholders of record.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the beneficial ownership of our common stock by certain individuals and entities. In general, “beneficial ownership” includes those shares a person or entity has the power to vote or transfer, and stock options and similar rights that are exercisable currently or within 60 days of the Record Date and restricted stock units, or RSUs, which are expected to vest or which may be settled within 60 days of the Record Date. The Record Date for the Annual Meeting is March 28, 2013. As of the Record Date, there were 21,554,391 shares of our common stock outstanding. The following table shows the amount of our common stock beneficially owned as of the Record Date by:

- Each person known by us to beneficially own more than 5% of our common stock;
- Each of our directors and nominees for director;
- Each of our named executive officers listed in the “*Summary Compensation Table*” included in this Proxy Statement; and
- All of our current directors and executive officers as a group.

Name and Address of Beneficial Owner(1)	Number of Shares Beneficially Owned	Percentage of Common Stock Outstanding
Phillip Gross/Robert Atchinson(2) 200 Clarendon Street, 52 nd Floor Boston, Massachusetts 02116	4,135,330	19.2%
FMR LLC(3) 82 Devonshire Street Boston, Massachusetts 02109	2,548,755	11.8%
BlackRock, Inc.(4) 40 East 52 nd Street New York, New York 10022	2,266,951	10.5%
T. Rowe Price Associates, Inc.(5) 100 E. Pratt Street Baltimore, Maryland 21202	1,976,300	9.2%
Patrick Lee M.D./Anthony Joonkyoo Yun, M.D.(6) 470 University Avenue Palo Alto, California 94301	1,813,724	8.4%
Martin Shkreli(7) 330 Madison Avenue, 6 th Floor New York, New York 10017	1,245,781	5.8%
First Manhattan Co.(8) 437 Madison Avenue New York, New York 10022	1,184,815	5.5%
Lee F. Allen, M.D. Ph.D.(9)	152,020	*
William K. Heiden(10)	110,000	*
Michael Narachi(11)	67,135	*
Christopher G. White(12)	56,500	*
Frank E. Thomas(13)	37,000	*
Davey S. Scoon(14)	33,644	*
Joseph V. Bonventre, M.D., Ph.D.(15)	33,300	*
Robert J. Perez(16)	29,300	*
Rajiv De Silva(17)	26,096	*
Lesley Russell, MB. Ch.B., MRCP(18)	20,833	*
Gino Santini(19)	11,274	*
Scott A. Holmes(20)	1,250	*
Scott B. Townsend(21)	—	*
All current directors and executive officers as a group (14 persons)(22)	443,499	2.0%

* Less than 1%.

- (1) Unless otherwise indicated, we believe that each stockholder referred to above has sole voting and investment power with respect to the shares indicated, and the address of each stockholder is: c/o AMAG Pharmaceuticals, Inc., 100 Hayden Avenue, Lexington, Massachusetts 02421.
- (2) Based solely upon a Schedule 13G filed with the U.S. Securities and Exchange Commission, or the SEC, on March 5, 2012. Reflects 4,135,330 shares beneficially owned by each of Adage Capital Partners, L.P., or ACP, Adage Capital Partners GP, L.L.C., or ACPGP, Adage Capital Advisors, L.L.C., or ACA, Robert Atchinson and Phillip Gross. ACPGP is the General Partner of ACP. ACA is the managing member of ACPGP. Robert Atchinson and Phillip Gross are managing members of ACA. Each of the foregoing have shared voting power and shared dispositive power with respect to the shares.
- (3) Based solely upon a Schedule 13G/A, as amended, filed with the SEC on February 14, 2013. Reflects 2,548,755 shares beneficially owned by Fidelity Management & Research Company, or Fidelity, a wholly-owned subsidiary of FMR LLC and an investment advisor registered under Section 203 of the Investment Advisors Act of 1940, as amended. Puritan Fund, an investment company registered under the Investment Company Act of 1940, as amended, with an address at 82 Devonshire Street, Boston, Massachusetts 02109, is the beneficial owner of 1,460,561 of the shares. Edward C. Johnson 3rd and FMR LLC, through its control of Fidelity and the funds, each has sole power to dispose of 2,548,755 shares owned by the funds.
- (4) Based solely upon a Schedule 13G/A, as amended, filed with the SEC on February 11, 2013.
- (5) Based solely upon a Schedule 13G/A, as amended, filed with the SEC on February 8, 2013. T. Rowe Price Associates, Inc. has sole voting power with respect to 295,400 of such shares.
- (6) Based solely upon a Schedule 13G/A, as amended, filed with the SEC on February 14, 2013. Includes 1,813,033 shares owned by each of Palo Alto Investors, LLC, Patrick Lee, M.D. and Anthony Joonkyoo Yun, M.D. Palo Alto Investors, LLC is the general partner and investment adviser of Palo Alto Healthcare Master Fund II, L.P. Palo Alto Healthcare Master Fund II, L.P., with an address of c/o Citco Fund Services (Cayman Islands) Limited, 89 Nexus Way, Camana Bay, Grand Cayman, Cayman Islands, is the beneficial owner of 1,091,396 of the shares. Dr. Lee and Dr. Yun each co-manage Palo Alto Investors, LLC and have shared voting and dispositive power with respect to 1,813,033 shares. Dr. Lee has sole voting and dispositive power with respect to 691 shares.
- (7) Based solely upon a Schedule 13D filed with the SEC on October 7, 2011. Reflects 1,245,781 shares beneficially owned by Martin Shkreli. Mr. Shkreli is the managing member of each of MSMB Capital Management, LLC, which beneficially owns 2,800 of the shares, MSMB Healthcare Investors LLC, which beneficially owns 1,242,981 of the shares, and MSMB Healthcare Management LLC, which beneficially owns 1,242,981 of the shares. Pompeii Management, LLC is the general partner of Bloomfield Partners LP, each of which beneficially own 2,800 of the shares. MSMB Capital Management, LLC is the special limited partner and investment manager of Bloomfield Partners LP. MSMB Healthcare Investors LLC is the general partner of MSMB Healthcare LP, which beneficially owns 1,242,981 of the shares, and MSMB Healthcare Management LLC is the investment advisor of MSMB Healthcare LP. Mr. Shkreli was quoted in an article (Forbes, December 18, 2012) that he has liquidated the MSMB Capital Funds (which would have included shares of our Company) and he has not filed any further information with the SEC since October 2011.
- (8) Based solely upon a Schedule 13G filed with the SEC on February 15, 2013.
- (9) Includes 132,187 shares issuable to Dr. Allen pursuant to options currently exercisable or exercisable within 60 days of the Record Date and 17,604 shares issuable to Dr. Allen pursuant to RSUs expected to vest or which may be settled within 60 days of the Record Date. In March 2013, Dr. Allen resigned from the Company. However, in April 2013 we entered into a Severance and Consulting Agreement with Dr. Allen under which the Company agreed to engage Dr. Allen as a consultant until at least March 2014. Dr. Allen's equity incentives with the Company will continue to vest during the consulting period in accordance with the regular vesting schedules provided in his equity incentive agreements.
- (10) Includes 75,000 shares issuable to Mr. Heiden pursuant to options currently exercisable or exercisable within 60 days of the Record Date and 25,000 shares issuable to Mr. Heiden pursuant to RSUs expected to vest within 60 days of the Record Date. Mr. Heiden joined the Company as its President and Chief Executive Officer in May 2012.
- (11) Includes 47,035 shares issuable to Mr. Narachi pursuant to options currently exercisable or exercisable within 60 days of the Record Date and 12,600 shares issuable to Mr. Narachi pursuant to RSUs expected to vest or which may be settled within 60 days of the Record Date.
- (12) Reflects 56,500 shares issuable to Mr. White pursuant to options currently exercisable or exercisable within 60 days of the Record Date.

- (13) Includes 15,000 shares issuable to Mr. Thomas pursuant to options currently exercisable or exercisable within 60 days of the Record Date.
- (14) Reflects 26,944 shares issuable to Mr. Scoon pursuant to options currently exercisable or exercisable within 60 days of the Record Date and 6,700 shares issuable to Mr. Scoon pursuant to RSUs expected to vest or which may be settled within 60 days of the Record Date.
- (15) Reflects 26,600 shares issuable to Dr. Bonventre pursuant to options currently exercisable or exercisable within 60 days of the Record Date and 6,700 shares issuable to Dr. Bonventre pursuant to RSUs expected to vest or which may be settled within 60 days of the Record Date.
- (16) Reflects 22,600 shares issuable to Mr. Perez pursuant to options currently exercisable or exercisable within 60 days of the Record Date and 6,700 shares issuable to Mr. Perez pursuant to RSUs expected to vest or which may be settled within 60 days of the Record Date.
- (17) Includes 8,499 shares issuable to Mr. De Silva pursuant to options currently exercisable or exercisable within 60 days of the Record Date and 2,775 shares issuable to Mr. De Silva pursuant to RSUs expected to vest or which may be settled within 60 days of the Record Date.
- (18) Reflects 14,733 shares issuable to Dr. Russell pursuant to options currently exercisable or exercisable within 60 days of the Record Date and 6,100 shares issuable to Dr. Russell pursuant to RSUs expected to vest or which may be settled within 60 days of the Record Date.
- (19) Reflects 8,499 shares issuable to Mr. Santini pursuant to options currently exercisable or exercisable within 60 days of the Record Date and 2,775 shares issuable to Mr. Santini pursuant to RSUs expected to vest or which may be settled within 60 days of the Record Date.
- (20) Reflects 1,250 shares issuable to Mr. Holmes pursuant to options currently exercisable or exercisable within 60 days of the Record Date.
- (21) Mr. Townsend joined the Company as its Senior Vice President of Legal Affairs, General Counsel and Secretary in August 2012.
- (22) Includes 302,660 shares issuable to all of our current directors and executive officers as a group pursuant to options currently exercisable or exercisable within 60 days of the Record Date and 69,350 shares issuable to all of our current directors and executive officers as a group pursuant to RSUs expected to vest or which may be settled within 60 days of the Record Date.

* * * * *

* * * * *

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Related Party Transactions Policies and Procedures and Transactions with Related Persons

In accordance with its charter and the Company's written related person transactions policy, discussed below, the Audit Committee reviews, approves and ratifies any related person transaction and monitors compliance with and periodically reviews the related person transactions policy. The term "related person transaction" refers to any transaction required to be disclosed in our filings with the SEC pursuant to Item 404 of Regulation S-K.

In considering any related person transaction, the Audit Committee considers the facts and circumstances regarding such transaction, including, among other things, the amounts involved, the relationship of the related person (including those persons identified in the instructions to Item 404(a) of Regulation S-K) with our company and the terms that would be available in a similar transaction with an unaffiliated third-party. The Audit Committee also considers its fiduciary duties, our obligations under applicable securities law, including disclosure obligations and director independence rules, and other applicable law in evaluating any related person transaction. The Audit Committee reports its determination regarding any related person transaction to our full Board.

In addition, our Board has adopted a written related person transactions policy, which provides that any related person transaction shall be consummated or shall continue only if:

- The Audit Committee approves or ratifies such transaction in accordance with our related person transactions policy and if the transaction is on terms comparable to those that could be obtained in arm's length dealings with an unrelated third person;
- The transaction is approved by the majority of the disinterested members of the Board; or
- If the transaction involves compensation, it is approved by the Compensation Committee or the Board.

Under our related person transactions policy, transactions between a related person and the Company that are available to all employees generally and transactions with a related person in a given fiscal year that involve an aggregate of less than \$10,000 must be reported to the Board but do not require approval. In addition, related person transactions should be submitted to the Audit Committee for approval or preliminarily entered into by management subject to ratification by the Audit Committee, provided, that, if such ratification shall not be forthcoming, management must make all reasonable efforts to cancel or annul such transaction. In determining whether to approve a related person transaction, consideration is given to whether approval thereof would affect the independent status of any current member of our Board. If approval of a transaction would cause less than a majority of our Board to be independent, such transaction will not be approved.

No new potential related person transactions were brought to the attention of the Audit Committee for consideration in 2012.

PROPOSAL 1: ELECTION OF DIRECTORS

You are being asked to vote for six directors at this Annual Meeting. If you are voting by proxy, the persons named in the enclosed proxy card will vote to elect as directors the six nominees named below, all of whom are currently directors of the Company, unless you withhold authority to vote for the election of any or all of the directors by delivering a proxy to that effect.

Each director elected will hold office until the next annual meeting of stockholders and until his or her successor is elected and qualified, or until his or her earlier death, resignation or removal. Each of the nominees has indicated his or her willingness to serve, if elected, but if a nominee should be unable to serve, the proxies may be voted for a substitute nominee designated by us.

Nominees

The Nominating and Corporate Governance Committee of our Board has not established specific minimum qualifications for recommended nominees or specific qualities or skills for our directors to possess. However, our Corporate Governance Guidelines provide that the backgrounds and qualifications of the directors considered as a group should provide a significant breadth of experience, knowledge and abilities that shall assist the Board in fulfilling its responsibilities. In considering candidates to serve as directors, the Nominating and Corporate Governance Committee uses a subjective process for identifying and evaluating nominees to serve on our Board based on consideration of all factors it deems relevant. In addition, our Corporate Governance Guidelines set forth general criteria for nomination as a director, which include the following:

- Nominees should have a reputation for integrity, honesty and adherence to high ethical standards.
- Nominees should have demonstrated business acumen, experience and ability to exercise sound judgment in matters that relate to the current and long-term objectives of the Company and should be willing and able to contribute positively to the decision-making process of the Company.
- Nominees should have a commitment to understand the Company and its industry and to regularly attend and participate in meetings of the Board and its committees.
- Nominees should have the interest and ability to understand the sometimes conflicting interests of the various constituencies of the Company, which include stockholders, employees, customers, governmental units, creditors and the general public, and to act in the interests of all stockholders.
- Nominees should not have, nor appear to have, a conflict of interest that would impair such nominee's ability to represent the interests of all the Company's stockholders and to fulfill the responsibilities of a director.
- Nominees shall not be discriminated against on the basis of race, religion, national origin, sex, sexual orientation, disability or any other basis proscribed by law. The value of diversity on the Board should be considered.
- Nominees should normally be able to serve for at least five years before reaching the age of 80.

Our Corporate Governance Guidelines also provide that the re-nomination of existing directors should not be viewed as automatic, but should be based on continuing qualification under the criteria set forth above. The Nominating and Corporate Governance Committee considers the existing directors' performance on our Board and its committees in making its nomination recommendations.

The brief biographies below include certain information, as of the date of this Proxy Statement, regarding the specific and particular experience, qualifications, attributes or skills of each nominee that

led the Nominating and Corporate Governance Committee to believe that such nominee should continue to serve on the Board. However, each of the members of the Nominating and Corporate Governance Committee may have a variety of reasons why he or she believes a particular person would be an appropriate nominee for the Board, and these views may differ from the views of other members.

William K. Heiden, age 53, has been a director since May 2012. Mr. Heiden has been President and Chief Executive Officer of the Company since May 2012. Prior to joining the Company, he was the President and Chief Executive Officer of GTC Biotherapeutics, Inc., now rEVO Biologics, Inc., a pharmaceutical company, from June 2010 to May 2012 and continues to serve as its non-executive Chairman. Mr. Heiden was President and Chief Executive Officer and a member of the Board of Directors of Elixir Pharmaceuticals, Inc., or Elixir, a pharmaceutical company, from September 2004 until December 2008. Prior to joining Elixir, he served as President and Chief Operating Officer of Praecis Pharmaceuticals, Inc., a public biopharmaceutical company which was subsequently acquired by GlaxoSmithKline plc, from May 2002 to September 2004. From 1987 to 2002, Mr. Heiden held various positions of increasing responsibility at Schering-Plough Corporation, now Merck & Co., including managing a number of businesses in the United States, Europe and Canada. He serves on the Board of Directors of LFB Biotechnologies S.A.S., a private French biotechnology company. Mr. Heiden holds a B.A. from the University of Florida, an M.B.A. from Cornell University's Johnson Graduate School of Management, and a M.I.M. from the University of Louvain. The Nominating and Corporate Governance Committee believes that Mr. Heiden's significant commercial expertise at both large pharmaceutical and emerging biotechnology companies, as well as strong deal making experience, provides the Board with valuable and specialized expertise as the Company builds upon recent accomplishments with *Feraheme* and *Rienso*® 30mg/ml solution for Injection, as it is marketed in certain territories outside of the U.S., and pursues broader business development opportunities.

Michael Narachi, age 53, has been a director since November 2006. Mr. Narachi is currently President and Chief Executive Officer of Orexigen Therapeutics, Inc., or Orexigen, a public biopharmaceutical company. Prior to joining Orexigen in March 2009, he served as Chairman, Chief Executive Officer and President of Ren Pharmaceuticals, Inc., a biotechnology company, from November 2006 until March 2009. He served as Executive Chairman of the Board of Directors of Naryx Pharma, Inc., a pharmaceutical company, from August 2004 to April 2008. In 2004, Mr. Narachi retired as an officer and Vice President of Amgen Inc., or Amgen, a leading public therapeutics company, where he served as General Manager of Amgen's Anemia Business from 1999 to 2004. Mr. Narachi joined Amgen in 1984 and held various positions throughout the organization including: Product Development Team Leader for NEUPOGEN®; Director of Clinical Operations in Thousand Oaks, CA and Cambridge, U.K.; Vice President of Development and Representative Director for Amgen Japan; Head of Corporate Strategic Planning; Chief Operations Officer of Amgen BioPharma; and Vice President, Licensing and Business Development. Mr. Narachi received a B.S. and M.A. degree in Molecular Genetics from the University of California at Davis. He completed the Executive M.B.A. program at the Anderson Graduate School of Management at the University of California, Los Angeles. The Nominating and Corporate Governance Committee believes that, in addition to his more recent experience as chief executive of multiple biotechnology/biopharmaceutical companies, Mr. Narachi's twenty year career at Amgen, during which he held numerous positions of increasing operational and strategic responsibility, including positions in which he had responsibility for pharmaceutical product development and commercialization, provides the Board with critical insight and experience as the Company seeks to advance the worldwide development and commercialization of *Feraheme/Rienso*. In particular, the Nominating and Corporate Governance Committee believes that Mr. Narachi's experience as General Manager of Amgen's Anemia Business provides the Board with unique and highly specialized experience in commercializing a pharmaceutical product which is indicated for the treatment of IDA, such as *Feraheme/Rienso*.

Robert J. Perez, age 48, has been a director since January 2009. He is currently President and Chief Operating Officer of Cubist Pharmaceuticals, Inc., or Cubist, a public pharmaceutical company. Mr. Perez joined Cubist in March 2003 as Senior Vice President, Sales and Marketing, and led the launch of Cubicin® (daptomycin for injection) and served as Executive Vice President and Chief Operating Officer from August 2007 to July 2012. Prior to joining Cubist, he served as Vice President of Biogen, Inc.'s CNS business unit from 2001 to 2003, where he was responsible for commercial leadership of an \$800 million neurology business unit, and from 1995 to 2001 he held positions of increasing responsibility within the commercial organization. From 1987 to 1995 Mr. Perez held various sales and marketing positions at Zeneca Pharmaceuticals. He also served as a member of the Board of Directors of Epix Pharmaceuticals, Inc., a public biopharmaceutical company, from 2006 to 2009. Mr. Perez has been a member of the Board of Trustees of the Dana-Farber Cancer Institute, Inc. since January 2013 and the Board of Advisors of the Citizen School of Massachusetts since 2010. Mr. Perez received a B.S. from California State University, Los Angeles and an M.B.A. from the Anderson Graduate School of Management at the University of California, Los Angeles. The Nominating and Corporate Governance Committee believes that Mr. Perez's twenty plus years of sales and marketing experience within the pharmaceutical and biotechnology industries has provided him with valuable commercial and operational experience, as well as leadership skills that are important to the Board. In particular, Mr. Perez's experience leading the launch and commercialization of highly successful specialty pharmaceutical products is especially valuable to the Board as the Company commercializes *Feraheme/Rienso* in the United States and abroad.

Lesley Russell, MB.Ch.B., MRCP, age 52, has been a director since December 2009. She was Senior Vice President and Head of Research and Development for Global Branded Products at Teva Pharmaceuticals, Inc., or Teva, a public pharmaceutical company from October 2011 to June 2012. Dr. Russell was appointed to this role upon Teva's acquisition of Cephalon Inc., or Cephalon, a public pharmaceutical company, where she served as Executive Vice President and Chief Medical Officer from September 2006 to October 2011. She joined Cephalon in 2000 as Vice President, Worldwide Clinical Research. Prior to Cephalon, Dr. Russell served as Vice President, Clinical Research at US Bioscience Inc., a pharmaceutical company, and held positions of increasing responsibility within US Bioscience Inc. from 1996 to 1999. From 1995 to 1996, she was a clinical research physician at Eli Lilly U.K. and a Medical Director at Amgen U.K. from 1992 to 1995. Dr. Russell was trained in Hematology/Oncology at Royal Infirmary of Edinburgh and at Royal Hospital for Sick Children, Edinburgh. She received an MB.Ch.B. from the University of Edinburgh, Scotland and is a member of the Royal College of Physicians, United Kingdom. Dr. Russell is registered with the General Medical Council, United Kingdom. She currently serves on the Board of Directors of Endocyte, Inc., a biopharmaceutical company, where she has been a director since January 2013. The Nominating and Corporate Governance Committee believes that Dr. Russell's broad-based expertise leading clinical research and development, medical, regulatory, and drug safety organizations, as well as her medical training, allow her to make valuable contributions to the medical and scientific understanding of the Board, which is particularly important as the Company seeks to expand the labeled indication of *Feraheme/Rienso* to a broader group of patients with IDA and evaluates potential merger and acquisition and in-licensing opportunities.

Gino Santini, age 56, has been a director since February 2012. From 1983 to 2010, Mr. Santini held a variety of commercial and operational roles at Eli Lilly and Company, or Eli Lilly, a public pharmaceutical company, serving most recently from April 2007 to December 2010 as Senior Vice President, Corporate Strategy and Business Development and as a member of the company's Executive Committee where he led corporate strategy and long-range planning, mergers and acquisitions, new product licensing and the expansion of Lilly Ventures in the United States and China. During his tenure at Eli Lilly, Mr. Santini held various leadership positions of increasing responsibility, including manager of various international regions, Senior Vice President of Corporate Strategy and Policy from 2004 to 2007, President of U.S. operations from 1999 to 2004 and President of the women's health

franchise from 1997 to 1999. Mr. Santini currently serves on the Board of Directors of Allena Pharmaceuticals, Inc., a pharmaceuticals company, where he has been a director since February 2012. He serves on the Board of Directors of Sorin S.p.A., a global medical device company, where he has been a director since April 2012, and on the Board of Directors of Finanziaria Saccarifera Italo Iberica S.p.A., a financial holding company, where he has been a director since January 2013. Mr. Santini also serves on the Board of Directors of Collegium Pharmaceuticals, Inc., a pharmaceutical company, where he has been a director since July 2012. Mr. Santini also serves on the Board of Directors, as well as the Audit Committee and Nominating and Corporate Governance Committee of the Board of Directors, of Horizon Pharma, Inc., a public biopharmaceutical company, where he has been a director since February 2012. Mr. Santini is a past Chairman of the Board of the National Pharmaceutical Council and of Noble of Indiana, a non-profit agency serving individuals with developmental disabilities. He also served on the Board of Directors for United Way and the Executive Committee and Board of Directors of the Indianapolis Chamber of Commerce. He holds an undergraduate degree in mechanical engineering from the University of Bologna and an M.B.A. from the Simon School of Business, University of Rochester. The Nominating and Corporate Governance Committee believes that Mr. Santini's long career at Eli Lilly and extensive domestic and international commercial, corporate strategy, business development and transaction experience will be valuable assets to the Board as it seeks to establish a solid foundation from which to drive growth and profitability and seek to acquire or in-license other assets to expand our product portfolio.

Davey S. Scoon, age 66, has been a director since December 2006. Mr. Scoon serves as Chairman of the Board of Directors of Tufts Health Plan, where he has been a director since 1981. He has been a member of the Board of Directors of Orthofix International, N.V., a medical device company, since June 2011 and a member of the Board of Directors of Biodel Inc., a public specialty biopharmaceutical company, since April 2012. Mr. Scoon also serves as Chairman of the Board of Trustees of Allianz Funds, a registered investment company consisting of 22 mutual funds, where he has been a director since January 2006. He was the Chairman of the Audit Committee of Cardiokine, Inc., a pharmaceutical company, where he was a director from 2005 to 2011. Mr. Scoon has been an Adjunct Assistant Professor at Tufts University School of Medicine since 2005 and a lecturer in accounting at the University of Wisconsin since 2011. He also previously served as the Chairman of the Audit Committee of NitroMed, Inc., a public pharmaceutical company, from 2003 to 2009, and a member of the Board of Directors of Inotek Pharmaceuticals Corporation, a pharmaceutical company, from 2006 to 2009. From 2003 to 2005, Mr. Scoon was Chief Administrative and Financial Officer of Tom's of Maine, a company that manufactures natural care products. From 2001 to 2003, Mr. Scoon served as Chief Financial and Administrative Officer for Sun Life Financial U.S., and from 1999 to 2001, Mr. Scoon served as Vice President and Chief Financial Officer for Sun Life Financial U.S. From 1985 to 1999, Mr. Scoon was employed by Liberty Funds Group of Boston (formerly Colonial Management) in various capacities, including Chief Financial Officer and Chief Operating Officer. Mr. Scoon holds a B.B.A. from the University of Wisconsin and an M.B.A. from Harvard Business School. The Nominating and Corporate Governance Committee believes that Mr. Scoon's extensive financial, accounting, human resources, and risk management experience gained through the various executive and board positions he has held over the past thirty years provides the Board with valuable and highly specialized expertise and advice, particularly in Mr. Scoon's role as the Chair of the Audit Committee.

Required Vote

Our directors are elected by a plurality of the votes cast by stockholders entitled to vote at the Annual Meeting.

**OUR BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS
A VOTE "FOR" THE NOMINEES LISTED ABOVE.**

INFORMATION REGARDING THE BOARD OF DIRECTORS AND CORPORATE GOVERNANCE
INDEPENDENCE OF THE BOARD OF DIRECTORS

The Board has determined that, other than Mr. Heiden, each current director is “independent” as such term is defined in the listing standards of the NASDAQ Global Select Market, or NASDAQ, and applicable SEC rules. The Board has affirmatively determined that no independent director has any material relationship with us that would interfere with the exercise of his or her independent judgment.

In reaching the foregoing conclusion, the Board considered that Dr. Bonventre’s daughter is employed by our independent registered public accounting firm, PricewaterhouseCoopers LLP. The Board determined that this relationship did not compromise the independence of Dr. Bonventre or his status as a non-employee director.

MEETINGS OF THE BOARD OF DIRECTORS

Our Board met eleven times and acted by unanimous written consent six times during the year ended December 31, 2012. Each director participated in at least 75% of the aggregate number of meetings of the Board and of each committee of the Board on which he or she served during the portion of the last fiscal year for which such person was a director or committee member. It is our policy that our directors are expected to attend each annual meeting of stockholders. All of our then serving directors attended our Annual Meeting held on May 23, 2012.

In addition, our independent directors meet regularly and at least annually in executive session without the presence of our management.

COMMITTEES OF THE BOARD OF DIRECTORS

Under our by-laws, our Board may designate committees comprised of members of the Board to exercise the power and authority of the Board in the management of the business and affairs of the Company, subject to limitations imposed by law. Our Board currently has the following permanent committees: an Audit Committee, a Compensation Committee, a Nominating and Corporate Governance Committee, and a Transaction Committee. The following table provides membership information for the current composition of these committees:

<u>Name</u>	<u>Audit Committee</u>	<u>Compensation Committee</u>	<u>Nominating and Corporate Governance Committee</u>	<u>Transaction Committee</u>
Joseph V. Bonventre, M.D., Ph.D. *	—	—	X	—
Rajiv De Silva *	X	—	—	—
William K. Heiden	—	—	—	X
Michael Narachi	—	X	—	X
Robert J. Perez	—	X	X**	—
Lesley Russell, MB.Ch.B., MRCP	X	—	—	X
Gino Santini	—	X**	—	X**
Davey S. Scoon	X**	—	X	—

* Dr. Bonventre and Mr. De Silva are not standing for re-election at our annual meeting of stockholders. Effective May 23, 2013, the size of our Board is expected to be reduced to six directors.

** Committee Chair

Audit Committee

Our Board has a standing Audit Committee, currently composed of Messrs. Scoon (Chair) and De Silva and Dr. Russell. Mr. Perez also served on the Audit Committee from January 2012 to May 2012. All individuals who served on the Audit Committee during 2012 were “independent” as such term is defined in the listing standards of the NASDAQ and applicable SEC rules. Based on Mr. Scoon’s extensive financial and accounting experience gained through the various executive and board positions he has held over the past thirty years, including his tenure as Chief Financial Officer and/or Chief Administrative Officer of several companies, our Board has determined that Mr. Scoon qualifies as an “audit committee financial expert” as defined by SEC rules. The Board has also determined that Mr. De Silva and Dr. Russell possess the requisite financial sophistication to qualify them for service on the Audit Committee in accordance with SEC rules. The current charter of the Audit Committee is available on our website at www.amagpharma.com, under the heading “Investors.”

Pursuant to its charter, the Audit Committee’s general responsibilities include, among other things, the following:

- Evaluating and selecting our independent registered public accounting firm;
- Reviewing our audited and unaudited financial statements;
- Reviewing and discussing the adequacy of our internal financial and accounting processes and internal control over financial reporting with management and our independent registered public accounting firm;
- Supervising the relationship between the Company and our independent registered public accounting firm;
- Reviewing and authorizing the scope of both audit and non-audit services and related fees;
- Evaluating the independence of our independent registered public accounting firm; and
- Reviewing and approving related person transactions.

The Audit Committee is empowered to engage such independent advisors, including external consultants, as it deems necessary or appropriate to carry out its responsibilities. The Audit Committee conducted eight formal meetings and acted by unanimous written consent once during the year ended December 31, 2012.

Report of the Audit Committee¹

The Audit Committee has reviewed and discussed our audited financial statements for the year ended December 31, 2012 with management of the Company. The Audit Committee has discussed with PricewaterhouseCoopers LLP, our independent registered public accounting firm, the matters required to be discussed by Statement on Auditing Standards No. 61, as amended (AICPA, *Professional Standards*, Vol. 1. AU section 380), as adopted by the Public Company Accounting Oversight Board, or PCAOB, in Rule 3200T. The Audit Committee has met with PricewaterhouseCoopers LLP, with and without management present, to discuss the results of its examinations, its evaluation of our internal control over financial reporting, and the overall quality of our financial reporting. The Audit Committee has also received the written disclosures and the letter from PricewaterhouseCoopers LLP required by applicable requirements of the PCAOB regarding the independent accountant’s communications with the Audit Committee concerning independence. The Audit Committee has discussed with PricewaterhouseCoopers LLP that firm’s independence from management and the Company and considered the compatibility of the firm’s provision of non-audit services with maintaining the firm’s independence and found the provision of such services to be compatible with the firm’s independence.

Based on the reviews and discussions referred to above, the Audit Committee concluded that it would be reasonable to recommend, and on that basis did recommend, to the Board (and the Board has approved) that the audited financial statements be included in the Company's Annual Report on Form 10-K for the year ended December 31, 2012 for filing with the SEC.

Respectfully Submitted by the Audit Committee of the Board of Directors of AMAG Pharmaceuticals, Inc.,

Davey S. Scoon, Chair
Rajiv De Silva
Lesley Russell

¹ The material in this report is not "soliciting material," is furnished to, but not deemed "filed" with, the SEC and is not deemed to be incorporated by reference in any filing of the Company under the Exchange Act, other than the Company's Annual Report on Form 10-K, where it shall be deemed to be "furnished," whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

Compensation Committee

Our Board has a standing Compensation Committee, currently composed of Messrs. Santini (Chair), Perez and Narachi, each of whom is "independent" as such term is defined in the listing standards of the NASDAQ and applicable SEC rules and is a "non-employee director" under applicable SEC rules. The current charter of the Compensation Committee is available on our website at www.amagpharma.com, under the heading "Investors." The Compensation Committee conducted seven formal meetings and acted by unanimous written consent four times during the year ended December 31, 2012.

Pursuant to its charter, the Compensation Committee's general responsibilities include, among other things, the following:

- The review, negotiation, authorization and approval of the recruitment, hiring and compensation for any of our executive officers and any other of our officers with a title of Senior Vice President or higher, other than our Chief Executive Officer or President;
- The review and recommendation to the full Board for approval of the compensation of our Chief Executive Officer, President and any other officer position with a title of Senior Vice President or higher which was not provided for in the Company's annual budget approved by the Board, each of which must be approved by all independent members of the Board;
- The exercise of any authority delegated by the full Board to determine and approve the compensation of our Chief Executive Officer, President and any other officer position with a title of Senior Vice President or higher which was not provided for in the Company's annual budget approved by the Board;
- Subject to certain limitations, the administration and grant of awards under our existing stock option, stock incentive, employee stock purchase and other equity-based award plans;
- The review and recommendation to the full Board with respect to certain incentive compensation plans and director compensation plans; and
- The engagement of independent advisors as it deems necessary or appropriate to carry out its responsibilities.

Nominating and Corporate Governance Committee

Our Board has established a standing Nominating and Corporate Governance Committee, which is currently composed of Messrs. Perez (Chair) and Scoon and Dr. Bonventre, each of whom is “independent” as such term is defined in the listing standards of the NASDAQ and applicable SEC rules. The current charter for the Nominating and Corporate Governance Committee is available on our website at www.amagpharma.com, under the heading “Investors.” The Nominating and Corporate Governance Committee conducted three formal meetings and acted by unanimous written consent once during the year ended December 31, 2012.

Pursuant to its charter, the Nominating and Corporate Governance Committee’s general responsibilities include, among other things, the following:

- Identifying individuals qualified to become members of our Board;
- Selecting or recommending the director nominees for each annual meeting of stockholders or when vacancies occur;
- Developing and recommending to the Board a set of corporate governance guidelines applicable to the Company and periodically reviewing such guidelines;
- Performing a self-evaluation by Board members and by members of the Committee from time to time to determine whether they are functioning effectively and to improve the performance of the Board and/or Committee as a whole; and
- Providing oversight of and guidance with respect to our internal compliance program.

Although the Nominating and Corporate Governance Committee has not established specific minimum qualifications for nominees or specific qualities or skills for our directors to possess, our Corporate Governance Guidelines provide that the backgrounds and qualifications of the directors, considered as a group, should provide a significant breadth of experience, knowledge and abilities that shall assist the Board in fulfilling its responsibilities. In addition, our Corporate Governance Guidelines set forth certain general criteria for nomination as a director, which are discussed in further detail under the heading “*Nominees*” above.

As provided in the criteria set forth in our Corporate Governance Guidelines, the Nominating and Corporate Governance Committee believes that the value of diversity on the Board should be considered as one of a number of factors that it takes into account in evaluating nominees and the Board as a whole. For this purpose the Nominating and Corporate Governance Committee evaluates diversity in terms of race, religion, national origin, gender, sexual orientation, and disability, as well as differences of viewpoint, professional experience, education, skill, and other individual qualities and attributes that contribute to heterogeneity on the Board.

Our Corporate Governance Guidelines also provide that the re-nomination of existing directors should not be viewed as automatic, but should be based on continuing qualification under the criteria set forth above. The Nominating and Corporate Governance Committee considers the existing directors’ performance on our Board and its committees in making its nomination recommendations. In seeking candidates for directors, members of our Nominating and Corporate Governance Committee may use their business, professional and personal contacts, accept recommendations from other Board members, stockholders or management, or engage a professional search firm. In 2012, the Board retained Stuart Spencer to conduct a search to identify candidates to serve on the Board. This search resulted in the appointments of Messrs. De Silva and Santini to the Board in February 2012.

The nominations for the election of directors at the Annual Meeting contained in this Proxy Statement are based upon the unanimous recommendation of the Nominating and Corporate Governance Committee to the full Board in April 2013.

Transaction Committee

In May 2012, our Board formed a standing Transaction Committee to oversee, advise and assist the Company's management with respect to the identification, evaluation, structuring, negotiation and execution of potential acquisition, in-license, merger and other strategic transactions involving the Company and to make recommendations with respect thereto to the full Board. The Transaction Committee is currently comprised of Messrs. Santini (Chair), Heiden and Narachi and Dr. Russell. Other than Mr. Heiden, each of the current members of the Transaction Committee is "independent" as such term is defined in the listing standards of the NASDAQ and SEC rules. This Committee was considered temporary upon its initial conception during the first quarter of 2012 at which time it was comprised of Messrs. Narachi (Chair), Santini, Perez and De Silva. The Transaction Committee conducted ten meetings during the year ended December 31, 2012.

Stockholder Recommendations For Nominees As Directors And The Proposal Of Other Business

Our Nominating and Corporate Governance Committee will consider recommendations for candidates for nominees as directors and proposals for business other than director nominations that are submitted by stockholders. Any recommendation of a nominee for the Board or any proposal for business other than director nominations by our stockholders with respect to our 2014 Annual Meeting must be submitted in writing to our principal executive offices at 100 Hayden Avenue, Lexington, Massachusetts 02421, attention: Secretary, and must be received by us no earlier than 120 days prior to the anniversary of our 2013 Annual Meeting and no later than 90 days prior to the anniversary of our 2013 Annual Meeting. If the date of our 2014 Annual Meeting is advanced by more than 30 days or delayed by more than 30 days from the anniversary of our 2013 Annual Meeting, any stockholder recommendation or proposal must be received by us no earlier than the close of business on the 120th day prior to such advanced or delayed annual meeting date and no later than the close of business on the later of (i) the 90th day prior to such advanced or delayed annual meeting date and (ii) the 10th day following the first public announcement of the meeting date.

Any such communication with respect to a candidate for nomination as a director must (i) describe why the candidate meets the Board's criteria for director nominees described above; (ii) include the candidate's and recommender's names and addresses and provide biographical information about the recommended candidate that would be required if the candidate were to be nominated; (iii) include the proposed nominee's written consent to serve as a nominee, if nominated, and as a director, if elected; and (iv) contain any additional information required by Regulation 14A under the Exchange Act.

Any such communication with respect to the proposal of business other than director nominations must include a brief description of the business desired to be brought before the meeting, the reasons for conducting such business at the meeting, and any material interest in such business of such stockholder or any stockholder associated person. A "stockholder associated person" with respect to any stockholder is defined as (i) any person controlling, directly or indirectly, or acting in concert with, such stockholder; (ii) any beneficial owner of shares of stock of the Company owned of record or beneficially by such stockholder; and (iii) any person controlling, controlled by or under common control with such stockholder associated person.

Additionally, the stockholder must provide the following information with respect to such stockholder and any stockholder associated person:

- The name and address of such stockholder, as they appear on our books, and of such stockholder associated person;
- The class and number of our shares which are owned beneficially and of record by such stockholder and such stockholder associated person;

- Whether either such stockholder or stockholder associated person intends to deliver a proxy statement and form of proxy to holders of, in the case of a nomination or nominations for director, a sufficient number of holders of our voting shares to elect such nominee or nominees or in the case of any other proposal, at least the percentage of our voting shares required under applicable law to carry such proposal;
- Whether and the extent to which any hedging or other transaction or series of transactions has been entered into by or on behalf of, or any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares) has been made, the effect or intent of which is to mitigate loss to or manage risk or benefit of share price changes for, or to increase or decrease the voting power of, such stockholder or any such stockholder associated person with respect to any shares of our stock; and
- All contracts, arrangements, understandings and relationships with respect to the stockholders' investment in the Company, including with other stockholders, potential investors in the Company and potential transaction advisers such as financial advisers, legal counsel and proxy solicitation firms.

The Board may request additional information from either the stockholder making the recommendation or the person recommended. Stockholder recommendations that meet the requirements set forth above will be considered using the same criteria as other candidates and proposals considered by our Nominating and Corporate Governance Committee.

Additional requirements for stockholder proposals, including director nominations, appear in our by-laws. Only such individuals who are nominated in accordance with the procedures described above and in our by-laws will be eligible for election by stockholders as directors and only such business shall be conducted at a meeting of stockholders as shall have been brought before the meeting in accordance with the procedures set forth above and in our by-laws.

We have not received any stockholder recommendations, nominations or any other proposals from our stockholders with respect to our 2013 Annual Meeting.

To be considered for inclusion in next year's proxy materials, your proposal must be submitted in writing to our principal executive offices at 100 Hayden Avenue, Lexington, Massachusetts 02421, attention: Secretary and must be received by us no later than December 20, 2013. Proposals must satisfy the procedures set forth in Rule 14a-8 under the Exchange Act.

If you wish to nominate a candidate for director or submit a proposal that is not to be otherwise included in next year's proxy materials, you must submit such proposal or nomination in writing to our principal executive offices at 100 Hayden Avenue, Lexington, Massachusetts 02421, attention: Secretary. Such proposal or nomination must be received by us no earlier than January 23, 2014 and no later than February 22, 2014 and must satisfy the requirements described in this section and in our by-laws.

In order to curtail controversy as to the date on which a proposal was received by us, we suggest that you submit your proposals by registered mail, return receipt requested.

STOCKHOLDER COMMUNICATION WITH THE BOARD OF DIRECTORS

Our Board believes it is important for stockholders to send communications to our Board. Accordingly, any stockholder who desires to communicate with our directors, individually or as a group, may do so by e-mailing the party or parties to whom the communication is intended at *contactus@amagpharma.com* or by writing to the party or parties for whom the communication is intended, to our principal executive offices at 100 Hayden Avenue, Lexington, Massachusetts 02421, attention: Secretary. Our Secretary will then deliver any communication to the appropriate party or parties.

BOARD LEADERSHIP STRUCTURE

Our Board is led by an independent Chair, currently Mr. Narachi, who has authority, among other things, to call and preside over Board meetings, including meetings of the independent directors, to set meeting agendas, and to determine the materials distributed to the Board. During 2012, our current chief executive officer, Mr. Heiden, was the only member of our Board who was not an independent director. Mr. Thomas, our current Executive Vice President and Chief Operating Officer, did not serve on our Board during his tenure as our interim President and Chief Executive Officer from November 2011 until May 2012. Although we do not have a formal policy regarding whether the offices of Chair of the Board and Chief Executive Officer should be separate, our Board believes that the existing leadership structure, with the separation of the Chair of the Board and Chief Executive Officer roles, enhances the accountability of the Chief Executive Officer to the Board and strengthens the Board's independence from management. In addition, the Board believes that having an independent Chair of the Board creates an environment that is more conducive to the objective evaluation and oversight of management's performance, increasing management accountability and improving the ability of the Board to monitor whether management's actions are in the best interests of the Company and our stockholders. The Board also believes that an independent Chair of the Board helps ensure that any potential strategic transactions involving the Company are evaluated independently and in light of the best interests of our stockholders. Finally, separating these roles alleviates the administrative burden on our chief executive officer and allows that person to focus his or her efforts on running our business and managing the Company in the best interests of our stockholders.

THE BOARD'S ROLE IN RISK OVERSIGHT

The Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board as a whole, as well as through various Board standing committees that address risks inherent in their respective areas of oversight. The Board believes that risk can arise in any decision or action taken by the Company, whether strategic or operational. The Board, therefore, seeks to ensure that risk management principles are incorporated in all of the Company's management processes and in the responsibilities of its employees at every level. This comprehensive approach is reflected in the reporting processes by which our management provides timely and comprehensive information to the Board to support the Board's role in oversight, approval, and decision-making.

The Board closely monitors the information it receives and/or requests from management and provides oversight and guidance to our senior management team concerning the assessment and management of risk. The Board approves the Company's high level goals, strategies, and policies to set the tone and direction for appropriate risk taking within the business. The Board and its committees then emphasize this tone and direction in its oversight of management's implementation of the Company's goals, strategies, and policies.

Our senior executives regularly attend meetings of the Board and its committees and provide the Board and its committees with regular reports regarding the Company's operations, strategies, and objectives and the risks inherent within them. Board and committee meetings also provide a venue for directors to discuss issues with, request additional information from, and provide guidance to, senior management. The Board and its committees call special meetings and request information and reports from senior management when necessary to address specific issues. In addition, our directors have direct access to senior management to discuss any matters of interest, including those related to risk. Those members of management most knowledgeable of the issues regularly attend Board and committee meetings to provide additional insight into items being discussed, including risk exposures.

The Board has delegated oversight for matters involving certain specific areas of risk exposure to most of its standing committees. The committees report to the Board at regularly scheduled Board

meetings, as needed, and more frequently if appropriate, with respect to the matters and risks for which the committee provides oversight. Each committee, with the exception of the Transaction Committee, is also authorized and empowered to retain such independent advisors as the committee deems to be appropriate in order to discharge its responsibilities under such committee's charter, and such independent advisors attend committee meetings as appropriate.

The Audit Committee oversees the integrity of our financial statements, reporting process and internal controls, the relationship with our independent registered public accounting firm, including its qualifications, independence and performance, and the Company's corporate finance matters, including its capital structure. The Audit Committee also provides oversight with respect to the Company's risk management process, discussing with management the Company's significant financial risk exposures, steps management has taken to monitor, control and report such exposures, and our policies with respect to risk assessment and risk management.

Our Compensation Committee is responsible primarily for the design and oversight of the Company's executive compensation policies, plans and practices. A key objective of the Compensation Committee is to ensure that the Company's overall executive compensation program appropriately links pay to performance and aligns the interests of the Company's executives with our stockholders. The Compensation Committee also monitors the design and administration of the Company's overall incentive compensation programs to ensure that they include appropriate safeguards to avoid encouraging unnecessary or excessive risk taking by Company employees. Elements of our executive compensation program that mitigate excessive risk taking, such as our combination of short- and long-term incentives, are described below under "*Compensation Discussion and Analysis*."

The Nominating and Corporate Governance Committee oversees risks related to our corporate governance, including Board and director performance, director succession, director education and the Company's Corporate Governance Guidelines and other governance documents. The Nominating and Corporate Governance Committee also oversees the Company's overall compliance program, with particular emphasis on the risks associated with our healthcare compliance program.

Periodically, our Board forms temporary committees to oversee, identify, evaluate or negotiate a specific issue or opportunity and to make recommendations to the full Board. For example, in 2012 our Board formed a CEO Search Committee, consisting of Messrs. Narachi (Chair), De Silva and Perez and Dr. Russell, to evaluate candidates for our then ongoing search for a permanent Chief Executive Officer.

RISK CONSIDERATIONS IN OUR COMPENSATION POLICIES AND PRACTICES

Our Compensation Committee believes that risks arising from our compensation policies and practices for our employees are not likely to have a material adverse effect on the Company. In addition, the Compensation Committee believes that the mix and design of the elements of executive compensation do not encourage management to take excessive risks. The considerations which led the Compensation Committee to this conclusion include the following:

- We provide executives with a competitive base salary which we believe mitigates risk-taking behavior by providing reasonable predictability in the level of income earned by each executive and alleviating pressure on executives to focus exclusively on stock price performance to the detriment of other important business metrics;
- We utilize a mixture of compensation elements that is intended to be competitive to that offered to similarly-situated executives, with significant weighting towards long-term incentive compensation, which discourages short-term risk taking;
- Our performance goals reflect a balanced mix of performance measures to avoid excessive weight on a certain goal or performance measure and are intended to be challenging yet

attainable, so that it is more likely than not that the executives will earn a substantial portion of their target bonus annually, which mitigates the potential that our executives will take excessive risks;

- Short-term incentives in the form of annual performance bonus payouts have never exceeded 150% of the target amount, which the Compensation Committee believes mitigates the likelihood that our executives will take excessive risks;
- Equity incentive awards are granted annually and generally vest annually over three to four years, discouraging excessive risk-taking as our executives generally have a significant amount of unvested awards that could decrease significantly in value if our business is not managed for the long-term;
- Compliance, ethical behavior and adherence to our corporate values and policies are integral factors considered in all performance assessments and serve to mitigate the potential that our executives will take excessive risks. The Board and the Compensation Committee retain discretion to adjust compensation based on both the quality of Company and individual performance and adherence to the Company's corporate governance and compliance programs, among other things; and
- We have a robust system of internal controls and a comprehensive compliance program, which includes extensive training of all employees, which we believe promotes a culture of ethical behavior and compliance, as well as an appropriate attitude toward minimizing risk-taking.

CODE OF ETHICS

Our Board has adopted a code of ethics that applies to our officers, directors and employees. We have posted the text of our code of ethics on our website at <http://www.amagpharma.com> in the "Investors" section. In addition, should any changes be made to our code of ethics, we intend to disclose within four business days, on our website (or in any other medium required by law or the NASDAQ): (i) the date and nature of any amendment to our code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver, and the date of the waiver.

DIRECTOR COMPENSATION

Overview

We seek to attract exceptional talent to serve on the Board and, therefore, the Company's policy is to compensate directors competitively relative to comparable companies. In addition, our Corporate Governance Guidelines provide that directors should be incentivized to focus on long-term stockholder value. Accordingly, director compensation is comprised of a mix of cash and equity compensation. The Board believes that including equity as part of director compensation helps align the interests of directors with those of the Company's stockholders. The Board also believes that it is appropriate for the Chair of the Board and the Chair of each standing committee of the Board to receive additional compensation for the additional workload and time commitment required for Board members who serve in such capacities. Our policy is that directors who are also employees of the Company shall receive no additional compensation for Board or committee service.

Non-Employee Director Compensation Policy

Our Non-Employee Director Compensation Policy applies to each director of the Company who is not an employee or affiliate of the Company. Under its charter, the Compensation Committee of the

Board is charged with periodically reviewing and making recommendations to the Board with respect to director compensation. In addition, our Corporate Governance Guidelines provide that the Compensation Committee shall, from time to time, present a report to the Board comparing the Company's director compensation to that of comparable peer companies.

During 2011, in accordance with its charter and our Corporate Governance Guidelines, the Compensation Committee retained Frederic W. Cook & Co., Inc., an independent compensation consulting firm, or F.W. Cook, to review our then-current non-employee director compensation policy, compare it to the director compensation practices of companies similar to us, and provide any recommendations for changes. The peer group used by F.W. Cook in conducting its evaluation was comprised of 16 drug development companies similar in size, based on revenues and market capitalization, whose non-employee director compensation data were available in F.W. Cook's pre-existing compensation database. The names of the 16 companies were not disclosed to the Board or Compensation Committee.

In its report, F.W. Cook concluded, among other things, that the cash compensation being provided to our directors at the time of the report was below the median relative to the peer group. In addition, F.W. Cook noted that this shortfall was exacerbated by the fact that our Board was smaller in size than most boards in the peer group, which results in an increased workload for each of our directors. Accordingly, the F.W. Cook report contained a number of recommendations for proposed amendments to our then existing Non-Employee Director Compensation Policy to, among other things, ensure that the value of total annual compensation being offered to non-employee directors on our Board was more competitive and closer to the median of that being offered by the companies in our peer group.

In December 2011, based primarily on the recommendations of the Compensation Committee and the F.W. Cook report, the Board amended our Non-Employee Director Compensation Policy, effective January 1, 2012.

The following is a summary of our Non-Employee Director Compensation Policy as in effect during 2012:

Equity Grant Upon Initial Appointment or Election as a Director

Each new non-employee director, on the date of his or her initial appointment or election to the Board, receives an equity grant comprised of two components: (i) an inducement grant and (ii) an annual grant.

As an inducement to joining the Board, each new non-employee director is granted a non-qualified stock option to purchase 6,000 shares of the Company's common stock pursuant to the Company's Second Amended and Restated 2007 Equity Incentive Plan, or the 2007 Plan, subject to automatic adjustment in the event of any stock split or other recapitalization affecting the Company's common stock. Such option shall vest in equal monthly installments over a period of two years from the date of his or her election to the Board, provided such non-employee director continues to serve as a member of the Board.

Upon joining the Board, each new non-employee director also receives an equity grant of non-qualified stock options and RSUs on the date of his or her appointment or election as described below under the heading "*Annual Equity Grant*;" provided, that the amount of options and RSUs will be pro-rated based on the number of expected months of service before the next annual meeting of stockholders.

Annual Equity Grant

Our Non-Employee Director Compensation Policy provides that, at the first meeting of the Board following the annual meeting of stockholders, each non-employee director, other than the Chair, is to receive an equity grant comprised of (i) a non-qualified stock option to purchase 3,800 shares of the Company's common stock and (ii) RSUs covering a total of 2,300 shares of the Company's common stock. The foregoing options and RSUs vest in twelve equal monthly installments beginning on the first day of the first full month following the annual meeting of stockholders and continuing on the first day of each of the following eleven months thereafter, so long as the non-employee director continues to serve as a member of the Board; provided, that delivery of any vested shares of common stock underlying the foregoing RSUs are deferred until the earlier of (i) the third anniversary of the date of grant and (ii) the date of the director's separation from service to the Company.

Our Non-Employee Director Compensation Policy also provides that at the first meeting of the Board following the annual meeting of stockholders, the Chair of the Board, if he or she is also a non-employee director, is to be provided an equity grant comprised of (i) a non-qualified stock option to purchase 7,600 shares of the Company's common stock and (ii) RSUs covering 3,800 shares of the Company's common stock. The foregoing options and RSUs vest in twelve equal monthly installments beginning on the first day of the first full month following the annual meeting of stockholders and continuing on the first day of each of the following eleven months thereafter, so long as the Chair continues to serve as a member of the Board; provided, that delivery of any vested shares of common stock underlying the foregoing RSUs are deferred until the earlier of (i) the third anniversary of the date of grant and (ii) the date of the Chair's separation from service to the Company.

Exercise Price and Term of Options

Each option granted to a non-employee director has an exercise price per share equal to the fair market value of the common stock of the Company on the date of grant of the option, has a term of ten years and is subject to the terms and conditions of the 2007 Plan.

Early Termination of Options or RSUs Upon Termination of Service

If a non-employee director ceases to be a member of the Board for any reason, any then vested and unexercised options granted to such non-employee director may be exercised by the departing director (or, in the case of the director's death or disability, by the director's personal representative, or the director's survivors) within three years after the date the director ceases to be a member of the Board and in no event later than the expiration date of the option.

If a non-employee director's service to the Company is terminated, all then vested and undelivered shares underlying any RSUs held by such director shall be delivered to him or her (or, in the case of the director's death or disability, by the director's personal representative, or the director's survivors) as of the date he or she ceases to be a member of the Board. If a non-employee director ceases to be a member of the Board for any reason or otherwise ceases to continue a business relationship with the Company, any unvested options and RSUs are immediately terminated and forfeited.

Retainer Fees

Each non-employee director, other than the Chair, receives an aggregate annual retainer fee of \$30,000, payable in four equal quarterly installments (in addition to the per meeting fees discussed below). The Chair, provided that he or she is also a non-employee director, receives an aggregate annual retainer fee of \$60,000, payable in four equal quarterly installments (in addition to the per meeting fees discussed below).

Each member, other than the Chair, of each of the Board's standing committees, with the exception of the Transaction Committee, is paid an additional aggregate annual retainer fee (in addition to the per meeting fees discussed below) in four equal quarterly installments as follows:

- Audit Committee: \$10,000 per year
- Compensation Committee: \$7,500 per year
- Nominating and Corporate Governance Committee: \$5,000 per year

The Chair of each of the standing committees is paid an additional aggregate annual retainer fee (in addition to the per meeting fees discussed below) in four equal quarterly installments as follows:

- Audit Committee: \$20,000 per year
- Compensation Committee: \$15,000 per year
- Nominating and Corporate Governance Committee: \$10,000 per year

Per Meeting Fees

In addition to the retainer fees described above, each non-employee director will receive (i) a per meeting fee of \$1,000 for each meeting of the full Board attended by such director, (ii) a per meeting fee of \$500 for each meeting of each standing Committee of the Board, with the exception of the Transaction Committee, attended by such director, (iii) a per meeting fee of \$1,000 for each meeting of any ad hoc Committee of the full Board, including the Transaction Committee, attended by such director, other than the Chair of such Committee, and (iv) a per meeting fee of \$2,000 for each meeting of any ad hoc Committee of the Board attended by the Chair of such ad hoc Committee, including the Transaction Committee.

Expenses

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each non-employee director is reimbursed for his or her reasonable out-of-pocket business expenses incurred in connection with attending meetings of the Board, committees thereof or in connection with other Board-related business.

Indemnification and Insurance

We also provide standard indemnification agreements and director and officer insurance for all directors.

Other Committee Fees

In 2012, the Board established an ad hoc committee to oversee the then-ongoing search for a permanent chief executive officer, or the CEO Search Committee. In March 2012, Messrs. Narachi, De Silva and Perez and Dr. Russell were elected to serve on the CEO Search Committee. In addition, in March 2012, the Board established an ad hoc committee, or the Transaction Committee, to oversee, advise and assist management with respect to the identification, evaluation, structuring, negotiation and execution of potential acquisition, in-license, merger and other strategic transactions involving the Company and to make recommendations to the full Board. Messrs. Narachi, De Silva, Perez and Santini were elected to serve on the Transaction Committee at that time. In May 2012, in recognition of the extraordinary amount of time and effort involved by members of both the CEO Search Committee and the Transaction Committee, including time and effort outside of formal meetings, the Board awarded each member of these committees, other than the de facto chair, a one-time fee of \$5,000. In addition, Mr. Narachi, as the de facto chair for each of the foregoing committees, was awarded a one-time fee of \$20,000.

Director Equity Grants for Directors Appointed in Fiscal 2012

In February 2012, the Board appointed Messrs. Santini and De Silva to serve as non-employee members of the Board. In accordance with the terms of our Non-Employee Director Compensation Policy, Messrs. Santini and De Silva were each granted an option to purchase 6,000 shares of the Company's common stock at an exercise price equal to \$17.25 per share, the fair market value of a share of our common stock on the date of grant. These options will vest in equal monthly installments over a two-year period beginning in March 2012 and have a ten-year term. In addition, Messrs. Santini and De Silva were each granted an option to purchase 950 shares of the Company's common stock at an exercise price equal to \$17.25 per share, the fair market value of a share of our common stock on the date of grant. These options vested in three equal monthly installments beginning on March 1, 2012 and have a ten-year term. Messrs. Santini and De Silva were also granted RSUs covering 475 shares of the Company's common stock which vested in three equal monthly installments beginning on March 1, 2012; provided, that delivery of the shares of common stock underlying the foregoing RSUs is deferred until the earlier of (i) the third anniversary of the grant date and (ii) the date of the director's separation from service to the Company. In addition, the Company entered into our standard form indemnification agreement with each of Messrs. Santini and De Silva.

Director Equity Grants for Fiscal 2012

In May 2012, the Board granted the Chair of our Board, Mr. Narachi, an annual equity award to coincide with his one-year term of service from May 2012 to May 2013 comprised of stock options to purchase 7,600 shares of our common stock and RSUs covering 3,800 shares of our common stock under the 2007 Plan. Each of the foregoing grants vests monthly in twelve equal installments beginning on June 1, 2012; provided, that delivery of the shares of common stock underlying the foregoing RSUs is deferred until the earlier of (i) the third anniversary of the grant date and (ii) the date of Mr. Narachi's separation from service to the Company. The foregoing stock option has an exercise price per share of \$13.30, which is equal to the fair market value of a share of our common stock on the grant date, and a ten-year term.

In addition, in May 2012, each of the non-employee members of the Board, other than Mr. Narachi, was granted an annual equity award to coincide with his or her one-year term of service from May 2012 to May 2013 comprised of stock options to purchase 3,800 shares of our common stock and RSUs covering 2,300 shares of our common stock under the 2007 Plan. Each of the foregoing grants vests monthly in twelve equal installments beginning on June 1, 2012; provided, that delivery of the shares of common stock underlying the foregoing RSUs is deferred until the earlier of (i) the third anniversary of the grant date and (ii) the date of the director's separation from service to the Company. Each stock option granted to the non-employee members of the Board has an exercise price per share of \$13.30, which is equal to the fair market value of a share of our common stock on the grant date, and a ten-year term.

Summary of Director Compensation for Fiscal 2012

The following table summarizes the compensation paid to or earned by our non-employee directors during the year ended December 31, 2012.

Name(1)	Fees Earned or Paid in Cash \$(2)	Stock Awards \$(3)	Option Awards \$(3)	Total (\$)
Joseph V. Bonventre, M.D., Ph.D.(4)	47,500	30,590	22,801	100,891
Rajiv De Silva(5)	61,500	38,784	70,073	170,357
Michael Narachi(6)	101,000	50,540	45,602	197,142
Robert J. Perez(7)	75,750	30,590	22,801	129,141
Lesley Russell, MB.Ch.B., MRCP(8)	69,000	30,590	22,801	122,391
Gino Santini(9)	53,000	38,784	70,073	161,857
Davey S. Scoon(10)	78,250	30,590	22,801	131,641

- (1) Mr. Heiden, who is also our employee, received no additional compensation for his service on our Board and is therefore not included in this table.
- (2) Represents the aggregate dollar amount of 2012 fees earned or paid in cash for services as a director, including annual retainer fees, committee fees and per meeting fees.
- (3) Amounts shown do not reflect compensation actually received by the listed directors but represent the aggregate grant date fair value of stock awards, which consist of RSUs and stock option awards granted to our non-employee directors calculated in accordance with current accounting guidance for stock-based compensation, disregarding adjustments for forfeiture assumptions. The assumptions used to value the stock option awards are set forth in Note I to our Annual Report on Form 10-K for the year ended December 31, 2012 filed with the SEC on March 4, 2013. The reported value of the RSUs awarded in 2012 was calculated by multiplying the closing market price of a share of our common stock on the grant date by the number of RSUs granted.
- (4) Dr. Bonventre was a member of the Nominating and Corporate Governance Committee during 2012. In May 2012, Dr. Bonventre was granted an option to purchase 3,800 shares of our common stock at an exercise price equal to \$13.30 per share. In addition, in May 2012, Dr. Bonventre was granted RSUs covering 2,300 shares of our common stock. As of December 31, 2012, Dr. Bonventre held outstanding stock options to purchase 35,016 shares and RSUs covering 5,741 shares of our common stock.
- (5) Mr. De Silva was elected to the Board in February 2012. Since May 2012, he has served as Chair of the standing Transaction Committee and a member of the Audit Committee. In addition, Mr. De Silva was a member of the CEO Search Committee and the ad hoc Transaction Committee, for which he received a one-time fee of \$5,000 for his services to each of these respective committees. In February 2012, in connection with his appointment as a non-employee director, Mr. De Silva was granted the following equity awards: (i) an option to purchase 6,000 shares of the Company's common stock at an exercise price equal to \$17.25 per share, which vests in equal monthly installments over a two-year period beginning in March 2012; (ii) an option to purchase 950 shares of the Company's common stock at an exercise price equal to \$17.25 per share, which vested in three equal monthly installments beginning on March 1, 2012; and (iii) RSUs covering 475 shares of the Company's common stock, which vested in three equal monthly installments beginning on March 1, 2012. In May 2012, Mr. De Silva was granted an option to purchase 3,800 shares of our common stock at an exercise price equal to \$13.30 per share. In addition, in May 2012, Mr. De Silva was granted RSUs covering 2,300 shares of our common stock. As of December 31, 2012, Mr. De Silva held outstanding stock options to purchase 5,665 shares and RSUs covering 1,816 shares of our common stock.

- (6) Mr. Narachi was the Chair of the Board and a member of the Compensation Committee throughout 2012. In addition, he was the de facto Chair of the CEO Search Committee and the ad hoc Transaction Committee, for which he received a one-time fee of \$10,000 for his services to each of these respective committees. In May 2012, Mr. Narachi was granted an option to purchase 7,600 shares of our common stock at an exercise price equal to \$13.30 per share. In addition, in May 2012, Mr. Narachi was granted RSUs covering 3,800 shares of our common stock. As of December 31, 2012, Mr. Narachi held outstanding stock options to purchase 43,868 shares and RSUs covering 11,016 shares of our common stock.
- (7) Mr. Perez was the Chair of the Compensation Committee and a member of the Audit Committee from January through May of 2012. In May 2012, he was appointed Chair of the Nominating and Corporate Governance Committee and a member of the Compensation Committee. In addition, Mr. Perez was also a member of the CEO Search Committee and the ad hoc Transaction Committee, for which he received a one-time fee of \$5,000 for his services to each of these respective committees. In May 2012, Mr. Perez was granted an option to purchase 3,800 shares of our common stock at an exercise price equal to \$13.30 per share. In addition, in May 2012, Mr. Perez was granted RSUs covering 2,300 shares of our common stock. As of December 31, 2012, Mr. Perez held outstanding stock options to purchase 18,516 shares and RSUs covering 5,741 shares of our common stock.
- (8) Dr. Russell was a member of the Nominating and Corporate Governance Committee from January through May of 2012, a member of the Audit Committee throughout 2012 and a member of the standing Transaction Committee since May 2012. She was also a member of the CEO Search Committee, for which she received a one-time fee of \$5,000 for her services to this committee. In May 2012, Dr. Russell was granted an option to purchase 3,800 shares of our common stock at an exercise price equal to \$13.30 per share. In addition, in May 2012, Dr. Russell was granted RSUs covering 2,300 shares of our common stock. As of December 31, 2012, Dr. Russell held outstanding stock options to purchase 13,149 shares and RSUs covering 5,141 shares of our common stock.
- (9) Mr. Santini was elected to the Board in February 2012. He was a member of the ad hoc Transaction Committee, for which he received a one-time fee of \$5,000 for his services to this committee. In May 2012, he was appointed Chair of the Compensation Committee and a member of the standing Transaction Committee. In February 2012, in connection with his appointment as a non-employee director, Mr. Santini was granted the following equity awards: (i) an option to purchase 6,000 shares of the Company's common stock at an exercise price equal to \$17.25 per share, which vests in equal monthly installments over a two-year period beginning in March 2012; (ii) an option to purchase 950 shares of the Company's common stock at an exercise price equal to \$17.25 per share, which vested in three equal monthly installments beginning on March 1, 2012; and (iii) RSUs covering 475 shares of the Company's common stock, which vested in three equal monthly installments beginning on March 1, 2012. In May 2012, Mr. Santini was granted an option to purchase 3,800 shares of our common stock at an exercise price equal to \$13.30 per share. In addition, in May 2012, Mr. Santini was granted RSUs covering 2,300 shares of our common stock. As of December 31, 2012, Mr. Santini held outstanding stock options to purchase 5,665 shares and RSUs covering 1,816 shares of our common stock.
- (10) Mr. Scoon was the Chair of the Audit Committee throughout 2012. He also served as Chair of the Nominating and Corporate Governance Committee and a member of the Compensation Committee from January through May 2012 and a member of the Nominating and Corporate Governance Committee since May 2012. In May 2012, Mr. Scoon was granted an option to purchase 3,800 shares of our common stock at an exercise price equal to \$13.30 per share. In addition, in May 2012, Mr. Scoon was granted RSUs covering 1,900 shares of our common stock.

As of December 31, 2012, Mr. Scoon held outstanding stock options to purchase 25,360 shares and RSUs covering 5,741 shares of our common stock.

Stock Ownership Guidelines

The Board believes that it is important that directors be incentivized to focus on long-term stockholder value to ensure that the Board's interests are aligned with those of our stockholders. Accordingly, in August 2010, the Board adopted stock ownership guidelines to further align the interests of our non-employee directors with the interests of our stockholders and to promote the Company's commitment to sound corporate governance.

Our Non-Employee Director Stock Ownership Guidelines require all non-employee directors to hold shares of our common stock with a value equal to three times the amount of the base annual retainer fee paid to non-employee directors for service on the Board, excluding additional committee retainer and meeting fees, if any. This ownership guideline is initially calculated using the base annual retainer fee for service as a non-employee director as of the date the person first became subject to the guidelines as a non-employee director. These ownership guidelines will be re-calculated based on the applicable annual non-employee director retainer fees as of the date of the Company's 2013 Annual Meeting of Stockholders and on the date of the annual meeting of stockholders each third year thereafter, and will be based on the applicable annual Board retainer fee in effect on such calculation date.

Non-employee directors are required to achieve the applicable level of ownership within five years of the later of the date the guidelines were adopted and the date the person first became a non-employee member of the Board. In the event that a non-employee director does not meet the foregoing stock ownership guidelines, such non-employee director is prohibited from selling any stock acquired through vesting of RSUs or similar full-value awards or upon the exercise of stock options, except to pay for applicable taxes or the exercise price, and must use the entire net after tax amount of his or her base annual retainer fee, excluding additional committee retainer and meeting fees, if any, to purchase shares of Company common stock until the director satisfies the requirements.

Shares that count toward satisfaction of the guidelines include shares owned outright by the director or his or her immediate family members residing in the same household and shares held in trust for the benefit of the director or his or her family. Unexercised and/or unvested equity awards do not count toward satisfaction of the guidelines.

The value of a share will be measured on the date of the Company's annual meeting each year as the greater of (i) the average closing price over the 12 months preceding the date of calculation or (ii) the purchase price actually paid by the person for such share of the Company's stock. The purchase price for shares acquired pursuant to RSUs and other similar full value awards is zero.

Our Non-Employee Director Stock Ownership Guidelines may be waived, at the discretion of the Nominating and Corporate Governance Committee, for directors joining the Board from government, academia, or similar professions. The guidelines may also be waived at the discretion of the Nominating and Corporate Governance Committee if compliance would create undue hardship or prevent a director from complying with a court order, as in the case of a divorce settlement. It is expected that these instances will be rare.

PROPOSAL 2: ADVISORY VOTE ON EXECUTIVE COMPENSATION

Under the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, or the Dodd-Frank Act, and Section 14A of the Exchange Act, we are conducting a stockholder advisory vote on the compensation paid to our named executive officers. This proposal, commonly known as “say-on-pay,” gives our stockholders the opportunity to express their views on our named executive officers’ compensation. The vote is advisory, and, therefore, it is not binding on the Board, the Compensation Committee, or the Company. Nevertheless, the Compensation Committee will take into account the outcome of the vote when considering future executive compensation decisions. We currently intend to conduct this advisory vote annually, with the next such vote to occur at next year’s Annual Meeting.

As described in detail in the “*Compensation Discussion and Analysis*” section of this Proxy Statement, our executive compensation program is designed to attract, motivate and retain our named executive officers who are critical to our success. Our Board believes that our executive compensation program is well tailored to retain and motivate key executives while recognizing the need to align our executive compensation program with the interests of our stockholders and our “pay-for-performance” philosophy. We encourage our stockholders to read the “*Compensation Discussion and Analysis*” section as well as the “*Summary Compensation Table for Fiscal 2012*” table below and other related compensation tables and narrative disclosures which describe our executive compensation philosophy, programs, and practices and the 2012 compensation of our named executive officers.

We are asking our stockholders to indicate their support for the compensation of our named executive officers as described herein. This vote is not intended to address any specific item of compensation, but rather the overall compensation of our named executive officers and our executive compensation philosophy, programs, and practices as described in this Proxy Statement.

Accordingly, we ask our stockholders to vote “FOR” the approval, on an advisory basis, of the compensation of our named executive officers, as described in this Proxy Statement.

Required Vote

Advisory approval of this proposal requires the affirmative vote of the holders of a majority of shares of common stock present or represented and voting at the Annual Meeting. The say-on-pay vote is advisory, and therefore not binding on our Board, the Compensation Committee or the Company. However, our Board and our Compensation Committee value the opinions of our stockholders, and to the extent there is a significant vote against the compensation of our named executive officers as disclosed in this Proxy Statement, we will consider our stockholders’ concerns, and the Compensation Committee will evaluate whether any actions are necessary to address those concerns.

OUR BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS A VOTE “FOR” THE APPROVAL OF, ON AN ADVISORY BASIS, THE COMPENSATION OF OUR NAMED EXECUTIVE OFFICERS.

EXECUTIVE OFFICERS AND COMPENSATION

Set forth below is a description of our current executive officers and of compensation received by our named executive officers for the year ended December 31, 2012.

EXECUTIVE OFFICERS

William K. Heiden, age 53, joined us in May 2012 as our President and Chief Executive Officer and a member of the Board of Directors. Prior to joining the Company, he was the President and Chief Executive Officer of GTC Biotherapeutics, Inc., now rEVO Biologics, Inc., a pharmaceutical company, from June 2010 to May 2012 and continues to serve as its non-executive Chairman. Mr. Heiden was President and Chief Executive Officer and a member of the Board of Directors of Elixir Pharmaceuticals, Inc., or Elixir, a pharmaceutical company, from September 2004 until December 2008. Prior to joining Elixir, he served as President and Chief Operating Officer of Praecis Pharmaceuticals, Inc., a public biopharmaceutical company, which was subsequently acquired by GlaxoSmithKline plc, from May 2002 to September 2004. From 1987 to 2002, Mr. Heiden held various positions of increasing responsibility at Schering-Plough Corporation, now Merck & Co., including managing a number of businesses in the United States, Europe and Canada. He serves on the Board of Directors of LFB Biotechnologies S.A.S., a private French biotechnology company. Mr. Heiden holds a B.A. from the University of Florida, an M.B.A. from Cornell University's Johnson Graduate School of Management, and a M.I.M. from the University of Louvain.

Scott A. Holmes, age 38, joined us in September 2011 as our Vice President of Finance and Controller. He became our Chief Accounting Officer in December 2011 and our Principal Financial Officer and Treasurer in March 2012. Prior to joining us, Mr. Holmes served as Vice President of Finance and Treasurer of Molecular Biometrics, Inc., a commercial stage medical diagnostics company, from June 2010 to September 2011. From August 2009 to May 2010, Mr. Holmes was Vice President of Finance and Administration at On-Q-ity Inc., an oncology diagnostics company. He served as a consultant with Altman & Company, a consulting firm, from January 2009 to August 2009. Prior to 2009, Mr. Holmes spent five years at Dynogen Pharmaceuticals, Inc., a privately held pharmaceutical company, as Vice President of Finance and Administration and Treasurer. He also served as the Controller at Keryx Biopharmaceuticals, Inc., a public biotechnology company from November 2001 to October 2003. Mr. Holmes holds a B.A. in History from Middlebury College and a dual M.S./M.B.A. degree from Northeastern University Graduate School of Business Administration.

Greg Madison, age 45, joined us in January 2013 as our Executive Vice President and Chief Commercial Officer. Prior to joining us, Mr. Madison spent 12 years at Genzyme Corporation, a Sanofi company, or Genzyme, a public biotechnology company, in various commercial roles of increasing responsibility, most recently as Vice President and General Manager of its Global Renal Division. Prior to joining Genzyme, Mr. Madison spent five years at Janssen Pharmaceuticals, Inc., a wholly-owned subsidiary of Johnson & Johnson, from 1995 to 2000, in sales and sales management roles, and began his career in the pharmaceutical industry in sales with Wyeth-Ayerst International, Inc., a private pharmaceutical products manufacturer from 1994 to 1995. From 2011 to 2013, he was a member of the Board of Directors, and a member of the Operations Committee, of Kidney Care Partners, a Washington D.C.-based organization focused on legislative, regulatory and public policy issues related to patients with chronic kidney disease. Mr. Madison holds a B.B.A. in Finance from the University of Massachusetts, Amherst.

Scott T. McMillan, age 54, joined us in March 2008 as our Executive Director, Manufacturing Operations. Dr. McMillan was promoted to Head of Quality and Vice President, Technical Operations in March 2010 and to Senior Vice President, Quality and Technical Operations in January 2013. Prior to joining us, Dr. McMillan spent three years at AVANT Immunotherapeutics, Inc., now Celldex Therapeutics, Inc., a public biopharmaceutical company, in various manufacturing operations and

process development positions of increasing responsibility, most recently as Senior Director, Manufacturing Operations/Process Development. Prior to 2005, he was Director, Purification Operations, at Johnson Matthey Pharmaceutical Materials, Inc., an international specialty chemicals company. Since 2011, Dr. McMillan has been a business mentor in the Department of Chemical Engineering, or the Department, at Northeastern University and has served on the Department's Industrial Advisory Board since 2010. He has authored or co-authored more than 75 presentations and publications. Dr. McMillan holds a B.S. in Chemical Engineering from the University of Delaware and a Ph.D. in Chemical Engineering from the Georgia Institute of Technology.

Frank E. Thomas, age 43, joined us in August 2011 as our Executive Vice President, Chief Financial Officer and Treasurer and currently serves as Executive Vice President and Chief Operating Officer. From November 2011 to May 2012, he also served as our Interim President and Chief Executive Officer. Prior to joining us, he served as Senior Vice President, Chief Operating Officer and Chief Financial Officer for Molecular Biometrics, Inc., or Molecular Biometrics, a commercial stage medical diagnostics company, from October 2008 to July 2011. Prior to Molecular Biometrics, Mr. Thomas spent four years at Critical Therapeutics, Inc., or Critical Therapeutics, a public biopharmaceutical company, from 2004 to 2008, where he was promoted to President in June 2006 and Chief Executive Officer in December 2006 from the position of Senior Vice President and Chief Financial Officer. He also served on the Board of Directors of Critical Therapeutics from 2006 to 2008. Prior to 2004, Mr. Thomas was the Chief Financial Officer and Vice President of Finance and Investor Relations at Esperion Therapeutics, Inc. Since 2007, he has been a member of the Board of Directors of the Massachusetts Biotechnology Council. Mr. Thomas holds a B.B.A. in Business Administration from the University of Michigan, Ann Arbor.

Scott B. Townsend, age 46, joined us in August 2012 as our Senior Vice President of Legal Affairs, General Counsel and Secretary. In December 2009, Mr. Townsend founded External GC Law Group and until August 2012, provided legal advice to a variety of life science companies, including biopharmaceutical and medical device companies. From October 2008 to June 2009, he served as Executive Vice President of Legal Affairs, General Counsel and Secretary for Cornerstone Therapeutics Inc., a public specialty pharmaceutical company. From August 2004 to October 2008, Mr. Townsend served as Senior Vice President, General Counsel and Secretary for Critical Therapeutics, a public biopharmaceutical company. From August 2000 to August 2004, he was a junior partner in the corporate department at Hale and Dorr LLP, now Wilmer Cutler Pickering Hale and Dorr LLP. Prior to joining Hale and Dorr LLP, Mr. Townsend served as a corporate lawyer at Goodwin Procter LLP in Boston, MA and Kilpatrick Stockton LLP in North Carolina. Mr. Townsend received his A.B. from Bowdoin College with a double-major in Economics and Government and Legal Studies and his J.D. from The University of Virginia School of Law.

Christopher G. White, age 51, joined us in September 2007 as our Vice President of Business Development and Corporate Planning. Mr. White was promoted to Senior Vice President of Business Development and Corporate Planning in May 2008 and to Senior Vice President and Chief Business Officer in November 2011. From 2005 through 2007, Mr. White was a Partner in the Pharmaceutical and Medical Products Practice at Accenture. Prior to Accenture, he was a Vice President and Partner in the Pharmaceuticals and Healthcare Practice at A.T. Kearney, Inc. from 1998 to 2005. From 1984 to 1998, Mr. White held positions of increasing responsibility at DuPont Pharmaceuticals Company, Merck & Co. Inc. and Arthur D. Little, respectively. Mr. White holds a B.S. in Chemical Engineering from Tufts University and an M.B.A. from Columbia University.

COMPENSATION DISCUSSION AND ANALYSIS

Executive Summary

Overview

Our Compensation Committee believes that our executive compensation program is appropriately designed and responsible in that it both encourages our executive officers to work for our long-term prosperity and reflects a pay-for-performance philosophy, without encouraging our employees to assume excessive risks.

The current members of our Compensation Committee are Gino Santini (Chair), Robert J. Perez, and Michael Narachi. Mr. Scoon also served on the Compensation Committee from January 2012 to May 2012. The Board has determined that each member of the Compensation Committee who serves or served on the Committee during 2012 is a “non-employee director” and is “independent” as such terms are defined in the listing standards of the NASDAQ and applicable SEC rules.

2012 Advisory Vote on Executive Compensation

At our 2012 Annual Meeting of Stockholders, we held our second advisory vote on executive compensation. Approximately 88% of the votes cast on the proposal were in favor of our named executive officer compensation as disclosed in our proxy statement for the 2012 meeting, and as a result our named executive officer compensation was approved by our stockholders on an advisory basis. Our Compensation Committee reviewed the final vote results and determined that, given the significant level of support, no material changes to our executive compensation policies and programs were necessary at that time. For 2013, as described below, the Compensation Committee hired Radford, an Aon Hewitt Company, or Radford, as an independent compensation consultant to the Compensation Committee to perform an executive compensation study for the Company, including a comprehensive review of the Company’s executive compensation practices and peer group. In addition, Radford was engaged to provide ad hoc general compensation consulting and advisory services to the Compensation Committee, including, but not limited to, executive and equity compensation and incentive design. The Compensation Committee has assessed the independence of Radford pursuant to SEC rules and concluded that no conflict of interest exists that would prevent Radford from serving as an independent consultant to the Compensation Committee.

The Compensation Committee also engaged F.W. Cook to provide input on the compensation packages offered to Mr. Heiden and Mr. Townsend in 2012. The Compensation Committee assessed the independence of F.W. Cook pursuant to SEC rules and concluded that no conflict of interest existed that would have prevented F.W. Cook from serving as an independent consultant to the Compensation Committee.

Important Features of Our Compensation Program

Our compensation program is administered under a rigorous process which includes the solicitation by the Compensation Committee of advice of an independent third-party consultant (which reports directly to the Compensation Committee, not to the Company) and long-standing, consistently applied practices with respect to the timing of equity grants and the pricing of stock options and the periodic review of peer group practices.

Other important features of our compensation program include:

- In line with our pay-for-performance philosophy, we offer employment agreements that do not contain multi-year guarantees for salary increases, or non-performance-based guaranteed bonuses or equity compensation.

- In accordance with our pay-for-performance philosophy, base salary is the only component of our executive officers' total compensation that is "fixed" and all other components of our executive officers' compensation are performance-based and variable or "at risk." The amount of each executive officer's annual bonus is based primarily, or in the case of Mr. Heiden, entirely, on pre-established company performance goals. Further, the actual economic value of the long-term incentives granted to our executive officers in the form of equity awards depends directly on the performance of our stock price over the period during which the awards vest and, with respect to stock options, could be as little as zero if our stock price is less than the exercise price of such stock options at the time of vesting. We also make a 401(k) plan contribution for our executive officers that is consistent with the contribution we make for all employees who participate in our 401(k) plan.
- In order to provide long-term incentives for our executive officers to continue their employment with us, equity awards generally vest over three or four years and our Compensation Committee typically applies an annual, or a combination of annual and quarterly, vesting schedules to such awards granted to our executive officers. In certain instances the Board and Compensation Committee believe it is appropriate to grant certain executive officers equity awards with performance or market condition-based vesting provisions to further align the interests of such executives with those of our stockholders.
- The cash and certain equity acceleration benefits received by our executive officers in the event of a change of control of the Company are structured on a double-trigger rather than a single-trigger basis, so that no cash benefits and limited acceleration are provided upon the consummation of a change in control transaction unless there is also a termination of service within one year from the date a change of control of the Company occurs, other than for death, disability or cause, or the executive officer resigns for good reason.
- We do not provide any tax gross-up benefits for excise taxes associated with change in control compensation, or otherwise.
- We do not provide any executive fringe benefits, such as access to personal security, private airplanes, financial planning advice, tax preparation services, car allowance, club memberships or similar benefits.
- We review the external marketplace and make internal comparisons among the executive officers when making compensation determinations. During 2012, our Compensation Committee did not benchmark to specific levels within the marketplace, but rather reviewed available external data as one of many factors considered when establishing executive compensation. However, in 2013, based on Radford's final report on its evaluation of our 2012 compensation practices and recommendations for changes in 2013, or the 2012 Radford Report, the Compensation Committee benchmarked base salaries and short-term incentives against the 50th percentile of our peer group and long-term equity incentives against the 50th percentile of our peer group with the potential to earn up to the 75th percentile of our peer group, depending on the stock price performance that will determine the payout under the performance-based RSUs granted to the executive officers in February 2013, as described under "*February 2013 Equity Awards.*"

Aligning Compensation with Our Performance

One of the key factors the Compensation Committee takes into account when approving compensation plans and programs for our executive officers is alignment with the Company's performance. To that end, we have structured our short-term and long-term incentives for our executive officers so that they reward achievement of key performance metrics that help realize our strategic goals and objectives. We believe that doing so will ultimately result in long-term stock price appreciation for our stockholders.

Our executive compensation program has consistently and meaningfully been focused on pay-for-performance principles, and has included payouts below target under our annual incentive plan when the Company's performance was below expectations. To ensure that our compensation program continues to be well aligned with our performance, we will continue to monitor and revise our compensation for our executive officers.

Executive Compensation Philosophy

The following is a summary of our overall executive compensation philosophy, as approved by our Compensation Committee and our Board.

Objectives of Our Executive Compensation Program

Our key executive compensation objectives are to attract and retain the highest quality executive talent, motivate executives by aligning their short- and long-term interests with those of our stockholders, and reward short- and long-term individual and company performance.

We use the following principles to guide our decisions regarding executive compensation:

External Competitiveness

We strive to ensure that our executives' total compensation levels are competitive with peer companies so that we can attract and retain high performing key executive talent. Given the highly competitive landscape for top talent and our relative position to compete for that talent, we recognize that it may, in some instances, be necessary to pay above market rates to attract critical talent.

To ensure that our executives' total compensation levels are competitive, our Compensation Committee, in consultation with its independent advisors and our senior management, periodically reviews the compensation policies and practices of other companies in our peer group, which we define to include companies with the following characteristics:

- Publicly-traded;
- Primary operations in the biotechnology/pharmaceuticals industries;
- Similar market capitalization;
- Similar stage of development;
- Similar amount of product revenue;
- Similar risk profile; and
- Similar number of employees.

The Compensation Committee also periodically reviews the composition of the peer group itself, in consultation with its independent advisors and senior management, to ensure that the peer group continues to accurately reflect comparable companies as our business evolves.

Internal Parity

To the extent practicable, base salary levels and short- and long-term incentive target levels for similarly-situated executives within the Company should be comparable to avoid divisiveness and encourage teamwork, collaboration, and a cooperative working environment.

Pay-for-Performance

Total compensation should reflect a "pay-for-performance" philosophy such that a substantial portion of executive compensation should include short- and long-term incentive awards that are tied to

the achievement of the short- and long-term performance objectives of both the Company and the individual.

Alignment with Stockholders' Interests

Total compensation levels should include a component that reflects relative stockholder returns and the Company's overall performance through the use of equity-based awards.

Simplicity and Flexibility

Our executive compensation program should be straightforward and easy to understand for both our employees and stockholders. The compensation program should also be sufficiently flexible to be able to adapt to rapid changes in the competitive environment for executives in the biotechnology and pharmaceuticals sectors.

Avoidance of Excessive Perquisites

Although we will consider certain perquisites that are common and appropriate for similarly-situated executives of public companies, as a general matter, we intend to avoid the payment of excessive, unusual, or unnecessary perquisites to executives.

Elements of Our Executive Compensation Program

Consistent with our executive compensation objectives, we have developed an executive compensation program consisting of the following elements:

- Base Salary;
- Short-term incentives in the form of annual cash bonus opportunities;
- Long-term incentives in the form of equity-based awards (stock options and RSUs); and
- Benefits/perquisites.

To further our guiding compensation principles, the relative mix of the foregoing components of each executive's total potential compensation should be weighted more toward short- and long-term incentive compensation. In addition, the value of such variable compensation is generally weighted more heavily toward long- than short-term incentives to ensure the interests of the executives are more closely aligned with those of our stockholders.

In determining the appropriate level of each element of total executive compensation, we seek to accomplish the goals set out below.

Base salary

Base salary levels are generally designed to provide fixed annual cash compensation that are competitive with base salary levels provided to executives of similar position, responsibility, experience, qualifications, and performance to the extent such comparable positions exist to (i) allow us to recruit and retain the best qualified executives in a very competitive market for talent in the biotechnology and pharmaceuticals sectors, and (ii) provide executives with reasonable predictability regarding their basic annual standard of living. Base salaries of executives are reviewed annually as part of our annual review process both in light of the executive's individual performance and the Company's performance during the year and the then current competitive conditions. We believe that it is appropriate during most years to provide an upward adjustment to executive salaries if the executive's performance warrants such adjustment and our financial condition permits.

Short-term incentives

Short-term incentives in the form of an annual cash bonus opportunity are intended to provide motivation for executives to achieve both the Company's annual operating goals and the individual's annual performance goals. The target amount for the annual bonus opportunity is generally established at the outset of the fiscal year or in the executive officer's employment agreement and is generally based on a percentage of the executive's base salary that is intended to be competitive with that offered to similarly-situated executives, to the extent such comparable positions exist. The actual amount paid for short-term incentives is generally based on a combination of company and individual performance with higher weighting to company performance as an executive's level of responsibility increases to reflect the executive's ability to influence overall company performance. In addition, the Compensation Committee has the flexibility to award additional discretionary bonuses to recognize and reward outstanding individual performance in excess of measurable performance objectives.

Long-term incentives

Long-term incentives in the form of annual equity-based awards are intended to align the interests of executives with those of our stockholders and to provide executives with a continuing ownership stake in our long-term success. The amount of a new hire and an annual equity-based award should be competitive to that offered to similarly-situated executives, to the extent such comparable positions exist, and total executive compensation should be more heavily weighted toward long-term incentive compensation to ensure that the interests of our executives are aligned with those of our stockholders. In addition, the Compensation Committee and the Board believe that the proportion of total at risk compensation should rise as an executive's level of responsibility increases because of the executive's increased ability to influence overall company performance. Equity-based awards are generally subject to three to four-year annual vesting, or in some cases quarterly vesting after the first year, to promote retention and align the executive's long-term interests with those of our stockholders. In certain instances it is appropriate to grant to certain executive officers equity awards with performance or market condition-based vesting provisions to further align the interests of such executives with those of our stockholders. As a general rule, equity awards to executive officers are reviewed by the Compensation Committee once per year in connection with our annual performance review process. However, we may issue equity-based awards throughout the year if appropriate. For example, in June 2012, following a corporate restructuring, the Board approved, based on the recommendations of the Compensation Committee, equity awards to certain of our executive officers, as further described below under "*Compensation Decisions Made Following Our June 2012 Corporate Restructuring.*" The Board and the Compensation Committee approved these equity awards outside of the normal executive performance review process to retain and motivate our remaining named executive officers, and, in certain cases, to compensate them for the additional responsibilities they would be assuming following our June 2012 corporate restructuring.

Benefits/Perquisites

We seek to provide an overall benefits package that is intended to be competitive to that offered by companies similar to us to ensure that we do not lose talented candidates or employees as a result of an inferior benefits package.

Executive Compensation Decisions and Processes

General

The Compensation Committee typically meets at least three times per year and more frequently as necessary. The Compensation Committee met seven times and acted by unanimous written consent four times during 2012. The agenda for each meeting is usually developed by the Chair of the

Compensation Committee, in close consultation with our chief executive officer, chief operating officer, general counsel, and other executives who may have input on a given agenda item. The Compensation Committee meets regularly in executive session. However, from time to time, various members of management as well as outside advisors and consultants may be invited to make presentations, to provide background information or advice, or to otherwise participate in a given meeting. Our chief executive officer is often present and actively participates in discussions and deliberations regarding the compensation of our executive officers. However, our chief executive officer is not permitted to be present or participate in discussions or deliberations regarding his own compensation, performance, or objectives.

Annual Executive Compensation Decision-Making Processes

The Compensation Committee conducts an annual review of the performance and compensation of each of our executive officers, including our chief executive officer. This review is typically conducted over a series of Compensation Committee meetings toward the end and just after the end of the completed fiscal year and is intended to coincide with the Company's annual company-wide performance review process.

To assist the Compensation Committee in its annual review, our chief executive officer and other members of the senior management team typically provide the Compensation Committee with a written self-evaluation based on the Company's overall performance on a regular basis throughout the year and, at the end of each year, a proposed score against the Company's performance goals established by the Compensation Committee and the Board at the outset of the year.

As discussed in further detail under "*Executive Compensation Decisions and Processes—Goals*" below, because the Company's overall performance goals allow for some amount of subjective and qualitative assessment, there are typically a series of meetings and discussions among senior management, the Compensation Committee and the Board as to the exact and appropriate scoring of the Company's performance against the goals established by the Board at the outset of the year. At the conclusion of the foregoing discussions, the Compensation Committee exercises its discretion to determine a final Company performance score for the completed fiscal year. For our chief executive officer, the Company's annual performance score above determines his bonus for the year. For other executive officers, the Company's annual performance score is combined with each individual executive's performance score to determine their bonus for the year. As discussed in further detail below, the weight of the corporate score for our executive officers is 80% in most cases and 70% in certain cases.

Our chief executive officer generally provides the Compensation Committee with a performance evaluation and proposed performance score for each executive officer, as well as recommendations with respect to each such executive officer's bonus amount for the completed fiscal year and annual salary and equity grant recommendations for the current year. The Compensation Committee typically gives substantial weight to our chief executive officer's views because he is in the best position to evaluate the performance of and determine the appropriate level at which each of the Company's executive officers should be compensated for past performance and to ensure that they remain incentivized and engaged. The Company's overall performance score determines the size of the company-wide bonus pool available. The blending of the corporate score and each executive's individual score, either on an 80-20 or a 70-30 basis, as applicable, determines his or her annual bonus. Notwithstanding this framework, the Compensation Committee may, in its discretion, increase or decrease an executive's bonus based on its assessment of his or her performance contribution or potential.

In general, at or around the time the Compensation Committee reviews and approves the bonus amounts for the executives for the completed fiscal year, it also reviews the salary level of each executive and determines the amount of the annual equity grant to each executive for the then current fiscal year. In accordance with our executive compensation philosophy, the Compensation Committee

seeks to ensure that each executive's salary and the value of the annual equity grant to each executive are competitive with that of similarly situated executives, to the extent such comparable positions exist.

With respect to our chief executive officer, the Compensation Committee conducts its own independent review of his performance. In addition, our chief executive officer generally provides the Compensation Committee and the Board with his own self-evaluation of his performance for the completed fiscal year. The Compensation Committee generally considers all of the foregoing and makes a determination as to the appropriate level of base salary, bonus and equity awards. Given that our chief executive officer has ultimate operational responsibility for the overall performance of the Company, the Compensation Committee and the Board believe that his individual annual performance goals and the Company's overall annual performance goals should be the same and therefore, that his bonus is entirely based on the Company's overall performance score. Generally, at or around the time the Compensation Committee reviews and approves the bonus amount for our chief executive officer for the completed fiscal year, it also reviews his annual salary and determines the amount of his annual equity grant for the then current fiscal year.

Goals

At the beginning of each year, the Board establishes goals against which it will evaluate the Company's performance at the end of the year for purposes of making executive compensation decisions. Senior management typically provides proposed Company goals for consideration by the Compensation Committee around the beginning of the fiscal year. The Compensation Committee then engages in a series of discussions, both in the presence of management and in executive session, and provides management with feedback on the proposed Company goals. There are typically several drafts presented to the Compensation Committee before management and the Compensation Committee agree on the Company goals and the weighting of each goal. The proposed Company goals and the weighting of each goal are then presented to the Board for approval, however, the Board tends to defer to the Compensation Committee's judgment. The weighting of the various Company goals is based on the Compensation Committee's and the Board's subjective determination of the Company's relative strategic and operating priorities for the upcoming fiscal year. Whenever possible, the Compensation Committee attempts to develop quantitative measures of performance to provide clarity throughout the year about how the Company is progressing against its goals.

The Compensation Committee endeavors to establish goals for the Company which are generally consistent with the Company's financial plan and operating budget for the year. Accordingly, the Compensation Committee generally has the expectation that the Company will achieve its baseline goals for the year and that scoring of the goals at the end of the year will likely yield a bonus payout at or about the target amount.

In addition, our chief executive officer works with each executive officer to establish his or her individual annual performance goals. Individual executive performance goals are not established or scored based on a strict mathematical calculation, in contrast to the manner in which the overall Company performance goals are established and scored. Rather, individual executive performance goals are established in a manner that allows for more qualitative and subjective assessment. Accordingly, each specific goal established for our executive officers is not scored on an individual basis, but rather, our chief executive officer evaluates the executive's overall achievement of his performance goals as well as his contributions to the Company's corporate goals and recommends a single overall score for each executive officer to the Compensation Committee. The Compensation Committee believes that our chief executive officer is in the best position to evaluate the performance of the executives, other than himself, and the Compensation Committee believes that substantial deference to our chief executive officer's evaluation of such executives and his related recommendations is generally appropriate.

2012 Performance Goals

In accordance with the process detailed above, and based on the recommendation of the Compensation Committee after consultation with senior management, in early 2012 the Board established the Company's 2012 performance goals, which also served as the 2012 performance goals of our chief executive officer, Mr. Heiden. In early 2013, the Compensation Committee scored the 2012 goals and awarded the Company 110 out of 100 points based on the following conclusions:

- 58.5 out of a targeted 55 points were awarded for the Company's U.S. *Feraheme* financial and sales performance goals. The Company recognized approximately \$58.3 million of U.S. *Feraheme* net sales during 2012, which, based on the scale set by the Board at the outset of the year, resulted in above-targeted points for this goal. In addition, the Company received the targeted points for reaching its year-end cash and investments balance goal and for exceeding its 2012 operating expenses goal by managing operating expenses below the target.
- 43 out of a targeted 40 points were awarded for the Company's indication and market expansion goals. The Company received its target score for its timely filing of the supplemental new drug application, or sNDA, which was filed with the U.S. Food and Drug Administration, or the FDA, in December 2012. In addition, the Company received above-target points in connection with its goal to receive approval by the European Medicines Agency for *Feraheme/Rienso* for the treatment of IDA in adult chronic kidney disease, or CKD, patients, which was received earlier than expected in June 2012. Finally, the Company received the targeted points for achieving our goal of obtaining regulatory approval for *Feraheme/Rienso* in Switzerland for the treatment of IDA in adult CKD patients in August 2012.
- Five out of a targeted five points were awarded for our progress in filing key regulatory filings in connection with our global manufacturing processes for *Feraheme/Rienso* for territories outside of the U.S.

Further, an additional three and a half points were awarded in recognition of the Company's above-target achievements mentioned above and for 2012 achievements realized beyond the established goals, including the Company's successful efforts in right-sizing the organization, the termination of commercial license agreements for GastroMARK®, which enabled the Company to close down its manufacturing facilities and move toward an outsourced manufacturing supply chain, the Company's successful improvement in the net revenue realized per unit of *Feraheme* sold, and the successful negotiation of an amendment to the collaboration agreement with our licensee, Takeda Pharmaceuticals, Limited, or Takeda. As a result, the Board and the Compensation Committee scored the Company's overall 2012 performance at 110 out of a targeted 100 points.

2013 Performance Goals

Based in part on the recommendation of the Compensation Committee and after consultation with senior management, the Board established the following 2013 Company performance goals, which also serve as the 2013 performance goals of our chief executive officer, Mr. Heiden:

- A target of 40 points for the Company's U.S. *Feraheme* financial and sales performance goals. The Compensation Committee and the Board believe that, given that U.S. *Feraheme* sales are currently the primary source of the Company's revenues, the Company's 2013 performance goals should be heavily weighted toward U.S. *Feraheme* sales performance, including the achievement of financial goals which are generally consistent with our previously-announced *Feraheme/Rienso* net sales guidance. In addition, we have previously announced guidance on our 2013 operating expenses, excluding our cost of goods sold and certain one-time expenses, and that we expect our cash and investments balance at December 31, 2013 to be between \$206 million and \$211 million. As a result, the Compensation Committee and the Board believe that the

achievement of these goals, which are generally consistent with our previously-stated 2013 operating expenses and year-end cash and investments balance guidance, are also key 2013 performance goals.

- A target of 20 points for the Company's indication and market expansion goals. The Compensation Committee and the Board believe that the Company's planned indication expansion for *Feraheme/Rienso* will be a significant driver of the future revenues and value for the Company. The Compensation Committee and the Board believe that the approval of the *Feraheme* sNDA for the treatment of IDA regardless of the underlying cause is particularly important to us because an expanded indication would effectively double the market opportunity for *Feraheme*, by allowing us to access the half of the current intravenous iron market that is beyond our current approved indication.
- A target of 25 points for the Company's portfolio expansion goals. We are seeking complementary products to expand our portfolio through the in-license or acquisition of additional marketed specialty pharmaceutical products. The Compensation Committee and the Board believe that the Company's goal to acquire or in-license one or more commercial products is important to the expansion of the Company and future revenue streams.
- A target of 15 points for the Company's manufacturing and human resources goals. The Compensation Committee and the Board believe that our 2012 movement to a fully outsourced manufacturing supply chain for *Feraheme/Rienso*, and the continued progress toward establishing alternative manufacturing facilities and suppliers is important to reduce our manufacturing risk, increase our manufacturing capacity, improve our *Feraheme/Rienso* cost of goods sold, and ultimately, to enhance the Company's financial performance. In addition, as a result of the Company's strategy to focus on the commercialization of *Feraheme/Rienso* and the in-licensing or acquisition of other marketed products there have been significant changes in our senior management in recent years. Therefore, the Compensation Committee and the Board believe it is important for the future of the Company to focus on stabilizing the leadership of the Company by attracting and retaining qualified senior management personnel that fit with this strategy.

Independent Compensation Consultants

Under its charter, the Compensation Committee is authorized to engage such independent advisors as it deems necessary or appropriate to carry out its responsibilities. The Compensation Committee generally intends to conduct a thorough independent review of the Company's overall executive compensation practices relative to its peer group, as well as the composition of the peer group itself, approximately every other year. The Compensation Committee believes that a biannual approach is the most efficient, given the amount of time, effort, and cost associated with conducting a comprehensive executive compensation review and making any necessary adjustments to our executive compensation practices. The Compensation Committee retained F.W. Cook during 2009 to conduct our previous comprehensive review of the Company's executive compensation practices and peer group and was due to conduct another review during 2011. However, in July 2011, we entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, with Allos Therapeutics, Inc., or Allos, and Alamo Acquisition Sub, Inc., a Delaware corporation and our former wholly-owned subsidiary. Given our then impending merger with Allos and the fact that the composition of the Board and the executive team of the combined company, as well as the business of the combined company, would be different than our existing company, the Compensation Committee decided not to conduct a comprehensive review of our executive compensation practices and peer group in 2011. Our stockholders voted not to approve the necessary actions to consummate the proposed merger with Allos, and we terminated the Merger Agreement in October 2011. The Compensation Committee at that time intended to next conduct a comprehensive review of the Company's executive compensation

practices and peer group in 2012. Accordingly, in 2012, the Compensation Committee interviewed, evaluated and discussed potential executive compensation consultants. In its evaluation of prospective executive compensation advisors, the Compensation Committee considered factors such as reputation, size, depth of experience in advising public life sciences companies, client referrals and geographic scope of operations. Following a thorough review process, the Compensation Committee determined that Radford best met the foregoing criteria and in October 2012, the Compensation Committee retained Radford to evaluate our 2012 compensation practices and suggest any recommended changes for 2013, as discussed below.

Because we did not conduct a comprehensive review of the Company's executive compensation practices in 2011, all decisions with respect to 2012 executive compensation in connection with the annual performance review process were made by the Compensation Committee and the Board based on their subjective determinations, with advice and input from F.W. Cook but without any reliance on any specific peer group data. However, the Compensation Committee consulted F.W. Cook in establishing the compensation packages for both Mr. Heiden, who joined us in May 2012 as President and Chief Executive Officer, and Mr. Townsend, who joined us in August 2012 as Senior Vice President of Legal Affairs, General Counsel and Secretary. F.W. Cook solicited input from senior management before making its recommendations to the Compensation Committee, which included the specific benchmarking peer group below, which the Compensation Committee accepted in making its determination of Mr. Heiden's and Mr. Townsend's compensation packages, as discussed below under "*Compensation Decisions With Respect To Our Named Executive Officers.*" The following peer group companies were selected primarily on the basis of industry, market capitalization, stage of development, annual revenue and number of employees:

- Affymax, Inc.
- Alnylam Pharmaceuticals, Inc.
- Array BioPharma, Inc.
- ArQule, Inc.
- Cadence Pharmaceuticals, Inc.
- Curis, Inc.
- Depomed, Inc.
- DUSA Pharmaceuticals, Inc.
- Dyax Corp.
- Enzon Pharmaceuticals, Inc.
- Infinity Pharmaceuticals, Inc.
- Immunomedics, Inc.
- Ligand Pharmaceuticals, Inc.
- NPS Pharmaceuticals, Inc.
- Optimer Pharmaceuticals, Inc.
- Progenics Pharmaceuticals, Inc.
- Repligen Corporation
- Santarus, Inc.
- Savient Pharmaceuticals, Inc.
- Sucampo Pharmaceuticals, Inc.

In December 2012, Radford provided the Compensation Committee with the 2012 Radford Report. In its report, Radford compared the overall compensation then provided by the Company, including annual salary, annual bonus opportunity, and annual equity grants, to each of its executive officers to publicly available compensation information from twenty peer companies, described below, identified in consultation with senior management and the Compensation Committee. The peer group companies were selected primarily on the basis of industry, market capitalization, stage of development, annual revenue and number of employees. In addition to publicly available proxy data from the selected peer group companies, Radford utilized published survey data from the Radford Global Life Sciences Survey for public biopharmaceutical companies of similar size (between 100 and 300 employees) or together "Radford's market compensation data."

With input from senior management, the Compensation Committee discussed, reviewed and approved the following criteria, which Radford then used to develop a proposed updated peer group for purposes of the Compensation Committee's 2012 evaluation of the Company's executive compensation practices:

- 20 companies to ensure a statistically significant and meaningful market sample;

- Publicly-traded U.S. companies;
- Companies with reasonable financial health and current with their SEC disclosures;
- Similarity in business model, industry, complexity, and size;
- Similar market capitalization (between \$200 million and \$980 million);
- Commercial stage companies with at least one approved drug product;
- Similar annual revenue (between \$26 million and \$312 million); and
- Employee headcount.

Radford solicited input from senior management before making its final recommendation regarding the Company's peer group to the Compensation Committee. After review and discussion with Radford, the Compensation Committee accepted the recommendations proposed by Radford with respect to our peer group. Accordingly, Radford utilized the following peer group to analyze our 2012 executive compensation in reaching the conclusions discussed below and, beginning with the 2013 performance and executive compensation review cycle, the Compensation Committee will base its executive compensation review utilizing the following peer group:

- | | |
|---------------------------------|----------------------------------|
| • Acorda Therapeutics, Inc. | • Ligand Pharmaceuticals, Inc. |
| • Affymax, Inc. | • Momenta Pharmaceuticals, Inc. |
| • Astex Pharmaceuticals, Inc. | • NPS Pharmaceuticals, Inc. |
| • AVANIR Pharmaceuticals, Inc. | • Optimer Pharmaceuticals, Inc. |
| • Cadence Pharmaceuticals, Inc. | • Repligen Corporation |
| • Curis, Inc. | • Santarus, Inc. |
| • DUSA Pharmaceuticals, Inc. | • SciClone Pharmaceuticals, Inc. |
| • Dyax Corp. | • Spectrum Pharmaceuticals, Inc. |
| • Immunomedics, Inc. | • Sucampo Pharmaceuticals, Inc. |
| • Isis Pharmaceuticals, Inc. | • Xenoport, Inc. |

The primary conclusions from the 2012 Radford Report were as follows:

- 2012 total target cash compensation for all of our then-named executive officers was positioned at the 50th percentile in the aggregate as compared to Radford's market compensation data;
- 2012 overall base salary rates for all of our then-named executive officers were positioned between the 25th and 50th percentiles in the aggregate as compared to Radford's market compensation data;
 - 2012 target bonus amounts as a percentage of base salary for all of our then-named executive officers were positioned between the 50th and 75th percentiles in the aggregate as compared to Radford's market compensation data;
 - The value of equity awards to our then-named executive officers who received an annual grant as part of the 2012 annual performance review process was positioned between the 50th and 75th percentiles in the aggregate as compared to Radford's market compensation data; and
- Total direct compensation paid to our then-named executive officers as part of the 2012 annual performance review process was positioned at the 50th percentile in the aggregate as compared to Radford's market compensation data.

The 2012 Radford Report confirmed that our existing executive compensation practices were generally in line with our overall executive compensation philosophy. In particular, the 2012 Radford Report confirmed that we had been adhering to our philosophy that total executive compensation

should be more heavily weighted toward long-term incentive compensation to ensure that the interests of our executives are aligned with those of our stockholders and that the proportion of total compensation at risk should rise as an executive's level of responsibility increases. In addition, the 2012 Radford Report noted that all of the current named executive officers fell within the 50th percentile as compared to Radford's market compensation data for both base salary and target total cash compensation. As such, based on the 2012 Radford Report, the Compensation Committee felt that a market-based adjustment was not necessary to the salaries of our current named executive officers and therefore provided them each with a 3% merit increase for 2013, which was in line with the 3% merit increase pool established for all other employees of the Company. Our recent practice has been to award a portion of the total annual equity grant to executives in the form of stock options and the remainder in the form of RSUs as part of the executives' annual award, with the value of the annual equity awards at or above the 50th percentile relative to similarly situated executives in our peer group. However, as discussed in further detail below under "*Recent Compensation Decisions with respect to our Named Executive Officers*," in reliance upon recommendations contained in the 2012 Radford Report, in February 2013 the Compensation Committee awarded our executive officers with a stock option grant and a time-based RSU grant, which when combined, and valuing the RSUs at a ratio of one-to-two as compared to stock options, provided the executive officers an award at the 50th percentile as compared to Radford's market compensation data. In addition, in February 2013, based on the advice of Radford and to ensure alignment with our pay-for-performance executive compensation philosophy, the Compensation Committee provided our executive officers with a performance-based RSU grant, which, if attained, would provide them a long term incentive value of up to the 75th percentile as compared to Radford's market compensation data.

Compensation Decisions With Respect To Our Named Executive Officers

Compensation Decisions Made at the Outset of 2012

Determinations of 2012 base salary and equity awards for our then-named executive officers were made at the beginning of 2012, as discussed in detail below. From November 2011 through May 2012, Mr. Thomas served as Interim President and Chief Executive Officer during the Company's search for a permanent chief executive officer. Since May 2012, he has served as Executive Vice President and Chief Operating Officer. In May 2012, Mr. Heiden joined us as President and Chief Executive Officer.

In January 2012, as part of our annual performance review process, each of our then executive officers, including Mr. Thomas, received equity awards the size and structure of which reflected the overall performance of the Company and the individual performance of each of the executives, as well as the extenuating circumstances following our unsuccessful merger with Allos, our November 2011 restructuring, our ongoing search for a permanent chief executive officer, and our ongoing exploration of strategic alternatives, including a potential sale of the Company. In addition, in determining the size and structure of the equity grants to our then executive officers, other than Mr. Thomas, the Compensation Committee and the Board gave substantial weight to the recommendations of Mr. Thomas in terms of what he felt was required to continue to retain and motivate his direct reports, including Mr. White and Dr. Allen. Given these factors, the Compensation Committee and the Board felt that it was important to ensure that our executives remained motivated and engaged during a period of uncertainty, while ensuring that their short- and long-term interests remained aligned with those of our stockholders and in January 2012 awarded each of our then executives, including Mr. Thomas, certain RSU grants which are described in detail below.

The January 2012 RSU awards granted to each of our executives, including Mr. Thomas, vest in three annual installments as follows: (i) 50% on the first anniversary of the grant date and (ii) 25% on each of the second and third anniversaries of the grant date. Further, if the executive's business relationship with the Company is terminated by the Company, other than in connection with a change of control, without cause, or by the executive for good reason, each as defined in the executive's employment agreement with the Company, then the number of RSUs scheduled to vest on the next scheduled vesting date following such termination shall accelerate immediately upon such termination and any remaining unvested RSUs shall be forfeited. Although our standard practice prior to 2011 had been to grant our executives equity which vests in four equal annual installments, the Compensation Committee and the Board gave substantial weight to Mr. Thomas' recommendation with respect to the foregoing vesting schedule to ensure that the executives remain motivated and engaged in the short-term as well as the long-term, particularly in light of the numerous short-term goals and challenges that faced the Company at that time, including the Company's goal to file a sNDA for *Feraheme* with the FDA in 2012, seeking approval of *Feraheme* for use in a broader group of patients with IDA and the need to successfully complete the Company's process of evaluating strategic alternatives in the short-term.

Based on the foregoing and the recommendation of the Compensation Committee, in January 2012, our Board approved the following RSU awards, pursuant to our 2007 Plan, to our then executive officers:

<u>Name</u>	<u>Number of Shares</u>
Frank E. Thomas, Executive Vice President and Chief Operating Officer .	40,000
Lee F. Allen, M.D. Ph.D., Former Executive Vice President of Medical Development and Chief Medical Officer	20,000
Christopher G. White, Senior Vice President and Chief Business Officer .	20,000

Compensation Decisions Made Following our June 2012 Corporate Restructuring

In June 2012, we initiated a corporate restructuring, including a workforce reduction plan, the majority of which was associated with our manufacturing and development infrastructure, including our decision to divest our Cambridge, Massachusetts manufacturing facility. Following this restructuring, Mr. Heiden made certain recommendations to the Compensation Committee with respect to equity awards for certain of the Company's executive officers, including Messrs. White and Holmes and Dr. Allen, as described in more detail below. In making his recommendations to the Board, Mr. Heiden sought to ensure that these executive officers were retained and remained motivated during the impending period of uncertainty following our June 2012 corporate restructuring and focused on the achievement of specific individual goals in support of the Company's 2012 goals. Based on the foregoing, in June 2012, the Compensation Committee approved the following stock option awards to our then-executive officers other than our chief executive officer and chief operating officer:

<u>Name</u>	<u>Number of Shares</u>
Scott A. Holmes, Vice President of Finance, Chief Accounting Officer and Treasurer	30,000
Lee F. Allen, M.D. Ph.D., Former Executive Vice President of Medical Development and Chief Medical Officer	40,000
Christopher G. White, Senior Vice President and Chief Business Officer .	40,000

The above stock option awards were granted pursuant to our 2007 Plan at an exercise price of \$14.89, which was the fair market value of a share of our common stock on the date of grant. These grants have a seven-year term and vest over four years after the grant date as follows: (i) 25% on the

first anniversary of the date of grant and (ii) equal quarterly installments over the next three years thereafter. As discussed below, the Compensation Committee provided Mr. White and Dr. Allen with certain performance-based acceleration provisions in their June 2012 option awards.

In light of the termination of our strategic alternatives search in May 2012 and our focus on expanding our product portfolio through the in-license or acquisition of additional marketed specialty pharmaceutical products, the Compensation Committee felt that Mr. White, as our Senior Vice President and Chief Business Officer, played an integral role in the pursuit of additional products to complement *Feraheme/Rienso*. As a result, the Compensation Committee provided that 50% of the unvested portion of Mr. White's June 2012 option award, discussed above, will be accelerated in the event the Company acquires an FDA-approved product that has generated at least \$10 million in revenue during the 12 month period preceding the acquisition, provided Mr. White continues to have primary responsibility over the Company's business development function at the time of such transaction. Further, in the event that after the above transaction has closed, the Company acquires a second product in a transaction that would be required to be reported to the SEC as a "material contract" or is otherwise deemed by the Board to be of material importance to the Company's growth strategy, then the balance of this option will become exercisable, provided Mr. White continues to have primary responsibility over the Company's business development function at the time of such transaction.

In addition, given the integral role that Dr. Allen was then expected to play in the preparation and timely filing of the Company's sNDA in 2012 seeking approval for *Feraheme* for the treatment of IDA in a broader group of patients and the critical importance of the sNDA to the Company, the Compensation Committee provided that in the event that our sNDA for the broad IDA indication for *Feraheme* was filed with the FDA by the end of 2012 and Dr. Allen remained employed by the Company as of the filing date, then the vesting of 50% of the number of shares subject to the June 2012 option that then remained unexercisable would become exercisable by accelerating the vesting of 50% of the shares with respect to each remaining vesting date. The Company filed its sNDA in December 2012 and therefore, 50% of Dr. Allen's shares became exercisable at that time. In addition, in the event that (i) FDA approval of the sNDA for the broad IDA indication for *Feraheme* is obtained by March 31, 2014 and (ii) at the time of FDA approval, Dr. Allen continues to be a service provider to the Company providing services with respect to the sNDA filing for the broad IDA indication for *Feraheme*, then all shares subject to the June 2012 option that then remain unexercisable shall become exercisable.

Further, for the reasons stated above, the Compensation Committee authorized the Company to enter into a retention agreement with Dr. Allen, which was entered into in August 2012. In March 2013, Dr. Allen resigned as the Company's Executive Vice President of Medical Development and Chief Medical Officer and in April 2013, entered into a Separation and Consulting Agreement with the Company. Pursuant to the terms of Dr. Allen's retention agreement and Separation and Consulting Agreement, and assuming he complies with all his obligations under all agreements with us and signs a general release of claims in a form acceptable to us, we are obligated to provide the following:

- 12 months of the \$375,000 base salary he was earning upon his departure from the Company to be paid in accordance with the Company's normal payroll practices;
- Within 60 days after FDA approval of the sNDA for the broad IDA indication for *Feraheme*, Dr. Allen will receive a cash bonus equal to his actual fiscal year 2012 bonus, or \$210,000, provided such approval is obtained by March 31, 2014 and provided that he continues to serve at the time as a consultant of the Company;
- Payment or reimbursement for the premiums for continued health and dental benefits until the earlier of (i) six months from the date of employment termination, and (ii) the date Dr. Allen is provided with health and dental coverage by another employer's health and dental plan; and

- The Company engaged Dr. Allen as a consultant at an hourly rate until March 31, 2014 to provide services to the Company as defined in his Separation and Consulting Agreement. The Company may not terminate the consulting relationship other than for Cause, as defined in Dr. Allen's prior employment agreement. The number of consulting hours per week will be determined by the Company in its sole discretion. During such consulting period, Dr. Allen's equity incentives with the Company will continue to vest in accordance with the regular vesting schedules provided in his equity incentive agreements.

In July 2012, following the June restructuring and in order to ensure that Mr. Holmes remained motivated and incentivized going forward, the Compensation Committee awarded him a cash performance bonus for the period of January 1, 2012 to June 30, 2012, representing 35% of his 2012 annual target performance bonus. Mr. Holmes received the remaining portion of his bonus in March 2013.

February 2013 Equity Awards

In February 2013, as part of our annual performance review process, the Compensation Committee provided each of our current executive officers, including Mr. Heiden, with certain equity awards the size and structure of which reflected the overall performance of the Company and the individual performance of each of the executives. As discussed above, in October 2012, the Company retained Radford to evaluate our 2012 executive compensation program and to recommend changes in our compensation program for 2013. In February 2013, based on the recommendations from both Radford and Mr. Heiden, the Compensation Committee authorized the following equity awards to our named executive officers:

- A stock option grant to purchase the following number of shares of our common stock pursuant to our 2007 Plan at an exercise price of \$16.55, which was the fair market value of a share of our common stock on the date of grant. These grants have a ten-year term and vest over four years after the grant date as follows: (i) 25% on the first anniversary of the grant date and (ii) equal quarterly installments over the next three years thereafter.

<u>Name</u>	<u>Number of Shares</u>
William K. Heiden, President and Chief Executive Officer	86,300
Frank E. Thomas, Executive Vice President and Chief Operating Officer .	37,500
Scott A. Holmes, Vice President of Finance, Chief Accounting Officer and Treasurer	15,000
Scott B. Townsend, Senior Vice President of Legal Affairs, General Counsel and Secretary	26,300
Christopher G. White, Senior Vice President and Chief Business Officer .	30,000

- A time-based RSU grant covering the following number of shares of our common stock pursuant to our 2007 Plan which vest in equal annual installments over a four-year period beginning on the first anniversary of the date of grant.

<u>Name</u>	<u>Number of Shares</u>
William K. Heiden, President and Chief Executive Officer	14,400
Frank E. Thomas, Executive Vice President and Chief Operating Officer .	6,300
Scott A. Holmes, Vice President of Finance, Chief Accounting Officer and Treasurer	2,500
Scott B. Townsend, Senior Vice President of Legal Affairs, General Counsel and Secretary	4,400
Christopher G. White, Senior Vice President and Chief Business Officer .	5,000

- A performance-based RSU grant pursuant to our 2007 Plan which will vest, if at all, at the end of the three-year period ending December 31, 2015.

<u>Name</u>	<u>Achievement of Minimum Stock Price Range</u>	<u>Achievement of Target Stock Price Range</u>	<u>Achievement of Maximum Stock Price Range</u>
William K. Heiden, President and Chief Executive Officer	9,200	18,300	27,500
Frank E. Thomas, Executive Vice President and Chief Operating Officer	4,200	8,300	12,500
Scott A. Holmes, Vice President of Finance, Chief Accounting Officer and Treasurer	1,700	3,300	5,000
Scott B. Townsend, Senior Vice President of Legal Affairs, General Counsel and Secretary	2,500	5,000	7,500
Christopher G. White, Senior Vice President and Chief Business Officer	3,400	6,700	10,000

This is a new performance-based incentive program where the level of reward earned by our named executive officers will be determined at the end of a three year period based on the value created for our stockholders, as measured by the increase in our stock price. Based on recommendations by Radford, the Compensation Committee felt that this was the appropriate time to implement a program designed to provide our executive officers with the potential to earn additional equity awards subject to the Company creating shareholder value in a simple pay-for-performance structure. The program is structured to link the amount of earned rewards directly to increases in the price of our common stock over a three year period within a pre-determined bandwidth of opportunity under a three-tier construct (minimum, target, maximum). In addition, if the minimum stock price range is not achieved at the measurement date, the executive officers will not receive any equity award under this grant. This performance-based award is simple and straight-forward, provides an easily quantifiable incentive for management to create long-term shareholder value and includes an effective retention tool. Achievement of the target stock price shall be measured based upon the average closing price for the 90-calendar-day period ending on the last day of the performance period; provided that if there is a change of control prior to such date, all or a portion of such performance-based RSU awards may vest if the per-share consideration in the transaction equals or exceeds the minimum target price.

The Compensation Committee awarded the executive officers the first two of the foregoing equity awards because they were equal in aggregate value to the 50th percentile of the equity awards granted to similarly situated executives in our peer group, according to the 2012 Radford Report, which is consistent with our current executive compensation philosophy. In addition, the Compensation Committee awarded each of our executive officers the performance-based RSU grant as an opportunity to earn up to the 75th percentile of the equity awards granted to similarly situated executives in our peer group, according to the 2012 Radford Report. The Compensation Committee and the Board felt that it was important to ensure that each of our executive officers remains motivated and engaged and that his short- and long-term interests are aligned with those of our stockholders, including performance-based incentive equity compensation, consistent with our “pay-for-performance” executive compensation philosophy.

Chief Executive Officer Compensation

William K. Heiden, President and Chief Executive Officer

2012 Base Salary, Equity and Other Awards and Bonus Target. Mr. Heiden joined us as President and Chief Executive Officer in May 2012. After consultation with F.W. Cook and recommendations

from the Compensation Committee, the Board authorized the terms of Mr. Heiden's employment agreement as follows:

- Annual base salary of \$500,000.
- Annual bonus target at 75% of his base salary.
- Stock options to purchase 300,000 shares of our common stock at an exercise price equal to \$12.99 per share, which was the fair market value of a share of our common stock on the date of grant. These options were granted outside of the Company's 2007 Plan, vest in four annual equal installments beginning on the first anniversary of the date of grant, and have a ten-year term.
- RSUs covering 100,000 shares of our common stock. These RSUs were granted outside of the Company's 2007 Plan and vest in four annual equal installments beginning on the first anniversary of the date of grant.
- A signing bonus of \$75,000, to compensate Mr. Heiden for the bonus he had to forgo at his previous employer.
- Reimbursement of \$15,326 in legal expenses in connection with the negotiation and execution of Mr. Heiden's employment agreement, which included a \$5,326 tax "gross up" payment.

The terms of Mr. Heiden's employment agreement, including his 2012 base salary, 2012 bonus target amount and new hire equity and other awards were negotiated at arm's length between Mr. Heiden and the Company. Based on advice and consultation by F.W. Cook and the peer group provided to us by F.W. Cook as described above under "*Independent Compensation Consultants*," the members of the CEO Search Committee negotiated the proposed terms of his employment agreement directly with Mr. Heiden based on a base salary amount and a bonus target percentage that were competitive with similarly-situated chief executive officers in our peer group and a new hire equity award that amounted to approximately the 75th percentile for similarly-situated chief executive officers in the peer group. Mr. Heiden was also awarded a new hire equity award that was, by design, more heavily weighted with stock options (75%) versus restricted stock units (25%), which amounted to approximately the 75th percentile for similarly-situated chief executive officers in the peer group. After negotiating his 2012 compensation directly with Mr. Heiden, the Compensation Committee presented the proposed compensation package and employment agreement to the full Board, which approved the compensation package in May 2012.

2012 Bonus Amount. In February 2013, the Compensation Committee awarded Mr. Heiden a 2012 performance bonus in the amount of \$259,875, or 110% of his target bonus amount, pro-rated for his partial year of employment in 2012. As described above under "*Executive Compensation Decisions and Processes—2012 Performance Goals*," the Board awarded the Company a 2012 performance score of 1.1, or 110 out of a possible 100 points, and the Company's score is the only factor for determining the bonus of our chief executive officer. Accordingly, Mr. Heiden's 2012 bonus amount was determined by multiplying his target bonus amount of 75% of his 2012 base salary (\$500,000) by 1.1 and pro-rating this amount by the time he was employed by the Company in 2012.

2013 Base Salary. In February 2013, the Compensation Committee approved an increase to Mr. Heiden's annual base salary from \$500,000 to \$515,000, effective March 2013. The Compensation Committee based its recommendation in part on the 2012 Radford Report, which stated that Mr. Heiden's current base salary fell within the 50th percentile as compared to Radford's market compensation data. Accordingly, the Compensation Committee felt that a market-based adjustment was not necessary to Mr. Heiden's salary and therefore provided him with a 3% merit increase for 2013, which was in line with the 3% merit increase pool established for all other employees of the Company.

2013 Target Bonus. Mr. Heiden's 2013 target bonus, as a percentage of his annual base salary is 75%. This represents no change in Mr. Heiden's target performance bonus amount from 2012, which was established in his May 2012 employment agreement.

2013 Equity Award. In February 2013, the Compensation Committee awarded Mr. Heiden three equity awards pursuant to our 2007 Plan as described above under "*February 2013 Equity Awards.*"

Frank E. Thomas, Executive Vice President, Chief Operating Officer, and Former Interim President and Chief Executive Officer

2012 Base Salary. Mr. Thomas' 2012 annual base salary of \$415,000 was established in November 2011 when he assumed the position of Interim President and Chief Executive Officer upon the resignation of our former president and chief executive officer. At that time, the Board and Compensation Committee, with advice and input from F.W. Cook, increased Mr. Thomas' salary from \$350,000 to \$415,000 to compensate him for the significant increase in his responsibilities and to ensure that he was retained and motivated during a period of uncertainty for the Company. Due to the increase in Mr. Thomas' base salary at the end of 2011, there was no change made to his base salary in 2012.

2012 Equity Award. In January 2012, the Board approved, based on the recommendation of the Compensation Committee, an RSU grant to Mr. Thomas pursuant to our 2007 Plan covering a total of 40,000 shares of our common stock, which vests in three annual installments as follows: (i) 50% on the first anniversary of the grant date and (ii) 25% on each of the second and third anniversaries of the grant date. Further, if Mr. Thomas' business relationship with the Company is terminated by the Company, other than in connection with a change of control, without cause, or by Mr. Thomas for good reason, each as defined in Mr. Thomas' employment agreement with the Company, then the number of RSUs scheduled to vest on the next scheduled vesting date following such termination shall accelerate immediately upon such termination and any remaining unvested RSUs shall be forfeited.

2012 Retention Agreement. In May 2012, the Company entered into a retention agreement with Mr. Thomas which provided that if Mr. Thomas remained employed by the Company on September 15, 2012, the Company would pay him a one-time retention bonus of \$150,000. Mr. Thomas received \$150,000 as part of this retention agreement in September 2012.

2012 Bonus Amount. In February 2013, the Compensation Committee approved, based in part on the recommendations of both Mr. Heiden and the 2012 Radford Report, a 2012 performance bonus to Mr. Thomas in the amount of \$230,325, or 111% of his target bonus amount. As described above under "*Executive Compensation Decisions and Processes—2012 Performance Goals,*" the Board awarded the Company a 2012 performance score of 1.1, or 110 out of a possible 100 points, and this was weighted 80% towards his overall blended score. In addition, Mr. Heiden recommended an individual performance score of 1.15, or 115% of Mr. Thomas' target amount, for 2012 given his considerable efforts and exemplary leadership through a period of uncertainty as interim president and chief executive officer from November 2011 through May 2012, his critical role during the Company's evaluation of strategic alternatives, including a potential sale of the Company, and his significant contributions toward supporting the Company's achievement of all of its 2012 Company performance goals, and this was weighted 20% towards his overall blended score. Accordingly, Mr. Thomas' 2012 bonus amount was determined by multiplying his target bonus amount of 50% of his 2012 base salary (\$415,000) by 1.11.

2013 Base Salary. In February 2013, the Compensation Committee approved an increase in Mr. Thomas' base salary from \$415,000 to \$425,000, effective March 2013. The Compensation Committee based its recommendation, in part on the recommendation of Mr. Heiden and, in part, on the 2012 Radford Report, which stated that Mr. Thomas' current base salary fell within the 50th percentile as compared to Radford's market compensation data. Accordingly, the Compensation Committee felt that a market-based adjustment was not necessary to Mr. Thomas' salary and therefore provided him with a 3% merit increase for 2013, which was in line with the 3% merit increase pool established for all other employees of the Company.

2013 Target Bonus. Mr. Thomas' 2013 target bonus as a percentage of his annual base salary is 50%. This represents no change in Mr. Thomas' target performance bonus amount from 2012, which was established in his August 2011 employment agreement.

2013 Equity Award. In February 2013, based on the recommendations of both Mr. Heiden and the 2012 Radford Report, the Compensation Committee awarded Mr. Thomas three equity awards under our 2007 Plan, as described above under "*February 2013 Equity Awards.*"

Other Named Executive Officers' Compensation

Lee F. Allen, M.D., Ph.D., Former Executive Vice President of Medical Development and Chief Medical Officer

2012 Base Salary. Dr. Allen's 2012 annual base salary of \$375,000 was established in November 2011. At that time, the Compensation Committee, based primarily upon the recommendation of Mr. Thomas, approved an increase to Dr. Allen's annual base salary from \$350,000 to \$375,000. In making his recommendation to the Board, Mr. Thomas sought to ensure that Dr. Allen was retained and remained motivated during the impending period of uncertainty following our unsuccessful merger with Allos, our corporate restructuring in November 2011, our announcement that our Board had begun a search for a permanent chief executive officer, and our subsequent announcement that the Company was evaluating strategic alternatives, including a potential sale of the Company, particularly given the integral role that Dr. Allen was expected to play in the preparation and timely filing of the Company's sNDA in 2012 seeking approval for *Feraheme* for the treatment of IDA in a broader group of patients. Due to the increase in Dr. Allen's base salary at the end of 2011, there was no change made to his base salary in 2012.

2012 Equity Awards. In January 2012, the Board approved, based on the recommendations of both the Compensation Committee and Mr. Thomas, an RSU grant to Dr. Allen pursuant to our 2007 Plan covering a total of 20,000 shares of our common stock, which vests in three annual installments as follows: (i) 50% on the first anniversary of the grant date and (ii) 25% on each of the second and third anniversaries of the grant date. Further, if Dr. Allen's business relationship with the Company is terminated by the Company, other than in connection with a change of control, without cause, or by Dr. Allen for good reason, each as defined in Dr. Allen's former employment agreement with the Company, then the number of RSUs scheduled to vest on the next scheduled vesting date following such termination shall accelerate immediately upon such termination and any remaining unvested RSUs shall be forfeited.

In June 2012, the Compensation Committee, based in part on the recommendation of Mr. Heiden, approved a stock option award to Dr. Allen to purchase 40,000 shares of our common stock pursuant to our 2007 Plan at an exercise price of \$14.89, which was the fair market value of a share of our common stock on the date of grant. This grant has a seven-year term and vests over four years after the grant date as follows: (i) 25% on the first anniversary of the grant date and (ii) equal quarterly installments over the next three years thereafter. In addition, the terms of the award provide that 50% of the unvested portion of this option award would be accelerated in the event the Company filed its sNDA with the FDA by the end of 2012 and Dr. Allen remained employed with the Company as of the

filing date. The Company filed its sNDA in December 2012 and therefore, 50% of Dr. Allen's shares became exercisable at that time. Further, if the FDA approves the Company's sNDA by March 31, 2014 and at the time of approval Dr. Allen continues to be a service provider to the Company, then all shares subject to this option will become exercisable.

2012 Bonus Amount. In February 2013, the Board approved, based on the recommendations of both the Compensation Committee and Mr. Heiden, a 2012 performance bonus to Dr. Allen in the amount of \$210,000, or 112% of his target bonus amount. As described above under "*Executive Compensation Decisions and Processes—2012 Performance Goals*," the Board awarded the Company a 2012 performance score of 1.1, or 110 out of a possible 100 points, and this was weighted 80% towards his overall blended score. In addition, Mr. Heiden recommended an individual performance score of 1.2, or 120% of Dr. Allen's target amount, for 2012 given his significant contributions toward the Company's achievement of its 2012 Company performance goals, particularly with respect to the timely filing of the Company's sNDA for *Feraheme* for the treatment of IDA in a broad range of patients and the approval of *Feraheme* for the treatment of IDA in adult CKD patients in the European Union and Switzerland and this was weighted 20% towards his overall blended score. Accordingly, Dr. Allen's 2012 bonus amount was determined by multiplying his target bonus amount of 50% of his 2012 base salary (\$375,000) by 1.12.

2012 Retention Agreement. In August 2012, the Company entered into a retention agreement with Dr. Allen, the details of which are discussed above under "*Compensation Decisions Made Following our June 2012 Corporate Restructuring*," to ensure that Dr. Allen remained motivated due to the importance of his role throughout the sNDA filing process.

Separation and Consulting Agreement. In April 2013, in connection with his departure from the Company, and pursuant to the terms of his employment agreement with the Company and his August 2012 retention agreement, we entered into a Separation and Consulting Agreement with Dr. Allen. Pursuant to the terms of the Separation and Consulting Agreement, Dr. Allen is entitled to receive 12 months of the \$375,000 base salary he was earning upon his departure from the Company to be paid in accordance with the Company's normal payroll practices. Dr. Allen is also being paid or reimbursed for the premiums for continued health and dental benefits until the earlier of (i) six months from the date of employment termination and (ii) the date Dr. Allen is provided with health and dental coverage by another employer's health and dental plan. In addition, we will engage Dr. Allen as a consultant until at least March 31, 2014 at an hourly rate to provide services to the Company related to the Company's *Feraheme/Rienso* regulatory filings. Further, under the terms of the Separation and Consulting Agreement, all equity awards held by Dr. Allen as of his date of termination will continue to vest in accordance with their original vesting schedules until such time as he is no longer serving as a consultant to the Company, at which time the vesting of his equity awards will cease. Dr. Allen will also receive a cash bonus equal to his 2012 actual cash bonus, or \$210,000, within sixty days after the FDA approval of the sNDA for the broad IDA indication for *Feraheme*, provided such approval is obtained by March 31, 2014.

Scott A. Holmes, Vice President of Finance, Chief Accounting Officer and Treasurer

2012 Base Salary. In March 2012, Mr. Holmes became a named executive officer when he was appointed the Company's principal financial officer. At that time, as part of our annual performance review process, Mr. Holmes' received a merit increase to his annual base salary from \$225,000 to \$233,000, effective March 2012.

2012 Equity Award. In June 2012, the Compensation Committee approved, based in part on the recommendation of Mr. Heiden, a stock option award to Mr. Holmes to purchase 30,000 shares of our common stock pursuant to our 2007 Plan at an exercise price of \$14.89, which was the fair market value of a share of our common stock on the date of grant. This grant has a seven-year term and vests

over four years after the grant date as follows: (i) 25% on the first anniversary of the grant date and (ii) equal quarterly installments over the next three years thereafter.

2012 Bonus Amount. In February 2013, the Compensation Committee approved, based in part on the recommendations of Mr. Heiden, Mr. Thomas and the 2012 Radford Report, a total 2012 performance bonus to Mr. Holmes in the amount of \$88,482, or 109% of his target bonus amount. In light of the June 2012 corporate restructuring and in an attempt to retain the remaining employees, in July 2012, the Compensation Committee approved a 35% payment of Mr. Holmes' 2012 annual target performance bonus, in the amount of \$28,543. Mr. Holmes received \$59,939, the remainder of his 2012 bonus amount, in March 2013. As described above under "*Executive Compensation Decisions and Processes—2012 Performance Goals*," the Board awarded the Company a 2012 performance score of 1.1, or 110 out of a possible 100 points, and this was weighted 70% towards his overall blended score. In addition, Mr. Heiden recommended an individual performance score of 1.05, or 105% of Mr. Holmes' target amount, for 2012 given his significant contributions toward ensuring that the Company's operating expenses and cash balances were in line with the 2012 budget, managing the Company's overall finance, accounting and reporting functions, ensuring a strong internal control environment and managing the relationship with the Company's audit and tax advisors, and this was weighted 30% toward his overall blended score. Accordingly, Mr. Holmes' 2012 bonus amount was determined by multiplying his target bonus amount of 35% of his 2012 base salary (\$233,000) by approximately 1.09.

2011 Retention Agreement. In December 2011, the Company entered into a retention agreement with Mr. Holmes following its November 2011 corporate restructuring in order to recognize Mr. Holmes for his hard work through a difficult period as well as motivate and retain him in order to help the Company realize its potential. Pursuant to the terms of Mr. Holmes' retention agreement, in each of July 2012 and January 2013, Mr. Holmes received a payment of \$18,750, for a total of \$37,500, based on the satisfaction of the goals stated in his retention agreement that the Company achieve or beat its aggregate operating expense target as set forth in the 2012 Company operating budget for each of the six and twelve month periods ending June 30, 2012 and December 31, 2012, respectively.

2013 Base Salary. In February 2013, the Compensation Committee approved an increase in Mr. Holmes' base salary from \$233,000 to \$240,000, effective March 2013. The Compensation Committee based its recommendation, in part on the recommendation of Mr. Heiden and, in part, on the 2012 Radford Report, which stated that Mr. Holmes' current base salary fell within the 50th percentile as compared to Radford's market compensation data. Accordingly, the Compensation Committee felt that a market-based adjustment was not necessary to Mr. Holmes' salary and therefore provided him with a 3% merit increase for 2013, which was in line with the 3% merit increase pool established for all other employees of the Company.

2013 Target Bonus. Mr. Holmes' 2013 target bonus as a percentage of his annual base salary is 35%, which is unchanged from his 2012 target performance bonus amount, which was established in his offer letter upon his hiring in September 2011.

2013 Equity Award. In February 2013, based on the recommendations of both Mr. Heiden and the 2012 Radford Report, the Compensation Committee awarded Mr. Holmes three equity awards under our 2007 Plan, as described above under "*February 2013 Equity Awards*."

Scott B. Townsend, Senior Vice President of Legal Affairs, General Counsel and Secretary

2012 Base Salary, Equity Award and Bonus Target. Mr. Townsend joined us as Senior Vice President of Legal Affairs, General Counsel and Secretary in August 2012. Upon joining the Company, Mr. Townsend entered into an employment agreement with us which established his annual salary at \$315,000 and his annual bonus target at 40% of his base salary. In addition, in connection with joining the Company, the Board, based on the recommendation of the Compensation Committee, granted Mr. Townsend an option to purchase 52,500 shares of our common stock at an exercise price equal to

\$14.99 per share, which was the fair market value of a share of our common stock on the date of grant, and RSUs covering a total of 17,500 shares of our common stock. The foregoing stock options and RSUs vest in four annual equal installments beginning on the first anniversary of the date of grant, and the stock options have a ten-year term. In addition, we paid Mr. Townsend a signing bonus of \$45,000.

The terms of Mr. Townsend's employment agreement, including his 2012 base salary, 2012 bonus target amount and new hire equity awards were negotiated at arm's length between Mr. Townsend and the Company. Based on advice and consultation by F.W. Cook and Radford and using the peer group provided to us by F.W. Cook as described above under "*Independent Compensation Consultants*," Mr. Heiden and Mr. Thomas proposed to Mr. Townsend a base salary amount and a bonus target percentage such that Mr. Townsend's total target annual cash compensation amounted to approximately the median for similarly-situated executives in the peer group and his new hire equity awards fell between the median and the 75th percentile for similarly-situated executives in the peer group. After negotiating his 2012 compensation directly with Mr. Townsend, Mr. Heiden and Mr. Thomas presented the agreed-upon compensation package and employment agreement to the full Board, which approved the compensation package and employment agreement.

2012 Bonus Amount. In February 2013, the Compensation Committee approved, based in part on the recommendations of Mr. Heiden, Mr. Thomas and the 2012 Radford Report, a 2012 performance bonus to Mr. Townsend in the amount of \$52,668, or 110% of his target bonus amount, pro-rated for his partial year of employment in 2012. As described above under "*Executive Compensation Decisions and Processes—2012 Performance Goals*," the Board awarded the Company a 2012 performance score of 1.1, or 110 out of a possible 100 points, and this was weighted 80% towards his overall blended score. In addition, Mr. Heiden recommended an individual performance score of 1.1, or 110% of Mr. Townsend's target amount, for 2012 given his significant contributions toward managing the Company's intellectual property portfolio in the U.S. and Europe, implementing corporate governance and healthcare compliance policies to comply with applicable laws and regulations, advising the Company and the Board on legal matters and providing legal advice on contracts and potential business development transactions, and this was weighted 20% towards his overall blended score. Accordingly, Mr. Townsend's 2012 bonus amount was determined by multiplying his target bonus amount of 40% of his 2012 base salary (\$315,000) by 1.1 and pro-rating this amount by the time he was employed by the Company in 2012.

2013 Base Salary. In February 2013, the Compensation Committee approved an increase in Mr. Townsend's base salary from \$315,000 to \$324,000, effective March 2013. The Compensation Committee based its recommendation, in part on the recommendation of Mr. Heiden and, in part, on the 2012 Radford Report, which stated that Mr. Townsend's current base salary fell within the 50th percentile as compared to Radford's market compensation data. Accordingly, the Compensation Committee felt that a market-based adjustment was not necessary to Mr. Townsend's salary and therefore provided him with a 3% merit increase for 2013, which was in line with the 3% merit increase pool established for all other employees of the Company.

2013 Target Bonus. Mr. Townsend's 2013 target bonus amount as a percentage of his annual base salary is 40%, which is unchanged from his 2012 target performance bonus amount, which was established in his August 2012 employment agreement.

2013 Equity Award. In February 2013, based on the recommendations of both Mr. Heiden and the 2012 Radford Report, the Compensation Committee awarded Mr. Townsend three equity awards under our 2007 Plan, as described above under "*February 2013 Equity Awards*."

Christopher G. White, Senior Vice President and Chief Business Officer

2012 Base Salary. Mr. White's 2012 annual base salary of \$320,000 was established in November 2011 when the Compensation Committee, based primarily upon the recommendation of Mr. Thomas,

approved an increase to Mr. White's base salary from \$290,000 to \$320,000. In making his recommendation to the Board, Mr. Thomas sought to ensure that Mr. White was retained and remained motivated during the impending period of uncertainty following our unsuccessful merger with Allos, our corporate restructuring in November 2011, our announcement that our Board had begun a search for a permanent chief executive officer, and our subsequent announcement that we had retained Jefferies to assist us in evaluating strategic alternatives, including a potential sale of the Company, particularly given the integral role that Mr. White was expected to play in the timely and successful execution of the Company's evaluation of strategic alternatives and the increased responsibilities Mr. White was being asked to assume in connection with his promotion to Chief Business Officer.

2012 Equity Awards. In January 2012, the Board approved, based on the recommendations of both Mr. Thomas and the Compensation Committee, an RSU grant to Mr. White pursuant to our 2007 Plan covering a total of 20,000 shares of our common stock, which vests in three annual installments as follows: (i) 50% on the first anniversary of the grant date and (ii) 25% on each of the second and third anniversaries of the grant date. Further, if Mr. White's business relationship with the Company is terminated by the Company, other than in connection with a change of control, without cause, or by Mr. White for good reason, each as defined in Mr. White's employment agreement with the Company, then the number of RSUs scheduled to vest on the next scheduled vesting date following such termination shall accelerate immediately upon such termination and any remaining unvested RSUs shall be forfeited.

In June 2012, the Compensation Committee, based in part on the recommendation of Mr. Heiden, granted a stock option award to Mr. White to purchase 40,000 shares of our common stock pursuant to our 2007 Plan at an exercise price of \$14.89, which was the fair market value of a share of our common stock on the date of grant. This grant has a seven-year term and vests over four years after the grant date as follows: (i) 25% on the first anniversary of the grant date and (ii) equal quarterly installments over the next three years thereafter. However, 50% of the unvested portion of this option award will be accelerated in the event the Company acquires an FDA-approved product that has generated at least \$10 million in revenue during the 12 month period preceding the acquisition, provided Mr. White continues to have primary responsibility over the Company's business development function at the time of such transaction. Further, in the event that after the above transaction has closed, the Company acquires a second product in a transaction that would be required to be reported to the SEC as a "material contract" or is otherwise deemed by the Board to be of material importance to the Company's growth strategy, then the balance of this option will become exercisable, provided Mr. White continues to have primary responsibility over the Company's business development function at the time of such transaction.

2012 Bonus Amount. In February 2013, the Compensation Committee approved, based in part on the recommendations of both Mr. Heiden and the 2012 Radford Report, a 2012 performance bonus to Mr. White in the amount of \$139,520, or 109% of his target bonus amount. As described above under "*Executive Compensation Decisions and Processes—2012 Performance Goals*," the Board awarded the Company a 2012 performance score of 1.1, or 110 out of a possible 100 points, and this was weighted 80% toward his overall blended score. In addition, Mr. Heiden recommended an individual performance score of 1.05, or 105% of Mr. White's target amount, for 2012 given his prominent role in the Company's evaluation of strategic alternatives, including a potential sale of the Company, his leadership in negotiating an amended agreement with our licensee, Takeda, his successful efforts in connection with the termination of commercial license agreements for *GastroMARK*, which enabled the Company to close down its manufacturing facilities and move toward an outsourced manufacturing supply chain, and his significant contributions toward supporting the achievement of all of the 2012 Company performance goals, and this was weighted 20% towards his overall blended score. Accordingly, Mr. White's 2012 bonus amount was determined by multiplying his target bonus amount of 40% of his 2012 base salary (\$320,000) by 1.09.

2013 Base Salary. In February 2013, the Compensation Committee approved an increase in Mr. White's base salary from \$320,000 to \$330,000, effective March 2013. The Compensation Committee based its recommendation, in part on the recommendation of Mr. Heiden and, in part, on the 2012 Radford Report, which stated that Mr. White's current base salary fell within the 50th percentile as compared to Radford's market compensation data. Accordingly, the Compensation Committee felt that a market-based adjustment was not necessary to Mr. White's salary and therefore provided him with a 3% merit increase for 2013, which was in line with the 3% merit increase pool established for all other employees of the Company.

2013 Target Bonus. Mr. White's 2013 target bonus as a percentage of his annual base salary is 40%. This represents no change in Mr. White's target performance bonus amount from 2012, which was established by the Board in January 2011.

2013 Equity Award. In February 2013, based on the recommendations of both Mr. Heiden and the 2012 Radford Report, the Compensation Committee awarded Mr. White three equity awards under our 2007 Plan, as described above, under "*February 2013 Equity Awards.*"

Compensation Committee Report²

The Compensation Committee has reviewed the "*Compensation Discussion and Analysis*" section of this Proxy Statement and discussed such section with management. Based on its review and discussions and its ongoing involvement with executive compensation matters, the Compensation Committee recommended to the Board that the "*Compensation Discussion and Analysis*" section of this Proxy Statement be included in this Proxy Statement and incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2012. This report is provided by the following independent directors who comprise the Compensation Committee:

Gino Santini, Chair
Robert J. Perez
Michael Narachi

² The material in this report is not "soliciting material," is furnished to, but not deemed "filed" with, the SEC and is not deemed to be incorporated by reference in any filing of the Company under the Exchange Act, other than the Company's Annual Report on Form 10-K, where it shall be deemed to be "furnished," whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

REGULATORY REQUIREMENTS

Tax Deductibility of Executive Compensation

Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code, prohibits us from deducting compensation paid in any year to certain executives in excess of \$1 million but does not subject performance-based compensation to this limit. While our Board intends to design certain components of executive compensation to preserve deductibility under Section 162(m) of the Code, it believes that stockholder interests are best served by not restricting our Board's or the Compensation Committee's discretion and flexibility in crafting compensation programs, even though such programs may result in certain non-deductible compensation expenses. Accordingly, our Board and the Compensation Committee have from time to time approved, and our Board or the Compensation Committee may in the future approve, compensation arrangements for certain officers, including the grant of equity-based awards, that may not be fully deductible for federal corporate income tax purposes.

Other Regulations Affecting Executive Compensation

We generally intend to structure post-termination compensation to our executive officers to minimize the effect of additional taxes imposed by Section 409A of the Code.

SUMMARY COMPENSATION TABLE FOR FISCAL 2012

The following table sets forth for the fiscal years ended December 31, 2012, 2011 and 2010 compensation awarded, paid to, or earned by, our current President and Chief Executive Officer, our former Interim President and Chief Executive Officer, our principal financial officer and three other most highly compensated executive officers at December 31, 2012, or our named executive officers:

Name and Principal Position	Year	Salary (\$)(1)	Bonus (\$)	Stock Awards (\$)(2)	Option Awards (\$)(2)	Non-Equity Incentive Plan Compensation (\$)(3)	All Other Compensation (\$)(4)	Total (\$)
William K. Heiden(5) President and Chief Executive Officer	2012	307,692	75,000(6)	1,299,000	1,892,430	259,875	22,826(7)	3,856,823
Frank E. Thomas(8) Executive Vice President and Chief Operating Officer, Former Interim President and Chief Executive Officer	2012	503,308(9)	150,000(10)	749,600	—	230,325	7,500	1,640,733
	2011	190,346(9)	—	654,200	423,018	82,800	5,710	1,356,074
Scott A. Holmes(11) Vice President of Finance, Chief Accounting Officer and Treasurer	2012	231,769	37,500(12)	—	209,646	88,482	7,500	574,897
Lee F. Allen, M.D., Ph.D.(13) Former Executive Vice President of Medical Development and Chief Medical Officer	2012	375,000	—	374,800	279,528	210,000	7,500	1,246,828
	2011	353,462	—	502,150	—	178,200	7,350	1,041,162
	2010	346,923	—	207,417	335,197	—	7,350	896,887
Scott B. Townsend(14) Senior Vice President of Legal Affairs, General Counsel and Secretary	2012	112,673	45,000(15)	262,325	382,888	52,668	4,730	860,284
Christopher G. White(16) Senior Vice President and Chief Business Officer	2012	320,000	—	374,800	279,528	139,520	7,500	1,121,348
	2011	294,154	—	329,720	—	121,600	7,350	752,824

- (1) Amounts shown represent base salary amounts earned by our named executive officers in fiscal years 2012, 2011 and 2010. Salary increases generally occur once each year and are not retroactive to the beginning of that year. For this reason, the amount earned by the named executive officer in a given fiscal year may be lower than such officer's base salary rate for the year.
- (2) The amounts shown do not reflect compensation actually received by the named executive officers but represent the aggregate grant date fair value of stock options or RSUs granted to our named executive officers and are calculated in accordance with current guidance under accounting for stock-based compensation, disregarding adjustments for the forfeiture assumptions. The assumptions used to value the stock option awards for all periods presented above are set forth in Note I to our Annual Report on Form 10-K for the year ended December 31, 2012 filed with the SEC on March 4, 2013. The reported value of the RSUs awarded in 2012 was calculated by multiplying the closing market price of a share of our common stock on the grant date by the number of RSUs granted. Further information regarding the 2012 awards is included in the "Grants of Plan-Based Awards in Fiscal 2012" and "Outstanding Equity Awards at December 31, 2012" tables below.
- (3) Amounts shown represent cash bonus awards earned by the named executive officers under our short-term incentive plan for performance during the years ended December 31, 2012, 2011 and 2010, which, with the exception of Mr. Holmes' 2012 bonus award, were generally paid in the first quarter of the respective following year. Mr. Holmes received 35% of his 2012 annual target performance bonus in July 2012 and the remainder in March 2013.
- (4) Unless otherwise specified, amounts shown represent Company 401(k) contributions for the applicable named executive officer.

- (5) Mr. Heiden joined us in May 2012. Because Mr. Heiden was not one of our named executive officers prior to 2012, compensation information is not provided for 2011 or 2010. Mr. Heiden's salary and bonus payment reflect a pro-rated amount for the time he was employed by the Company in 2012.
- (6) Represents a one-time \$75,000 signing bonus to Mr. Heiden paid in 2012 in accordance with the terms of his May 2012 employment agreement.
- (7) Includes \$15,326 paid to Mr. Heiden for certain legal expenses in connection with the negotiation and execution of and in accordance with his May 2012 employment agreement. Included in the \$15,326 is a \$5,326 tax gross-up payment.
- (8) Mr. Thomas joined us in August 2011. Because Mr. Thomas was not one of our named executive officers prior to 2011, compensation information is not provided for 2010. Mr. Thomas' salary and bonus payment reflect a pro-rated amount for the time he was employed by the Company in 2011.
- (9) In November 2011, the Board increased Mr. Thomas' annual salary from \$350,000 to \$415,000 when he became Executive Vice President and Chief Operating Officer. In addition, the Board awarded Mr. Thomas with a monthly supplemental cash payment of \$20,000 to be paid to Mr. Thomas for the period he served as Interim President and Chief Executive Officer and which was paid to Mr. Thomas from November 2011 through May 2012.
- (10) Reflects a \$150,000 retention bonus paid to Mr. Thomas in September 2012 pursuant to the terms of his May 2012 retention agreement with the Company.
- (11) Mr. Holmes joined us in September 2011 and became our Principal Financial Officer and Treasurer in March 2012. Because Mr. Holmes was not one of our named executive officers prior to 2012, compensation information is not provided for 2011 or 2010.
- (12) Reflects two payments of \$18,750 each for retention bonuses paid to Mr. Holmes in July 2012 and January 2013, pursuant to the terms of his December 2011 retention agreement with the Company and in exchange for certain performance-based metrics and his continued employment with the Company through June 30, 2012 and December 31, 2012.
- (13) Dr. Allen resigned from his position as an officer of the Company in March 2013.
- (14) Mr. Townsend joined us in August 2012. Because Mr. Townsend was not one of our named executive officers prior to 2012, compensation information is not provided for 2011 or 2010. Mr. Townsend's salary and bonus payment reflect a pro-rated amount for the time he was employed by the Company in 2012.
- (15) Represents a one-time \$45,000 signing bonus paid to Mr. Townsend in 2012 in accordance with the terms of his August 2012 employment agreement.
- (16) Mr. White joined us in September 2007. Because Mr. White was not one of our named executive officers prior to 2011, compensation information is not provided for 2010.

GRANTS OF PLAN-BASED AWARDS IN FISCAL 2012

The following table sets forth grants of plan-based awards to each of our named executive officers for the year ended December 31, 2012:

Name	Grant Date	Grant Type	Estimated Possible Payouts Under Non-Equity Incentive Plan Awards		Estimated Possible Payouts Under Equity Incentive Plan Awards	All Other Stock Awards: Number of Shares of Stock or Units (#)(2)	All Other Option Awards: Number of Securities Underlying Options (#)(2)	Exercise or Base Price of Option Awards (\$)	Grant Date Fair Value of Stock and Option Awards (\$)(3)
			Target (\$)(1)	Maximum (\$)(1)	Target (#)(2)				
William K. Heiden		Incentive Plan	375,000	562,500	—	—	—	—	—
	5/14/2012	RSUs(4)	—	—	—	100,000	—	—	1,299,000
	5/14/2012	Stock Options(5)	—	—	—	—	300,000	12.99	1,892,430
Frank E. Thomas		Incentive Plan	207,500	311,250	—	—	—	—	—
	1/3/2012	RSUs(6)	—	—	—	40,000	—	—	749,600
Scott A. Holmes		Incentive Plan	81,550	122,325	—	—	—	—	—
	6/25/2012	Stock Options(7)	—	—	—	—	30,000	14.89	209,646
Lee F. Allen, M.D., Ph.D.		Incentive Plan	187,500	281,250	—	—	—	—	—
	1/3/2012	RSUs(6)	—	—	—	20,000	—	—	374,800
	6/25/2012	Stock Options(8)	—	—	40,000	—	—	14.89	279,528
Scott B. Townsend		Incentive Plan	126,000	189,000	—	—	—	—	—
	8/15/2012	RSUs(9)	—	—	—	17,500	—	—	262,325
	8/15/2012	Stock Options(10)	—	—	—	—	52,500	14.99	382,888
Christopher G. White		Incentive Plan	128,000	192,000	—	—	—	—	—
	1/3/2012	RSUs(6)	—	—	—	20,000	—	—	374,800
	6/25/2012	Stock Options(11)	—	—	40,000	—	—	14.89	279,528

- (1) The amounts reported in these columns represent the 2012 targeted and maximum cash incentive compensation award potential for each named executive officer. The target bonus amounts for each of the named executive officers, other than Dr. Allen and Mr. Holmes, were established as a percentage of their respective base salaries in the employment agreements each negotiated at arm's length with the Company. Dr. Allen's target bonus as a percentage of his salary was established by the Board in January 2011. Mr. Holmes' target bonus as a percentage of his salary was established upon commencement of his employment with the Company in September 2011. Both Messrs. Heiden and Townsend received pro-rated amounts based on the time they were employed by the Company in 2012. Although the Board and the Compensation Committee do not establish maximum bonus amounts, the Board and the Compensation Committee have never approved payment of more than 150% of any executive officer's target bonus amount. Accordingly, for purposes of this table, we have assumed that the maximum bonus amount payable to any named executive officer is equal to 150% of his target bonus amount. In addition, the Board and the Compensation Committee do not establish threshold bonus amounts.
- (2) Amounts shown represent the number of shares underlying options and RSUs granted under our 2007 Plan, or in the case of Mr. Heiden outside of our 2007 Plan, to our named executive officers during the year ended December 31, 2012. There are no thresholds or maximums associated with these awards.
- (3) Amounts shown represent the aggregate grant date fair value calculated in accordance with current guidance under accounting for stock-based compensation, disregarding adjustments for forfeitures. The assumptions used to value the stock option awards are set forth in Note I to our Annual Report on Form 10-K for the year ended December 31, 2012 filed with the SEC on March 4, 2013. The reported value of the RSUs awarded in 2012 was calculated by multiplying the closing market price of a share of our common stock on the grant date by the number of RSUs granted. The fair value shown above may not be indicative of the value realized on the date the options are exercised or the RSUs vest due to variability in the share price of our common stock.
- (4) The RSUs granted to Mr. Heiden vest in four equal annual installments beginning on the first anniversary of the grant date. These RSUs were granted to Mr. Heiden as an employment inducement award in connection with the commencement of Mr. Heiden's employment as President and Chief Executive Officer. This grant was made in reliance on NASDAQ Listing Rule 5635(c)(4).
- (5) The exercise price of Mr. Heiden's stock option award is the fair market value of a share of our common stock on the date of grant. This stock option has a ten-year term and vests in four equal annual installments beginning on the first anniversary of the grant date. These stock options were granted to Mr. Heiden as an employment inducement award in connection with the commencement of his employment as President and Chief Executive Officer. This grant was made in reliance on NASDAQ Listing Rule 5635(c)(4).
- (6) These RSU grants vest in three annual installments as follows: (i) 50% on the first anniversary of the grant date and (ii) 25% on each of the second and third anniversaries of the grant date. In addition, if the executive officer's business relationship with the Company is terminated by the Company, other than in connection with a change of control, without cause, or by the executive for good reason, each as defined in his employment agreement with the Company, then the number of RSUs scheduled to vest on the next scheduled vesting date following such termination shall accelerate immediately upon such termination and any remaining unvested RSUs shall be forfeited.

- (7) The exercise price of Mr. Holmes' stock option award is the fair market value of a share of our common stock on the date of grant. This stock option has a seven-year term and vests over four years after the grant date as follows: (i) 25% on the first anniversary of the grant date and (ii) equal quarterly installments over the next three years thereafter.
- (8) The exercise price of Dr. Allen's stock option award is the fair market value of a share of our common stock on the date of grant. This stock option has a seven-year term and vests over four years after the grant date as follows: (i) 25% on the first anniversary of the grant date and (ii) equal quarterly installments over the next three years thereafter. In addition, the terms of the option award provide for the accelerated vesting of 50% of the number of shares subject to the option that then remained unexercisable in the event that our sNDA for the broad IDA indication for *Feraheme* was filed with the FDA by the end of 2012 and Dr. Allen remained employed by the Company as of the filing date. The Company filed its sNDA in December 2012 and therefore, 50% of Dr. Allen's shares became exercisable at that time. Further, in the event that (i) FDA approval of the sNDA for the broad IDA indication for *Feraheme* is obtained by March 31, 2014 and (ii) at the time of FDA approval, Dr. Allen continues to be a service provider to the Company providing services with respect to the sNDA filing for the broad IDA indication for *Feraheme*, then all shares subject to the option that then remain unexercisable shall become exercisable.
- (9) The RSUs granted to Mr. Townsend vest in four equal annual installments beginning on the first anniversary of the grant date.
- (10) The exercise price of Mr. Townsend's stock option award is the fair market value of a share of our common stock on the date of grant. This stock option has a ten-year term and will vest in four equal annual installments beginning on the first anniversary of the grant date.
- (11) The exercise price of Mr. White's stock option award is the fair market value of a share of our common stock on the date of grant. This stock option has a seven-year term and vests over four years after the grant date as follows: (i) 25% on the first anniversary of the grant date and (ii) equal quarterly installments over the next three years thereafter. In addition, 50% of the unvested portion of this option award will be accelerated in the event the Company acquires an FDA-approved product that has generated at least \$10 million in revenue during the 12 month period preceding the acquisition, provided Mr. White continues to have primary responsibility over the Company's business development function at the time of such transaction. Further, in the event that after the above transaction has closed, the Company acquires a second product in a transaction that would be required to be reported to the SEC as a "material contract" or is otherwise deemed by the Board to be of material importance to the Company's growth strategy, then the remaining shares subject to this option will become exercisable, provided Mr. White continues to have primary responsibility over the Company's business development function at the time of such transaction.

OUTSTANDING EQUITY AWARDS AT DECEMBER 31, 2012

The following table sets forth certain information regarding outstanding equity awards held by each of our named executive officers at December 31, 2012:

Name	Grant Date	Option Awards(1)				Stock Awards(1)			
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)(1)	Option Expiration Date(1)	Number of Shares or Units of Stock That Have Not Vested (#)(2)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(3)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)(2)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$)(3)
William K. Heiden	5/14/2012	—	300,000(4)	12.99	5/14/2022	—	—	—	—
	5/14/2012	—	—	—	—	100,000(4)	1,471,000(4)	—	—
Frank E. Thomas	8/1/2011	15,000	45,000	14.91	8/1/2021	—	—	—	—
	8/1/2011	—	—	—	—	15,000	220,650	—	—
	11/30/2011	—	—	—	—	10,000(5)	147,100(5)	—	—
	1/3/2012	—	—	—	—	40,000(6)	588,400(6)	—	—
Scott A. Holmes	9/12/2011	1,250	3,750	14.38	9/12/2021	—	—	—	—
	9/12/2011	—	—	—	—	2,250	33,098	—	—
	12/5/2011	—	—	—	—	2,500(7)	36,775(7)	—	—
	6/25/2012	—	30,000(8)	14.89	6/25/2019	—	—	—	—
Lee F. Allen, M.D., Ph.D.	8/6/2007	50,000	—	52.17	8/6/2017	—	—	—	—
	2/26/2008	20,000	—	47.08	2/26/2018	—	—	—	—
	2/25/2009	22,500	7,500	34.26	2/25/2019	—	—	—	—
	2/24/2010	8,125	8,125	38.29	2/24/2020	—	—	—	—
	2/24/2010	—	—	—	—	2,709	39,849	—	—
	1/7/2011	—	—	—	—	12,500(9)	183,875(9)	—	—
	1/7/2011	—	—	—	—	—	—	5,000(10)	73,550(10)
	1/3/2012	—	—	—	—	20,000(6)	294,200(6)	—	—
	6/25/2012	20,000(11)	20,000(11)	14.89	6/25/2019	—	—	—	—
	8/15/2012	—	52,500	14.99	8/15/2022	—	—	—	—
Scott B. Townsend	8/15/2012	—	—	—	—	17,500	257,425	—	—
	8/15/2012	—	—	—	—	—	—	—	—
Christopher G. White	9/4/2007	15,000	—	54.66	9/4/2017	—	—	—	—
	2/26/2008	14,000	—	47.08	2/26/2018	—	—	—	—
	2/25/2009	15,000	5,000	34.26	2/25/2019	—	—	—	—
	2/24/2010	5,000	5,000	38.29	2/24/2020	—	—	—	—
	2/24/2010	—	—	—	—	1,667	24,522	—	—
	1/7/2011	—	—	—	—	8,000(9)	117,680(9)	—	—
	1/7/2011	—	—	—	—	—	—	4,000(10)	58,840(10)
	1/3/2012	—	—	—	—	20,000(6)	294,200(6)	—	—
	6/25/2012	—	40,000(12)	14.89	6/25/2019	—	—	—	—

- (1) The exercise price for all stock option awards set forth in this table is the fair market value of a share of our common stock on the date of grant. Unless otherwise specified, all option and RSU awards were granted under our Amended and Restated 2000 Stock Plan or our 2007 Plan and vest in equal annual installments over a four-year period beginning on the first anniversary of the grant date, and options have a ten-year term.
- (2) The grant of an RSU entitles the recipient to receive one share of our common stock for each RSU granted.
- (3) The market value of stock and equity incentive plan awards of stock is calculated by multiplying the closing price of a share of our common stock of \$14.71 as reported on the NASDAQ on December 31, 2012, the last trading day of 2012, by the number of shares or units of stock or the amount of equity incentive plan awards.
- (4) In May 2012, pursuant to his employment agreement entered into upon joining the Company, Mr. Heiden was granted an option to purchase 300,000 shares of the Company's common stock. In addition, Mr. Heiden was granted 100,000 RSUs. These grants were both issued outside of our 2007 Plan pursuant to the inducement grant exception set forth in NASDAQ Listing Rule 5635(c)(4).

- (5) On November 30, 2011, Mr. Thomas was granted 20,000 RSUs which vests in three annual installments as follows: (i) 50% on the first anniversary of the grant date and (ii) 25% on each of the second and third anniversaries of the grant date. Further, if Mr. Thomas' employment is terminated by the Company, other than in connection with a change of control, without cause, or by Mr. Thomas for good reason, each as defined in Mr. Thomas' employment agreement with the Company, then the number of RSUs scheduled to vest on the next scheduled vesting date following such termination shall accelerate immediately upon such termination and any remaining unvested RSUs shall be forfeited.
- (6) On January 3, 2012, all of our then serving executive officers were granted RSUs which vest in three annual installments as follows: (i) 50% on the first anniversary of the grant date and (ii) 25% on each of the second and third anniversaries of the grant date. Further, if the executive's employment is terminated by the Company, other than in connection with a change of control, without cause, or by the executive for good reason, each as defined in executive's employment agreement with the Company, then the number of RSUs scheduled to vest on the next scheduled vesting date following such termination shall accelerate immediately upon such termination and any remaining unvested RSUs shall be forfeited.
- (7) On December 5, 2011, Mr. Holmes was granted 5,000 RSUs which vests in three annual installments as follows: (i) 50% on the first anniversary of the grant date and (ii) 25% on each of the second and third anniversaries of the grant date. Further, if Mr. Holmes' employment is terminated by the Company, other than for death, disability or cause, then the number of RSUs scheduled to vest on the next scheduled vesting date following such termination shall accelerate immediately upon such termination and any remaining unvested RSUs shall be forfeited.
- (8) On June 25, 2012, Mr. Holmes was granted an option to purchase 30,000 shares of our common stock. This option has a seven-year term and vests over four years after the grant date as follows: (i) 25% on the first anniversary of the grant date and (ii) equal quarterly installments over the next three years thereafter.
- (9) On January 7, 2011, all of our then serving executive officers, including Dr. Allen and Mr. White, were granted RSUs which vest in three annual installments as follows: (i) 50% on the first anniversary of the grant date and (ii) 25% on each of the second and third anniversaries of the grant date.
- (10) On January 7, 2011, all of our then serving executive officers, including Dr. Allen and Mr. White, were granted RSUs which vest in a single installment on the earlier of (i) the fourth anniversary of the date of grant and (ii) immediately prior to a change of control of the Company, provided, that in either case the closing price of a share of the Company's common stock is at least \$30.00 per share.
- (11) On June 25, 2012, Dr. Allen was granted an option to purchase 40,000 shares of our common stock. The option has a seven-year term and vests over four years after the grant date as follows: (i) 25% on the first anniversary of the grant date and (ii) equal quarterly installments over the next three years thereafter. In addition, the terms of the option award provided for the accelerated vesting of 50% of the number of shares subject to the option that then remained unexercisable in the event that our sNDA for the broad IDA indication for *Feraheme* was filed with the FDA by the end of 2012 and Dr. Allen remained employed by the Company as of the filing date. The Company filed its sNDA in December 2012 and therefore, 50% of Dr. Allen's shares became exercisable at that time. Further, in the event that (i) FDA approval of the sNDA for the broad IDA indication for *Feraheme* is obtained by March 31, 2014 and (ii) at the time of FDA approval, Dr. Allen continues to be a service provider to the Company providing services with respect to the sNDA filing for the broad IDA indication for *Feraheme*, then all shares subject to the option that then remain unexercisable shall become exercisable.
- (12) On June 25, 2012, Mr. White was granted an option to purchase 40,000 shares of our common stock. The option has a seven-year term and vests over four years after the grant date as follows: (i) 25% on the first anniversary of the grant date and (ii) equal quarterly installments over the next three years thereafter. In addition, 50% of the unvested portion of this option award will be accelerated in the event the Company acquires an FDA-approved product that has generated at least \$10 million in revenue during the 12 month period preceding the acquisition, provided Mr. White continues to have primary responsibility over the Company's business development function at the time of such transaction. Further, in the event that after the above transaction has closed, the Company acquires a second product in a transaction that would be required to be reported to the SEC as a "material contract" or is otherwise deemed by the Board to be of material importance to the Company's growth strategy, then the remaining shares subject to this option will become exercisable, provided Mr. White continues to have primary responsibility over the Company's business development function at the time of such transaction.

OPTION EXERCISES AND STOCK VESTED IN FISCAL 2012

The following table sets forth certain information regarding option exercises and stock vested during the year ended December 31, 2012 with respect to each of our named executive officers:

Name	Option Awards		Stock Awards	
	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise \$(1)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting \$(2)
William K. Heiden	—	—	—	—
Frank E. Thomas	—	—	15,000	225,150
Scott A. Holmes	—	—	3,250	47,755
Lee F. Allen, M.D., Ph.D.	—	—	18,854	269,721
Scott B. Townsend	—	—	—	—
Christopher G. White	—	—	12,583	205,099

- (1) Unless otherwise specified, value is calculated by determining the difference between the market price of the underlying stock on the exercise date and the exercise price of the options.
- (2) Unless otherwise specified, value is calculated by multiplying the number of underlying shares by the closing price of a share of our common stock on the vesting date.

CHANGE OF CONTROL AND SEVERANCE COMPENSATION

Our change of control and severance compensation arrangements are designed to meet the following objectives:

Change of Control

Our philosophy is that appropriate provision should be made for our executive officers both upon the occurrence of a change of control of the Company and in the event their employment is terminated within one year following such a change of control. We believe that providing severance compensation if an executive officer is terminated as a result of a change of control promotes the ability of our executives to act in the best interests of our stockholders even where a transformative transaction may result in termination of the executive's employment. We also believe that these mutually-agreed to severance arrangements are appropriate because they are necessary to recruit, retain and motivate key executive talent.

Termination Without Cause

Our philosophy is that appropriate provision should be made for our executive officers in the event of a termination of their employment with us without cause or if they resign for good reason. We believe that providing such severance compensation encourages our executives to exercise independent business judgment in what they believe to be in the best interests of the Company and those of our stockholders without concern of being terminated without appropriate compensation. We also believe that these mutually-agreed to severance arrangements are appropriate because they are necessary to recruit, retain and motivate key executive talent.

We have entered into employment agreements with each of our named executive officers, with the exception of Mr. Holmes, which provide for the severance and change of control compensation arrangements described below. In December 2011, we entered into a retention agreement with Mr. Holmes which provided that in the event that we terminate Mr. Holmes' employment without cause and he has complied with all his obligations under all agreements with us and signs a general release of claims in a form acceptable to us, then we are obligated to pay Mr. Holmes the following: (i) 100% of the retention bonus amounts then payable to Mr. Holmes on any payment date scheduled to occur after the date of such termination; and (ii) nine months of severance pay based upon Mr. Holmes' then current salary paid in equal installments over the severance period in accordance with our usual payroll schedule. Our retention agreement with Mr. Holmes was in effect through December 31, 2012.

Chief Executive Officer

On May 6, 2012, we entered into an employment agreement with Mr. Heiden. Our employment agreement with Mr. Heiden provides that in the event that we terminate the employment of Mr. Heiden, other than for death, disability or cause, or Mr. Heiden resigns for good reason, and he has complied with all his obligations under all agreements with us and signs a general release of claims in a form acceptable to us, then we are obligated to pay severance to Mr. Heiden in an amount equal to 24 months of his then current base salary, paid in equal installments over the severance period in accordance with our usual payroll schedule. This provision does not apply during the one-year period following a change of control.

Further, in the event that within one year from the date a change of control of the Company occurs, we or our successor terminates the employment of Mr. Heiden other than for death, disability or cause, or Mr. Heiden resigns for good reason, and he has complied with all his obligations under all agreements with us and signs a general release of claims in a form acceptable to us or our successor,

then we or our successor are obligated to provide Mr. Heiden with the following benefits post-termination:

- 12 months of base salary if a change of control occurs prior to the six month anniversary of the date Mr. Heiden began his employment with the Company (i.e. May 14, 2012), or the Effective Date; 18 months of base salary if a change of control occurs after the six month anniversary but prior to the 12 month anniversary of the Effective Date; and 24 months of base salary if a change of control occurs after the 12 month anniversary of the Effective Date;
- A lump sum equal to one times Mr. Heiden's target annual bonus amount if a change of control occurs prior to the six month anniversary of the Effective Date; one and one-half times Mr. Heiden's target annual bonus amount if a change of control occurs after the six month anniversary but prior to the 12 month anniversary of the Effective Date; and two times Mr. Heiden's target annual bonus amount if a change of control occurs after the 12 month anniversary of Mr. Heiden's Effective Date;
- Payment or reimbursement of the premiums for continued health and dental benefits until the earlier of (i) 12 months post termination and (ii) health and dental coverage being provided to Mr. Heiden under another employer's health and dental plans; and
- The full acceleration of vesting of any then unvested outstanding stock options, RSUs and other equity incentives that were granted before such change of control.

In addition, Mr. Heiden's employment agreement contains a provision which provides that any payments otherwise due to Mr. Heiden in connection with a change of control shall be reduced to the extent necessary so that no excise taxes would be due on any such payments.

Mr. Heiden's employment agreement also provides that, in the event of the death or permanent disability of Mr. Heiden, all unvested equity awards then held by him shall become immediately vested in full. In addition, in the event of his death, Mr. Heiden's estate shall be eligible to receive a pro rata portion of his performance bonus for such year based upon the Board's determination that any individual performance objectives were met as of the time of Mr. Heiden's death.

Other Named Executive Officers

We currently have employment agreements in place with all of our named executive officers, with the exception of Mr. Holmes. These employment agreements each provide for the executive to receive a base salary, subject to adjustment at the discretion of the Board or the Compensation Committee, as discussed above under "*Other Named Executive Officers' Compensation.*" In addition, these agreements all contain the following severance and change of control provisions. In the event that we terminate the named executive officer's employment, other than for death, disability or cause, or he resigns for good reason, and he has complied with all his obligations under all agreements with us and signs a general release of claims in a form acceptable to us, then we are obligated to pay severance to the executive in an amount equal to 12 months of his then current base salary, paid in equal installments over the severance period in accordance with our usual payroll schedule. This provision does not apply during the one-year period following a change of control. In addition, certain RSUs granted to the named executive officers contain terms that provide for acceleration of a portion of the outstanding RSUs in the event that we terminate the named executive officer's employment, other than for death, disability or cause, or he resigns for good reason.

Further, our employment agreements with each of our named executive officers, other than Mr. Holmes, provide that upon a change of control of the Company, 50% of the unvested portion of any options to purchase common stock, RSUs and other equity incentives then held by the executive will become immediately vested. The remaining unvested portions of such grants shall continue to vest after the closing of a change of control on the same vesting schedule, but at 50% of the number of

shares that were to vest on each vesting date prior to the change of control. However, in the event that upon a change of control, the Company or the successor to or acquirer of the Company's business elects not to assume all the then unvested outstanding stock options, RSUs and other equity incentives that were granted to the executive officer prior to the change of control, such securities will become vested in full as of the date of the change of control.

In addition, in the event that within one year from the date a change of control of the Company occurs, we or our successor terminates the employment of the named executive officer, other than Mr. Holmes, and other than for death, disability or cause, or he resigns for good reason, and he has complied with all his obligations under all agreements with us and signs a general release of claims in a form acceptable to us or our successor, then we or our successor, are obligated to provide the executive with the following benefits post-termination:

- 12 months of base salary, paid in equal installments over the severance period in accordance with our usual payroll schedule;
- A lump sum equal to one times the executive's target annual bonus amount for the year in which the change of control occurs;
- Payment or reimbursement of the premiums for continued health and dental benefits until the earlier of (i) 24 months post termination and (ii) health and dental coverage being provided to the executive under another employer's health and dental plan; and
- The full acceleration of vesting of any then unvested outstanding stock options, RSUs and other equity incentives that were granted before such change of control.

In addition, our employment agreements with each of our named executive officers, other than Mr. Holmes, contain a provision which allows any payments otherwise due to the executive in connection with a change of control to be reduced to the extent necessary so that no excise taxes would be due on any such payments, but only if such reduction would result in the executive retaining a larger portion of such payments on an after-tax basis than if no reduction was made and the excise taxes had been paid.

Our employment agreements with each of our named executive officers, other than Mr. Holmes, also provide that, in the event of the death or permanent disability of the executive, all unvested equity awards then held by him shall become immediately vested in full. In addition, in the event of a named executive officer's death, other than Mr. Holmes, such named executive officer's estate shall be eligible to receive a pro rata portion of such officer's performance bonus for such year based upon the Board's determination that any individual performance objectives were met as of the time of such officer's death.

POTENTIAL PAYMENTS UPON TERMINATION OR CHANGE OF CONTROL

The table below sets forth the estimated amount of payments and other benefits each named executive officer would have been entitled to receive upon the occurrence of the indicated event, assuming that the event occurred on December 31, 2012. The information is provided relative to the named executive officer's termination or change of control policies or arrangements in place on such date. The values relating to vesting of stock options and RSU awards are based upon a per share fair market value of our common stock of \$14.71, the closing price of a share of our common stock as reported on the NASDAQ on December 31, 2012. Actual payments made at any future date will fluctuate based on various factors, including salary and bonus levels, the vesting schedules of the various equity-based awards, and the price of our common stock at the time of termination or change of control.

<u>Name</u>	<u>Salary and Other Cash Payments (\$)</u>	<u>Vesting of Stock Options (\$)(1)</u>	<u>Vesting of RSUs (\$)(2)</u>	<u>Health and Dental Benefits (\$)(3)</u>	<u>Total (\$)(11)</u>
William K. Heiden					
Termination without cause or resignation for good reason other than in the context of a change of control	1,000,000(4)	—	—	—	1,000,000
Change of control without termination of employment	—	—	—	—	—
Termination without cause or resignation for good reason within 12 months following a change of control	1,312,500(4)	516,000(4)	1,471,000(4)	19,012(4)	3,318,512
Termination upon death	259,875(10)	516,000(10)	1,471,000(10)	—	2,246,875
Termination upon disability	—	516,000(10)	1,471,000(10)	—	1,987,000
Frank E. Thomas					
Termination without cause or resignation for good reason other than in the context of a change of control	415,000(5)	—	367,750(6)	—	782,750
Change of control without termination of employment	—	—	478,075(7)	—	478,075
Termination without cause or resignation for good reason within 12 months following a change of control	622,500(5)	—	956,150(7)	38,023	1,616,673
Termination upon death	230,325(10)	—	956,150(10)	—	1,186,475
Termination upon disability	—	—	956,150(10)	—	956,150
Scott A. Holmes					
Termination without cause or resignation for good reason other than in the context of a change of control	193,500(8)	—	18,388(9)	—	211,888
Change of control without termination of employment	—	619(9)	34,936(9)	—	35,555
Termination without cause or resignation for good reason within 12 months following a change of control	193,500(8)	1,238(9)	69,873(9)	—	264,611
Termination upon death	—	—	—	—	—
Termination upon disability	—	—	—	—	—

<u>Name</u>	<u>Salary and Other Cash Payments (\$)</u>	<u>Vesting of Stock Options \$(1)</u>	<u>Vesting of RSUs \$(2)</u>	<u>Health and Dental Benefits \$(3)</u>	<u>Total \$(11)</u>
Lee F. Allen, M.D., PhD.					
Termination without cause or resignation for good reason other than in the context of a change of control	375,000(5)	—	147,100(6)	9,506	531,606
Change of control without termination of employment	—	—	258,962(7)	—	258,962
Termination without cause or resignation for good reason within 12 months following a change of control	562,500(5)	—	517,924(7)	38,023	1,118,447
Termination upon death	210,000(10)	—	517,924(10)	—	727,924
Termination upon disability	—	—	517,924(10)	—	517,924
Scott B. Townsend					
Termination without cause or resignation for good reason other than in the context of a change of control	315,000(5)	—	—	—	315,000
Change of control without termination of employment	—	—	128,713(7)	—	128,713
Termination without cause or resignation for good reason within 12 months following a change of control	441,000(5)	—	257,425(7)	38,023	736,448
Termination upon death	52,668(10)	—	257,425(10)	—	310,093
Termination upon disability	—	—	257,425(10)	—	257,425
Christopher G. White					
Termination without cause or resignation for good reason other than in the context of a change of control	320,000(5)	—	147,100(6)	—	467,100
Change of control without termination of employment	—	—	218,201(7)	—	218,201
Termination without cause or resignation for good reason within 12 months following a change of control	448,000(5)	—	436,402(7)	38,023	922,425
Termination upon death	139,520(10)	—	436,402(10)	—	575,922
Termination upon disability	—	—	436,402(10)	—	436,402

(1) The amount shown in this column represents the difference between the exercise price and the fair market value of the accelerated options assuming an \$14.71 fair market value of a share of our common stock based on the reported closing price on the NASDAQ on December 31, 2012. Any option with an exercise price of greater than \$14.71 was assumed to be cancelled for no consideration and, therefore, had no intrinsic value.

- (2) The amount shown in this column was calculated by multiplying the executive's number of unvested shares at December 31, 2012 scheduled to vest upon the specified event by \$14.71, the fair market value of a single share of our common stock on December 31, 2012.
- (3) Under the terms of our employment agreements with each of our named executive officers, other than Messrs. Heiden and Holmes, who was employed by the Company at December 31, 2012, if, within one year from the date a change of control of the Company occurs, we or our successor terminates the employment of the named executive officer other than for death, disability or cause, or he resigns for good reason, he is entitled to continued health and dental coverage for the earlier of (i) twenty-four months from the date of termination and (ii) the date he is provided with health and dental coverage by another employer's health and dental plan. For purposes of this table we have assumed twenty-four months of coverage under each named executive officer's current health and dental benefits.
- (4) Under the terms of our employment agreement with Mr. Heiden, he is entitled to twenty-four months of severance pay based on his then current salary if he is terminated without cause or resigns for good reason. In addition, if Mr. Heiden is terminated without cause or resigns for good reason within one year following a change of control, he will receive between twelve and twenty-four months of severance, depending on his length of service when the change of control occurs, as described above under "*Change of Control And Severance Compensation.*" Based on our assumption that December 31, 2012 would be Mr. Heiden's date of termination, he would be entitled to eighteen months of severance if a change of control had occurred. Further, Mr. Heiden will also receive a lump sum equal to one and one-half times his target bonus amount, based on our assumptions noted herein. Mr. Heiden is also entitled to continued health and dental coverage for the earlier of (i) twelve months from the date of termination and (ii) the date he is provided with health and dental coverage by another employer's health and dental plan. In addition, 100% of any unvested options to purchase common stock, RSUs and other equity incentives then held by Mr. Heiden will become immediately vested and exercisable if Mr. Heiden is terminated without cause or resigns for good reason within one year following a change of control.
- (5) Under the terms of our employment agreements with each of our named executive officers, other than Messrs. Heiden and Holmes, who was employed by the Company at December 31, 2012, each executive is entitled to twelve months of severance pay based on his then current salary if he is terminated without cause or resigns for good reason. In addition, if the named executive officer is terminated without cause or resigns for good reason within one year following a change of control, he will receive twelve months of severance pay based on his then current salary as well as one times the target annual bonus payable to him for the year in which the change of control occurs.
- (6) In January 2012, Messrs. Thomas and White and Dr. Allen were each awarded an RSU grant which vests in three annual installments as follows: (i) 50% on the first anniversary of the grant date and (ii) 25% on each of the second and third anniversaries of the grant date. In addition, if the executive officer's business relationship with the Company is terminated by the Company, other than in connection with a change of control, without cause, or by the executive for good reason, each as defined in his employment agreement with the Company, then the number of RSUs scheduled to vest on the next scheduled vesting date following such termination shall accelerate immediately upon such termination and any remaining unvested RSUs shall be forfeited. In addition, in November 2011, Mr. Thomas was awarded an RSU grant which vests in three annual installments as follows: (i) 50% on the first anniversary of the grant date and (ii) 25% on each of the second and third anniversaries of the grant date. If Mr. Thomas' business relationship with the Company is terminated by the Company, other than in connection with a change of control, without cause, or by the executive for good reason, each as defined in his employment agreement with the Company, then the number of RSUs scheduled to vest on the next scheduled vesting date following such termination shall accelerate immediately upon such termination and any remaining unvested RSUs shall be forfeited.
- (7) Under the terms of our employment agreements with each of our named executive officers, other than Messrs. Heiden and Holmes, who was employed at December 31, 2012, 50% of any unvested options to purchase common stock, RSUs and other equity incentives then held by the executive will become immediately vested upon a change of control, and the remaining unvested amount will become immediately vested and exercisable if the executive is terminated without cause or resigns for good reason within one year following a change of control.
- (8) Our December 2011 retention agreement with Mr. Holmes provides that in the event that we terminate Mr. Holmes' employment without cause, including in connection with or following a change of control, and he has complied with all his obligations under all agreements with us and signs a general release of claims in a

form acceptable to us, we are obligated to pay Mr. Holmes the following: (i) 100% of the retention bonus amounts then payable to Mr. Holmes on any payment date scheduled to occur after the date of such termination; and (ii) nine months of severance pay based upon Mr. Holmes' then current salary paid in equal installments over the severance period in accordance with our usual payroll schedule.

- (9) In September of 2011, Mr. Holmes was awarded an option to purchase 5,000 shares of our common stock and an RSU grant of 3,000 shares of our common stock. Both awards vest in equal annual installments over four years from the grant date. In addition, in December 2011, Mr. Holmes was awarded an RSU grant of 5,000 shares of our common stock. This grant vests in three annual installments as follows: (i) 50% on the first anniversary of the grant date and (ii) 25% on each of the second and third anniversaries of the grant date. In addition, pursuant to the terms of Mr. Holmes' December 2011 grant, if Mr. Holmes' business relationship with the Company is terminated by the Company, other than in connection with a change of control, without cause, or by the executive for good reason, then the number of RSUs scheduled to vest on the next scheduled vesting date following such termination shall accelerate immediately upon such termination and any remaining unvested RSUs shall be forfeited. Under the Company's change of control policy, 50% of Mr. Holmes' unvested options and other equity incentives shall vest immediately. In the event Mr. Holmes is terminated within one year following a change of control, the remaining 50% of his unvested options and other equity incentives shall vest immediately.
- (10) Under the terms of our employment agreements with each of our named executive officers, other than Mr. Holmes, who was employed at December 31, 2012, all unvested equity awards then held by him shall become immediately vested in full in the event of the death or permanent disability of the executive. In addition, in the event of a named executive officer's death, other than Mr. Holmes, such named executive officer's estate shall be eligible to receive a pro rata portion of such officer's performance bonus for such year based upon the Board's determination that any individual performance objectives were met as of the time of such officer's death.
- (11) In the case of a change of control, such total amounts may be reduced if such amounts constitute "parachute payments" within the meaning of Section 280G of the Code and are subject to the excise tax under Section 4999 of the Code. Mr. Heiden's employment agreement contains a provision which provides that any payments otherwise due to Mr. Heiden in connection with a change of control shall be reduced to the extent necessary so that no excise taxes would be due on any such payments. The employment agreement of each of Messrs. Thomas, Townsend and White and Dr. Allen contains a provision which provides that any payments otherwise due such executive officer in connection with a change of control may be reduced to the extent necessary so that no excise taxes would be due on such payments, but only to the extent such reduction would result in such executive officer retaining a larger portion of such payments on an after-tax basis than if no reduction was made and the excise taxes had been paid.

In March 2013, Dr. Allen resigned as the Company's Executive Vice President for Medical Development and Chief Medical Officer and entered into a consulting agreement with the Company, the terms of which are summarized under "*Executive Compensation Decisions and Processes— Compensation Decisions Made Following our June 2012 Corporate Restructuring.*"

401(K) PLAN

We provide a 401(k) Plan to our employees under which they may defer compensation for income tax purposes under Section 401(k) of the Code. Under our current 401(k) Plan, the Company provides a fully vested contribution equal to 3% of each employee's, including each named executive officer's, base salary and bonus payments for each plan year. All contributions to the 401(k) plan by or on behalf of employees, including the Company's 3% contribution, are subject to the aggregate annual limits prescribed by the Code.

COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

Our Compensation Committee is currently comprised of Messrs. Santini (Chair), Perez, and Narachi. From January through May 2012, the Compensation Committee consisted of Messrs. Perez (Chair), Narachi and Scoon. No one who served as a member of the Compensation Committee during 2012 is or has been an officer or employee of the Company or had any relationship that is required to

be disclosed as a transaction with a related party. During the year ended December 31, 2012, none of our executive officers served as a member of the board of directors or compensation committee of any entity that has one or more executive officers who serve on our Board or our Compensation Committee.

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires our directors, executive officers and holders of more than 10% of our common stock, referred to herein as "Reporting Persons," to file with the SEC, initial reports of ownership and reports of changes in ownership of our common stock. Such persons are required by regulations of the SEC to furnish us with copies of all such filings. Based on our review of the copies of such filings received by us with respect to the year ended December 31, 2012, and written representations from our directors and executive officers who served in such capacity during the year ended December 31, 2012, we believe that all Reporting Persons complied with all Section 16(a) filing requirements for the year ended December 31, 2012.

PROPOSAL 3: APPROVAL OF THE THIRD AMENDED AND RESTATED 2007 EQUITY INCENTIVE PLAN

Overview

Our Board believes that stock options and other stock-based incentive awards can play an important role in the success of the Company by encouraging and enabling the employees, officers, non-employee directors and consultants of the Company and its subsidiaries upon whose judgment, initiative and efforts we largely depend for the successful conduct of our business to acquire a proprietary interest in the Company. Our Board anticipates that providing such persons with a direct stake in the Company will assure a closer identification of the interests of such individuals with those of the Company and our stockholders, thereby stimulating their efforts on our behalf and strengthening their desire to remain with the Company.

On April 12, 2013, our Board approved an amendment and restatement of the Company's 2007 Plan, subject to stockholder approval, in the form of the Third Amended and Restated 2007 Equity Incentive Plan, or the Restated Plan. The Restated Plan increases the aggregate number of shares authorized for issuance under the Restated Plan by 1,100,000 shares from 3,415,325 shares to 4,515,325 shares. Shares underlying any awards under the Company's Amended and Restated 2000 Stock Plan, or the 2000 Plan, that are forfeited, canceled or otherwise terminated (other than by exercise) on or after November 27, 2007 shall be added to the shares available for issuance under the Restated Plan. The expiration of the Restated Plan will be extended until May 23, 2023, which is ten years from the date of the annual meeting, and incentive stock options may be granted until April 12, 2023, which is ten years from the date the Board approved the Restated Plan.

The Company commits that, with respect to the number of shares subject to awards granted over the next three fiscal years, we will maintain an average annual burn rate over that period that does not exceed 6.7% of weighted common shares outstanding. For purposes of calculating the number of shares granted in a particular year, all awards will first be converted into option-share equivalents. In this case, each share that is subject to awards other than options will count as equivalent to 2.0 option shares for purposes of calculating the average annual burn rate.

This amendment and restatement was designed to enhance the flexibility of the Compensation Committee in granting stock options and other awards to our officers, employees, non-employee directors and consultants and to ensure that we can continue to grant stock options and other awards to such persons at levels determined to be appropriate by the Compensation Committee. If the proposed amendment and restatement of our 2007 Plan is not approved by our stockholders, we currently anticipate that we will exhaust all the shares available for issuance under our 2007 Plan prior to our 2014 company-wide annual performance grants, which typically are granted in the first quarter of each year and prior to our annual stockholders meeting. A copy of the Restated Plan is attached as Appendix A to this Proxy Statement and is incorporated herein by reference.

As of December 31, 2012, we have granted options and RSUs covering 5,283,775 shares of common stock under our 2007 Plan, of which 2,273,686 stock options and 615,430 RSUs have expired or terminated, and of which 38,338 options have been exercised and 347,725 shares of common stock were issued upon settlement of vested RSUs. The number of options and RSUs outstanding under this plan as of December 31, 2012 was 1,734,920 and 273,676, respectively, and there were 1,513,918 shares of common stock available for grant under the 2007 Plan, not including any shares that might in the future be added back to the shares available for issuance under the Restated Plan as a result of forfeiture, cancellation or other termination (other than by exercise).

As of the Record Date, we have granted options and RSUs covering 6,085,975 shares of common stock under our 2007 Plan, of which 2,368,235 stock options and 617,587 RSUs have expired or terminated, and of which 38,525 options have been exercised and 382,908 shares of common stock were

issued upon settlement of vested RSUs. The number of options and RSUs outstanding under this plan as of the Record Date was 2,301,584 and 377,136, respectively, and there were 900,814 shares of common stock available for grant under the 2007 Plan, not including any shares that might in the future be added back to the shares available for issuance under the Restated Plan as a result of forfeiture, cancellation or other termination (other than by exercise). A total of 21,554,391 shares of our common stock were outstanding as of the Record Date.

Proposal 3 seeks stockholder approval of the Restated Plan. Stockholder approval of Proposal 3 will also allow certain awards granted under the Restated Plan to qualify as performance-based compensation exempt from the cap imposed by Section 162(m) of the Code on the Company's tax deduction with respect to compensation paid to certain executive officers.

Summary of Material Features of the Restated Plan

While our Board is aware of and has considered the potential dilutive effect of additional awards and option grants, it also recognizes the performance and motivational benefits of equity compensation and believes that the proposed Restated Plan, including an increase in available shares, is consistent with our Executive Compensation Philosophy Statement and the compensatory practices of other bio-pharmaceutical companies in our peer group. The exercise price of any option grants under the Restated Plan will be at or above the fair market value of our common stock on the close of business on the date such option is granted. Furthermore, since our Board typically grants awards to employees that vest over a three or four year period, employees must generally remain with the Company in order to reap the potential benefits of their awards.

The following material features of the Restated Plan are designed to protect our stockholders' interests and to reflect corporate governance best practices including:

- *Flexibility in designing equity compensation scheme.* The Restated Plan allows us to provide a broad array of equity incentives, including awards of stock options (both incentive and non-qualified options), stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, performance units, dividend equivalent rights, and cash-based awards.
- *Share counting provisions.* Grants of "full value" awards are deemed for purposes of determining the number of shares available for future grants under the Restated Plan as an award for 1.5 shares for each share of common stock subject to the award. Grants of stock option or stock appreciation rights are deemed to be an award of one share for each share of common stock subject to the award. This helps to ensure that management and our Compensation Committee are using the share reserve effectively and with regard to the value of each type of equity award.
- *No Liberal Share Recycling.* Shares tendered or held back for taxes will not be added back to the reserved pool under the Restated Plan. Upon the exercise of a stock appreciation right, the full number of shares underlying the award will be charged to the reserved pool. Additionally, shares reacquired by the Company on the open market or otherwise using cash proceeds of option exercises will not be added to the reserved pool.
- *Minimum vesting provisions.* Minimum vesting provisions are required for certain grants of restricted stock, restricted stock units and performance share awards to employees.
- *Limited vesting acceleration.* Subject to limited exceptions, the Restated Plan provides that the vesting of awards may only be accelerated upon death, disability, retirement or a sale event unless provided for in the terms of the original grant.
- *Repricing is not allowed.* The exercise price of stock options and stock appreciation rights will not be decreased in any manner without stockholder approval.

- *Stockholder approval is required for additional shares.* The Restated Plan does not contain an “evergreen” provision. Thus, any increase to the maximum share reserve in the Restated Plan is subject to approval by our stockholders allowing our stockholders the ability to have a say on our equity compensation programs.
- *Broad-based eligibility for equity awards.* We grant equity awards to a large portion of our employees. By doing so, we tie our employees’ interests with stockholder interests and motivate our employees to act as owners of the business.
- *Reasonable limit on equity awards.* The Restated Plan limits the number of shares of common stock available for equity awards such that no employee may be granted an equity award covering more than 300,000 shares in a calendar year.

Based solely on the closing price of our common stock as reported by the NASDAQ on April 5, 2013 and the maximum number of shares that would have been available for awards under the Restated Plan as of such date taking into account the proposed increase described herein, the maximum aggregate market value of the common stock that could potentially be issued under the Restated Plan is \$48,076,029. The shares of common stock underlying any awards under the Restated Plan or the 2000 Plan that are forfeited, canceled or are otherwise terminated (other than by exercise) are added back to the shares of common stock available for issuance under the Restated Plan. The following shares will not be added back to the shares authorized for issuance under the Restated Plan: shares tendered or held back upon exercise of an option or settlement of an award to cover the exercise price or tax withholding, and shares subject to a stock appreciation right that are not issued in connection with the stock settlement of the stock appreciation right upon exercise.

Qualified Performance-Based Compensation under Code Section 162(m)

To ensure that certain awards granted under the Restated Plan to a “Covered Employee” (as defined in the Code) qualify as “performance-based compensation” under Section 162(m) of the Code, the Restated Plan provides that the Compensation Committee may require that the vesting of such awards be conditioned on the satisfaction of performance criteria that may include any or all of the following: (1) total shareholder return; (2) earnings before interest, taxes, depreciation and/or amortization; (3) net income (loss) (either before or after interest, taxes, depreciation and/or amortization); (4) changes in the market price of the stock; (5) economic value-added; (6) funds from operations or similar measure; (7) sales or revenue; (8) acquisitions or strategic transactions; (9) operating income (loss); (10) cash flow (including, but not limited to, operating cash flow and free cash flow); (11) return on capital, assets, equity or investment; (12) return on sales; (13) revenues; (14) return on assets; (15) return on operating assets; (16) return on equity; (17) profits; (18) gross or net profit levels; (19) productivity; (20) expense; (21) margins; (22) operating efficiency; (23) customer satisfaction; (24) working capital; (25) earnings (loss) per share of stock; (26) sales or market shares; and (27) number of customers, any of which may be measured in absolute terms or as compared to any incremental increase or as compared to results of a peer group. Performance goals may be based upon specified levels of Company, subsidiary, affiliate or division performance under one or more of the criteria set forth above relative to the performance of other entities, divisions or subsidiaries. The Compensation Committee will select the particular performance criteria within the time period specified by Section 162(m) of the Code. Subject to adjustments for stock splits and similar events, the maximum award granted to any one individual that is intended to qualify as “performance-based compensation” under Section 162(m) of the Code will not exceed 300,000 shares of common stock for any performance cycle and options or stock appreciation rights with respect to no more than 300,000 shares of common stock may be granted to any one individual during any calendar year period. If a performance-based award is payable in cash, it cannot exceed \$5,000,000 for any calendar year.

Summary of the Restated Plan

The following description of certain features of the Restated Plan is intended to be a summary only. The summary is qualified in its entirety by the full text of the Restated Plan that is attached hereto as Appendix A.

Plan Administration. The Restated Plan is administered by the Compensation Committee. The Compensation Committee have full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the Restated Plan. The Compensation Committee may delegate to the Chief Executive Officer the authority to grant stock options and/or restricted stock units to employees who are not subject to the reporting and other provisions of Section 16 of the Exchange Act and not subject to Section 162(m) of the Code, subject to certain limitations and guidelines.

Eligibility. Persons eligible to participate in the Restated Plan will be those full- or part-time officers, employees, non-employee directors and other key persons (including consultants) of the Company and its subsidiaries or affiliates as selected from time to time by the Compensation Committee in their discretion. Approximately 136 individuals are currently eligible to participate in the Restated Plan, which includes seven officers, 124 employees who are not officers, and five non-employee directors.

Plan Limits. The maximum award of stock options granted to any one individual will not exceed 300,000 shares of common stock (subject to adjustment for stock splits and similar events) for any calendar year period. If any award of restricted stock, restricted stock units or performance shares granted to an individual is intended to qualify as "performance-based compensation" under Section 162(m) of the Code, then the maximum award shall not exceed 300,000 shares of common stock (subject to adjustment for stock splits and similar events) to any one such individual in any performance cycle. If any cash-based award is intended to qualify as "performance-based compensation" under Section 162(m) of the Code, then the maximum award to be paid in cash in any performance cycle may not exceed \$5,000,000. In addition, no more than 4,515,325 shares may be issued in the form of incentive stock options.

Stock Options. The Restated Plan permits the granting of (1) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and (2) options that do not so qualify. Options granted under the Restated Plan will be non-qualified options if they fail to qualify as incentive options or exceed the annual limit on incentive stock options. Incentive stock options may only be granted to employees of the Company and its subsidiaries. Non-qualified options may be granted to any persons eligible to receive incentive options and to non-employee directors, consultants and key persons. The option exercise price of each option will be determined by the Compensation Committee but may not be less than 100% of the fair market value of the common stock on the date of grant. Fair market value for this purpose will be the closing price of the shares of common stock on the NASDAQ on the date of grant. The exercise price of an option may not be reduced after the date of the option grant, other than to appropriately reflect changes in our capital structure.

The term of each option will be fixed by the Compensation Committee and may not exceed ten years from the date of grant. The Compensation Committee will determine at what time or times each option may be exercised. Options may be made exercisable in installments and the exercisability of options may be accelerated by the Compensation Committee. In general, unless otherwise permitted by the Compensation Committee, no option granted under the Restated Plan is transferable by the optionee other than by will or by the laws of descent and distribution or pursuant to a qualified

domestic relations order, and options may be exercised during the optionee's lifetime only by the optionee, or by the optionee's legal representative or guardian in the case of the optionee's incapacity.

Upon exercise of options, the option exercise price must be paid in full either in cash, by certified or bank check or other instrument acceptable to the Compensation Committee or by delivery (or attestation to the ownership) of shares of common stock that are beneficially owned by the optionee. Subject to applicable law, the exercise price may also be delivered to the Company by a broker pursuant to irrevocable instructions to the broker from the optionee. In addition, the Compensation Committee may permit non-qualified options to be exercised using a net exercise feature which reduces the number of shares issued to the optionee by the number of shares with a fair market value equal to the exercise price.

To qualify as incentive options, options must meet additional federal tax requirements, including a \$100,000 limit on the value of shares subject to incentive options that first become exercisable by a participant in any one calendar year.

Stock Appreciation Rights. The Compensation Committee may award stock appreciation rights, subject to such conditions and restrictions as the Compensation Committee may determine. Stock appreciation rights entitle the recipient to shares of common stock equal to the value of the appreciation in the stock price over the exercise price. The exercise price may not be less than the fair market value of the common stock on the date of grant. The term of a stock appreciation right shall be determined by the Compensation Committee, but may not exceed ten years.

Restricted Stock. The Compensation Committee may award shares of common stock to participants subject to such conditions and restrictions as the Compensation Committee may determine. These conditions and restrictions may include the achievement of certain performance goals, as summarized above, and/or continued employment with us through a specified restricted period.

Restricted Stock Units. The Compensation Committee may award restricted stock units to any participants. Restricted stock units are ultimately payable in the form of shares of common stock and may be subject to such conditions and restrictions as the Compensation Committee may determine. These conditions and restrictions may include the achievement of certain performance goals, as summarized above, and/or continued employment with the Company through a specified vesting period.

Unrestricted Stock Awards. The Compensation Committee may also grant shares of common stock which are free from any restrictions under the Restated Plan. Unrestricted stock may be granted to any participant in recognition of past services or other valid consideration and may be issued in lieu of cash compensation due to such participant.

Performance Share Awards. The Compensation Committee may grant performance share awards to any participant which entitle the recipient to receive shares of common stock upon the achievement of certain performance goals, as summarized above, and such other conditions as the Compensation Committee shall determine.

Dividend Equivalent Rights. The Compensation Committee may grant dividend equivalent rights to participants which entitle the recipient to receive credits for dividends that would be paid if the recipient had held specified shares of common stock. Dividend equivalent rights granted as a component of another award subject to performance vesting may be paid only if the related award becomes vested.

Cash-Based Awards. The Compensation Committee may grant cash bonuses under the Restated Plan to participants. The cash bonuses may be subject to the achievement of certain performance goals, as summarized above.

Minimum Vesting Requirements. Except in the case of death, disability, retirement or a sale event, and with certain exceptions applicable to awards granted prior to May 5, 2009 or awards with respect to no more than 10% of shares available for issuance under the Restated Plan, the minimum restriction or vesting period with respect to any restricted stock award, restricted stock unit award and performance share award granted to employees or consultants shall be no less than one year in the case of a performance-based restriction or vesting period and no less than three years in the case of a time-based restriction or vesting period (provided such time-based restriction or vesting period may lapse or vest incrementally over such three year period).

Change of Control Provisions. The Restated Plan provides that upon the effectiveness of a “sale event,” as defined in the Restated Plan, except as otherwise provided by the Compensation Committee in the award agreement, the parties to the sale event may agree that awards shall be assumed or continued by the successor entity. Upon the effective time of the sale event, the plan and all awards will terminate. In the event of such termination (i) the Company shall have the option, in its sole discretion, to make or provide for a cash payment to participants holding options and stock appreciation rights equal to the difference between the per share cash consideration and the exercise price of the options or stock appreciation rights or (ii) each grantee will be permitted, within a specified period of time prior to the sale event, to exercise all outstanding options and stock appreciation rights, to the extent then exercisable.

Adjustments for Stock Dividends, Stock Splits, Etc. The Restated Plan requires the Compensation Committee to make appropriate adjustments to the number of shares of common stock that are subject to the Restated Plan, to certain limits in the Restated Plan, and to any outstanding awards to reflect stock dividends, stock splits, extraordinary cash dividends and similar events.

Tax Withholding. Participants in the Restated Plan are responsible for the payment of any federal, state or local taxes that the Company is required by law to withhold upon the exercise of options or stock appreciation rights or vesting of other awards. Subject to approval by the Compensation Committee, participants may elect to have the minimum tax withholding obligations satisfied by authorizing us to withhold shares of common stock to be issued pursuant to the exercise or vesting.

Amendments and Termination. The Compensation Committee may at any time amend or discontinue the Restated Plan and the Compensation Committee may at any time amend or cancel any outstanding award for the purpose of satisfying changes in the law or for any other lawful purpose. However, no such action may adversely affect any rights under any outstanding award without the holder’s consent. To the extent required under the rules of the NASDAQ, any amendments that materially change the terms of the Restated Plan will be subject to approval by our stockholders. Amendments shall also be subject to approval by our stockholders if and to the extent determined by the Compensation Committee to be required by the Code to preserve the qualified status of incentive options or to ensure that compensation earned under the Restated Plan qualifies as performance-based compensation under Section 162(m) of the Code.

Effective Date of Restated Plan. The Board adopted the Restated Plan on April 12, 2013, and the Restated Plan becomes effective on the date it is approved by stockholders. No awards may be granted under the Restated Plan after ten years from the date of stockholder approval, and no incentive stock options may be granted under the Restated Plan after ten years from the date the Restated Plan is approved by the Board. If the Restated Plan is not approved by stockholders, the Second Amended and Restated 2007 Equity Incentive Plan will continue in effect until it expires, and awards may be granted thereunder, in accordance with its terms.

New Plan Benefits

Because the grant of awards under the Restated Plan is within the discretion of the Compensation Committee, we cannot determine the dollar value or number of shares of common stock that will in the future be received by or allocated to any participant in the Restated Plan. Accordingly, in lieu of providing information regarding benefits that will be received under the Restated Plan, the following table provides information concerning the benefits that were received by the following persons and groups during 2012: each named executive officer; all current executive officers, as a group; all current directors who are not executive officers, as a group; and all employees who are not executive officers, as a group.

Name and Position	Options		Restricted Stock and RSUs	
	Average Exercise Price(1)	Number (#)	Dollar Value(2)	Number (#)
William K. Heiden, President and Chief Executive Officer	\$12.99	300,000	\$1,299,000	100,000
Frank E. Thomas, Executive Vice President and Chief Operating Officer, Former Interim President and Chief Executive Officer	—	—	\$ 749,600	40,000
Scott A. Holmes, Vice President of Finance, Chief Accounting Officer and Treasurer	\$14.89	30,000	\$ —	—
Lee F. Allen, M.D., Ph.D., Former Executive Vice President of Medical Development and Chief Medical Officer	\$14.89	40,000	\$ 374,800	20,000
Scott B. Townsend, Senior Vice President, General Counsel and Secretary	\$14.99	52,500	\$ 262,325	17,500
Christopher G. White, Senior Vice President and Chief Business Officer	\$14.89	40,000	\$ 374,800	20,000
All current executive officers, as a group	\$14.75	450,500	\$2,685,725	177,500
All current non-employee directors, as a group	\$14.54	44,300	\$ 250,468	18,550
All employees who are not executive officers, as a group . .	\$15.21	725,750	\$ 43,920	3,000

(1) The average exercise price was calculated using a weighted average basis.

(2) The amount shown in this column was calculated by multiplying the number of RSUs by the fair market value on the date of grant.

Tax Aspects Under the Code

The following is a summary of the principal federal income tax consequences of certain transactions under the Restated Plan. It does not describe all federal tax consequences under the Restated Plan, nor does it describe state or local tax consequences.

Incentive Options. No taxable income is generally realized by the optionee upon the grant or exercise of an incentive option. If shares of common stock issued to an optionee pursuant to the exercise of an incentive option are sold or transferred after two years from the date of grant and after one year from the date of exercise, then (i) upon sale of such shares, any amount realized in excess of

the option price (the amount paid for the shares) will be taxed to the optionee as a long-term capital gain, and any loss sustained will be a long-term capital loss, and (ii) the Company will not be entitled to any deduction for federal income tax purposes. The exercise of an incentive option will give rise to an item of tax preference that may result in alternative minimum tax liability for the optionee.

If shares of common stock acquired upon the exercise of an incentive option are disposed of prior to the expiration of the two-year and one-year holding periods described above (a “disqualifying disposition”), generally (i) the optionee will realize ordinary income in the year of disposition in an amount equal to the excess (if any) of the fair market value of the shares of common stock at exercise (or, if less, the amount realized on a sale of such shares of common stock) over the option price thereof, and (ii) we will be entitled to deduct such amount. Special rules will apply where all or a portion of the exercise price of the incentive option is paid by tendering shares of common stock.

If an incentive option is exercised at a time when it no longer qualifies for the tax treatment described above, the option is treated as a non-qualified option. Generally, an incentive option will not be eligible for the tax treatment described above if it is exercised more than three months following termination of employment (or one year in the case of termination of employment by reason of disability). In the case of termination of employment by reason of death, the three-month rule does not apply.

Non-Qualified Options. No income is realized by the optionee at the time the option is granted. Generally (i) at exercise, ordinary income is realized by the optionee in an amount equal to the difference between the option price and the fair market value of the shares of common stock on the date of exercise, and we receive a tax deduction for the same amount, and (ii) at disposition, appreciation or depreciation after the date of exercise is treated as either short-term or long-term capital gain or loss depending on how long the shares of common stock have been held. Special rules will apply where all or a portion of the exercise price of the non-qualified option is paid by tendering shares of common stock. Upon exercise, the optionee will also be subject to Social Security taxes on the excess of the fair market value over the exercise price of the option.

Other Awards. The Company generally will be entitled to a tax deduction in connection with an award under the Restated Plan in an amount equal to the ordinary income realized by the participant at the time the participant recognizes such income. Participants typically are subject to income tax and recognize such tax at the time that an award is exercised, vests or becomes non-forfeitable, unless the award provides for a further deferral.

Parachute Payments. The vesting of any portion of an option or other award that is accelerated due to the occurrence of a change in control may cause a portion of the payments with respect to such accelerated awards to be treated as “parachute payments” as defined in the Code. Any such parachute payments may be non-deductible to the Company, in whole or in part, and may subject the recipient to a non-deductible 20% federal excise tax on all or a portion of such payment (in addition to other taxes ordinarily payable).

Limitation on Deductions. Under Section 162(m) of the Code, the Company’s deduction for certain awards under the Restated Plan may be limited to the extent that the Chief Executive Officer or other executive officer whose compensation is required to be reported in the summary compensation table (other than the Principal Financial Officer) receives compensation in excess of \$1 million a year (other than performance-based compensation that otherwise meets the requirements of Section 162(m) of the Code). The Restated Plan is structured to allow certain awards to qualify as performance-based compensation.

Equity Compensation Plan Information

The following table presents information at December 31, 2012 regarding shares of common stock that may be issued under the Company's equity compensation plans consisting of the Restated Plan and our 2010 Employee Stock Purchase Plan.

Plan Category	Equity Compensation Plan Information		
	Number of securities to be issued upon exercise of outstanding options, RSUs and rights	Weighted average exercise price of outstanding options, and rights(1)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities referenced in column (a))(2)
	(a)	(b)	(c)
Equity compensation plans approved by security holders . .	2,163,749	\$24.67	1,535,851
Equity compensation plans not approved by security holders(3)	400,000	\$12.99	—
Total	2,563,749(4)		1,535,851

- (1) Since restricted stock units do not have any exercise price, such units are not included in the weighted average exercise price calculation.
- (2) As of December 31, 2012, there were 1,513,918 shares available for grants under the 2007 Plan and 21,933 shares available for grants under the Company's 2010 Employee Stock Purchase Plan.
- (3) Consists of (i) 300,000 shares of our common stock which are issuable upon exercise of a stock option and (ii) 100,000 restricted stock units granted to Mr. Heiden outside of the 2007 Plan as an employment inducement award in connection with the commencement of his employment as President and Chief Executive Officer in May 2012. This grant was made in reliance on NASDAQ Listing Rule 5635(c)(4).
- (4) Includes 2,190,073 shares of common stock issuable upon the exercise of outstanding options and 373,676 shares of common stock issuable upon the vesting of restricted stock units.

Required Vote

The affirmative vote of the holders of a majority of the shares of our common stock present or represented and voting at the Annual Meeting is required to approve the Restated Plan.

OUR BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS, AND DEEMS ADVISABLE, THAT STOCKHOLDERS VOTE "FOR" THE APPROVAL OF THE THIRD AMENDED AND RESTATED 2007 EQUITY INCENTIVE PLAN.

PROPOSAL 4: RATIFICATION OF APPOINTMENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Our Audit Committee has appointed the firm of PricewaterhouseCoopers LLP, an independent registered public accounting firm, as the Company's independent registered public accounting firm for the year ending December 31, 2013, and the Board has ratified such appointment. The Board has directed that management submit the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for ratification by our stockholders at the Annual Meeting.

PricewaterhouseCoopers LLP or its predecessor has served as our independent registered public accounting firm since our inception in 1981. Representatives of PricewaterhouseCoopers LLP are expected to be at the Annual Meeting, will have an opportunity to make a statement if they so desire, and will be available to respond to appropriate questions.

Stockholder ratification of the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm is not required by our by-laws or otherwise. However, the Board is submitting this appointment to the stockholders for ratification as a matter of good corporate practice. In the event our stockholders fail to ratify the appointment of PricewaterhouseCoopers LLP, the Audit Committee will not be required to replace PricewaterhouseCoopers LLP as our independent registered public accounting firm. In the event of such a failure to ratify, the Audit Committee and the Board will reconsider whether or not to retain that firm for future service. Even if the appointment is ratified, the Audit Committee in its discretion may direct the appointment of a different independent registered public accounting firm at any time if the Audit Committee determines that such a change would be in our and our stockholders' best interests.

Principal Accountant Fees and Services

The following table summarizes the fees billed for professional services by PricewaterhouseCoopers LLP for the years ended December 31, 2012 and 2011:

<u>Fee Category</u>	<u>Year Ended December 31, 2012</u>	<u>Year Ended December 31, 2011</u>
Audit Fees(1)	\$700,772	\$678,721
Audit-Related Fees(2)	—	282,975
All Other Fees(3)	1,800	1,800
Total	<u>\$702,572</u>	<u>\$963,496</u>

- (1) Audit fees consisted of fees for the audit of our financial statements, the review of our interim financial statements included in our quarterly reports on Form 10-Q, assistance with and review of documents provided to the SEC in responding to SEC comments and other professional services provided in connection with regulatory filings or engagements.
- (2) Audit-related fees consisted of fees for services related to due diligence, accounting consultations and advice and 2011 costs related to our proposed merger with Allos. All audit-related fees were pre-approved by the Audit Committee.
- (3) All other fees represent payment for access to the PricewaterhouseCoopers LLP on-line accounting research database. All other fees were pre-approved by the Audit Committee.

In connection with the audit of our 2012 financial statements, we entered into an engagement agreement with PricewaterhouseCoopers LLP which sets forth the terms by which PricewaterhouseCoopers LLP would perform audit services for the Company.

All services expected to be rendered by PricewaterhouseCoopers LLP in 2013 are permissible under applicable laws and regulations, and are expected to be pre-approved by the Audit Committee.

The Audit Committee also expects to approve certain non-audit services to be performed by PricewaterhouseCoopers LLP in 2013.

Pre-Approval Policies and Procedures

Consistent with policies of the SEC regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation and overseeing the work of our independent registered public accounting firm.

The Audit Committee has approved the engagement of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm and has approved the provision of certain specific non-audit services expected to be performed by PricewaterhouseCoopers LLP in 2013. In addition, circumstances may arise during the year necessitating the engagement of PricewaterhouseCoopers LLP or another independent registered public accounting firm for additional audit or permissible non-audit services. In those instances, under our current pre-approval policy, each member of the Audit Committee has the authority to approve any additional audit services and permissible non-audit services provided that such member promptly informs the Audit Committee of such approval.

Required Vote

The affirmative vote of the stockholders holding a majority of shares of common stock present or represented and voting at the Annual Meeting is required to ratify the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the year ending December 31, 2013.

OUR BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS A VOTE "FOR" THE APPROVAL OF THE RATIFICATION OF THE APPOINTMENT OF PRICEWATERHOUSECOOPERS LLP AS OUR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM.

By Order of the Board of Directors,



Scott B. Townsend
Secretary

The Board welcomes stockholders who wish to attend the Annual Meeting. Whether or not you plan to attend, you are urged to complete and deliver a proxy by one of the methods provided in the enclosed proxy card. A prompt response will greatly facilitate arrangements for the Annual Meeting, and your cooperation will be appreciated. Stockholders who attend the Annual Meeting may vote their stock personally even though they have sent in their proxies.

Copies of the Proxy Statement, the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and any other proxy materials are available without charge upon written request to our principal executive offices at 100 Hayden Avenue, Lexington, Massachusetts 02421, attention: Investor Relations.

AMAG PHARMACEUTICALS, INC.
THIRD AMENDED AND RESTATED
2007 EQUITY INCENTIVE PLAN

SECTION 1. GENERAL PURPOSE OF THE PLAN; DEFINITIONS

The name of the plan is the AMAG Pharmaceuticals, Inc. Third Amended and Restated 2007 Equity Incentive Plan (the "Plan"). The purpose of the Plan is to encourage and enable the officers, employees, Non-Employee Directors and other key persons (including Consultants) of AMAG Pharmaceuticals, Inc., a Delaware corporation (the "Company") and its Subsidiaries upon whose judgment, initiative and efforts the Company largely depends for the successful conduct of its business to acquire a proprietary interest in the Company. It is anticipated that providing such persons with a direct stake in the Company's welfare will assure a closer identification of their interests with those of the Company and its stockholders, thereby stimulating their efforts on the Company's behalf and strengthening their desire to remain with the Company.

The following terms shall be defined as set forth below:

"Act" means the Securities Act of 1933, as amended, and the rules and regulations thereunder.

"Administrator" means either the Board or the Compensation Committee of the Board or a similar committee performing the functions of the compensation committee and which is comprised of not less than two Non-Employee Directors who are independent.

"Award" or "Awards," except where referring to a particular category of grant under the Plan, shall include Incentive Stock Options, Non-Qualified Stock Options, Stock Appreciation Rights, Restricted Stock Units, Restricted Stock Awards, Unrestricted Stock Awards, Cash-Based Awards, Performance Share Awards and Dividend Equivalent Rights.

"Award Certificate" means a written or electronic document setting forth the terms and provisions applicable to an Award granted under the Plan. Each Award Certificate is subject to the terms and conditions of the Plan.

"Board" means the Board of Directors of the Company.

"Cash-Based Award" means an Award entitling the recipient to receive a cash-denominated payment.

"Code" means the Internal Revenue Code of 1986, as amended, and any successor Code, and related rules, regulations and interpretations.

"Consultant" means any natural person that provides bona fide services to the Company, and such services are not in connection with the offer or sale of securities in a capital-raising transaction and do not directly or indirectly promote or maintain a market for the Company's securities.

"Covered Employee" means an employee who is a "Covered Employee" within the meaning of Section 162(m) of the Code.

"Dividend Equivalent Right" means an Award entitling the grantee to receive credits based on cash dividends that would have been paid on the shares of Stock specified in the Dividend Equivalent Right (or other award to which it relates) if such shares had been issued to and held by the grantee.

"Effective Date" means the date on which the Plan is approved by stockholders as set forth in Section 21.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder.

“Fair Market Value” of the Stock on any given date means the fair market value of the Stock determined in good faith by the Administrator; provided, however, that if the Stock is admitted to quotation on the National Association of Securities Dealers Automated Quotation System (“NASDAQ”), NASDAQ Global Market or another national securities exchange, the determination shall be made by reference to market quotations. If there are no market quotations for such date, the determination shall be made by reference to the last date preceding such date for which there are market quotations.

“Incentive Stock Option” means any Stock Option designated and qualified as an “incentive stock option” as defined in Section 422 of the Code.

“Non-Employee Director” means a member of the Board who is not also an employee of the Company or any Subsidiary.

“Non-Qualified Stock Option” means any Stock Option that is not an Incentive Stock Option.

“Option” or *“Stock Option”* means any option to purchase shares of Stock granted pursuant to Section 5.

“Performance-Based Award” means any Restricted Stock Award, Restricted Stock Units, Performance Share Award or Cash-Based Award granted to a Covered Employee that is intended to qualify as “performance-based compensation” under Section 162(m) of the Code and the regulations promulgated thereunder.

“Performance Criteria” means the criteria that the Administrator selects for purposes of establishing the Performance Goal or Performance Goals for an individual for a Performance Cycle. The Performance Criteria (which shall be applicable to the organizational level specified by the Administrator, including, but not limited to, the Company or a unit, division, group, or Subsidiary of the Company) that will be used to establish Performance Goals are limited to the following: total shareholder return, earnings before interest, taxes, depreciation and amortization, net income (loss) (either before or after interest, taxes, depreciation and/or amortization), changes in the market price of the Stock, economic value-added, funds from operations or similar measure, sales or revenue, acquisitions or strategic transactions, operating income (loss), cash flow (including, but not limited to, operating cash flow and free cash flow), return on capital, assets, equity, or investment, return on sales, gross or net profit levels, productivity, expense, margins, operating efficiency, customer satisfaction, working capital, earnings (loss) per share of Stock, sales or market shares and number of customers, any of which may be measured either in absolute terms or as compared to any incremental increase or as compared to results of a peer group.

“Performance Cycle” means one or more periods of time, which may be of varying and overlapping durations, as the Administrator may select, over which the attainment of one or more Performance Criteria will be measured for the purpose of determining a grantee’s right to and the payment of a Restricted Stock Award, Restricted Stock Units, Performance Share Award or Cash-Based Award, the vesting and/or payment of which is subject to the attainment of one or more Performance Goals. Each such period shall not be less than 12 months.

“Performance Goals” means, for a Performance Cycle, the specific goals established in writing by the Administrator for a Performance Cycle based upon the Performance Criteria.

“Performance Share Award” means an Award entitling the recipient to acquire shares of Stock upon the attainment of specified Performance Goals.

“*Restricted Stock Award*” means an Award of shares of Stock subject to such restrictions and conditions as the Administrator may determine at the time of grant.

“*Restricted Stock Units*” means an Award of phantom stock units to a grantee.

“*Sale Event*” shall mean (i) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (ii) a merger, reorganization or consolidation pursuant to which the holders of the Company’s outstanding voting power and outstanding stock immediately prior to such transaction do not own a majority of the outstanding voting power and outstanding stock or other equity interests of the resulting or successor entity (or its ultimate parent, if applicable) immediately upon completion of such transaction, (iii) the sale of all of the Stock of the Company to an unrelated person, entity or group thereof acting in concert, or (iv) any other transaction in which the owners of the Company’s outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power of the Company or any successor entity immediately upon completion of the transaction other than as a result of the acquisition of securities directly from the Company.

“*Sale Price*” means the value as determined by the Administrator of the consideration payable, or otherwise to be received by stockholders, per share of Stock pursuant to a Sale Event.

“*Section 409A*” means Section 409A of the Code and the regulations and other guidance promulgated thereunder.

“*Stock*” means the common stock of the Company, subject to adjustments pursuant to Section 3.

“*Stock Appreciation Right*” means an Award entitling the recipient to receive shares of Stock having a value equal to the excess of the Fair Market Value of the Stock on the date of exercise over the exercise price of the Stock Appreciation Right multiplied by the number of shares of Stock with respect to which the Stock Appreciation Right shall have been exercised.

“*Subsidiary*” means any corporation or other entity (other than the Company) in which the Company has at least a 50 percent interest, either directly or indirectly.

“*Ten Percent Owner*” means an employee who owns or is deemed to own (by reason of the attribution rules of Section 424(d) of the Code) more than 10 percent of the combined voting power of all classes of stock of the Company or any parent or subsidiary corporation.

“*Unrestricted Stock Award*” means an Award of shares of Stock free of any restrictions.

SECTION 2. ADMINISTRATION OF PLAN; ADMINISTRATOR AUTHORITY TO SELECT GRANTEES AND DETERMINE AWARDS

(a) *Administration of Plan.* The Plan shall be administered by the Administrator, provided that the amount, timing and terms of the grants of Awards to Non-Employee Directors shall be determined by the compensation committee or similar committee comprised solely of Non-Employee Directors.

(b) *Powers of Administrator.* The Administrator shall have the power and authority to grant Awards consistent with the terms of the Plan, including the power and authority:

(i) to select the individuals to whom Awards may from time to time be granted;

(ii) to determine the time or times of grant, and the extent, if any, of Incentive Stock Options, Non-Qualified Stock Options, Stock Appreciation Rights, Restricted Stock Awards, Restricted Stock Units, Unrestricted Stock Awards, Cash-Based Awards, Performance Share Awards and Dividend Equivalent Rights, or any combination of the foregoing, granted to any one or more grantees;

(iii) to determine the number of shares of Stock to be covered by any Award;

(iv) to determine and modify from time to time the terms and conditions, including restrictions, not inconsistent with the terms of the Plan, of any Award, which terms and conditions may differ among individual Awards and grantees, and to approve the forms of Award Certificates;

(v) to accelerate at any time the exercisability or vesting of all or any portion of any Award, provided that the Administrator generally shall not exercise such discretion to accelerate Awards subject to Sections 7 and 8 except in the event of the grantee's death, disability or retirement, or a change in control (including a Sale Event) (the "Vesting Acceleration Requirements");

(vi) subject to the provisions of Section 5(b), to extend at any time the period in which Stock Options may be exercised; and

(vii) at any time to adopt, alter and repeal such rules, guidelines and practices for administration of the Plan and for its own acts and proceedings as it shall deem advisable; to interpret the terms and provisions of the Plan and any Award (including related written instruments); to make all determinations it deems advisable for the administration of the Plan; to decide all disputes arising in connection with the Plan; and to otherwise supervise the administration of the Plan.

All decisions and interpretations of the Administrator shall be binding on all persons, including the Company and Plan grantees.

(c) *Delegation of Authority to Grant Options.* Subject to applicable law, the Administrator, in its discretion, may delegate to the Chief Executive Officer of the Company all or part of the Administrator's authority and duties with respect to the granting of Options and/or Restricted Stock Units to individuals who are (i) not subject to the reporting and other provisions of Section 16 of the Exchange Act and (ii) not Covered Employees. Any such delegation by the Administrator shall include a limitation as to the amount of Options and/or Restricted Stock Units that may be granted during the period of the delegation and shall contain guidelines as to the determination of the exercise price and the vesting criteria. The Administrator may revoke or amend the terms of a delegation at any time but such action shall not invalidate any prior actions of the Administrator's delegate or delegates that were consistent with the terms of the Plan.

(d) *Award Certificate.* Awards under the Plan shall be evidenced by Award Certificates that set forth the terms, conditions and limitations for each Award which may include, without limitation, the term of an Award and the provisions applicable in the event employment or service terminates.

(e) *Indemnification.* Neither the Board nor the Administrator, nor any member of either or any delegate thereof, shall be liable for any act, omission, interpretation, construction or determination made in good faith in connection with the Plan, and the members of the Board and the Administrator (and any delegate thereof) shall be entitled in all cases to indemnification and reimbursement by the Company in respect of any claim, loss, damage or expense (including, without limitation, reasonable attorneys' fees) arising or resulting therefrom to the fullest extent permitted by law and/or under the Company's articles or by-laws or any directors' and officers' liability insurance coverage which may be in effect from time to time and/or any indemnification agreement between such individual and the Company.

(f) *Foreign Award Recipients.* Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws in other countries in which the Company and its Subsidiaries operate or have employees or other individuals eligible for Awards, the Administrator, in its sole discretion, shall have the power and authority to: (i) determine which Subsidiaries shall be covered by the Plan; (ii) determine which individuals outside the United States are eligible to participate in the Plan; (iii) modify the terms and conditions of any Award granted to individuals outside the United States to comply with applicable foreign laws; (iv) establish subplans and modify exercise procedures and other terms and procedures, to the extent the Administrator determines such actions to be necessary or

advisable (and such subplans and/or modifications shall be attached to this Plan as appendices); provided, however, that no such subplans and/or modifications shall increase the share limitations contained in Section 3(a) hereof; and (v) take any action, before or after an Award is made, that the Administrator determines to be necessary or advisable to obtain approval or comply with any local governmental regulatory exemptions or approvals. Notwithstanding the foregoing, the Administrator may not take any actions hereunder, and no Awards shall be granted, that would violate the Exchange Act or any other applicable United States securities law, the Code, or any other applicable United States governing statute or law.

(g) *Full Value Award Minimum Vesting Requirements.* Notwithstanding any other provision in the Plan to the contrary, after May 5, 2009, the minimum restriction or vesting period with respect to any Restricted Stock Award, Restricted Stock Unit Award and Performance Share Award granted to employees shall be no less than one year in the case of a performance-based restriction or vesting period and no less than three years in the case of a time-based restriction or vesting period (the "Minimum Vesting Requirements"); provided, however, that an Award with a time-based restriction or vesting period may become unrestricted and vested incrementally over such three year period; and provided further that, (i) the vesting of any such Award may accelerate (or be accelerated by the Administrator) if one or more of the Vesting Acceleration Requirements is met and (ii) notwithstanding the foregoing, after May 5, 2009, Restricted Stock Awards, Restricted Stock Unit Awards and Performance Share Awards that result in the issuance of up to 10% of the shares of Stock available for issuance under the Plan pursuant to Section 3(a) may be granted in the aggregate to any one or more eligible participants in the Plan or may be accelerated (other than Awards for which the vesting is accelerated pursuant to arrangements entered into before May 5, 2009) without respect to such Minimum Vesting Requirements or Vesting Acceleration Requirements.

SECTION 3. STOCK ISSUABLE UNDER THE PLAN; MERGERS; SUBSTITUTION

(a) *Stock Issuable.* The maximum number of shares of Stock reserved and available for issuance under the Plan shall be 4,515,325 shares, subject to adjustment as provided in this Section 3. For purposes of this limitation, the shares of Stock underlying any Awards under the Plan as well as shares of Stock underlying any awards under the Company's Amended and Restated 2000 Stock Plan that are forfeited, canceled or otherwise terminated (other than by exercise) on or after November 27, 2007 shall be added back to the shares of Stock available for issuance under the Plan. Notwithstanding the foregoing, the following shares shall not be added to the shares authorized for grant under the Plan: (i) shares tendered or held back upon exercise of an Option or settlement of an Award to cover the exercise price or tax withholding, and (ii) shares subject to a Stock Appreciation Right that are not issued in connection with the stock settlement of the Stock Appreciation Right upon exercise thereof. In the event the Company repurchases shares of Stock on the open market, such shares shall not be added to the shares of Stock available for issuance under the Plan. Subject to such overall limitations, shares of Stock may be issued up to such maximum number pursuant to any type or types of Award; provided, however, that Stock Options or Stock Appreciation Rights with respect to no more than 300,000 shares of Stock may be granted to any one individual grantee during any one calendar year period, no more than 10 percent of the total number of shares of Stock authorized for issuance under the Plan may be granted in the form of Unrestricted Stock Awards and no more than 4,515,325 shares of the Stock may be issued in the form of Incentive Stock Options. The shares available for issuance under the Plan may be authorized but unissued shares of Stock or shares of Stock reacquired by the Company.

(b) *Effect of Awards.* The grant of any full value Award (i.e., an Award other than an Option or a Stock Appreciation Right) shall be deemed, for purposes of determining the number of shares of Stock available for issuance under Section 3(a), as an Award of 1.5 shares of Stock for each such share of Stock actually subject to the Award. The grant of an Option or a Stock Appreciation Right shall be

deemed, for purposes of determining the number of shares of Stock available for issuance under Section 3(a), as an Award for one share of Stock for each such share of Stock actually subject to the Award. Any forfeitures, cancellations or other terminations (other than by exercise) of such Awards shall be returned to the reserved pool of shares of Stock under the Plan in the same manner.

(c) *Changes in Stock.* Subject to Section 3(d) hereof, if, as a result of any reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock, the outstanding shares of Stock are increased or decreased or are exchanged for a different number or kind of shares or other securities of the Company, or additional shares or new or different shares or other securities of the Company or other non-cash assets are distributed with respect to such shares of Stock or other securities, or, if, as a result of any merger or consolidation, sale of all or substantially all of the assets of the Company, the outstanding shares of Stock are converted into or exchanged for securities of the Company or any successor entity (or a parent or subsidiary thereof), the Administrator shall make an appropriate or proportionate adjustment in (i) the maximum number of shares reserved for issuance under the Plan, including the maximum number of shares that may be issued in the form of Incentive Stock Options, (ii) the number of Stock Options or Stock Appreciation Rights that can be granted to any one individual grantee and the maximum number of shares that may be granted under a Performance-Based Award, (iii) the number and kind of shares or other securities subject to any then outstanding Awards under the Plan, (iv) the repurchase price, if any, per share subject to each outstanding Restricted Stock Award, and (v) the exercise price for each share subject to any then outstanding Stock Options and Stock Appreciation Rights under the Plan, without changing the aggregate exercise price (i.e., the exercise price multiplied by the number of Stock Options and Stock Appreciation Rights) as to which such Stock Options and Stock Appreciation Rights remain exercisable. The Administrator shall also make equitable or proportionate adjustments in the number of shares subject to outstanding Awards and the exercise price and the terms of outstanding Awards to take into consideration cash dividends paid other than in the ordinary course or any other extraordinary corporate event. The adjustment by the Administrator shall be final, binding and conclusive. No fractional shares of Stock shall be issued under the Plan resulting from any such adjustment, but the Administrator in its discretion may make a cash payment in lieu of fractional shares.

(d) *Mergers and Other Transactions.* Except as the Administrator may otherwise specify with respect to particular Awards in the relevant Award Certificate, in the case of and subject to the consummation of a Sale Event, the parties thereto may cause the assumption or continuation of Awards theretofore granted by the successor entity, or the substitution of such Awards with new Awards of the successor entity or parent thereof, with appropriate adjustment as to the number and kind of shares and, if appropriate, the per share exercise prices, as such parties shall agree. Upon the effective time of the Sale Event, the Plan and all outstanding Awards granted hereunder shall terminate. In the event of such termination, (i) the Company shall have the option (in its sole discretion) to make or provide for a cash payment to the grantees holding Options and Stock Appreciation Rights, in exchange for the cancellation thereof, in an amount equal to the difference between (A) the Sale Price multiplied by the number of shares of Stock subject to outstanding Options and Stock Appreciation Rights (to the extent then exercisable at prices not in excess of the Sale Price) and (B) the aggregate exercise price of all such outstanding Options and Stock Appreciation Rights; or (ii) each grantee shall be permitted, within a specified period of time prior to the consummation of the Sale Event as determined by the Administrator, to exercise all outstanding Options and Stock Appreciation Rights (to the extent then exercisable) held by such grantee.

(e) *Substitute Awards.* The Administrator may grant Awards under the Plan in substitution for stock and stock based awards held by employees, directors or other key persons of another corporation in connection with the merger or consolidation of the employing corporation with the Company or a Subsidiary or the acquisition by the Company or a Subsidiary of property or stock of the employing

corporation. The Administrator may direct that the substitute awards be granted on such terms and conditions as the Administrator considers appropriate in the circumstances. Any substitute Awards granted under the Plan shall not count against the share limitation set forth in Section 3(a).

SECTION 4. ELIGIBILITY

Grantees under the Plan will be such full or part-time officers and other employees, Non-Employee Directors and key persons (including Consultants) of the Company and its Subsidiaries as are selected from time to time by the Administrator in its sole discretion.

SECTION 5. STOCK OPTIONS

Any Stock Option granted under the Plan shall be in such form as the Administrator may from time to time approve.

Stock Options granted under the Plan may be either Incentive Stock Options or Non-Qualified Stock Options. Incentive Stock Options may be granted only to employees of the Company or any Subsidiary that is a "subsidiary corporation" within the meaning of Section 424(f) of the Code. To the extent that any Option does not qualify as an Incentive Stock Option, it shall be deemed a Non-Qualified Stock Option.

Stock Options granted pursuant to this Section 5 shall be subject to the following terms and conditions and shall contain such additional terms and conditions, not inconsistent with the terms of the Plan, as the Administrator shall deem desirable. If the Administrator so determines, Stock Options may be granted in lieu of cash compensation at the optionee's election, subject to such terms and conditions as the Administrator may establish.

(a) *Exercise Price.* The exercise price per share for the Stock covered by a Stock Option granted pursuant to this Section 5 shall be determined by the Administrator at the time of grant but shall not be less than 100 percent of the Fair Market Value on the date of grant. In the case of an Incentive Stock Option that is granted to a Ten Percent Owner, the option price of such Incentive Stock Option shall be not less than 110 percent of the Fair Market Value on the grant date.

(b) *Option Term.* The term of each Stock Option shall be fixed by the Administrator, but no Stock Option shall be exercisable more than ten years after the date the Stock Option is granted. In the case of an Incentive Stock Option that is granted to a Ten Percent Owner, the term of such Stock Option shall be no more than five years from the date of grant.

(c) *Exercisability; Rights of a Stockholder.* Stock Options shall become exercisable at such time or times, whether or not in installments, as shall be determined by the Administrator at or after the grant date. The Administrator may at any time accelerate the exercisability of all or any portion of any Stock Option. An optionee shall have the rights of a stockholder only as to shares acquired upon the exercise of a Stock Option and not as to unexercised Stock Options.

(d) *Method of Exercise.* Stock Options may be exercised in whole or in part, by giving written or electronic notice of exercise to the Company, specifying the number of shares to be purchased. Payment of the purchase price may be made by one or more of the following methods to the extent provided in the Option Award Certificate:

- (i) In cash, by certified or bank check or other instrument acceptable to the Administrator;
- (ii) Through the delivery (or attestation to the ownership) of shares of Stock that are not then subject to restrictions under any Company plan. Such surrendered shares shall be valued at Fair Market Value on the exercise date;

(iii) By the optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company for the purchase price; provided that in the event the optionee chooses to pay the purchase price as so provided, the optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; or

(iv) With respect to Stock Options that are not Incentive Stock Options, by a “net exercise” arrangement pursuant to which the Company will reduce the number of shares of Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price.

Payment instruments will be received subject to collection. The transfer to the optionee on the records of the Company or of the transfer agent of the shares of Stock to be purchased pursuant to the exercise of a Stock Option will be contingent upon receipt from the optionee (or a purchaser acting in his stead in accordance with the provisions of the Stock Option) by the Company of the full purchase price for such shares and the fulfillment of any other requirements contained in the Option Award Certificate or applicable provisions of laws (including the satisfaction of any withholding taxes that the Company is obligated to withhold with respect to the optionee). In the event an optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the optionee upon the exercise of the Stock Option shall be net of the number of attested shares. In the event that the Company establishes, for itself or using the services of a third party, an automated system for the exercise of Stock Options, such as a system using an internet website or interactive voice response, then the paperless exercise of Stock Options may be permitted through the use of such an automated system.

(e) *Annual Limit on Incentive Stock Options.* To the extent required for “incentive stock option” treatment under Section 422 of the Code, the aggregate Fair Market Value (determined as of the time of grant) of the shares of Stock with respect to which Incentive Stock Options granted under this Plan and any other plan of the Company or its parent and subsidiary corporations become exercisable for the first time by an optionee during any calendar year shall not exceed \$100,000. To the extent that any Stock Option exceeds this limit, it shall constitute a Non-Qualified Stock Option.

SECTION 6. STOCK APPRECIATION RIGHTS

(a) *Exercise Price of Stock Appreciation Rights.* The exercise price of a Stock Appreciation Right shall not be less than 100 percent of the Fair Market Value of the Stock on the date of grant.

(b) *Grant and Exercise of Stock Appreciation Rights.* Stock Appreciation Rights may be granted by the Administrator independently of any Stock Option granted pursuant to Section 5 of the Plan.

(c) *Terms and Conditions of Stock Appreciation Rights.* Stock Appreciation Rights shall be subject to such terms and conditions as shall be determined from time to time by the Administrator. The term of a Stock Appreciation Right may not exceed ten years.

SECTION 7. RESTRICTED STOCK AWARDS

(a) *Nature of Restricted Stock Awards.* The Administrator shall determine the restrictions and conditions applicable to each Restricted Stock Award at the time of grant. Conditions may be based on continuing employment (or other service relationship) and/or achievement of pre-established performance goals and objectives. The terms and conditions of each such Award Certificate shall be determined by the Administrator, and such terms and conditions may differ among individual Awards and grantees.

(b) *Rights as a Stockholder.* Upon the grant of the Restricted Stock Award and payment of any applicable purchase price, a grantee shall have the rights of a stockholder with respect to the voting of the Restricted Stock and receipt of dividends; provided that if the lapse of restrictions with respect to the Restricted Stock Award is tied to the attainment of performance goals, any dividends paid by the Company during the performance period shall accrue and shall not be paid to the grantee until and to the extent the performance goals are met with respect to the Restricted Stock Award. Unless the Administrator shall otherwise determine, (i) uncertificated Restricted Stock shall be accompanied by a notation on the records of the Company or the transfer agent to the effect that they are subject to forfeiture until such Restricted Stock are vested as provided in Section 7(d) below, and (ii) certificated Restricted Stock shall remain in the possession of the Company until such Restricted Stock is vested as provided in Section 7(d) below, and the grantee shall be required, as a condition of the grant, to deliver to the Company such instruments of transfer as the Administrator may prescribe.

(c) *Restrictions.* Restricted Stock may not be sold, assigned, transferred, pledged or otherwise encumbered or disposed of except as specifically provided herein or in the Restricted Stock Award Certificate. Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 18 below, in writing after the Award is issued, if a grantee's employment (or other service relationship) with the Company and its Subsidiaries terminates for any reason, any Restricted Stock that has not vested at the time of termination shall automatically and without any requirement of notice to such grantee from or other action by or on behalf of, the Company be deemed to have been reacquired by the Company at its original purchase price (if any) from such grantee or such grantee's legal representative simultaneously with such termination of employment (or other service relationship), and thereafter shall cease to represent any ownership of the Company by the grantee or rights of the grantee as a stockholder. Following such deemed reacquisition of unvested Restricted Stock that are represented by physical certificates, a grantee shall surrender such certificates to the Company upon request without consideration.

(d) *Vesting of Restricted Stock.* The Administrator at the time of grant shall specify the date or dates and/or the attainment of pre-established performance goals, objectives and other conditions on which the non-transferability of the Restricted Stock and the Company's right of repurchase or forfeiture shall lapse. Subsequent to such date or dates and/or the attainment of such pre-established performance goals, objectives and other conditions, the shares on which all restrictions have lapsed shall no longer be Restricted Stock and shall be deemed "vested." Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 18 below, in writing after the Award is issued, a grantee's rights in any shares of Restricted Stock that have not vested shall automatically terminate upon the grantee's termination of employment (or other service relationship) with the Company and its Subsidiaries and such shares shall be subject to the provisions of Section 7(c) above.

SECTION 8. RESTRICTED STOCK UNITS

(a) *Nature of Restricted Stock Units.* The Administrator shall determine the restrictions and conditions applicable to each Restricted Stock Unit at the time of grant. Conditions may be based on continuing employment (or other service relationship) and/or achievement of pre-established

performance goals and objectives. The terms and conditions of each such Award Certificate shall be determined by the Administrator, and such terms and conditions may differ among individual Awards and grantees. At the end of the deferral period, the Restricted Stock Units, to the extent vested, shall be settled in the form of shares of Stock. To the extent that an award of Restricted Stock Units is subject to Section 409A, it may contain such additional terms and conditions as the Administrator shall determine in its sole discretion in order for such Award to comply with the requirements of Section 409A.

(b) *Election to Receive Restricted Stock Units in Lieu of Compensation.* The Administrator may, in its sole discretion, permit a grantee to elect to receive a portion of future cash compensation otherwise due to such grantee in the form of an award of Restricted Stock Units. Any such election shall be made in writing and shall be delivered to the Company no later than the date specified by the Administrator and in accordance with Section 409A and such other rules and procedures established by the Administrator. Any such future cash compensation that the grantee elects to defer shall be converted to a fixed number of Restricted Stock Units based on the Fair Market Value of Stock on the date the compensation would otherwise have been paid to the grantee if such payment had not been deferred as provided herein. The Administrator shall have the sole right to determine whether and under what circumstances to permit such elections and to impose such limitations and other terms and conditions thereon as the Administrator deems appropriate. Any Restricted Stock Units that are elected to be received in lieu of cash compensation shall be fully vested, unless otherwise provided in the Award Certificate.

(c) *Rights as a Stockholder.* A grantee shall have the rights as a stockholder only as to shares of Stock acquired by the grantee upon settlement of Restricted Stock Units; provided, however, that the grantee may be credited with Dividend Equivalent Rights with respect to the phantom stock units underlying his Restricted Stock Units, subject to such terms and conditions as the Administrator may determine.

(d) *Termination.* Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 18 below, in writing after the Award is issued, a grantee's right in all Restricted Stock Units that have not vested shall automatically terminate upon the grantee's termination of employment (or cessation of service relationship) with the Company and its Subsidiaries for any reason.

SECTION 9. UNRESTRICTED STOCK AWARDS

Grant or Sale of Unrestricted Stock. The Administrator may, in its sole discretion, grant (or sell at par value or such higher purchase price determined by the Administrator) an Unrestricted Stock Award under the Plan. Unrestricted Stock Awards may be granted in respect of past services or other valid consideration, or in lieu of cash compensation due to such grantee.

SECTION 10. CASH-BASED AWARDS

Grant of Cash-Based Awards. The Administrator may, in its sole discretion, grant Cash-Based Awards to any grantee in such number or amount and upon such terms, and subject to such conditions, as the Administrator shall determine at the time of grant. The Administrator shall determine the maximum duration of the Cash-Based Award, the amount of cash to which the Cash-Based Award pertains, the conditions upon which the Cash-Based Award shall become vested or payable, and such other provisions as the Administrator shall determine. Each Cash-Based Award shall specify a cash-denominated payment amount, formula or payment ranges as determined by the Administrator. Payment, if any, with respect to a Cash-Based Award shall be made in accordance with the terms of the Award and may be made in cash or in shares of Stock, as the Administrator determines.

SECTION 11. PERFORMANCE SHARE AWARDS

(a) *Nature of Performance Share Awards.* The Administrator may, in its sole discretion, grant Performance Share Awards independent of, or in connection with, the granting of any other Award under the Plan. The Administrator shall determine whether and to whom Performance Share Awards shall be granted, the Performance Goals, the periods during which performance is to be measured, and such other limitations and conditions as the Administrator shall determine.

(b) *Rights as a Stockholder.* A grantee receiving a Performance Share Award shall have the rights of a stockholder only as to shares actually received by the grantee under the Plan and not with respect to shares subject to the Award but not actually received by the grantee. A grantee shall be entitled to receive shares of Stock under a Performance Share Award only upon satisfaction of all conditions specified in the Performance Share Award Certificate (or in a performance plan adopted by the Administrator).

(c) *Termination.* Except as may otherwise be provided by the Administrator either in the Award agreement or, subject to Section 18 below, in writing after the Award is issued, a grantee's rights in all Performance Share Awards shall automatically terminate upon the grantee's termination of employment (or cessation of service relationship) with the Company and its Subsidiaries for any reason.

SECTION 12. PERFORMANCE-BASED AWARDS TO COVERED EMPLOYEES

(a) *Performance-Based Awards.* Any employee or other key person providing services to the Company and who is selected by the Administrator may be granted one or more Performance-Based Awards in the form of a Restricted Stock Award, Restricted Stock Units, Performance Share Awards or Cash-Based Award payable upon the attainment of Performance Goals that are established by the Administrator and relate to one or more of the Performance Criteria, in each case on a specified date or dates or over any period or periods determined by the Administrator. The Administrator shall define in an objective fashion the manner of calculating the Performance Criteria it selects to use for any Performance Cycle. Depending on the Performance Criteria used to establish such Performance Goals, the Performance Goals may be expressed in terms of overall Company performance or the performance of a division, business unit, or an individual. The Administrator, in its discretion, may adjust or modify the calculation of Performance Goals for such Performance Cycle in order to prevent the dilution or enlargement of the rights of an individual (i) in the event of, or in anticipation of, any unusual or extraordinary corporate item, transaction, event or development, (ii) in recognition of, or in anticipation of, any other unusual or nonrecurring events affecting the Company, or the financial statements of the Company, or (iii) in response to, or in anticipation of, changes in applicable laws, regulations, accounting principles, or business conditions provided however, that the Administrator may not exercise such discretion in a manner that would increase the Performance-Based Award granted to a Covered Employee. Each Performance-Based Award shall comply with the provisions set forth below.

(b) *Grant of Performance-Based Awards.* With respect to each Performance-Based Award granted to a Covered Employee, the Administrator shall select, within the first 90 days of a Performance Cycle (or, if shorter, within the maximum period allowed under Section 162(m) of the Code) the Performance Criteria for such grant, and the Performance Goals with respect to each Performance Criterion (including a threshold level of performance below which no amount will become payable with respect to such Award). Each Performance-Based Award will specify the amount payable, or the formula for determining the amount payable, upon achievement of the various applicable performance targets. The Performance Criteria established by the Administrator may be (but need not be) different for each Performance Cycle and different Performance Goals may be applicable to Performance-Based Awards to different Covered Employees.

(c) *Payment of Performance-Based Awards.* Following the completion of a Performance Cycle, the Administrator shall meet to review and certify in writing whether, and to what extent, the

Performance Goals for the Performance Cycle have been achieved and, if so, to also calculate and certify in writing the amount of the Performance-Based Awards earned for the Performance Cycle. The Administrator shall then determine the actual size of each Covered Employee's Performance-Based Award, and, in doing so, may reduce or eliminate the amount of the Performance-Based Award for a Covered Employee if, in its sole judgment, such reduction or elimination is appropriate.

(d) *Maximum Award Payable.* The maximum Performance-Based Award payable to any one Covered Employee under the Plan for a Performance Cycle is 300,000 shares of Stock (subject to adjustment as provided in Section 3(c) hereof) or \$5 million in the case of a Performance-Based Award that is a Cash-Based Award.

SECTION 13. DIVIDEND EQUIVALENT RIGHTS

(a) *Dividend Equivalent Rights.* A Dividend Equivalent Right may be granted hereunder to any grantee as a component of an award of Restricted Stock Units, Restricted Stock Award or Performance Share Award or as a freestanding award. The terms and conditions of Dividend Equivalent Rights shall be specified in the Award Certificate. Dividend equivalents credited to the holder of a Dividend Equivalent Right may be paid currently or may be deemed to be reinvested in additional shares of Stock, which may thereafter accrue additional equivalents. Any such reinvestment shall be at Fair Market Value on the date of reinvestment or such other price as may then apply under a dividend reinvestment plan sponsored by the Company, if any. Dividend Equivalent Rights may be settled in cash or shares of Stock or a combination thereof, in a single installment or installments. A Dividend Equivalent Right granted as a component of an award of Restricted Stock Units or Restricted Stock Award with performance vesting or Performance Share Award shall provide that such Dividend Equivalent Right shall be settled only upon settlement or payment of, or lapse of restrictions on, such other Award, and that such Dividend Equivalent Right shall expire or be forfeited or annulled under the same conditions as such other Award.

(b) *Interest Equivalents.* Any Award under this Plan that is settled in whole or in part in cash on a deferred basis may provide in the grant for interest equivalents to be credited with respect to such cash payment. Interest equivalents may be compounded and shall be paid upon such terms and conditions as may be specified by the grant.

(c) *Termination.* Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 18 below, in writing after the Award is issued, a grantee's rights in all Dividend Equivalent Rights or interest equivalents granted as a component of an award of Restricted Stock Units, Restricted Stock Award or Performance Share Award that has not vested shall automatically terminate upon the grantee's termination of employment (or cessation of service relationship) with the Company and its Subsidiaries for any reason.

SECTION 14. TRANSFERABILITY OF AWARDS

(a) *Transferability.* Except as provided in Section 14(b) below, during a grantee's lifetime, his or her Awards shall be exercisable only by the grantee, or by the grantee's legal representative or guardian in the event of the grantee's incapacity. No Awards shall be sold, assigned, transferred or otherwise encumbered or disposed of by a grantee other than by will or by the laws of descent and distribution or pursuant to a domestic relations order. No Awards shall be subject, in whole or in part, to attachment, execution, or levy of any kind, and any purported transfer in violation hereof shall be null and void.

(b) *Administrator Action.* Notwithstanding Section 14(a), the Administrator, in its discretion, may provide either in the Award Certificate regarding a given Award or by subsequent written approval that the grantee (who is an employee or director) may transfer his or her Non-Qualified Options to his or her immediate family members, to trusts for the benefit of such family members, or to partnerships in which such family members are the only partners, provided that the transferee agrees in writing with

the Company to be bound by all of the terms and conditions of this Plan and the applicable Award. In no event may an Award be transferred by a grantee for value.

(c) *Family Member.* For purposes of Section 14(b), “family member” shall mean a grantee’s child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, any person sharing the grantee’s household (other than a tenant of the grantee), a trust in which these persons (or the grantee) have more than 50 percent of the beneficial interest, a foundation in which these persons (or the grantee) control the management of assets, and any other entity in which these persons (or the grantee) own more than 50 percent of the voting interests.

(d) *Designation of Beneficiary.* Each grantee to whom an Award has been made under the Plan may designate a beneficiary or beneficiaries to exercise any Award or receive any payment under any Award payable on or after the grantee’s death. Any such designation shall be on a form provided for that purpose by the Administrator and shall not be effective until received by the Administrator. If no beneficiary has been designated by a deceased grantee, or if the designated beneficiaries have predeceased the grantee, the beneficiary shall be the grantee’s estate.

SECTION 15. TAX WITHHOLDING

(a) *Payment by Grantee.* Each grantee shall, no later than the date as of which the value of an Award or of any Stock or other amounts received thereunder first becomes includable in the gross income of the grantee for Federal income tax purposes, pay to the Company, or make arrangements satisfactory to the Administrator regarding payment of, any Federal, state, or local taxes of any kind required by law to be withheld by the Company with respect to such income. The Company and its Subsidiaries shall, to the extent permitted by law, have the right to deduct any such taxes from any payment of any kind otherwise due to the grantee. The Company’s obligation to deliver evidence of book entry (or stock certificates) to any grantee is subject to and conditioned on tax withholding obligations being satisfied by the grantee.

(b) *Payment in Stock.* Subject to approval by the Administrator, a grantee may elect to have the Company’s minimum required tax withholding obligation satisfied, in whole or in part, by authorizing the Company to withhold from shares of Stock to be issued pursuant to any Award a number of shares with an aggregate Fair Market Value (as of the date the withholding is effected) that would satisfy the withholding amount due.

SECTION 16. SECTION 409A AWARDS

To the extent that any Award is determined to constitute “nonqualified deferred compensation” within the meaning of Section 409A (a “409A Award”), the Award shall be subject to such additional rules and requirements as specified by the Administrator from time to time in order to comply with Section 409A. In this regard, if any amount under a 409A Award is payable upon a “separation from service” (within the meaning of Section 409A) to a grantee who is then considered a “specified employee” (within the meaning of Section 409A), then no such payment shall be made prior to the date that is the earlier of (i) six months and one day after the grantee’s separation from service, or (ii) the grantee’s death, but only to the extent such delay is necessary to prevent such payment from being subject to interest, penalties and/or additional tax imposed pursuant to Section 409A. Further, the settlement of any such Award may not be accelerated except to the extent permitted by Section 409A.

SECTION 17. TRANSFER, LEAVE OF ABSENCE, ETC.

For purposes of the Plan, the following events shall not be deemed a termination of employment:

(a) a transfer to the employment of the Company from a Subsidiary or from the Company to a Subsidiary, or from one Subsidiary to another; or

(b) an approved leave of absence for military service or sickness, or for any other purpose approved by the Company, if the employee's right to re-employment is guaranteed either by a statute or by contract or under the policy pursuant to which the leave of absence was granted or if the Administrator otherwise so provides in writing.

SECTION 18. AMENDMENTS AND TERMINATION

The Board may, at any time, amend or discontinue the Plan and the Administrator may, at any time, amend or cancel any outstanding Award for the purpose of satisfying changes in law or for any other lawful purpose, but no such action shall adversely affect rights under any outstanding Award without the holder's consent. Except as provided in Section 3(c) or 3(d), without prior stockholder approval, in no event may the Administrator exercise its discretion to reduce the exercise price of outstanding Stock Options or Stock Appreciation Rights or effect repricing through cancellation and re-grants or cancellation of Stock Options or Stock Appreciation Rights in exchange for cash. To the extent required under the rules of any securities exchange or market system on which the Stock is listed, to the extent determined by the Administrator to be required by the Code to ensure that Incentive Stock Options granted under the Plan are qualified under Section 422 of the Code, or to ensure that compensation earned under Awards qualifies as performance-based compensation under Section 162(m) of the Code, Plan amendments shall be subject to approval by the Company stockholders entitled to vote at a meeting of stockholders. Nothing in this Section 18 shall limit the Administrator's authority to take any action permitted pursuant to Section 3(c) or 3(d).

SECTION 19. STATUS OF PLAN

With respect to the portion of any Award that has not been exercised and any payments in cash, Stock or other consideration not received by a grantee, a grantee shall have no rights greater than those of a general creditor of the Company unless the Administrator shall otherwise expressly determine in connection with any Award or Awards. In its sole discretion, the Administrator may authorize the creation of trusts or other arrangements to meet the Company's obligations to deliver Stock or make payments with respect to Awards hereunder, provided that the existence of such trusts or other arrangements is consistent with the foregoing sentence.

SECTION 20. GENERAL PROVISIONS

(a) *No Distribution.* The Administrator may require each person acquiring Stock pursuant to an Award to represent to and agree with the Company in writing that such person is acquiring the shares without a view to distribution thereof.

(b) *Delivery of Stock Certificates.* Stock certificates to grantees under this Plan shall be deemed delivered for all purposes when the Company or a stock transfer agent of the Company shall have mailed such certificates in the United States mail, addressed to the grantee, at the grantee's last known address on file with the Company. Uncertificated Stock shall be deemed delivered for all purposes when the Company or a Stock transfer agent of the Company shall have given to the grantee by electronic mail (with proof of receipt) or by United States mail, addressed to the grantee, at the grantee's last known address on file with the Company, notice of issuance and recorded the issuance in its records (which may include electronic "book entry" records). Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any certificates evidencing shares of

Stock pursuant to the exercise of any Award, unless and until the Administrator has determined, with advice of counsel (to the extent the Administrator deems such advice necessary or advisable), that the issuance and delivery of such certificates is in compliance with all applicable laws, regulations of governmental authorities and, if applicable, the requirements of any exchange on which the shares of Stock are listed, quoted or traded. All Stock certificates delivered pursuant to the Plan shall be subject to any stop-transfer orders and other restrictions as the Administrator deems necessary or advisable to comply with federal, state or foreign jurisdiction, securities or other laws, rules and quotation system on which the Stock is listed, quoted or traded. The Administrator may place legends on any Stock certificate to reference restrictions applicable to the Stock. In addition to the terms and conditions provided herein, the Administrator may require that an individual make such reasonable covenants, agreements, and representations as the Administrator, in its discretion, deems necessary or advisable in order to comply with any such laws, regulations, or requirements. The Administrator shall have the right to require any individual to comply with any timing or other restrictions with respect to the settlement or exercise of any Award, including a window-period limitation, as may be imposed in the discretion of the Administrator.

(c) *Stockholder Rights.* Until Stock is deemed delivered in accordance with Section 20(b), no right to vote or receive dividends or any other rights of a stockholder will exist with respect to shares of Stock to be issued in connection with an Award, notwithstanding the exercise of a Stock Option or any other action by the grantee with respect to an Award.

(d) *Other Compensation Arrangements; No Employment Rights.* Nothing contained in this Plan shall prevent the Board from adopting other or additional compensation arrangements, including trusts, and such arrangements may be either generally applicable or applicable only in specific cases. The adoption of this Plan and the grant of Awards do not confer upon any employee any right to continued employment with the Company or any Subsidiary.

(e) *Trading Policy Restrictions.* Option exercises and other Awards under the Plan shall be subject to the Company's insider trading policies and procedures, as in effect from time to time.

(f) *Forfeiture of Awards under Sarbanes-Oxley Act.* If the Company is required to prepare an accounting restatement due to the material noncompliance of the Company, as a result of misconduct, with any financial reporting requirement under the securities laws, then any grantee who is one of the individuals subject to automatic forfeiture under Section 304 of the Sarbanes-Oxley Act of 2002 shall reimburse the Company for the amount of any Award received by such individual under the Plan during the 12-month period following the first public issuance or filing with the United States Securities and Exchange Commission, as the case may be, of the financial document embodying such financial reporting requirement.

SECTION 21. EFFECTIVE DATE OF PLAN

This Plan shall become effective upon stockholder approval in accordance with applicable state law, the Company's by-laws and articles of incorporation, and applicable stock exchange rules. No grants of Stock Options and other Awards may be made hereunder after the tenth anniversary of the Effective Date and no grants of Incentive Stock Options may be made hereunder after the tenth anniversary of the date the Plan is approved by the Board.

SECTION 22. GOVERNING LAW

This Plan and all Awards and actions taken thereunder shall be governed by, and construed in accordance with, the laws of the State of Delaware, applied without regard to conflict of law principles.

DATE APPROVED BY BOARD OF DIRECTORS: April 12, 2013

DATE APPROVED BY STOCKHOLDERS: