No. _____

In the Supreme Court of the United States

AMAG Pharmaceuticals, Inc.; Brian J.G. Pereira, M.D.; David A. Arkowitz; Joseph V. Bonventre, M.D.; Michael Narachi; Robert J. Perez; Lesley Russell, M.D.; Davey S. Scoon; Ron Zwanziger; Morgan Stanley & Co. Incorporated; J.P. Morgan Securities LLC; Goldman, Sachs & Co.; Leerink Swann LLC; Robert W. Baird & Co. Incorporated; Canaccord Genuity Inc.,

Petitioners,

v.

Silverstrand Investments; Briarwood Investments, Inc.; Safron Capital Corporation, on behalf of themselves and all others similarly situated,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the First Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Respondents filed suit under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, alleging that Items 303 and 503 of Regulation S-K required AMAG Pharmaceuticals, Inc. ("AMAG") to disclose in its registration statement that 23 serious adverse events were reported during the six-month period between FDA approval of AMAG's drug *Feraheme* and its January 2010 stock offering. Five Circuits have held that the materiality of information allegedly omitted in violation of Section 11 must be assessed under the same standard applicable to claims under Section 10(b) of the Securities Exchange Act of 1934. Under that standard, the "materiality requirement is satisfied when there is a 'substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available.'" *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1318 (2011) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988)). In this case, however, the First Circuit rejected the *Basic*/*Matrixx* standard, concluding, as the Ninth Circuit has, that an alleged violation of Regulation S-K is sufficient, by itself, to state a claim under Section 11, and that no separate materiality analysis is required. The question presented is:

To survive a motion to dismiss, must a plaintiff asserting a Section 11 claim premised on an alleged violation of SEC regulations plead facts establishing that the allegedly omitted information is material under *Basic* and *Matrixx*?

PARTIES TO THE PROCEEDING

Petitioners are AMAG, Brian J.G. Pereira, M.D., David A. Arkowitz, Joseph V. Bonventre, M.D., Michael Narachi, Robert J. Perez, Lesley Russell, M.D., Davey S. Scoon, and Ron Zwanziger, defendants-appellees below (collectively, the "AMAG Petitioners").

Joining this Petition are Morgan Stanley & Co. LLC (f/k/a Morgan Stanley & Co. Incorporated), J.P. Morgan Securities LLC (f/k/a J.P. Morgan Securities Inc.), Goldman, Sachs & Co., Leerink Swann LLC, Robert W. Baird Co. Inc., and Canaccord Genuity Inc., also defendants-appellees below (collectively, the "Underwriter Petitioners").

Respondents are plaintiffs Silverstrand Investments, Briarwood Investments, Inc., and Safron Capital Corp., on behalf of themselves and all others similarly situated who purchased common stock of AMAG traceable to AMAG's January 21, 2010 stock offering, plaintiffs-appellants below ("Plaintiffs" or "Respondents").

RULE 29.6 STATEMENT

AMAG is a publicly-traded company. It has no parent corporation, and no publicly-held corporation owns 10% or more of its stock.

Morgan Stanley & Co. LLC (f/k/a Morgan Stanley & Co. Incorporated) is a limited liability company whose sole member is Morgan Stanley Domestic Holdings, Inc., a corporation wholly owned by Morgan Stanley Capital Management, LLC, a limited liability company whose sole member is Morgan Stanley. Morgan Stanley is a publicly-held corporation that has no parent corporation. Based on Securities and Exchange Commission Rules regarding beneficial ownership, Mitsubishi UFJ Financial Group, Inc. 7-1 Marunouchi 2-chome, Chiyoda-ku, Tokyo 100-8330, beneficially owns greater than 10% of Morgan Stanley's outstanding common stock.

J.P. Morgan Securities LLC (f/k/a J.P. Morgan Securities Inc.) is a wholly-owned indirect subsidiary of J.P. Morgan Chase & Co. ("JPMC"). JPMC is a publicly-held company whose shares are traded on the New York Stock Exchange. JPMC has no parent company and, to the best of J.P. Morgan Securities LLC's knowledge, no publicly-held company owns more than 10% of JPMC's shares.

Goldman, Sachs & Co. is an indirect subsidiary of The Goldman Sachs Group, Inc. ("GS Group"). No other publicly-held corporation owns more than 10% of Goldman, Sachs & Co. Shares of GS Group are publicly traded on the New York Stock Exchange and, to the best of Goldman, Sachs & Co.'s knowledge, no

publicly held corporation owns 10% or more of the common stock of GS Group.

Leerink Swann LLC is wholly owned by Leerink Swann Holdings, LLC, a Delaware Limited Liability Company. No publicly-held corporation owns more than 10% of Leerink Swann Holdings, LLC.

Robert W. Baird & Co. Incorporated is a majority-owned subsidiary of Baird Financial Corporation, which is a majority-owned subsidiary of Baird Holding Company, which is a majority-owned subsidiary of Baird Financial Group, Inc. No publicly-held corporation owns 10% or more of Robert W. Baird & Co. Incorporated's stock.

Canaccord Genuity Inc. is an indirect wholly-owned subsidiary of Canaccord Financial Inc., a British Columbia Corporation. Canaccord Financial Inc. has shares that are publicly traded on the Toronto Stock Exchange and on AIM in London.

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PETITION FOR WRIT OF CERTIORARI

The AMAG Petitioners respectfully seek a writ of certiorari to review the judgment of the United States Court of Appeals for the First Circuit in this case, *Silverstrand Investments et al. v. AMAG Pharmaceuticals, Inc. et al.*, No. 11-2063, which directly conflicts with decisions of five other Circuits. The Underwriter Petitioners join this Petition.

OPINIONS BELOW

The district court's Memorandum and Order dismissing Respondents' Second Amended Class Action Complaint ("SAC") is available at 2011 WL 3566990 (D. Mass. Aug. 11, 2011) and reprinted in the Appendix to the Petition ("App.") at 31–48. The First Circuit's decision affirming in part and vacating in part the district court's Memorandum and Order is reported at 707 F.3d 95 (1st Cir. 2013) and reprinted at App. 1–29. The First Circuit's Order denying panel rehearing and rehearing *en banc* is reprinted at App. 49–51. The First Circuit's Order granting the AMAG Petitioners' motion to stay mandate is reprinted at App. 52–54.

STATEMENT OF JURISDICTION

The First Circuit issued its decision on February 4, 2013, and denied a petition for panel rehearing and rehearing *en banc* on March 15, 2013. App. 49-51. This petition for certiorari is timely filed within 90 days of the denial of rehearing. *See* S. Ct. R. 13.3. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED IN THIS CASE

Section 11 of the Securities Act of 1933 ("Section 11") provides in relevant part:

> (a) Persons possessing cause of action; persons liable
>
> In case any part of the registration statement, when such part became effective, contained an untrue statement of a material fact ***or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading***, any person acquiring such security (unless it is proved that at the time of such acquisition he knew of such untruth or omission) may, either at law or in equity, in any court of competent jurisdiction, sue . . . .

15 U.S.C. § 77k(a) (emphasis added).

Item 303 of Regulation S-K, entitled "Management's discussion and analysis of financial condition and results of operations" ("Item 303"), provides in relevant part:

> (a) Full fiscal years. Discuss registrant's financial condition, changes in financial condition and results of operations. The discussion shall provide information as specified in paragraphs (a)(1) through (5) of this Item and also shall provide such other information that the registrant believes to be necessary to an understanding of its financial condition, changes

> in financial condition and results of operations
> . . . .
>
> (3) Results of operations
> . . .
>
> (ii) ***Describe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations.*** If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed.

17 C.F.R. § 229.303(a)(3)(ii) (emphasis added).

Item 503 of Regulation S-K, entitled "Prospectus summary, risk factors, and ratio of earnings to fixed charges" ("Item 503"), provides in pertinent part:

> (c) Risk factors. ***Where appropriate, provide under the caption "Risk Factors" a discussion of the most significant factors that make the offering speculative or risky.*** This discussion must be concise and organized logically. Do not present risks that could apply to any issuer or any offering. Explain how the risk affects the issuer or the securities being offered. Set forth each risk factor under a subcaption that adequately describes the risk

> . . . . The risk factors may include, among other things, the following:
>
> (1) Your lack of an operating history;
> (2) Your lack of profitable operations in recent periods;
> (3) Your financial position;
> (4) Your business or proposed business; or
> (5) The lack of a market for your common equity securities or securities convertible into or exercisable for common equity securities.

17 C.F.R. § 229.503(c) (emphasis added).

Further, the relevant provisions of Section 10(b) of the Securities and Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b), are reproduced at App. 212. The relevant provisions of SEC Rule 10b–5, 17 C.F.R. § 240.10b–5, which implements 15 U.S.C. § 78j(b), are reproduced at App. 212–13. The relevant provisions of Section 12(a)(2) of the Securities Act of 1933 ("Securities Act"), 15 U.S.C. § 77l(a)(2), are reproduced at App. 210–11. The relevant provisions of Section 15 of the Securities Act, 15 U.S.C. § 77o, are reproduced at App. 211.

INTRODUCTION

This case presents a question of recurring importance on which the courts of appeals are divided: whether a plaintiff asserting a Section 11 claim premised on the alleged failure to comply with Items 303 and 503 of Regulation S-K must plead facts establishing that the allegedly omitted information is

material under the standard articulated in *Basic*, 485 U.S. 224, and reaffirmed in *Matrixx*, 131 S. Ct. 1309. Items 303 and 503 are SEC regulations, commonly invoked in Section 11 claims, requiring that issuers disclose certain known trends, uncertainties and risks in their registration statements. The First Circuit concluded that, so long as a complaint adequately pleads the omission of information allegedly required to be stated under Item 303 or 503 (here, the existence of 23 serious adverse event ("SAE") reports associated with AMAG's drug, *Feraheme*), a Section 11 claim will be permitted to proceed regardless of whether the information allegedly omitted was material under *Basic* and *Matrixx*. Similarly, the Ninth Circuit has held that an alleged violation of Item 303 is sufficient, in and of itself, to state a Section 11 claim. However, the First Circuit's decision directly conflicts with decisions of five other Circuits. In particular, the Second Circuit has repeatedly held that, to adequately plead a Section 11 claim based on Item 303, a plaintiff must plead *both* a duty to disclose under Item 303 *and* materiality under *Basic*. Likewise, the Third, Fifth, Eighth and Eleventh Circuits all apply *Basic* to assess the materiality of information allegedly omitted from a registration statement in violation of Section 11, including information allegedly required by Regulation S-K.

Absent review by this Court, the First and Ninth Circuit's erroneous decisions will have significant consequences for all companies that seek to raise capital through public stock offerings. By holding that shareholders may state viable Section 11 claims based on the alleged omission of information required to be disclosed by SEC regulations whether or not that

information alters the total mix of information available, these outlier Circuits have effectively written out of Section 11 the express statutory requirement that a plaintiff plead the omission of "a ***material*** fact required to be stated." 15 U.S.C. § 77k(a) (emphasis added). As a result, the pleading requirements for stating a Section 11 securities claim – and the protections afforded by this Court's decisions in *Basic* and *Matrixx* – will depend entirely on the jurisdiction in which a plaintiff chooses to bring suit.

The First Circuit's decision also runs afoul of *Matrixx* in another way that is of particular concern to all pharmaceutical companies and their investors and consumers. In *Matrixx*, this Court held that "the mere existence of reports of adverse events . . . says nothing . . . about whether the drug is causing the adverse events" and is insufficient to satisfy the materiality standard. 131 S. Ct. at 1321. However, in evaluating the adequacy of Respondents' Section 11 claim, the First Circuit simply presumed that all 23 SAEs reported after the commercial launch of *Feraheme* were caused by the drug, even though the SAC does not allege causation or any facts from which causation might be inferred. In other words, the First Circuit afforded Respondents the very inference that *Matrixx* expressly rejected. Accordingly, pharmaceutical companies seeking to raise capital to fund important research and development work will run the risk of Section 11 liability in the First Circuit unless their registration statements disclose in detail every adverse event reported, even if the adverse events in question are fully consistent with prior disclosures and the FDA-approved package insert (as were the 23 SAEs at issue here) and regardless of whether they were caused by

the drug, the patient's underlying disease or a totally unrelated event. Such a result would harm not only investors, who depend on receiving significant rather than useless information, but also consumers, who may be deterred from using drugs that they desperately need. That is precisely what the Court in *Matrixx* was determined to avoid.

To resolve the significant conflict in the Circuits, establish uniform national pleading requirements under Section 11 and ensure that the holdings in *Matrixx* and *Basic* are properly followed and applied, the Court should grant certiorari and hold that the *Basic*/*Matrixx* materiality standard applies to Section 11 claims premised on alleged violations of SEC regulations, including Items 303 and 503 of Regulation S-K.

STATEMENT OF THE CASE

I. RELEVANT FACTUAL BACKGROUND

A. AMAG Repeatedly Disclosed the Safety Risks Associated with *Feraheme* in its SEC Filings

AMAG sells an intravenous iron-replacement therapy known as *Feraheme*. *Feraheme* was approved by the Food and Drug Administration ("FDA") in June 2009 for the treatment of anemia in adult patients with chronic kidney disease ("CKD"), an irreversibly progressive and debilitating condition characterized by

persistent kidney dysfunction.[1] (App. 60–61 ¶¶ 3, 5.) Morbidity and mortality rates among CKD patients are high, and they often suffer from other serious health problems, including high blood pressure, anemia, nerve damage, and heart and blood vessel disease. (App. 154 (citing AMAG's 01/31/08 8-K, 2008 10-K, and 2007 10-K).) Before obtaining FDA approval, *Feraheme* underwent three rigorous phases of clinical trials, including four Phase III clinical studies. (App. 155–56.)[2] AMAG publicly disclosed the safety data from these trials in its FDA submissions and its public filings with the SEC. (App. 161–64.)

Among other key safety data, AMAG disclosed in its SEC filings that:

- 9.8 percent of *Feraheme*-treated patients experienced SAEs[3] in the first three Phase III

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[1] Before a drug may be approved for sale in the United States, the manufacturer must demonstrate to experts at the FDA that it is "safe and effective" for its intended use. 21 U.S.C. § 355. "No drug is absolutely safe; all drugs have side effects." *FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm289601.htm. Pursuant to FDA regulations, a drug is "safe" if its "benefits appear to outweigh the risks." 21 C.F.R. §§ 312.84, 314.105.

[2] The first three Phase III studies were open-label, randomized efficacy and safety studies. The fourth was a double-blind, placebo-controlled safety study. (App. 156.)

[3] Serious adverse events are "[a]ny adverse drug experience occurring at any dose that results in . . . [d]eath, a life-threatening adverse drug experience [or] inpatient hospitalization . . . , a

studies (App. 157, 184 n.12 (citing 2007 10-K and 01/31/08 8-K));

- 2.9 percent of *Feraheme*-treated patients experienced SAEs in the fourth Phase III study (App. 157, 173 (citing 2007 10-K and 2008 10-K));

- 1.1 percent of *Feraheme*-treated patients across all four Phase III studies died after receiving the drug (App. 173, 185 (citing 2007 10-K and 01/31/08 8-K)); and

- 0.17 percent of *Feraheme*-treated patients across all four Phase III studies experienced "drug-related SAEs," i.e., SAEs that were determined to be caused by the drug itself (App. 94 ¶ 86 (citing 2008 10-K).)

In addition, the FDA-approved product insert (or "label") for *Feraheme* explicitly warned about the safety risks associated with *Feraheme*:

> ***Feraheme may cause serious hypersensitivity reactions, including anaphylaxis and/or anaphylactoid reactions.*** In clinical studies, serious hypersensitivity reactions were reported in 0.2% (3/1,726) of subjects receiving *Feraheme*. Other adverse reactions potentially associated with hypersensitivity . . . were reported in 3.7%

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persistent or significant disability/incapacity, or a congenital anomaly/birth defect." 21 C.F.R. § 310.305(b).

> (63/1,726) of these subjects. Observe patients for signs and symptoms of hypersensitivity for at least 30 minutes following *Feraheme* injection . . . .

(App. 160–61 (quoting label) (emphasis added).)[4]

AMAG repeatedly warned investors that these safety issues could impact its financial performance. For example, in its 2008 10-K, AMAG warned that SAEs occurring after FDA approval could significantly affect *Feraheme*'s commercial viability:

> The FDA also requires all companies with approved products to submit reports on adverse drug experiences that occur after marketing approval. These requirements include specific and timely notification of certain serious, unexpected and/or frequent adverse events, as well as regular periodic reports summarizing adverse drug experiences . . . . [T]he FDA could place additional limitations on a product's use, such as labeling changes and, potentially, withdrawal or suspension of the product from the market.

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[4] After the FDA approves a drug, regulations require that it publish "all safety and effectiveness data" and "adverse reaction reports." 21 C.F.R. § 314.430. Accordingly, the FDA made its "Drug Approval Package" for *Feraheme* publicly available on its website on November 25, 2009, just two months before the Offering. (*See* App. 159 (citing FDA Drug Approval Package Cover Page).)

(App. 163 (quoting 2008 10-K).) The 2008 10-K went on to identify a number of specific factors that could affect *Feraheme's* success in the market, including:

> [AMAG's] ability to demonstrate to the medical community . . . the clinical efficacy and safety of *Feraheme* as an alternative to current treatments . . . ; [t]he actual or perceived safety profile of *Feraheme* relative to alternative iron therapeutic agents; [and t]he *Feraheme* labeling and product insert required by the FDA . . . .

(App. 163–64 (quoting 2008 10-K).)

In its Form 10-Q publicly filed on November 5, 2009, just eleven weeks before the Offering, AMAG stated:

> *Feraheme* may not receive the same level of market acceptance as . . . competing iron replacement therapy products . . . . The iron replacement therapy market is highly sensitive to several factors including . . . the perceived safety profile of the available products . . . .

(App. 164 (quoting 11/5/09 10-Q).)

Due to these and other fully disclosed uncertainties respecting *Feraheme,* AMAG specifically cautioned that its stock price could be affected: "[t]he 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." (*Id.*)

B. The Safety Risks Associated with *Feraheme* Were Fully Disclosed in the Offering Documents

In anticipation of the Offering, AMAG filed its registration statement and prospectus ("Offering Documents") with the SEC on January 19 and 20, 2010, respectively. (App. 165.) The Offering Documents specifically incorporated by reference, among other documents, AMAG's 2008 10-K and July 1, 2009 8-K, which in turn incorporated by reference the *Feraheme* product insert. (*Id.*) Thus, as of the Offering date, investors had been fully apprised of the clinical trials results, the nature and frequency of SAEs reported therein, the FDA's risk assessment of *Feraheme*, the possibility of additional adverse events being reported post-marketing, and the potential impact of each of these factors on AMAG's commercial success.

AMAG also discussed risks to potential investors in the prospectus: "Factors which may affect the market price of our common stock include . . . [s]afety concerns related to *Feraheme* . . . ." (*Id.* (quoting prospectus).) The prospectus also stated that the "degree of market acceptance of *Feraheme* depends on a number of factors, including . . . [t]he development of unanticipated adverse reactions to *Feraheme* resulting in safety concerns among prescribers." (*Id.*) And it identified other risks that could negatively impact any investment in AMAG:

- "We are subject to ongoing FDA regulatory requirements and review pertaining to *Feraheme's* manufacture, labeling,

> packaging, [and] adverse event reporting . . . . Failure to comply with such regulatory requirements or the later discovery of previously unknown problems with *Feraheme* . . . may result in restrictions on our ability to market and sell *Feraheme* . . . [;] FDA warning letters; . . . [and] FDA-imposed label changes . . . . Any of these sanctions would have a material adverse impact on our ability to generate revenues and to achieve profitability." (App. 166.)

- "Significant safety or drug interaction problems could arise . . . resulting in recalls, restrictions in *Feraheme's* label, or withdrawal of *Feraheme* from the market." (*Id.*)

- "[I]f the FDA changes the label for *Feraheme* to include additional discussion of potential safety issues . . . [, this] could have a material adverse impact on our ability to generate revenues from sales of *Feraheme* . . . ." (*Id.*)

On January 21, 2010, AMAG successfully completed a secondary Offering of approximately 3.6 million shares of common stock at a price to the public of $48.25 per share. (App. 62 ¶ 8).

II. RESPONDENTS' ALLEGATIONS

Respondents filed their Second Amended Class Action Complaint on December 17, 2010, alleging claims under Sections 11, 12(a)(2) and 15 of the

Securities Act.[5] The SAC alleges that the Offering Documents should have disclosed that 23 SAEs, including two anaphylactic reactions and one death, were reported during the six-month period between FDA approval of *Feraheme* and the Offering (collectively, the "23 SAEs"). (App. 78–82 ¶¶ 64–75.) Respondents allege that the "actual rate of incidence" of these 23 SAEs was arguably as high as 0.45%. (App. 112 ¶ 108.)[6] They also allege that 16 of the 23 SAEs (or as many as 0.18%) involved *Feraheme*-treated patients who "exhibited one or more symptoms associated with anaphylaxis . . . ." (App. 80 ¶ 71.)[7] According to the SAC, AMAG had a duty to disclose the 23 SAEs in the Offering Documents pursuant to Items 303 and 503 of

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[5] Subject matter jurisdiction in the district court was predicated upon 15 U.S.C. §77v.

[6] "Feraheme is administered in a minimum of two and as many as four injections," so Respondents calculate that the 35,000 post-marketing *Feraheme* injections that allegedly had occurred as of February 5, 2010 (two weeks after the Offering) translate to a minimum of 8,750 patients (assuming all patients received four injections) and a maximum of 35,000 patients (assuming all patients received only one injection). (App. 111 ¶ 106; *see also* App. 112 ¶ 108.) Dividing the total number of post-marketing SAEs allegedly reported as of that date (40) by 35,000 and 8,750, respectively, yields, according to Respondents, a true post-marketing SAE incidence rate of between 0.11% and 0.45%. (*Id.*) The AMAG Petitioners accept as true (as they did below) Respondents' most aggressive alleged post-marketing SAE rate of 0.45%.

[7] Dividing these 16 alleged SAEs by 35,000 and 8,750, respectively, yields a rate of between 0.045% and 0.18%. Again, the AMAG Petitioners accept Respondents' most aggressive alleged rate of 0.18% for purposes of this Petition.

Regulation S-K and to make other statements in the Offering Documents not misleading. (App. 81, 102 ¶¶ 74, 95.)

Critically, the SAC never alleges that the 23 SAEs were "drug-related." Rather, it alleges merely that the 23 SAEs were "associated with" or "linked to" *Feraheme*. (*See, e.g.*, App. 62, 64, 65, 80, 98, 102–03 ¶¶ 6, 7, 15, 18, 71, 92, 95–96.) Respondents' word choice was deliberate and critical. As explained more fully in Section IV below, the FDA clearly distinguishes between SAEs that are merely *associated with* the use of a drug (*i.e.*, experienced by a patient after receiving a drug), and those that can properly be considered *drug-related* (*i.e.*, caused by the drug). *See* FDA, *Guidance for Industry, Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products*, p. 13 (Jan. 2006), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075057.pdf (defining adverse event as "an untoward medical event ***associated with*** the use of a drug in humans, ***whether or not considered to be drug-related***") (emphasis added).

III. THE *MATRIXX* DECISION

Petitioners moved to dismiss the SAC on February 23, 2011. While that motion was pending, this Court decided *Matrixx* on March 22, 2011. In *Matrixx*, the plaintiffs alleged that defendants had committed securities fraud by making false and misleading statements about Zicam – an over-the-counter nasal spray. 131 S. Ct. at 1315–16. Among other things, plaintiffs alleged that Matrixx had received

"information that plausibly indicated a reliable causal link between Zicam and anosmia [the loss of smell]," including reports from medical professionals presented at an industry conference. *Id.* at 1322. In addition, nine product liability lawsuits had been filed against Matrixx asserting a causal link between Zicam and anosmia. *Id.* Nevertheless, the company, without disclosing any of this information, allegedly made unabashedly positive statements that it expected revenues from Zicam "to rise 50 and then 80 percent." *Id.* at 1323. Thereafter, when the anosmia data was publicized by others, Matrixx characterized it as "completely unfounded and misleading" and stated that Zicam's safety was "well established," even though, as Matrixx later conceded, the scientific evidence was "insufficient" to determine if Zicam affects a person's ability to smell. *Id.* This Court held that the complaint adequately alleged a claim for securities fraud under Section 10(b) and Rule 10b-5. *Id.* at 1317–23.

In so holding, the Court reaffirmed the "total mix" standard for materiality enunciated in *Basic*. *Id.* at 1321–22 ("The question remains whether a *reasonable* investor would have viewed the nondisclosed information 'as having *significantly* altered the 'total mix' of information made available.'") (emphasis in original) (quoting *Basic*, 485 U.S. at 232). The Court then rejected the bright-line rule advocated by the defendants that adverse event reports need only be disclosed if they establish a statistically significant causal link between the adverse event and the product. *Id*. at 1321. Importantly, however, the Court also clarified that the mere existence of adverse event reports is not sufficient to trigger a duty to disclose:

> Application of *Basic*'s "total mix" standard does not mean that pharmaceutical manufacturers must disclose all reports of adverse events. Adverse event reports are daily events in the pharmaceutical industry . . . . ***[T]he mere existence of reports of adverse events – which says nothing in and of itself about whether the drug is causing the adverse events – will not satisfy this standard. Something more is needed*** . . . .

Id. (emphasis added). Further, the Court reaffirmed that "[s]ilence, absent a duty to disclose, is not misleading," and emphasized that the principles in *Matrixx* "do not create an affirmative duty to disclose any and all material information." *Id.* at 1321–22.

IV. *MATRIXX* MEMORIALIZED YEARS OF FDA GUIDANCE ON ADVERSE EVENT REPORTING

SAEs reported after a patient takes a drug have no inherent causal relationship to the drug. The FDA encourages healthcare providers to notify drugmakers and the FDA of all adverse events occurring in patients receiving FDA-approved drugs. Drug makers, in turn, are required to report all adverse events of which they become aware, even though such events may have nothing to do with the drug at issue. *See* FDA, *Guidance for Industry, Good Pharmacovigilance Practice and Good Pharmacoepidemiologic Assessment* (Mar. 2005), *available at* 2005 WL 3628217, at *4. In fact, adverse events should be reported even if the reporting person does not believe that there is any causal relationship between the event and the drug. 21

C.F.R. § 314.80(a), (k). Accordingly, by way of example, every CKD patient who dies after receiving *Feraheme* – even if the death was caused by CKD, itself, or any of the other serious health issues associated with CKD – is an SAE. Every CKD patient who experiences *any* serious adverse health event after receiving *Feraheme* is an SAE. And because morbidity and mortality rates among CKD patients are high (App. 154), SAEs associated with *Feraheme* – which is prescribed for the purpose of treating these very ill patients – are also expectedly high.

Because adverse events must be reported irrespective of causation, the FDA has specifically instructed that post-marketing SAE reports are not reliable as a measure of drug safety:

> There are some important things to remember when reviewing or analyzing data from [the FDA's Adverse Event Reporting System] . . .
>
> 2. The information contained in the reports has not been scientifically or otherwise verified.
>
> *3*. For any given report, there is no certainty that the suspected drug caused the reaction . . . . *The event may have been related to the underlying disease for which the drug was given, to concurrent drugs being taken or may have occurred by chance at the same time the suspected drug was taken.*
>
> *4*. ***Accumulated case reports cannot be used to calculate incidence or estimates of drug risk.***

> 5. Numbers from these data must be carefully interpreted as reporting rates and not occurrence rates. True incidence rates cannot be determined from this database.

(App. 167–68 (quoting Adverse Event Reporting System (AERS) – Background, Report Definitions, and Caveats, Aug. 1, 2006) (emphasis added).)

Matrixx memorializes this guidance, holding that SAE reports, standing alone, do not establish or reflect any causal relationship between administration of the drug and the SAEs and, accordingly, that the mere existence of SAEs will not satisfy the *Basic* materiality standard. 131 S. Ct. at 1321.

V. THE DISTRICT COURT PROPERLY DISMISSED ALL CLAIMS

The district court granted Petitioners' motion to dismiss the SAC with prejudice on August 11, 2011. It reasoned that, under *Matrixx*, the mere existence of the 23 SAE reports was insufficient to give rise to a duty to disclose them. (App. 44.) Moreover, AMAG had "repeatedly disclosed in its Offering Documents and other public filings the safety information for *Feraheme*, including the fact that SAEs were observed during the clinical trials." (*Id.*) In particular, the "Offering Documents . . . contained extensive disclosures of the risks associated with *Feraheme,* including . . . how SAEs could impact *Feraheme*'s success." (App. 45.) Indeed, the rate of incidence of post-approval SAEs alleged by Respondents (at most 0.45%) was significantly lower than and, thus, "consistent with the previously and publicly-disclosed

rates [of SAEs] observed in the clinical trial[s]." (*Id.* at 44–45.)[8] Thus, the district court concluded that disclosure of the 23 SAEs was not required under Items 303 or 503 of Regulation S-K or to make other disclosures in the Offering Documents not misleading, and the SAC failed to allege a material omission giving rise to a violation of the Securities Act. (App. 40–45.)

VI. THE FIRST CIRCUIT ERRONEOUSLY VACATED THE DISTRICT COURT'S DECISION AND DENIED REHEARING

On February 4, 2013, the First Circuit affirmed in part and vacated in part the district court's decision and remanded for further proceedings. It found that Respondents "plead[ed] plausible claims for omissions under § 11 due to undisclosed Item 303 uncertainties and undisclosed Item 503 risks" insofar as the SAC

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[8] The overall SAE rates of 2.9% and 9.8% (App. 157, 173, 184 n.12) disclosed by AMAG were 6 to 22 times higher than the 0.45% post-launch SAE rate alleged by Respondents. Similarly, AMAG disclosed that the death rate for *Feraheme*-treated patients in clinical trials was 1.1%. (App. 173, 185.) At that rate, one might have expected at least 96 patients treated with *Feraheme* post-marketing (1.1% of 8,750 patients) to have died by the time Respondents filed suit. Respondents, however, allege only one death. (App. 78–82 ¶¶ 64–75.) Finally, Respondents' alleged rate of post-marketing SAEs involving "one or more symptoms associated with anaphylaxis," or 0.18% (*see supra*, note 7), is also lower than that disclosed by AMAG. (*See* App. 160–61 (disclosing that 0.2% of clinical trial patients experienced serious hypersensitivity reactions, including anaphylaxis and anaphylactoid reactions, and that "other adverse reactions potentially associated with hypersensitivity . . . were reported in 3.7% [] of these subjects") (quoting label).)

alleged that the registration statement failed to disclose the 23 SAEs.[9] (App. 18–20.) In reaching this conclusion, the First Circuit refused to conduct a materiality analysis, finding that *Basic* and *Matrixx* are inapposite where, as here, the SAC alleges a Section 11 claim premised on the alleged violation of Items 303 and 503. (App. 24 n.9 (*Matrixx* "addressed claims of omissions under § 10(b) . . . , which imposes completely different exigencies than those of Items 303 and 503.") (citing Mgmt.'s Discussion and Analysis of Fin. Conditions and Results of Operations, SEC Release No. 6835 ("SEC Release"), 1989 WL 1092885, at *6 n.27) (stating that "[t]he probability/magnitude

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[9] Notably, the First Circuit did not address or disturb the district court's finding that disclosure of the 23 SAEs was not required to make other disclosures in the Offering Documents not misleading. (*See* App. 25.) This effectively nullifies Respondents' Section 12(a)(2) claim, as Respondents do not allege any affirmative misstatements and, unlike Section 11 claims, a Section 12(a)(2) claim cannot be premised on an alleged failure to disclose information "required to be stated" under SEC regulations. *See, e.g.*, *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1204 (1st Cir. 1996) (describing the "required to be stated" prong as "unique to Section 11; neither Section 12(a)(2) of the Securities Act nor Section 10(b) . . . [of] the Exchange Act contains comparable language"). Accordingly, the First Circuit erred in holding that Respondents' Section 12(a)(2) claim should proceed simply because it found that Respondents had adequately pleaded a Section 11 claim under the "required to be stated" prong. (App. 26.) However, because reversal of the First Circuit's ruling on Respondents' Section 11 claim would, in turn, result in dismissal of Respondents' claims under Section 12(a)(2) and 15 (*id.*), this Petition is directed strictly to the First Circuit's erroneous conclusion that the SAC adequately states a Section 11 claim premised on an alleged duty of disclosure under Items 303 and 503.

test for materiality approved by the Supreme Court in *Basic* . . . , [a test *Matrixx* reaffirmed] is inapposite to Item 303 disclosure").) The First Circuit also incorrectly assumed that the 23 SAEs were alleged to be and were, in fact, "drug-related," i.e., caused by *Feraheme* (App. 22), even though the SAC contains no such allegation and *Matrixx* explicitly bars any such inference.[10] 131 S. Ct. at 1321.

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[10] Because the First Circuit assumed that the 23 SAEs were all "drug-related," it compared the maximum rate of those SAEs alleged by Respondents (0.45%) to the 0.17% rate of "*drug-related*" SAEs observed in clinical trials (App. 94 ¶ 86), and concluded that the undisclosed, post-launch rate was "over two times higher." (App. 22.) These figures, however, are entirely unrelated. The 0.45% figure alleged by Respondents refers to *all* post-marketing SAEs reported, not "*drug-related*" SAEs as the First Circuit improperly inferred. (App. 112 ¶ 108.) Indeed, even Respondents never argued – before the district court or on appeal – that their alleged SAE rate of 0.45% should be compared to the 0.17% figure. Instead, under *Matrixx*, the First Circuit should have compared Respondents' alleged 0.45% rate of post-marketing SAEs to the overall rate of *all* SAEs reported in clinical trials (9.8% in the first 3 Phase III trials, and 2.9% in the fourth). (App. 157, 173, 184 n.12.) Had it done so, the district court's conclusion that "the 23 SAEs . . . were consistent with the previously and publicly-disclosed rates observed in the trials" would have been self-evident. (App. 44–45.) Alternatively, the First Circuit could have compared the disclosed rate of SAEs caused by *Feraheme* (0.17%) with the rate of post-launch SAEs determined to have been drug-related. However, the SAC is devoid of any allegations with regard to the latter number, making any such comparison impossible. Indeed, Respondents concede that AMAG concluded that the single reported death was <u>not</u> drug-related, and they do not challenge that conclusion in the SAC. (App. 109–110 ¶ 104; *see also* App. 170–71.)

On February 19, 2013, the AMAG Petitioners filed a petition for panel rehearing and rehearing *en banc* before the First Circuit, which the Underwriter Petitioners joined. The petition requested rehearing on the grounds that the panel erred by refusing to apply the *Basic*/*Matrixx* materiality standard and by inferring that the 23 SAEs were caused by *Feraheme* in contravention of *Matrixx*. The First Circuit denied rehearing on March 15, 2013. (App. 50.) On March 22, 2013, the AMAG Petitioners filed a motion to stay the First Circuit's mandate pending the filing of this petition seeking a writ of certiorari. On April 8, 2013, the First Circuit granted the motion to stay the mandate. (App. 53.)

REASONS FOR GRANTING THE PETITION

The central question presented in this Petition is whether the materiality standard enunciated in *Basic* and reaffirmed in *Matrixx* applies in Section 11 omissions cases premised on an alleged violation of Items 303 and 503 of Regulation S-K. This question is substantial and deserving of review, both because it is of exceptional importance and because the Circuits conflict in their answers to it. A Section 11 claim premised on the omission of information allegedly required to be stated under SEC regulations, such as Regulation S-K, should be permitted to proceed only when there is a substantial likelihood that the disclosure of the allegedly omitted information would have been viewed by the reasonable investor as having significantly altered the total mix of information made available. *Matrixx*, 131 S. Ct. at 1318; *Basic*, 485 U.S. at 231–32. The Court should grant certiorari and reverse the judgment below.

I. THE COURTS OF APPEALS ARE DIVIDED ON THE QUESTION PRESENTED

There is a well-developed split of authority among seven Circuits on the question presented in this case. The Second, Third, Fifth, Eighth and Eleventh Circuits have all concluded that the *Basic* materiality standard applies in Section 11 cases, including those premised on alleged violations of Regulation S-K, whereas the First Circuit has now joined the Ninth Circuit in reaching the opposite conclusion. As such, there exists an obvious conflict between the Circuits on the critical issue of how the requirements of Section 11 should be interpreted and applied.

A. Five Circuits Have Held That the *Basic/Matrixx* Standard Applies to Section 11 Claims

Numerous decisions from the Second, Third, Fifth, Eighth and Eleventh Circuits hold squarely that Section 11 claims, including those predicated on violations of Regulation S-K, are subject to the *Basic* materiality standard.

The Second Circuit and district courts therein have repeatedly held that, to sufficiently plead a Section 11 claim based on Item 303, a plaintiff must not only plead facts demonstrating a duty of disclosure under Item 303, but also facts demonstrating that the allegedly omitted information is material under *Basic*. For example, in *Hutchison v. Deutsche Bank Securities Inc.*, 647 F.3d 479, 485–89 (2d Cir. 2011), the Second Circuit determined that the alleged impairment of two mezzanine loans constituted known trends or

uncertainties for purposes of Item 303, but nevertheless affirmed dismissal of the complaint, as the information allegedly omitted was immaterial as a matter of law under *Basic*. 647 F.3d 479, 485–89 (2d Cir. 2011). Similarly, in *Litwin v. Blackstone Group, L.P.*, the Second Circuit stated clearly that "[i]t is only when there is both materiality [under *Basic*] and a duty to disclose [under Item 303] that a company may be held liable for omitting information from a registration statement or prospectus [under Section 11]." 634 F.3d 706, 723 (2d Cir. 2011); *see also McKenna v. Smart Techs. Inc.*, No. 11 Civ. 7673(KBF), 2012 WL 1131935, at *13-14 (S.D.N.Y. Apr. 3, 2012) (articulating that the *Basic* materiality standard and Item 303 duty to disclose standard are discrete inquiries, both of which are essential in assessing claims under Section 11); *Garber v. Legg Mason, Inc.*, 347 F. App'x 665, 668 (2d Cir. 2009) (quoting *Basic* and stating: "[t]he test for whether an alleged misstatement or omission is material under section 12(a)(2) or section 11 is identical to that under section 10(b) of the Securities and Exchange Act of 1934 . . . .").

The proper analysis in examining a Section 11 claim based on the alleged violation of Item 303 is perhaps best illustrated by the Second Circuit's recent decision in *Arfa v. Mecox Lane Ltd.*, 504 F. App'x 14 (2d Cir. 2012). There, the court first examined whether the allegedly omitted financial information constituted a known trend or uncertainty required to be stated under Item 303, and then separately examined the materiality of that allegedly omitted information under *Basic*:

> Drawing all reasonable inferences in favor of the Plaintiffs, the third and fourth quarter 2010 data, which showed increased online sales and decreased directly-operated store sales, described trends a reasonable registrant would expect to materially impact . . . net sales, revenue, or income. However, the third and fourth quarter data were not material to those trends, because the Registration Statement already disclosed the trends. The third and fourth quarter data would not alter the "total mix" of available information.

Id. at 16; *see also Underland v. Alter*, No. 10–3621, 2012 WL 2912330, at *6-7 (E.D. Pa. July 16, 2012) (first finding a duty to disclose under Item 303, and then determining whether the omitted information was material under the *Basic* "total mix" of information standard such that a Section 11 claim should be permitted to proceed).[11]

The Eighth and Eleventh Circuits have also applied the *Basic* materiality test in concluding that facts allegedly required to be stated pursuant to Item 303 were immaterial as a matter of law and, therefore, could not support an omissions claim under Section 11.

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[11] The analysis of a Section 11 claim premised on a violation of Item 503 is no different. As another district court within the Second Circuit has explained, a plaintiff alleging a violation of Item 503 similarly must sufficiently allege materiality. *See City of Roseville Emps' Ret. Sys. v. EnergySolutions, Inc.*, 814 F. Supp. 2d 395, 426 (S.D.N.Y. 2011) ("[C]ourts typically analyze the sufficiency of Item 503 disclosures with the familiar materiality standard.").

In *Romine v. Acxiom Corp.*, for example, the plaintiff brought a Section 11 claim, alleging that Acxiom was obligated under Item 303 to describe in its prospectus the details of its contract with Allstate Insurance. 296 F.3d 701, 707–08 (8th Cir. 2002). In particular, the plaintiff contended that this contract "would result in lower pricing for traditional services performed by Acxiom" and "represented a negative trend for Acxiom in that the price reductions were reflective of the adverse competitive environment in which Acxiom was working." *Id.* After finding that "one individually negotiated contract with a major customer does not establish or even effectively allege a competitive trend" under Item 303, the Eighth Circuit went on to separately conclude that the omission was not material under *Basic*. *Id.* at 708.

In *Oxford Asset Mgmt., Ltd. v. Jaharis*, the Eleventh Circuit engaged in the same two-part analysis. 297 F.3d 1182, 1189–92 (11th Cir. 2002). There, the plaintiffs brought a complaint under Section 11 alleging omissions concerning the safety, efficacy, and sales volume of the drug Niaspan. The Court first analyzed whether the omitted Niaspan sales data constituted a "trend" under Item 303, and then separately concluded that the offering documents were not materially misleading under the *Basic* standard without the omitted sales data. *Id.*

Finally, the Third and Fifth Circuits have similarly acknowledged that "[s]ections 11 and 10(b) share the materiality element and the [*Basic*] materiality definition." *In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 274 (3d Cir. 2005); *see also Kapps v. Torch Offshore, Inc.*, 379 F.3d 207, 215 (5th Cir. 2004) ("While

it is true that scienter is not required here, many cases say that 'materiality,' as it is used in Section 11, in effect means the same thing as it does in section 10(b).") (citing *Rosenzweig v. Azurix Corp.,* 332 F.3d 854, 873–74 (5th Cir. 2003) (holding that plaintiffs' claims under Section 11 failed because none of the challenged representations were material, and "[e]ven though the district court did not explicitly consider the materiality issue with respect to § 11, its analysis would be identical" to that under section 10b-5)); *Klein v. Gen. Nutrition Cos.,* 186 F.3d 338, 342 (3d Cir. 1999) (holding in a Section 11 case that information allegedly omitted was not material under *Basic*, and observing that a "determination of 'materiality' takes into account considerations as to the certainty of the information, its availability in the public domain, and the need for the information in light of cautionary statements being made"); *In re Donald J. Trump Casino Sec. Litig.,* 7 F.3d 357, 368 n.10 (3d Cir. 1993) ("Because our analysis here is predicated on the materiality requirement, which is common to [plaintiffs' section 10(b), 11 and 12(2) claims], we do not here distinguish between [those provisions.]").

B. In Joining the Ninth Circuit, the First Circuit's Decision Creates an Irreconcilable Conflict Between the Circuits

In sharp contrast to the decisions discussed above, the First Circuit in this case refused to analyze whether the SAC adequately pleads that the 23 SAEs are material under the *Basic*/*Matrixx* standard. Instead, it made a sweeping pronouncement that the *Basic*/*Matrixx* standard is "inapposite" in Section 11

cases, like this one, premised on Items 303 and 503. (App. 24 n.9.) In so holding, the First Circuit effectively joined the Ninth Circuit's conclusion that "any omission of facts 'required to be stated' under Item 303 will produce liability under Section 11," regardless of whether those facts would significantly alter the total mix of available information. *Steckman v. Hart Brewing, Inc.*, 143 F.3d 1293, 1296 (9th Cir. 1998).

In *Steckman*, plaintiffs alleged claims under Sections 11 and 12(a)(2) based on allegations that the defendant brewing company failed to disclose in its prospectus and registration statement flat fourth quarter earnings of which it must have been aware by the time of its stock offering. *Id.* at 1294–95. The district court dismissed the complaint for failure to state a claim, and the plaintiffs appealed. On appeal, the defendants-appellees argued, among other things, that even if the complaint adequately pleaded a violation of Item 303, that "would not be sufficient to state a cause of action under the Securities Act." *Id.* at 1296. The Ninth Circuit summarily rejected this argument and reversed, concluding:

> There is liability under section 11 if a registrant "omit[s] to state a material fact required to be stated" in the registration statement. *See* section 11(a) . . . . Thus, allegations which sufficiently state a claim under Item 303 also state a claim under section 11.

Id. The court also reasoned, like the First Circuit, that cases assessing the materiality of omitted information in the Section 10(b) context are inapposite because

Section 10(b) "differs significantly from Sections 11 and 12(a)(2) of the Securities Act." *Id.*

As a result of the First and Ninth Circuits' rejection of the *Basic*/*Matrixx* materiality standard, the pleading requirements for stating a Section 11 claim will depend entirely on the jurisdiction in which a plaintiff chooses to bring suit. Companies defending such claims in the Second, Third, Fifth, Eighth and Eleventh Circuits will be able to obtain prompt dismissals where the allegedly omitted information is immaterial as a matter of law. Those unlucky companies forced to defend Section 11 claims in the First and Ninth Circuits, however, will be required to incur the costs and settlement pressures of proceeding past the pleading stage to discovery, even where the information allegedly omitted is immaterial as a matter of law (*e.g.*, where, as here, the risks and uncertainties allegedly arising from that information have been fully disclosed to investors). No valid purpose is served by fostering such disparity. To the contrary, allowing the conflict to continue unresolved would foster forum-shopping and force companies to waste precious resources defending baseless litigation. This Court should grant certiorari to resolve the conflict in the Circuits and prevent the rule announced by the First and Ninth Circuits from becoming the *de facto* law of the land.

II. THE QUESTION PRESENTED IS A RECURRING ISSUE OF NATIONAL IMPORTANCE, AND THIS CASE PRESENTS AN IDEAL VEHICLE FOR RESOLVING THAT ISSUE

The question presented by this Petition is of such importance to all publicly-traded pharmaceutical companies that it should be resolved by the Court even if there were no conflict among the Circuits. In attempting to circumvent the *Basic*/*Matrixx* materiality standard and finding that Respondents adequately pleaded a Section 11 claim, the First Circuit improperly afforded Respondents an inference that the 23 SAEs were all caused by *Feraheme*, even though the SAC alleges merely that these adverse events had been reported and provides no factual basis upon which a finding of causation might be based. In *Matrixx*, this Court explicitly rejected such an inference in the Section 10(b) context, holding that the "mere existence of reports of adverse events . . . says nothing . . . about whether the drug is causing the adverse events" and, therefore, "will not satisfy th[e *Basic* materiality] standard." 131 S. Ct. at 1321. Absent review by this Court and clarification that the bar on such an inference is equally applicable in Section 11 cases, pharmaceutical companies involved in the important work of developing new drugs will be forced to either refrain from seeking capital in the public markets or to disclose any and all adverse event reports no matter how immaterial they may be to the reasonable shareholder.

This is no small dilemma. Many pharmaceutical companies depend on capital from stock offerings to

fund their research and development work. Accordingly, to avoid liability under Section 11 for alleged violations of Items 303 and 503, such companies would be required to disclose in their registration statements information about every adverse event report received, even though they have no reason to believe that the reports reflect in any way on the safety of the drug, and even though such reports would have no material significance to reasonable investors. To put this into perspective, in 2010 alone, the FDA received a total of 758,890 adverse event reports for drugs and therapeutic biologic products. *See* FDA, *Adverse Event Reporting System (AERS), Reports Received and Reports Entered into AERS by Year* (2010), *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm. As this Court has recognized before, providing investors with that volume of information "is hardly conducive to informed decisionmaking." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448-49 (1976); *see also Matrixx*, 131 S. Ct. at 1318 ("We were careful not to set too low a standard of materiality, for fear that management would bury the shareholders in an avalanche of trivial information.") (internal quotations omitted) (quoting *Basic*, 485 U.S. at 231 and *TSC Indus.*, 426 U.S. at 448).

Disclosing every adverse event report would, in fact, be tremendously detrimental to consumers. Because such information, no matter how carefully phrased, is likely to create confusion as consumers attempt to compare and contrast the adverse event reports with the information publicly available on the drug's product insert and elsewhere, the unfortunate effect would be

to deter sick people from buying and using drugs necessary to maintain or improve their health. This risk is especially high for drugs, like *Feraheme*, aimed at treating serious medical conditions such as CKD. Patients with CKD are extremely ill and depend on medication to manage their disease and prolong their lives. They also suffer many adverse events and SAEs while taking these medications, precisely because the mortality and morbidity rates associated with their medical condition are so high. And because all adverse events associated with use of drugs like *Feraheme* must be reported irrespective of causation, the reporting requirements already disproportionately burden companies who make drugs aimed at helping the sickest people. Forcing companies like AMAG to disclose all adverse events occurring prior to an offering – even if those adverse events are consistent with prior disclosures and the FDA-approved drug label – would lead to the absurd result that the patients who most need critical medications will be too afraid to use them.

The First Circuit's decision also dramatically expands the number of investor suits against pharmaceutical companies that will be able to withstand a motion to dismiss. This will inevitably increase the pressure on defendants named in such suits to settle meritless claims. This Court has previously granted review in similar circumstances. In *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 347 (2005), for instance, the Court rejected a Ninth Circuit rule that "permit[ted] a plaintiff with a largely groundless claim to simply take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the

settlement value, rather than a reasonably founded hope that the [discovery] process will reveal relevant evidence." 544 U.S. 336, 347 (2005) (internal quotations omitted); *see also Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 81–82 (2006) (explaining that the Private Securities Litigation Reform Act was, in part, instituted to help curb discovery abuse in securities fraud cases). This Court has similarly held that the pleading rules provide an important gate-keeping function to ensure that defendants are not compelled to either undergo expensive discovery or settle baseless suits absent a complaint setting out factual allegations establishing a plausible claim for relief. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558-62 (2007)("It is no answer to say that a claim just shy of a plausible entitlement to relief can, if groundless, be weeded out early in the discovery process through careful case management given the common lament that the success of judicial supervision in checking discovery abuse has been on the modest side.").

Finally, this case presents an ideal vehicle for resolving the question presented. The First Circuit reached the conclusion that Respondents had adequately pleaded a violation of Items 303 and 503 (and, by extension, Section 11) only by disregarding the materiality standards reaffirmed in *Matrixx*. Application of those standards in this case, however, would result in dismissal of the SAC because the mere existence of the 23 SAE reports would be insufficient to sustain a materiality finding, without which Respondents' Section 11 claim could not proceed.

III. THE COURT OF APPEALS ERRED IN HOLDING THAT THE *BASIC/MATRIXX* MATERIALITY STANDARD DOES NOT APPLY TO SECTION 11 CLAIMS PREMISED ON ALLEGED VIOLATIONS OF ITEMS 303 AND 503

The First Circuit effectively held, as did the Ninth Circuit in *Steckman*, 143 F.3d at 1296, that shareholders may state viable Section 11 claims based solely on the alleged omission of information called for by SEC regulations. (*See* App. 24 n.9.) That holding constitutes clear error. The omission of information "required to be stated" is merely one element of a viable Section 11 claim. The plain language of Section 11 also requires that the omitted fact be "material" before liability will attach. 15 U.S.C. § 77k(a) (imposing liability where registration statement "omit[s] to state a ***material*** fact required to be stated therein") (emphasis added). The First Circuit's statutory construction writes the word "material" out of Section 11 and "flout[s] the venerable principle that '[a]ll words and provisions of statutes' should 'be given effect.'" *United States v. Walker*, 665 F.3d 212, 225 (1st Cir. 2011) (citation omitted); *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.") (internal quotations omitted).

Moreover, it has long been acknowledged by the federal courts that the materiality requirement is, in effect, the only real hurdle to liability against an issuer in a Section 11 omissions case (aside from the

requirement that the information omitted must have existed at the time of the offering). As the Supreme Court explained in *Herman & MacLean v. Huddleston*:

> If a plaintiff purchased a security issued pursuant to a registration statement, he need only show a ***material*** misstatement or omission to establish his *prima facie* case. Liability against the issuer of a security is virtually absolute, even for innocent misstatements.

459 U.S. 375, 382 (1983) (emphasis added). Or, as the Second Circuit has explained:

> Issuers are subject to virtually absolute liability under section 11, and plaintiffs alleging violations of Sections 11 and 12(a)(2) need not plead scienter, reliance, or loss causation.

Hutchison, 647 F.3d at 484 (internal quotations and citations omitted). By eliminating the materiality requirement in Section 11 claims premised on violations of SEC regulations, the First Circuit imposes what is, in effect, absolute strict liability to investors for the omission of information called for by Item 303 no matter how immaterial that information may be to shareholders' investment decisions. In so doing, the First Circuit has created a new, private right of action for violation of Item 303 that has heretofore been universally rejected by the courts. *See, e.g., Oran v. Stafford*, 226 F.3d 275, 287 (3d Cir. 2000) (Alito, J.) (rejecting a private right of action for violation of Item 303 and stating: "Neither the language of the regulation nor the SEC's interpretive releases construing it suggest that it was intended to establish

a private cause of action, and courts construing the provision have unanimously held that it does not do so.") (citing numerous cases); THOMAS LEE HAZEN, *Common Disclosure Problems—Dilution of the Public's Investment, Business Risks, Transactions With Controlling Persons, and Projections, in* TREATISE ON THE LAW OF SECURITIES REGULATION, § 3.9 (2013), *available at* Westlaw 1 Law Sec. Reg. § 3.9 ("The MD&A disclosure requirements of Item 303(a) or Regulation S-K do not by themselves provide a basis for a private right of action.").

Finally, the 1989 SEC Release cited by the First Circuit provides no support for its holding that Section 11 claims premised on Item 303 are somehow exempt from the *Basic/Matrixx* standard. *See* SEC Release, 1989 WL 1092885, at *6 n.27 ("The probability/magnitude test for materiality approved by the Supreme Court in *Basic* . . . is inapposite to Item 303 disclosure."). The SEC Release provides merely that the standard for ascertaining whether information is required to be stated under Item 303 – that is, whether Item 303 creates a duty of disclosure – *is specified in Item 303*, not *Basic*. Failure to provide the information required by Item 303 subjects the registrant to substantial risks and penalties, such as rejection of the registration statement or the issuance of an SEC comment letter. However, the existence of a disclosure obligation, standing alone, is insufficient to plead a claim for violation of Section 11. Materiality under *Basic/Matrixx* must also be adequately alleged. *See Oran*, 226 F.3d at 288 (holding that "a violation of SK-303's reporting requirements does not automatically give rise to a material omission under Rule 10b-5"). Accordingly, the First Circuit erred in

allowing Respondents' Section 11 claim to proceed absent allegations establishing a substantial likelihood that disclosure of the 23 SAEs would have significantly altered the total mix of information available to investors. Under *Matrixx*, the SAC simply does not satisfy that standard as the 23 SAEs were entirely consistent in nature and frequency with the SAEs observed in clinical trials and repeatedly disclosed to the public by AMAG. The First Circuit's Decision was erroneous, and it should be reversed.

CONCLUSION

The Petition for a writ of certiorari should be granted, and the First Circuit's Decision should be reversed.

Dated: June 13, 2013

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APPENDIX

APPENDIX

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APPENDIX A

United States Court of Appeals
For the First Circuit

No. 11-2063

[Filed February 4, 2013]

SILVERSTRAND INVESTMENTS; BRIARWOOD INVESTMENTS, INC.; SAFRON CAPITAL CORPORATION, on behalf of themselves and all others similarly situated,	)
Plaintiffs, Appellants,	)
v.	)
AMAG PHARMACEUTICALS, INC.; BRIAN J.G. PEREIRA, M.D.; DAVID A. ARKOWITZ; JOSEPH V. BONVENTRE, M.D.; MICHAEL NARACHI; ROBERT J. PÉREZ; LESLEY RUSSELL, M.D.; DAVEY S. SCOON; RON ZWANZIGER; MORGAN STANLEY & CO. INCORPORATED; J.P. MORGAN SECURITIES LLC; GOLDMAN, SACHS & CO.; LEERINK SWANN LLC; ROBERT W. BAIRD & CO.	)

INCORPORATED; CANACCORD GENUITY INC.,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
[Hon. Nathaniel M. Gorton, U.S. District Judge]

Before
Torruella, Lipez, and Howard,
Circuit Judges.

Ian D. Berg, with whom Abraham, Fruchter & Twersky, LLP, Mitchell M.Z. Twersky, Jack G. Fruchter, and Ximena R. Skovron, were on brief for appellants.

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February 4, 2013

TORRUELLA, Circuit Judge. This appeal arises from a pleading-stage dismissal of a putative class action suit brought under sections 11, 12, and 15 of the Securities Act of 1933, 15 U.S.C. §§ 77k, 77l(a)(2), 77o. Lead plaintiffs Silverstrand Investments, Safron Capital Corporation, and Briarwood Investments (collectively, "Plaintiffs") challenge the dismissal, arguing that the Complaint plausibly pleads actionable omissions from a prospectus and a registration statement (the "Offering Documents") issued by AMAG Pharmaceutical, Inc. ("AMAG") in connection with a secondary stock offering held on January 21, 2010 (the "Offering"). Specifically, Plaintiffs point to two omissions by AMAG: (1) failure to disclose 23 reports of serious adverse effects (including a death) linked to Feraheme, a make-or-break drug for AMAG's future; and (2) failure to disclose information the Food and Drugs Administration ("FDA") revealed in a Warning Letter issued nine months after the Offering.

The district court premised the dismissal of the entire Complaint on the relatively narrow ground that Plaintiffs failed to sufficiently plead § 11 claims pursuant to Items 303 and 503 of Securities and Exchange Commission ("SEC") Regulation S-K. We affirm in part and reverse in part that dismissal. First, we conclude that the Complaint states claims of actionable omissions because the 23 undisclosed reports gave rise to (1) uncertainties AMAG reasonably knew would adversely affect future revenues, see 17 C.F.R. § 229.303(a)(3)(ii) (requiring disclosures of uncertainties that reasonably will adversely affect a registrant's business); and (2) risk factors that made the Offering risky and speculative, see id. § 229.503(c) (requiring disclosure of risks that make an offering

risky or speculative). We, however, also hold that as to the information the FDA revealed nine months after the Offering, the Complaint failed to allege omissions sufficient to state a claim. We thus affirm as to that claim.[1]

To get to our conclusion we first have to answer three questions: (1) whether the district court's decision was consistent with Items 303 and 503 of Regulation S-K; (2) whether the district court properly dismissed Plaintiffs' §§ 12 and 15 claims based on the determination that the complaint failed to allege claims under § 11; and (3) whether the district court erred in implicitly denying a request for leave to amend by not addressing it. We reach this latter issue only because Plaintiffs move us to grant them leave to amend their allegations in connection with the information revealed by the FDA, a request we deny.

I. Background

A. The Parties

Plaintiffs filed this suit on behalf of themselves and all other investors who purchased AMAG's shares pursuant or traceable to the Offering Documents. Defendants-appellees are AMAG, all officers and

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[1] The district court also dismissed a claim premised on AMAG's failure to disclose that the FDA twice declined to approve Feraheme due to safety concerns. Plaintiffs have not challenged that determination; therefore, we summarily affirm it. See DeCaro v. Hasbro, Inc., 580 F.3d 55, 64 (1st Cir. 2009)(stating that "contentions not advanced in an appellant's opening brief are deemed waived").

directors of AMAG who signed the Offering Documents, as well as the investment firms that underwrote the Offering (collectively, "Defendants").

B. Events Leading up to Plaintiffs' Suit

As related in the Complaint and stated by the district court, the events leading up to this appeal began with AMAG's development of Feraheme, an intravenous iron-replacement drug used to treat iron-deficiency anemia in adult patients with chronic kidney disease. Although two competing FDA-approved iron-replacement therapies dominated the market in which Feraheme intended to compete, AMAG hoped to capitalize on the drug's faster and shorter treatment turn-around time.[2] In December 2007, AMAG thus sought approval from the FDA to market Feraheme as an iron-replacement treatment.

AMAG disclosed to investors details about Feraheme's FDA-approval process. AMAG's disclosures included information concerning "Serious Adverse Events" ("SAEs") that resulted during Feraheme's clinical trials.[3] For example, in a January 31, 2008 SEC

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[2] Feraheme could be administered in as little as 17 seconds, with a complete course of treatment requiring two to four visits to a physician. Competing alternatives, in contrast, would be administered over a 15-to-60 minute interval and would require five to ten visits to a physician.

[3] SAEs are defined as "[a]ny adverse drug experience occurring at any dose that results in any of the following outcomes: [d]eath, a life-threatening adverse drug experience, in-patient hospitalization or prolongation of existing hospitalization, a persistent or

8-K Form, AMAG disclosed results of one of the phases of Feraheme's clinical trials, including that "the SAE rate was 9.8% among [Feraheme] subjects compared to 12.1% among oral subjects." AMAG also apprised investors that "in the [Feraheme] clinical development program that included 2,074 subjects, 31 deaths were observed," but "[n]one of these deaths were considered to be related to study treatment."

AMAG made similar disclosures in an SEC 10-K Form filed for the fiscal year ending December 31, 2008. There, AMAG stated that, "[a]cross all phases of the Feraheme clinical development program with approximately 2,800 total administered doses of Feraheme, there were no cases of anaphylaxis and no deaths determined by the [FDA] investigators to be drug-related."[4]

AMAG's efforts to secure FDA approval for Feraheme initially failed. By letter dated October 17,

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significant disability/incapacity, or a congenital anomaly/birth defect." 21 C.F.R. § 310.305(b). Pharmaceutical companies are required to report to the FDA all SAEs of which they become aware. See FDA, Guidance for Industry, Good Pharmacovigilance Practice and Good Pharmacoepidemiologic Assessment, 2005 WL 3628217, at *4 (Mar. 2005). Nevertheless, the fact that an SAE is reported does not necessarily mean that a specific drug caused it. See Matrixx Initiatives, Inc. v. Siracusano, ___ U.S. ___, 131 S. Ct. 1309, 1318-19 (2011).

[4] According to the Complaint, anaphylaxis is "a life-threatening whole-body allergic reaction to a drug or allergen . . . . The onset of anaphylaxis is rapid, and must be treated, typically . . . by injection of epinephrine." The FDA eventually concluded that Feraheme could cause anaphylaxis.

2008, the FDA declined to approve Feraheme due, in part, to a single occurrence of anaphylaxis among 1,726 patients exposed to the drug. The letter also expressed concerns with (1) the occurrence of "serious hypotensive reactions" in approximately 0.3% of the exposed population; (2) inconsistencies in the reports of SAEs;[5] and (3) systematic deficiencies in Feraheme's manufacturing process. The FDA again declined to approve Feraheme on December 22, 2008. It took AMAG until June 30, 2009 to finally obtain the FDA's imprimatur for Feraheme.

In approving Feraheme, the FDA sanctioned a product insert for AMAG to include with the drug. Among other things, the product insert explicitly disclosed several safety risks associated with the drug:

> Feraheme may cause serious hypersensitivity reactions, including anaphylaxis and/or anaphylactoid reactions. In clinical studies, serious hypersensitivity reactions were reported in 0.2% (3/1,726) of subjects receiving Feraheme. Other adverse reactions potentially associated with hypersensitivity (e.g., pruritus, rash, urticaria or wheezing) were reported in 3.7% (63/1,726) of these subjects.

An SEC 8-K Form AMAG filed in July 1, 2009, announced the FDA's approval of Feraheme and shared

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[5] This is an example of an inconsistency the FDA cited: "To illustrate, subject 554 appears to have experienced a serious hypotensive event that prompted the delay of a second dose of [Feraheme]. The adverse report denoted this event as a 'headache' and did not describe the other clinical problems."

with potential investors the information in Feraheme's FDA-approved package insert.

Feraheme hit the market in July 2009, and AMAG quickly geared up for the Offering. On November 5, 2009, AMAG issued an SEC 10-K Form which disclosed to investors that "Feraheme may not receive the same level of market acceptance . . . as competing iron replacement therapy products . . . . The iron replacement therapy market is highly sensitive to several factors including . . . the perceived safety profile of the available products . . . ."

The Offering Documents were issued in January 2010. The Prospectus included detailed disclosures about the results of Feraheme's clinical trials, the FDA approval process, and the FDA-approved package insert. It also incorporated by reference some of AMAG's filings with the SEC and contained a section regarding the risk factors associated with the Offering, which, according to AMAG, included "[o]ur ability to demonstrate to the medical community . . . the clinical efficacy and safety of Feraheme as an alternative to current treatments for iron deficiency anemia . . . ." The Prospectus further appraised investors that

> [AMAG is] subject to ongoing FDA regulatory requirements . . . . Failure to comply with such regulatory requirements or the later discovery of previously unknown problems with Feraheme . . . may result in restrictions on our ability to market and sell Feraheme[;] . . . FDA warning letters; . . . [and] FDA-imposed label changes . . . . Any of these sanctions would have a

> material adverse impact on our ability to generate revenues and to achieve profitability.
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> [AMAG's] ability to generate future revenue is solely dependent on our successful commercialization and development of Feraheme . . . . Accordingly, if we are unable to generate sufficient revenues from sales of Feraheme, we may never be profitable, our financial condition will be materially adversely affected, and our business prospects will be limited.

The Offering Documents, however, did not mention that AMAG had reported to the FDA at least 23 reports of SAEs since Feraheme's inception to the market. Two of those reports documented, respectively, anaphylactic reactions in two female patients with a "life-threatening" outcome requiring hospitalization. Fourteen of the other 23 reports stated that SAEs had resulted in hospitalizations due to one or more symptoms associated with anaphylaxis, including cardiac arrest, shortness of breath, a reduction in blood pressure, loss of consciousness, hives, dizziness, or vomiting. The Offering Documents similarly failed to mention that on December 31, 2009, AMAG had reported to the FDA that a 70-year-old patient died following one 510 mg injection of Feraheme and that the drug had been identified by the treating physician as the "Primary Suspect" for the fatality.

The Offering took place on January 21, 2010. Over three million shares of AMAG's common stock were

sold to the public at $48.25 per share, bringing AMAG approximately $174 million in net proceeds and over $7.8 million in fees to the underwriters. Within weeks, however, the market value of AMAG's shares began to plummet.

On February 4, 2010, a securities analyst reported that several patients using Feraheme had experienced adverse reactions to the drug and that at least one patient had died for reasons that "may or may not be directly related to Feraheme." The report also stated that it was impossible to determine whether those incidents fell within the occurrence rate of SAEs disclosed in Feraheme's package insert and that "consultants continu[ed] to use Feraheme but adoption rates were slowing." AMAG's shares closed at $38.12 after the issuance of the report.

The next day, AMAG issued a press release stating, among other things, that the SAEs identified by the analyst were consistent with the rates disclosed in Feraheme's package insert. According to AMAG's press release, "[o]f the estimated 35,000 patient exposures to date, 40 serious adverse events have been reported . . . . No mortality signal has been observed. A single reported death occurred in a patient two days post-Feraheme treatment, which the Company does not believe was the result of Feraheme." Notwithstanding, AMAG's shares still dropped an additional 35 cents at market end.

The market price of AMAG's shares took another hit on February 8, 2010. That day, a follow-up analyst report expressed skepticism regarding AMAG's representations as set forth in its press release and

stated that one of Feraheme's competing alternatives had been associated with only one SAE and one death during its ten-year market life. AMAG's shares slipped to $36.67.

C. Plaintiffs File Suit

Plaintiffs filed the Complaint on March 18, 2010. They sought compensatory damages under § 11 of the Securities Act, claiming, in essence, that AMAG failed to disclose in the Offering Documents "the existing fact that Feraheme users had already suffered adverse reactions to Feraheme requiring hospitalization."

AMAG's shares continued to perform poorly in the market after Plaintiffs' suit. On October 18, 2010, the FDA issued a Warning Letter to AMAG, stating that AMAG's website had misrepresented Feraheme's approved uses. The Letter also asserted that AMAG's website had failed "to communicate any of the risks associated with the drug," suggesting that Feraheme was "safer than ha[d] been demonstrated and therefore plac[ing] the public at risk." Ten days later, AMAG "announced for the first time that (1) the FDA had created a Tracked Safety Issue for Feraheme's cardiac-related SAEs; (2) the FDA had met with the company in September [2010] to discuss SAEs; and (3) the Company was in discussions with the FDA concerning labeling changes." AMAG's shares fell from $19.30 to $15.91 on that day.

On November 26, 2010, prompted by the FDA, AMAG announced changes in Feraheme's package insert. The changes included warnings of post-Offering SAEs as well as a requirement that physicians increase

the observation period after administering Feraheme to patients. When that news hit the market, AMAG's shares fell to $14.05, a 71% decrease from the Offering price of $48.25 per share.

Plaintiffs filed a Second Amended Complaint on December 17, 2010. This time the Complaint pled causes of action under §§ 11, 12 and 15 of the Securities Act and advanced the two claims of omissions at issue here. Among other things, the Complaint alleged that between Feraheme's approval and the Offering "AMAG [had] reported to the FDA (but failed to disclose to investors) twenty-three (23) SAEs associated with Feraheme's use, including documented anaphylactic reactions in two female patients . . . with a life-threatening outcome requiring hospitalization . . . ." According to the Complaint, AMAG had a duty to disclose the 23 SAEs under Item 303, 17 C.F.R. § 229.303(a)(3)(ii), because the SAEs gave rise to uncertainties that AMAG knew would reasonably have a negative impact on its business. Similarly, the Compliant alleged that the 23 SAEs made the Offering risky or speculative, and therefore, that AMAG had a duty to disclose them under Item 503. 17 C.F.R. § 229.503(c).

Further, the Complaint alleged that AMAG failed to disclose that a material portion of its revenues was derived from the internet practices highlighted in the FDA's October 18, 2010 Warning Letter, and thus, implied that AMAG was already engaging in such practices when the Offering took place nine months earlier.

D. Plaintiffs' Suit is Dismissed

In February 2011, Defendants moved to dismiss under Fed. R. Civ. P. 12(b)(6). Plaintiffs opposed and moved to amend the Complaint. In dismissing Plaintiffs' § 11 claims, the court concluded that the 23 SAEs neither were a "known trend or uncertainty" pursuant to Item 303 nor made the Offering "speculative or risky" pursuant to Item 503, because "the 23 SAEs that occurred after the launch of Feraheme but prior to the Offering were consistent with the previously . . . publicly-disclosed rates observed in the clinical trials." The court also remarked that "one death does not a trend make."

Plaintiffs' contentions regarding the information underlying the October 18, 2010 FDA Letter were also dismissed. According to the district court, no allegation in the Complaint linked the internet practices questioned in the Letter to AMAG's business practices at the time of the Offering.

Plaintiffs' claims under §§ 12 and 15 fared no better. The district court dismissed Plaintiffs' § 12 claims under the same reasoning used to dismiss the § 11 claims, noting that both sections require a showing of an actionable omission. The district court also dismissed Plaintiffs' § 15 claims, on the basis that Plaintiffs failed to state requisite claims under either §§ 11 or 12. The court made no ruling in connection with Plaintiffs' request for leave to amend the Complaint, and thus implicitly denied it. This appeal timely followed.

II. Standard of Review

We review a dismissal under Rule 12 (b)(6) de novo. Gray v. Evercore Restructuring L.L.C., 544 F.3d 320, 324 (1st Cir. 2008). To do so, we first discard bald assertions and conclusory allegations. Ocasio-Hernández v. Fortuño-Burset, 640 F.3d 1, 12 (1st Cir. 2011). Then we "view the well-pleaded facts in the light most favorable to the non-moving party, drawing all reasonable inferences in its favor." Gray, 544 F.3d at 324. In performing this analysis, we cannot dismiss a "complaint [that] satisfies Rule 8(a)(2)'s requirement of a 'short and plain statement of the claim showing that the pleader is entailed to relief.'" Ocasio-Hernández, 640 F.3d at 11 (quoting Fed. R. Civ. P. 8(a)(2)). In other words, a complaint passes muster at the pleading stage if we find that it contains "enough detail to provide a defendant with 'fair notice of what the . . . claim is and the grounds upon which it rests.'" Id. at 12 (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

In contrast, we review for abuse of discretion denials of motions for leave to amend the pleadings, and "will affirm if any adequate reason for the denial is apparent from the record." O'Connell v. Hyatt Hotels of P.R., 357 F.3d 152, 154 (1st Cir. 2004).

III. Analysis

A. Plaintiffs' § 11 claims and Items 303 and 503

In their first point of error, Plaintiffs challenge the district court's determination that AMAG was not duty-bound to disclose the 23 SAEs and the information the

FDA revealed in the Warning Letter issued nine months after the Offering. Specifically, Plaintiffs find error in the district court's determination that said information did not constitute uncertainties or risks under Items 303 and 503, both of which are actionable through § 11.

"Section[] 11 . . . [is an] enforcement mechanism[] for the mandatory disclosure requirements of the Securities Act." Glassman v. Computervision Corp., 90 F.3d 617, 623 (1st Cir. 1996) (internal quotation marks omitted). As relevant here, § 11 is triggered "[i]n case any part of [a] registration statement, when such part became effective . . . omitted to state a material fact required to be stated therein . . . ." 15 U.S.C. § 77k(a). Section 11 is "notable . . . for the limitations on [its] scope as well as the interrorem nature of the liability [it] create[s]." In re Morgan Stanley Info. Fund Secs. Litig., 592 F.3d 347, 359 (2d Cir. 2010). When applicable, it imposes strict liability on issuers of a security, and any "remaining [] defendants . . . may be held liable for mere negligence." Id. Moreover, unlike § 10(b) of the Securities and Exchange Act, § 11 does not have a scienter or reliance requirement, and neither the heightened pleading standard of Fed. R. Civ. P. 9(b) nor of the Private Securities Litigation Reform Act applies unless a § 11 claim sounds in fraud. Id.; Glassman, 90 F.3d at 628 n.13.[6] "Thus, the

[6] In their motion to dismiss, Defendants argued that the Complaint sounded in fraud, but the district court declined to reach this argument, concluding that "[D]efendants frame their arguments primarily with respect to Fed. R. Civ. P. 8 and [P]laintiffs' Second Amended Complaint fails to state a claim even under that standard . . . ." Defendants did not brief us on this issue, and we do

provision[] place[s] a relatively minimal burden on a plaintiff," who need only satisfy the notice-pleading standard of Fed. R. Civ. P. 8(a). Panther Partners, Inc. v. Ikanos Commc'ns, Inc., 681 F.3d 114, 120 (2d Cir. 2012) (internal quotation marks and alteration omitted).

As Plaintiffs correctly point out, an actionable § 11 omission may arise when a registration statement fails to comply with Item 303 or 503 of SEC Regulation S-K. Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1202 n.3 (1st Cir. 1996)(stating that a duty to disclose under § 11 arises "when a . . . regulation requires disclosure") abrogated on other grounds by 15 U.S.C. § 78u-4(b)(2). Item 303 imposes upon registrants of securities a series of disclosure duties "intended to give the investor an opportunity to look at the company through the eyes of management," so that they may "assess the financial condition and results of operations of the registrant, with particular emphasis on the registrant's prospects for the future." Mgmt.'s Discussion and Analysis of Fin. Conditions and Results of Operations; Certain Inv. Co. Disclosures, SEC Release No. 6835, 1989 WL 1092885, at *3 (May 18, 1989). For that purpose, Item 303 requires the disclosure of "any known . . . uncertainties that . . . the registrant reasonably expects will have a

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not decide it here. In any case, "[i]t is up to the district court in the first instance to weigh the adequacy of the complaint for purposes of Rule 9(b) and, if appropriate, to provide 'an opportunity to correct [any] pleading deficiencies.'" United States ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 384 n.8 (1st Cir. 2011) (quoting United States ex rel. Poteet v. Bahler Med., Inc., 619 F.3d 104, 115 (1st Cir. 2010)). We do not decide whether Plaintiffs may assert any waiver arguments.

material . . . unfavorable impact on net sales[,] revenues[,] or income from continuing operations." 17 C.F.R. § 229.303(a)(3)(ii). To plausibly plead such a failure to disclose claim, a complaint must allege (1) that a registrant knew about an uncertainty before an offering; (2) that the known uncertainty is "reasonably likely to have material effects on the registrant's financial condition or results of operation"; and (3) that the offering documents failed to disclose the known uncertainty. Mgmt.'s Discussion and Analysis of Fin. Conditions and Results of Operations, SEC Release No. 6835, 1989 WL 1092885, at *4.

Item 503, in turn, is intended "to provide investors with a clear and concise summary of the material risks to an investment in the issuer's securities." Securities Offering Reform, SEC Release No. 8501, 2004 WL 2610458, at *86 (Nov. 3, 2004). Accordingly, it requires that a prospectus include "a discussion of the most significant factors that make the offering speculative or risky." 17 C.F.R. § 229.503(c). The discussion must "describe the most significant factors that may adversely affect the issuer's business . . . or its future financial performance." In re WorldCom, Inc. Secs. Litig., 346 F. Supp. 2d 628, 690 (S.D.N.Y. 2004) (quoting Securities Offering Reform, SEC Release No. 8501, 2004 WL 2610458, at *86). Moreover, the "discussion of risk factors . . . 'should explain how the risk affects the . . . securities being offered. Generic or boilerplate discussions do not tell the investors how the risks may affect their investment.'" Id. (quoting Statement of the Commission Regarding Disclosure of Year 2000 Issues and Consequences by Public Companies, Investment Advisers, Investment Companies, and Municipal Securities Issuers, SEC

Release No. 7558, 1998 WL 455894, at *14 (July 29, 1998)). In other words, to withstand dismissal at the pleading stage, a complaint alleging omissions of Item 503 risks needs to allege sufficient facts to infer that a registrant knew, as of the time of an offering, that (1) a risk factor existed; (2) the risk factor could adversely effect the registrant's present or future business expectations; and (3) the offering documents failed to disclose the risk factor.

(i) The 23 SAEs

Our de novo review satisfies us that the allegations in the Complaint, when read in context, plausibly plead Item 303 and 503 omissions in connection with the 23 SAEs. The relevant allegations for this analysis are the following: (1) that as of the time of the Offering, Feraheme had been in the market for six months; (2) that Feraheme was sold in a market dominated by well-known alternatives with proven safety and efficacy records; (3) that AMAG's profitability entirely depended on Feraheme's commercial success; (4) that the FDA twice declined to approve Feraheme due to safety concerns, which included one incident of anaphylaxis; (5) that during Feraheme's clinical trials "there were no deaths determined by the [FDA] investigators to be drug-related"; (6) that as of the time of the Offering, AMAG had disclosed to the FDA 23 SAEs, including one death in which Feraheme had been identified by a reporting physician as the "Primary Suspect," two incidents of "life-threatening" anaphylactic reactions attributed to Feraheme, and fourteen hospitalizations caused by anaphylactic symptoms attributed to Feraheme; and (7) that AMAG's Offering Documents did not disclose either the

death, the "life-threatening" incidents, or the fourteen hospitalizations attributed to Feraheme.

Taking the preceding factual allegations as true, we have no trouble drawing the reasonable inference that before the Offering AMAG knew that a death, two life-threatening reactions, and fourteen hospitalizations would have been relevant to consumers when deciding whether to use Feraheme, as opposed to another proven and safer alternative. The Offering Documents stated as much: "The iron replacement therapy market is highly sensitive to several factors including . . . the perceived safety profile of the available products." Common sense also dictates that AMAG knew that the riskier Feraheme appeared, the less attractive the drug would be as a method of treatment, and the less likely an investor would be to invest in AMAG, whose profits entirely depended on Feraheme's commercial success.

The allegations also allow the reasonable inference that, before the Offering, AMAG knew that the 23 SAEs could have prompted FDA action in connection with Feraheme. If the FDA initially declined to approve Feraheme due to a single case of anaphylaxis during clinical trials, a death, two life-threatening anaphylactic reactions, and fourteen hospitalizations undoubtedly could have raised red flags with the agency. Moreover, because the FDA investigators had found no drug-related deaths as of the time of Feraheme's approval, we can reasonably infer that the FDA could have sprung into action due to a Feraheme-related death.

Similarly, the allegations allow us to reasonably infer that FDA intervention due to the 23 SAEs would

have meant trouble for AMAG. We need go no further than the excerpts of the Offering Documents cited above to get an idea of one of at least two possible consequences: FDA action "may result in restrictions on [AMAG's] ability to market and sell Feraheme," the issuance of "FDA warning letters," and "FDA-imposed label changes. Any of th[o]se sanctions would have a material adverse impact on [AMAG's] ability to generate revenues and to achieve profitability. . . . [AMAG's] ability to generate future revenue is solely dependent on [its] successful commercialization and development of Feraheme." Regarding the other possible consequence, let's just say that we doubt that AMAG believed that an untimely FDA intervention would positively impact the Offering. To plead plausible claims for omissions under § 11 due to undisclosed Item 303 uncertainties and undisclosed Item 503 risks, the type of allegations and inferences just described more than suffice.

The district court, however, concluded otherwise primarily because "the 23 SAEs that occurred after the launch of Feraheme but prior to the Offering were consistent with the previously . . . publicly-disclosed rates observed in the clinical trials." Defendants invite us to affirm that conclusion, arguing that "it is a matter of simple math that the rate of post-marketing SAEs alleged by Plaintiff . . . is dramatically less than the SAE rate observed during clinical trials and

disclosed to the public . . . ."[7] We cannot accept Defendants' invitation.

To reach its conclusion, the district court compared the information disclosed prior to the Offering with the data disclosed in the press release AMAG issued on February 5, 2010 -- that is, 35,000 patient exposures to Feraheme and 40 serious adverse events reported. This comparison is problematic for at least three reasons.

First, the Complaint alleges that AMAG misleadingly calculated the rate of occurrence of post-marketing SAEs. In its press release, AMAG reported the rate as 0.1% based on the estimated 35,000 injections of Feraheme to date, rather than based on the number of patients, the metric used during the clinical trials. Because Feraheme is administered in as many as four injections, the changed metric understated the rate of SAEs. The Complaint alleges that the "true" rate of post-marketing SAEs is as high as 0.45% based on the per patient metric. Defendants apparently succeeded in convincing the district court to compare that rate with a 2.9% rate of occurrence

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[7] Defendants also move us to conclude that Item 303 does not apply in this case because "AMAG filed an SEC Form S-3 registration statement, not an S-1 . . . . [and] Item 303 does not apply to Forms S-3." In support they cite Shaw, 82 F.3d at 1205. However, Shaw clearly states that Form S-3 registrants are required to comply with Regulation S-K, which, among other things, specifically requires that "the prospectus provides investors with an update of the information required to be disclosed in the incorporated Exchange Act filings, including the information provided in those filings concerning 'known trends and uncertainties' with respect to 'net sales or revenues or income from continuing operations.'" Id. (quoting 17 C.F.R. § 229.303(a)(3)(ii)).

reported during one of the many phases of Feraheme's clinical trials.[8] But in so doing, Defendants did not reveal, either to the district court or to us, that the disclosure documents also set forth a separate category for "drug-related SAEs," which were reported as occurring only in 0.17% of the patients in the clinical trials. Since Plaintiffs allege that the unreported SAEs were all drug-related, the 0.45% rate alleged in the Complaint appears to have been over two times higher than what AMAG had previously reported, which negates the district court's conclusion.

Second, AMAG's press release refers to the state of affairs two weeks after the Offering. That two-week gap is dispositive in itself, as the inquiry under § 11, as well as under Items 303 and 503, requires us to assess the information a registrant knows exclusively as of the time of the stock offering. See 15 U.S.C. § 77k(a) ("In case any part of the registration statement, when such part became effective . . . .") (emphasis supplied).

Last but not least, our analysis under Items 303 and 503 cannot be limited to simple arithmetical computations. The question is not whether the 23 SAEs

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[8] Without explaining its rationale, the district court appears to have made the sweeping inference that investors can always predict how a drug would behave after FDA approval by analyzing scattered data regarding SAE rates observed during clinical trials, in a controlled environment, while a drug is being developed and has yet to be approved by the FDA. We cannot subscribe to that inference without knowing its underlying basis. However, because Plaintiffs do not raise a point of error on this front, and because the district court's decision is reversed on other grounds, we do not address this issue further.

comported with past experiences but rather whether the 23 SAEs, in the context in which they occurred, created uncertainties or risks that AMAG needed to disclose under Items 303 and 503. Panther Partners, 681 F.3d at 114, a decision issued after the district court's dismissal, offers guidance on this issue.

In that case, investors brought §§ 11, 12 and 15 claims following a secondary stock offering by a manufacturer of programmable semiconductors. Their complaint alleged that the offering documents ran afoul of Item 303 in failing to disclose known defects, and thus possible recalls, on all semiconductors sold in a transaction representing 72% of the company's yearly revenues. The district court dismissed the complaint under Rule 12(b)(6), finding that "[i]t is no secret that chips are subject to some percentage of failure . . . . The plaintiff must tell the Court what was going on . . . and how much the defect experienced actually differed from the norm." Id. at 118 (quoting Panther Partners, Inc. v. Ikanos Commc'ns, Inc., No. 06 Civ. 12967, 2008 WL 2414047, at *3 (S.D.N.Y. June 12, 2008) (internal citations omitted)). The Second Circuit granted a motion for leave to amend the complaint, but the district court, on remand, still found the proposed amendments insufficient to allege that defendants "knew the defect rate was above average" before filing the registration statement. Id. In reversing, the Second Circuit stated:

> We believe that, viewed in the context of Item 303's disclosure obligations, the defect rate, in a vacuum, is not what is at issue. Rather, it is the manner in which uncertainty surrounding that defect rate, generated by an increasing flow of

> highly negative information from key customers, might reasonably be expected to have a material impact on future revenues.
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> In focusing on whether plaintiff alleged that [defendants] knew the defect rate was "above average" before the Secondary Offering, the district court construed the proposed complaint and our remand order too narrowly. Item 303's disclosure obligations, like materiality under the federal securities laws' anti-fraud provisions, do not turn on restrictive mechanical or quantitative inquiries.

Id. at 120, 122 (internal citations omitted)(citing Matrixx Initiatives, Inc. v. Siracusano, ___ U.S. ___, 131 S. Ct. 1309 (2011) (rejecting contention that SAEs associated with pharmaceutical company's product could not be material absent a statistically significant number of reports establishing a causal link between the product and the SAEs)).[9]

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[9] The parties heavily relied on Matrixx in their briefs and oral arguments to the Court. Matrixx, however, addressed claims of omissions under § 10(b) of the Securities and Exchange Act of 1934, which imposes completely different exigencies than those of Items 303 and 503. See Mgmt.'s Discussion and Analysis of Fin. Conditions and Results of Operations, SEC Release No. 6835, 1989 WL 1092885, at *6 n.27 (stating that "[t]he probability/magnitude test for materiality approved by the Supreme Court in Basic, Inc. v. Levinson, 485 U.S. 224 (1988), [a test Matrixx reaffirmed] is inapposite to Item 303 disclosure").

Under the foregoing analysis, the statistical comparison Defendants advance, even if it worked in their favor, is not dispositive. Rather, at this stage, we are more concerned with the allegation that, when the Offering took place, the news that Feraheme had possibly caused a death, as well as the other serious side effects reported in the 23 SAEs, was already circulating within the medical community AMAG needed to win over to remain as a going concern. Because the Complaint alleged that AMAG failed to disclose the 23 SAEs, even though it knew about them, we cannot conclude that it failed to state plausible § 11 claims for omissions of Item 303 uncertainties and Item 503 risks.

(ii) The FDA's Warning Letter

The claim that Item 503 required AMAG to disclose the information revealed in the FDA Warning Letter issued nine months after the Offering is a completely different story. Not much elaboration is needed on this front. As the district court correctly noted, the Complaint is devoid of factual allegations to allow the inference that AMAG's website contained the problematic information when the Offering took place. The Complaint also lacks allegations to support the inference that as of the time of the Offering AMAG derived a significant amount of revenue from internet sales. Without such allegations, Plaintiffs' contentions amount to nothing more than dispensable unsupported conclusions. See Ocasio-Hernández, 640 F.3d at 12.

B. Plaintiffs' §§ 12 and 15 Claims

Plaintiffs' second and third points of error challenge the dismissal of their §§ 12 and 15 causes of action, arguing that the district court exclusively premised its decision on the erroneous determination that the Complaint had failed to plead a cause of action under § 11. Given our conclusion regarding the claims under § 11, Plaintiffs are correct. See In re Morgan Stanley Info. Fund Secs. Litig., 592 F.3d at 359 ("Claims under sections 11 and 12(a)(2) are . . . Securities Act siblings with roughly parallel elements . . . .") (citing Pinter v. Dahl, 486 U.S. 622, 646 (1988)); see also Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp., 632 F.3d 762, 776 (1st Cir. 2011) (stating that a liability finding under either §§ 11 or 12 is a prerequisite for success under § 15).[10]

C. Plaintiffs' Leave to Amend Request

As stated above, in their third point of error, Plaintiffs challenge the district court's failure to allow a third amended complaint and move us to grant them

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[10] In dismissing Plaintiffs' claims, the district court sidestepped the issue whether Plaintiffs have standing to assert § 12 claims against some of the Defendants. Although the parties briefed us on that issue, Defendants move us to exercise our discretion not to address it at this juncture. See St. Marys Foundry, Inc. v. Emp'rs Ins. of Wausau, 332 F.3d 989, 995-96 (6th Cir. 2003) (stating the general rule that courts of appeal "exercise [their] discretion to rule on an issue not decided below only in 'exceptional cases'"). Because there are no exceptional circumstances requiring us to decide the issue now, and because the case will continue onward at the district court level regardless of how the issue is decided, we see no reason to entertain it here.

"leave to replead [the] allegations regarding AMAG's misrepresentations on its website." Plaintiffs included their request for another attempt at making a plausible claim on this front within their submission opposing dismissal, but failed to provide the district court with the reasons supporting their request and with the substance of possible amendments. Instead, Plaintiffs relied on four boilerplate sentences stating the well-settled "freely given" standard under which a request for leave to amend is generally analyzed. The district court never addressed the request, and Plaintiffs believe that that constituted a reversible error.

Plaintiffs' request for leave to amend had one basic problem: it failed to abide by our oft-quoted maxim that litigants should not seriously expect to obtain a remedy without doing the necessary leg work first. See, e.g., United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990)("It is not enough to mention a possible argument in the most skeletal way, leaving the court to do counsel's work, create the ossature for the argument, and put flesh on its bones."). Not much is needed to satisfy this rule. Litigants simply have to set forth the factual and legal predicate for the remedy sought. See Rodríguez-Machado v. Shinseki, 700 F.3d 48 (1st Cir. 2012)(per curiam).

This is for good reason. On the one hand, "busy judges, faced with lengthy and growing dockets, necessarily must rely on litigants to present the relevant facts and law governing the disputes that the judges are asked to resolve." Powers v. Hamilton County Public Defender Com'n, 501 F.3d 592, 610 (6th Cir. 2007). And on the other, federal litigation "is less a game of blind man's buff and more a fair contest with

the basic issues [of] facts [and law] disclosed to the fullest practicable extent," United States v. Procter & Gamble Co., 356 U.S. 677, 682 (1958), so as to give each party a meaningful opportunity to present its case. Truncated at the factual end, Plaintiffs' request for leave to amend ran afoul of both of these principles. The district court therefore acted well within its discretion when completely disregarding the request. See In re Olympic Mills Corp., 477 F.3d 1, 17 (1st Cir. 2007) (finding a damages claim waived because "as presented to the district court . . . the argument was fatally undeveloped, comprising only four sentences, a citation to a district court opinion, and no analysis whatsoever"); see also In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 220 (2d Cir. 2006) ("It is within the [district] court's discretion to deny leave to amend implicitly by not addressing the request when [it is presented] informally in a brief filed in opposition to a motion to dismiss.").

All the same, we have no basis under which to assess Plaintiffs' request at this juncture, as they failed to provide us with any information from which to conclude that their already fatally flawed claim can somehow spring back to life. Plaintiffs' main contention on this front is that Matrixx "overturned decades of existing case law interpreting the materiality [standard] . . . for purposes of the federal securities laws. Plaintiffs [therefore] should, at least, be given the opportunity to replead in light of this significant intervening change in law." But Matrixx, which is not controlling here, did not have such a far-reaching effect. See Hill v. Gozani, 651 F.3d 151, 152 (1st Cir. 2011) ("Matrixx . . . reaffirmed the long-standing rule that the possession of material, non-public information

does not create a duty to disclose."). Moreover, we have been provided with no explanation whatsoever as to why any additional facts Plaintiffs might add now were not included in the Complaint or in the two amendments preceding it. See Foman v. Davis, 371 U.S. 178, 182 (1962) (stating that "repeated failure to cure deficiencies by amendments previously allowed" constitutes an appropriate ground to deny leave to amend). And because Plaintiffs failed to even generally describe their intended amendments, we do not know what sort of new facts they may allege now to cure the deficiencies in their twice-amended complaint. See Mann v. Chase Manhattan Mortg. Corp., 316 F.3d 1, 6-7 (1st Cir. 2003) (stating that leave to amend may be denied "as a matter of law, where a proposed amendment would not cure the deficiencies in the original complaint").

IV. Conclusion

For the foregoing reasons, the district court's judgment dismissing the case is vacated and the case is remanded for further proceedings consistent with this opinion. Each party shall bear their own costs.

Vacated and Remanded.

APPENDIX B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 10-10470-NMG

[Filed August 15, 2011]

Silverstrand Investments	)
Plaintiffs	)
	)
V.	)
	)
Amag Pharmaceuticals, Inc. et al	)
Defendants	)
	)

ORDER OF DISMISSAL

GORTON, D. J.

In accordance with the Court's Memorandum & Order dated 8/11/2011 , granting defendants' motion to Dismiss (Docket No. 64), it is hereby ORDERED that the above-entitled action be and hereby is dismissed.

By the Court,

8/15/2011	/s/ Diep Duong
Date	Deputy Clerk

APPENDIX C

United States District Court
District of Massachusetts

Civil Action No. 10-10470-NMG

[Filed August 11, 2011]

SILVERSTRAND INVESTMENTS, BRIARWOOD INVESTMENTS, INC. and SAFRON CAPITAL CORPORATION, Plaintiffs,	)
v.	)
AMAG PHARMACEUTICALS, INC., et al. Defendants.	)

MEMORANDUM & ORDER

GORTON, J.

This is a putative federal securities class action brought pursuant to the Securities Act of 1933 ("Securities Act") for alleged failures to disclose material information pertaining to a pharmaceutical drug. Before the Court are defendants' motions to dismiss the Second Amended Complaint and to strike certain exhibits submitted by plaintiffs.

I. Factual Background

Lead plaintiffs Silverstrand Investments ("Silverstrand"), Safron Capital Corporation ("Safron") and Briarwood Investments, Inc. ("Briarwood") (collectively, "the plaintiffs") bring this federal securities class action on behalf of themselves and all purchasers of the common stock of AMAG Pharmaceuticals, Inc. ("AMAG") pursuant or traceable to SEC Form S-3/ASR, No. 333-164400, dated January 19, 2010 ("the Registration Statement") and Prospectus dated January 21, 2010 ("the Prospectus") (collectively, "the Offering Documents") issued in connection with the secondary offering conducted on January 21, 2010 ("the Offering"). The Offering Documents incorporate by reference therein various other public filings, including several Forms 10-K, 10-Q and 8-K filed with the SEC in 2008 and 2009.

AMAG is a biopharmaceutical company incorporated in Delaware with its principal place of business in Massachusetts. Defendants Brian J.G. Pereira ("Pereira"), David A. Arkowitz ("Arkowitz"), Joseph V. Bonventre ("Bonventre"), Michael Narachi ("Narachi"), Robert J. Perez ("Perez"), Lesley Russell ("Russell"), Davey S. Scoon ("Scoon") and Ron Zwanziger ("Zwanziger") (collectively, "the individual defendants") are officers and/or directors of AMAG who signed the Registration Statement. Defendants Morgan Stanley & Co. Inc. ("Morgan Stanley"), J.P. Morgan Securities Inc. ("J.P. Morgan"), Goldman, Sachs & Co. ("Goldman"), Leerink Swann LLC ("Leerink"), Robert W. Baird Co. Inc. ("Robert Baird") and Canaccord Genuity Inc. ("Canaccord") (collectively, "the underwriter defendants") are various investment banks

which provided underwriting services to AMAG for the Offering.

A. The Development of Feraheme

AMAG developed and commercialized Feraheme, an intravenous iron-replacement drug used to treat iron deficiency anemia in adult patients with chronic kidney disease. Feraheme, also known as ferumoxytol injection, is administered in a bolus (i.e. rapid) injection of 510 milligrams in as little as 17 seconds and a complete course of treatment can be accomplished in two to four physician visits. By contrast, competing iron-replacement therapies Venofer and Ferrlecit must be administered as an intravenous infusion (i.e. "slow push") of 100 to 200 milligrams over a 15 to 60 minute interval and require five to ten physician visits.

In December, 2007, AMAG submitted a new drug application ("NDA") to the Food and Drug Administration ("FDA") seeking approval of Feraheme as an iron-replacement treatment. After more than 20 NDA amendments by AMAG and two action letters dated October 17 and December 22, 2008, in which the FDA declined to approve Feraheme based, in part, on safety concerns, the FDA approved Feraheme for sale on June 30, 2009. AMAG launched the drug in the United States in July, 2009.

The only other drug that AMAG currently sells is GastroMARK, an oral contrast agent used for delineating the bowel in magnetic resonance imaging ("MRI"), which received FDA approval in 1996.

B. The Offering

On January 21, 2010, AMAG completed the Offering pursuant to the Offering Documents. AMAG sold 3.6 million shares of its common stock to the public for a price of $48.25 per share, resulting in net proceeds of approximately $174 million. The Offering was a firm commitment secondary offering, meaning AMAG sold the shares to the underwriter defendants who then sold the shares to investors. The underwriter defendants received $7.8 million in fees as a result of the Offering.

C. Post-Offering Developments

On February 4, 2010, an analyst report stated that there were "several patients hospitalized with anaphylactoid reactions to Feraheme [and] one death that may or may not be directly related to Feraheme." The price of AMAG stock decreased from $45.25 per share to close at $38.12 per share that day.

On February 5, 2010, AMAG issued a safety update in a press release, disclosing that it had received reports of 40 serious adverse events ("SAEs") since the launch of Feraheme and the rate of SAEs was "reported at a rate consistent with that contained in the U.S. package insert." AMAG's stock price declined from $38.12 per share to close at $37.77 per share that day.

On February 8, 2010, a follow-up analyst report 1) questioned the validity of comparing the 0.1% "per patient exposure" rate (i.e. 40 SAEs per 35,000 exposures) used by AMAG in its safety update with the 0.2% "per patient" rate (i.e. 3 SAEs per 1726 patients) used during clinical trials and 2) noted competitor

Venofer had been associated with one SAE and one death in the ten years since it was introduced to the market. The price of AMAG's stock fell from $37.77 per share to close at $36.67 per share that day.

In total, AMAG's stock price declined 24% from $48.25 per share at the Offering on January 21, 2010 to close at $36.67 per share on February 8, 2010.

D. Post-Suit Developments

In August, 2010, the FDA created a Tracked Safety Issue ("TSI") for Feraheme. On October 18, 2010, the FDA issued a Warning Letter to AMAG finding that it had misbranded Feraheme in violation of the Food, Drug and Cosmetic Act, 21 U.S.C. § 352(a), (f)(1) and (n), as well as various FDA regulations and stating that AMAG had failed:

> to communicate any of the risks associated with the drugs [and thus] the webpages misleadingly suggest that GastroMARK and Feraheme are safer than has been demonstrated and therefore place the public at risk.

Shortly thereafter, AMAG held a conference call with analysts to discuss the recent developments. On October 29, 2010, the following day, AMAG's stock price fell from $19.30 per share to close at $15.91 per share.

On November 26, 2010, after AMAG announced changes in the product insert (i.e. label) for Feraheme, its stock closed at $14.05 per share. The new label included warnings that post-marketing SAEs had

occurred and required an increase in the observation period in patients after use of Feraheme.

In total, AMAG's stock price declined 71% from $48.25 per share at the Offering on January 21, 2010 to close at $14.05 per share on November 26, 2010.

E. The Alleged Material Omissions

The crux of the prolix Second Amended Complaint is that the Offering Documents omitted material facts, including facts necessary to make the statements therein not misleading, as a result of which plaintiffs purchased securities whose true value was less than their purchase price. Although plaintiffs plead a barrage of alleged material omissions, their laundry list boils down to three:

1) Although the Offering Documents stated that there was a risk of development of SAEs, they failed to disclose that, as of the date of the Offering, AMAG had reported 23 post-marketing SAEs associated with Feraheme to the FDA. Those 23 SAEs allegedly established a clear and significant pattern and were likely to affect the safety profile and commercial viability of Feraheme.

2) The Offering Documents failed to disclose that the FDA had twice declined to approve Feraheme because of safety concerns, including one case of anaphylaxis. Because the SAEs were of concern to the FDA in its approval process, post-marketing SAEs raised the risk that Feraheme would be adversely impacted, such as by being removed from the market or having stricter label warnings imposed.

3) The Offering Documents failed to disclose that a portion of AMAG's revenue was derived from "the illegal and misleading marketing practices" identified by the FDA in its Warning Letter.

II. Procedural History

In March, 2010, plaintiffs filed a class action complaint seeking relief under Section 11 of the Securities Act, 15 U.S.C. § 77k. Following their appointment as lead plaintiffs in July, 2010, Silverstrand, Safron and Briarwood filed an amended complaint which named additional defendants and asserted two new causes of action under Sections 12(a)(2) and 15 of the Securities Act, 15 U.S.C. §§ 771(a)(2) and 77o.

On December 17, 2010, plaintiffs filed a second amended complaint pursuant to a stipulation entered into by the parties under Fed. R. Civ. P. 15(a)(2). The Second Amended Complaint alleges violations of § 11 against all defendants (Count I), § 12(a)(2) against defendants AMAG, Pereira, Arkowitz and the underwriter defendants (Count II) and § 15 against Pereira and Arkowitz (Count III).

In February, 2011, after an unopposed extension of time, the individual defendants and the underwriter defendants filed motions to dismiss the Second Amended Complaint which plaintiffs timely opposed in an omnibus motion. The individual defendants also moved to strike certain exhibits submitted by plaintiffs in its opposition which plaintiffs timely opposed.

Pending before the Court are defendants' motions to dismiss and to strike certain of plaintiffs' exhibits.

III. Analysis

A. Legal Standard

In order to survive a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6), a complaint must contain factual allegations sufficient "to raise a right to relief above the speculative level." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). In considering the merits of a motion to dismiss, the Court may look only to the facts alleged in the pleadings, documents attached as exhibits or incorporated by reference in the complaint and matters of which judicial notice can be taken. Nollet v. Justices of the Trial Court of Mass., 83 F. Supp. 2d 204, 208 (D. Mass. 2000), aff'd, 248 F.3d 1127 (1st Cir. 2000). Furthermore, the Court must accept all factual allegations in the complaint as true and draw all reasonable inferences in the plaintiff's favor. Langadinos v. Am. Airlines, Inc., 199 F.3d 68, 69 (1st Cir. 2000). If the facts in the complaint are sufficient to state a cause of action, a motion to dismiss the complaint must be denied. See Nollet, 83 F. Supp. 2d at 208.

Although the Court must accept as true all of the factual allegations contained in a complaint, that doctrine is not, however, applicable to legal conclusions. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009). Threadbare recitals of the legal elements, supported by mere conclusory statements, do not suffice to state a cause of action. Id. Accordingly, a

complaint does not state a claim for relief where the well-pled facts fail to warrant an inference of any more than the mere possibility of misconduct. Id. at 1950.

B. Application

As an initial matter, defendants contend plaintiffs' claims "sound in fraud" and thus are subject to the heightened pleading requirements of Fed. R. Civ. P. 9(b). See Cooperman, 171 F.3d at 47 n.6 (noting Rule 9(b) does not apply to claims that do not "sound in fraud"); In re Sonus Networks, Inc. Sec. Litig., 2006 WL 1308165, *6 (D. Mass. May 10, 2006). Because, however, defendants frame their arguments primarily with respect to Fed. R. Civ. P. 8 and plaintiffs' Second Amended Complaint fails to state a claim even under that standard, the Court need not determine whether Rule 9(b) applies.

1. Motion to Strike

Defendants move to strike two exhibits submitted by plaintiffs with their opposition: minutes from a September 23, 2010, meeting between AMAG representatives and the FDA (Exhibit 2) ("FDA Meeting Minutes") and a letter dated January 31, 2011, from the FDA to plaintiffs in response to their Freedom of Information Act ("FOIA") request (Exhibit 3) ("FOIA Letter"). Defendants contend the FDA Meeting Minutes should be stricken because, inter alia, they were not referenced in the Second Amended Complaint and are not "freely available" to the public. Plaintiffs assert the documents were unavailable at the time the Second Amended Complaint was filed and urge the Court to take judicial notice of their existence but not

the truth of their contents or, in the alternative, to give them leave to amend the Second Amended Complaint.

Pursuant to Fed. R. Evid. 201, the Court may take judicial notice of a fact "not subject to reasonable dispute." Here, the Court takes judicial notice of the existence of the FDA Meeting Minutes and accompanying FOIA Letter but not the truth of the contents therein. See McGuire v. Dendreon Corp., 2008 WL 1791381, *4 (W.D. Wash. Apr. 18, 2008) (taking judicial notice of documents but declining to draw any inferences therefrom); see also Funk v. Stryker Corp., 631 F.3d 777, 783 (5th Cir. 2011) (upholding taking of judicial notice of FDA letter and transcripts); In re Vertex Pharms. Inc. Sec. Litig., 357 F. Supp. 2d 343, 351 n.4 (D. Mass. 2005) (taking judicial notice of public record); Peviani v. Hostess Brands, Inc., 750 F. Supp. 2d 1111, 1116 (C.D. Cal. 2010) (taking judicial notice of FDA Food Labeling Guide and listing cases). Moreover, notice to either party is not a concern here. See Watterson v. Page, 987 F.2d 1, 3-4 (1st Cir. 1993) (explaining that when court reviews statements extraneous to complaint, concern is generally lack of notice). The Court will, therefore, deny defendants' motion to strike.

2. Section 11 of the Securities Act (Count I)

Count I of the Second Amended Complaint alleges violations of § 11 against all defendants. The Second Amended Complaint alleges only that defendants omitted to state material facts or, in the alternative, that they omitted material facts necessary to make the statements in the Offering Documents not misleading.

Section 11 imposes liability on the issuer of a security, as well as any person who signed the registration statement and/or served as a director or performed similar functions, if the registration statement 1) contained an untrue statement of material fact, 2) omitted to state a material fact or 3) omitted a material fact necessary to make the statements therein not misleading. 15 U.S.C. § 77k(a); see Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1201 (1st Cir. 1996), superseded on other grounds by statute, Private Securities Litigation Reform Act of 1995; In re Evergreen Ultra Short Opportunities Fund Sec. Litig., 705 F. Supp. 2d 86, 91 (D. Mass. 2010). Thus, to avoid dismissal of their § 11 claim, plaintiffs must successfully allege that: 1) AMAG's Offering Documents contained an omission, 2) the omission was material, 3) defendants were under a duty to disclose the omitted information and 4) such omitted information existed at the time the Offering Documents became effective. See, e.g., Cooperman v. Individual, Inc., 171 F.3d 43, 47 (1st Cir. 1999).

Unlike § 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), § 11 has no scienter or reliance requirement. Evergreen, 705 F. Supp. 2d at 91. As long as the plaintiff can prove a material misstatement or omission, § 11 liability for the issuer of the security is "virtually absolute, even for innocent misstatements." Herman v. Huddleston, 459 U.S. 375, 381-82 (1983). Thus, to establish a prima facie violation of § 11, a plaintiff need only show a material misstatement or omission. Sonus, 2006 WL 1308165 at *11.

The same standard of materiality applies, however, to § 11 and § 12 claims as to § 10(b) claims. Shaw, 82

F.3d at 1217. A fact is material if its disclosure "would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Basic Inc. v. Levinson, 485 U.S. 224, 231-32 (1988). Moreover, the "mere fact that an investor might find information interesting or desirable is not sufficient to satisfy the materiality requirement." Lucia v. Prospect St. High Income Portfolio, Inc., 36 F.3d 170, 175 (1st Cir. 1994).

Even a material omission is not, however, necessarily actionable. In re Pharm., Inc. Sec. Litig., 2007 WL 951695 at *3 (D. Mass. March 28, 2007). There must also be a duty to disclose. Garvey v. Arkoosh, 453 F. Supp. 2d 73, 80-81 (D. Mass. 2005); see also Backman v. Polaroid Corp., 910 F.2d 10, 13 (1st Cir. 1990) (noting silence, absent a duty to disclose, is not misleading); Pharm., Inc., 2007 WL 951695 at *3 ("Absent a legal duty to disclose, there is no liability for simple non-disclosure."). A duty to disclose may be triggered by, inter alia, a statute or regulation or when a company has made inaccurate, incomplete or misleading prior disclosures. Garvey, 453 F. Supp. 2d at 81 n.10. In addition, if a corporation does make a disclosure, whether voluntary or required, there is a duty to make it complete and accurate. Roeder v. Alpha Indus., Inc., 814 F.2d 22, 26 (1st Cir. 1987).

The Court considers each of plaintiffs' nondisclosure allegations in turn.

a. The 23 SAEs

Plaintiffs' predominant allegation is that, pursuant to SEC Regulation S-K Items 303(a)(3)(ii) and 503(c),

defendants were required but failed to disclose 23 post-marketing SAEs associated with Feraheme which AMAG had reported to the FDA prior to the Offering.

There is "a strong affirmative duty of disclosure in the context of a public offering." Glassman v. Computervision Corp., 90 F.3d 617, 623 (1st Cir. 1996) (citing Shaw, 82 F.3d at 1202). It is clear, however, that there is "no absolute duty to disclose all material information." Cooperman, 171 F.3d at 49; see also Hill v. Gozani, 2011 WL 2566142, *1 (1st Cir. May 26, 2011) (noting possession of material, non-public information does not create an automatic duty to disclose). The question is whether the securities law imposes a specific obligation to disclose the specific kind of information allegedly omitted. Cooperman, 171 F.3d at 50.

Regulation S-K governs the disclosure requirements of registration statements, periodic reports and annual reports filed with the SEC. 17 C.F.R. § 229.10. Item 303(a)(3)(ii) of that regulation requires the disclosure of, inter alia:

> any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations.

17 C.F.R. § 229.303(a)(3)(ii). That language has been interpreted as referring to "those trends discernible from hard information alone." Glassman, 90 F.3d at 631. In other words, "Item 303(a)(3)(ii) essentially says to a registrant: If there has been an important change

in your company's business or environment that significantly or materially decreases the predictive value of your reported results, explain this change in the prospectus." Kapps v. Torch Offshore, Inc., 379 F.3d 207, 218 (5th Cir. 2004) (quoting Oxford Asset Mgmt., Ltd. v. Jaharis, 297 F.3d 1182, 1191-92 (11th Cir. 2002)). A breach of the duty to disclose under Item 303 may be actionable under § 11. See In re Thornburg Mortg., Inc. Sec. Litig., 2011 WL 2429189, *28, *34 (D.N.M. June 2, 2001) (listing cases).

Turning its attention to Item 303(a)(3)(ii), the Court finds no actionable omission even though AMAG knew of the 23 SAEs at the time of the Offering. The mere existence of reports of SAEs is insufficient and indeed, "something more is needed." See Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309, 1321 (2011). Even if the Court assumes that the 23 SAEs are material, however, plaintiffs' claim still is deficient because the 23 SAEs do not amount to a "known trend or uncertainty" and thus need not be disclosed.

AMAG repeatedly disclosed in its Offering Documents and other public filings the safety information for Feraheme, including the fact that SAEs were observed during the clinical trials. See, e.g., Oxford Asset Mgmt., Ltd. v. Jaharis, 297 F.3d 1182, 1193 (11th Cir. 2002) (holding prospectus not misleading because warnings included risk of relevant side effect). Specifically, the Prospectus warned about risks, including "the development of unanticipated adverse reactions to Feraheme resulting in safety concerns among prescribers." In addition, the 23 SAEs that occurred after the launch of Feraheme but prior to the Offering were consistent with the previously and

publicly-disclosed rates observed in the clinical trial. Thus, the 23 SAEs did not constitute a known trend that would have a material unfavorable impact on sales, revenue or income. Plaintiffs emphasize in rebuttal that a death occurred post-marketing, pre-Offering but one death does not a trend make.

Item 503 of Regulation S-K requires an issuer to include "a discussion of the most significant risk factors that make the offering risky or speculative." 17 C.F.R. § 229.503. Plaintiffs contend that the 23 SAEs constituted a significant factor that made the Offering risky or speculative and thus should have been disclosed. The Offering Documents, however, contained extensive disclosures of the risks associated with Feraheme, including data from the clinical trials and how SAEs could impact Feraheme's success. Based on those disclosures and for substantially the same reasons that plaintiffs' claim with respect to Item 303(a)(3)(ii) is wanting, their claim as to Item 503 also fails.

b. The FDA Action Letters

Plaintiffs further allege that the Offering Documents failed to disclose that the FDA had twice declined to approve Feraheme due to safety concerns, citing a "clinical pattern of serious adverse reactions."

That argument is unavailing, however, because the FDA's subsequent approval of the NDA prior to the Offering indicates any concerns raised previously in the letters had been resolved. See, e.g., In re Alkermes Sec. Litig., 2005 WL 2848341, *16 (D. Mass. Oct. 6, 2005) (holding FDA's eventual approval meant defendants

had remedied whatever problem existed); In re Syntex Corp. Sec. Litig., 95 F.3d 922, 930-31 (9th Cir. 1996) (explaining FDA's approval indicates company remedied any defects and thus statements were not false or materially misleading). Moreover, the defendants had no duty to disclose because both action letters had already been publicly disclosed by the FDA prior to the Offering. See, e.g., In re Progress Energy, Inc., 371 F. Supp. 2d 548, 552-53 (S.D.N.Y.2005) ("It is well-established law that the securities laws do not require disclosure of information that is publicly known.").

c. The FDA Warning Letter

Plaintiffs allege the Offering Documents failed to disclose that AMAG derived revenue from "the illegal and misleading marketing practices" identified by the FDA in a Warning Letter dated October 18, 2010.

That argument is unpersuasive because § 11 imposes liability only if the registration statement contains material misstatements or omissions as of its effective date. Shaw, 82 F.3d at 1204; see Zucker v. Quasha, 891 F. Supp. 1010, 1017 (D.N.J. 1995) (stating that even § 11 "does not impose liability for the omission of material information which was unknown to, and not reasonably discoverable by, the defendants"). Indeed, the Court "may not employ 20/20 hindsight" but rather must consider whether the omission was material on the date the Offering Documents were issued. See Panther Partners, Inc. v. Ikanos Commc'ns, Inc., 538 F. Supp. 2d 662, 668 (S.D.N.Y. 2008). The Second Amended Complaint fails to establish any connection between the Warning

Letter or the allegations contained therein and the time of the Offering. See Zucker, 891 F. Supp. at 1017 ("In order to prevail, a plaintiff must show that the omitted information in fact existed at the time that the allegedly misleading statement was made.").

Count I will, therefore, be dismissed.

3. Section 12 of the Securities Act (Count II)

Count II alleges violations of § 12(a)(2) against defendants AMAG, Pereira, Arkowitz and the underwriter defendants. Section 12(a)(2) of the Securities Act imposes liability on any person who "offers or sells" a security by means of a prospectus or oral communication that contains an untrue statement of material fact or a misleading omission. 15 U.S.C. § 771(a)(2). For the same reasons that plaintiffs' § 11 claim fails, the § 12(a)(2) claim is also unsuccessful. See In re Barclays Bank PKC Sec. Litig., 2011 WL 31548, *5 (S.D.N.Y. Jan. 5, 2011) ("Sections 11 and 12(a)(2) are Securities Act siblings with roughly parallel elements."). Count II will, therefore, be dismissed and the Court need not reach the issue of standing raised in the underwriter defendants' motion to dismiss.

4. Section 15 of the Securities Act (Count III)

Count III alleges violations of § 15 for control person liability based on violations of § 11 and § 12(a)(2) by AMAG against defendants Pereira and Arkowitz. Section 15 of the Securities Act provides for joint and several liability for persons who control any person

liable under § 11 or § 12 of the Securities Act. 15 U.S.C. § 77o. In order for "control person" liability under § 15 to attach, the plaintiffs must allege 1) an underlying violation by the controlled person or entity and 2) that the defendants controlled the violator. Aldridge v. A.T. Cross Corp., 284 F.3d 72, 85 (1st Cir. 2002). Because plaintiffs have failed to state a claim for a primary violation of either § 11 or § 12(a)(2), they have also fallen short of stating a claim under § 15. See, e.g., Cooperman, 171 F.3d at 52. Count III will, therefore, be dismissed.

ORDER

In accordance with the foregoing,

1) motion to strike (Docket No. 55) is **DENIED**;

2) motion to dismiss (Docket No. 42) is **ALLOWED**; and

3) underwriter defendants' motion to dismiss (Docket No. 44) is **ALLOWED**.

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated August 11, 2011

APPENDIX D

United States Court of Appeals
For the First Circuit

No. 11-2063

[Filed March 15, 2013]

SILVERSTRAND INVESTMENTS; BRIARWOOD INVESTMENTS, INC.; SAFRON CAPITAL CORPORATION, on behalf of themselves and all others similarly situated	)
Plaintiffs - Appellants	)
v.	)
AMAG PHARMACEUTICALS, INC.; BRIAN J.G. PEREIRA, M.D.; DAVID A. ARKOWITZ; JOSEPH V. BONVENTRE, M.D.; MICHAEL NARACHI; ROBERT J. PEREZ; LESLEY RUSSELL, M.D.; DAVEY S. SCOON; RON ZWANZIGER; MORGAN STANLEY & CO. INCORPORATED; J.P. MORGAN SECURITIES LLC.; GOLDMAN, SACHS & CO.; LEERINK SWANN LLC; ROBERT W. BAIRD & CO.	)

INCORPORATED; CANACCORD GENUITY INC.

Defendants - Appellees

Before

Lynch,[*] Chief Judge,
Torruella, Boudin,[**] Lipez, Howard,
Thompson and Kayatta,
Circuit Judges.

ORDER OF COURT
Entered: March 15, 2013

The petition for rehearing having been denied by the panel of judges who decided the case, and the petition for rehearing en banc having been submitted to the active judges of this court and a majority of the judges not having voted that the case be heard en banc, it is ordered that the petition for rehearing and the petition for rehearing en banc be denied.

By the Court:

/s/ Margaret Carter, Clerk

[*] Chief Judge Lynch is recused and did not participate in the consideration of this matter.

[**] Judge Boudin did not participate in the vote.

cc:
Laura B. Angelini
Gilles R. Bissonnette
Justin P. O'Brien
Betsy L. Ehrenberg
Jack G. Fruchter
Karen L. Burhans
Ximena R. Skovron
Mitchell Twersky
Ian D. Berg
Robert B. Lovett
John Charles Dwyer
Kevin J. O'Connor
Sameer Advani
Tariq Mundiya
Angela L. Dunning

APPENDIX E

United States Court of Appeals
For the First Circuit

No. 11-2063

[Filed April 8, 2013]

SILVERSTRAND INVESTMENTS; BRIARWOOD INVESTMENTS, INC.; SAFRON CAPITAL CORPORATION, on behalf of themselves and all others similarly situated,	)
Plaintiffs - Appellants	)
v.	)
AMAG PHARMACEUTICALS, INC.; BRIAN J.G. PEREIRA, M.D.; DAVID A. ARKOWITZ; JOSEPH V. BONVENTRE, M.D.; MICHAEL NARACHI; ROBERT J. PEREZ; LESLEY RUSSELL, M.D.; DAVEY S. SCOON; RON ZWANZIGER; MORGAN STANLEY & CO. INCORPORATED; J.P. MORGAN SECURITIES LLC.; GOLDMAN, SACHS & CO.; LEERINK SWANN LLC; ROBERT W. BAIRD & CO.	)

INCORPORATED; CANACCORD GENUITY INC.,

Defendants - Appellees.

ORDER OF COURT
Entered: April 8, 2013

Upon consideration of defendants-appellees' motion to stay the mandate, the motion is granted. The issuance of the mandate is hereby stayed for 90 days and if within that period a timely petition for certiorari is filed, the stay of mandate shall continue until final disposition by the United States Supreme Court. If the petition for certiorari is denied, mandate shall issue forthwith. Counsel for defendants-appellees is directed to promptly notify the Clerk of this court both of the filing of any such petition for certiorari and the disposition.

By the Court:

/s/ Margaret Carter, Clerk

cc:
Laura B. Angelini
Gilles R. Bissonnette
Justin P. O'Brien
Betsy L. Ehrenberg
Jack G. Fruchter
Karen L. Burhans
Ximena R. Skovron
Mitchell Twersky
Ian D. Berg

Robert B. Lovett
John Charles Dwyer
Kevin J. O'Connor
Sameer Advani
Tariq Mundiya
Angela L. Dunning

APPENDIX F

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

Civil Action No. 10-cv-10470-NMG

[Filed December 17, 2010]

JURY TRIAL DEMANDED

SILVERSTRAND INVESTMENTS, SAFRON CAPITAL CORPORATION, and BRIARWOOD INVESTMENTS, INC., On Behalf of Themselves And All Others Similarly Situated,	)
Plaintiff,	)
vs.	)
AMAG PHARMACEUTICALS, INC., BRIAN J.G. PEREIRA, DAVID A. ARKOWITZ, JOSEPH V. BONVENTRE, MICHAEL NARACHI, ROBERT J. PEREZ, LESLEY RUSSELL, M.D., DAVEY S. SCOON, RON ZWANZIGER, MORGAN STANLEY & CO. INCORPORATED, J.P. MORGAN SECURITIES INC., GOLDMAN, SACHS CO., LEERINK SWANN LLC, ROBERT W. BAIRD CO.	)

INCORPORATED, and CANACCORD GENUITY INC.,

Defendants.

SECOND AMENDED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

Lead Plaintiff, as defined in paragraph 1 below ("Lead Plaintiff") hereby brings this second amended class action complaint against AMAG Pharmaceuticals, Inc. ("AMAG" or "the Company"), the Individual Defendants (as defined herein) and the Underwriter Defendants (as defined herein, and collectively with AMAG and the Individual Defendants, the "Defendants"). The allegations against Defendants are based on personal knowledge as to Lead Plaintiff's own acts and on information and belief as to all other matters, with such information and belief having been informed by the investigation conducted by and under the supervision of their counsel ("Lead Counsel") which included, among other things: (i) review and analysis of AMAG's public filings with the U.S. Securities and Exchange Commission ("SEC"), press releases, conference presentations, earnings call transcripts, and other public statements issued by the Company; (ii) review and analysis of records of the Food and Drug Administration ("FDA") and other documents concerning, among other things, the clinical trials and approval process for Feraheme, the post-marketing safety issues associated with Feraheme, and the "FDA Warning Letter" issued to the Company on October 18, 2010 (the FDA Warning Letter); (iii) securities analysts' reports and advisories about the Company; and (iv) interviews with former employees and other persons with knowledge of the matters alleged herein, some of whom have provided information in confidence (these confidential witnesses ("CWs") will be identified herein by number (e.g., CW1, CW2)). Lead Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION AND OVERVIEW

1. Court-appointed Lead Plaintiffs Silverstrand Investments, Safron Capital Corporation and Briarwood Investments, Inc. (collectively, "Lead Plaintiff") bring this federal securities class action on behalf of all purchasers of common stock of AMAG ("Common Stock") pursuant or traceable to the Company's Registration Statement filed with the SEC, No. 333-164400, dated January 19, 2010 (the "Registration Statement") and accompanying Prospectus (the "Prospectus", together with the Registration Statement and all documents incorporated by reference therein, the "Offering Documents") issued in connection with the secondary offering conducted on or about January 21, 2010 (the "Offering"). Lead Plaintiff seeks remedies under the Securities Act of 1933 (the "Securities Act").

2. AMAG is a biopharmaceutical company engaged in the development and commercialization of two drugs, Feraheme® (ferumoxytol injection) (herein "Feraheme"), a powerful intravenous iron-replacement drug that rapidly administers a high quantity of iron directly into the bloodstream, and GastroMARK® (herein "GastroMARK"), an oral contrast agent used for delineating the bowel in magnetic resonance imaging (MRI).

3. Feraheme is indicated for the treatment of iron deficiency anemia ("IDA") in adult patients with chronic kidney disease ("CKD"). This action arises from material misrepresentations and omissions in the

Offering Documents concerning the safety profile and commercial viability of Feraheme.

4. AMAG is dependent on the commercial success of Feraheme. As stated in pertinent part in the Prospectus:

> ***Our ability to generate future revenues is solely dependent on our successful commercialization and development of Feraheme. We currently sell only one other product, GastroMARK, in the U.S. and in certain foreign jurisdictions through our partners.*** However, sales of G*astroMARK* have been at their current levels for the last several years, and we do not expect sales of *GastroMARK* to materially increase. ***Accordingly, if we are unable to generate sufficient revenues from sales of Feraheme, we may never be profitable, our financial condition will be materially adversely affected, and our business prospects will be limited.*** (Emphasis added.)

5. Prior to the Offering, the FDA twice denied AMAG's application for approval of Feraheme, citing serious concern about (i) the occurrence of a single reported case of anaphylaxis during clinical trials; (ii) accusing the Company of underreporting and/or minimizing the occurrence of serious adverse events ("SAEs"); and (iii) finding systemic defects in the Company's manufacturing processes. Following numerous amendments to its application, Feraheme was finally approved for sale by the FDA on June 30, 2009.

6. Within months of Ferahemes launch, and prior to the Offering, AMAG had already received dozens of reports of SAEs, including anaphylactic and cardiac related reactions, which resulted in hospitalizations and at least one report of a death associated with a Feraheme injection. Indeed, one former AMAG sales representative ("CW1") affirmed that all five sales representatives in his territory alone were receiving frequent reports of SAEs, with some physicians reporting multiple SAE cases among their patients. Further, the SAEs occurred across a broad spectrum of patients, ranging in ages from 32 to 96 with varied medical conditions.

7. In total, since its launch in July 2009, Feraheme has been linked to at least 146 SAEs, including 11 fatalities and 14 cases of anaphylaxis. Eight of the eleven deaths were preceded by cardiac related SAEs, and six of the deaths were the result of cardiac arrest.

8. On January 21, 2010, the Company completed the Offering, selling 3,600,000 shares of its Common Stock for a price of $48.25 per share, resulting in net proceeds to the Company of approximately $165.6 million.

9. The Offering Documents failed to disclose the occurrence of any SAEs, let alone anaphylactic reactions, cardiac events, or any fatalities; or that SAEs were occurring at a significant rate. As a result of Defendants misstatements and omissions of material fact, investors were unaware of the true safety profile and commercial viability of Feraheme.

10. Two weeks after the Offering, on February 4, 2010, an analyst with Summer Street Capital Partners ("Summer Street") revealed for the first time that there were "several patients hospitalized with anaphylactoid reactions to Feraheme . . . [and] one death that may or may not be directly related to Feraheme."

11. Following the February 4th Summer Street report, AMAGs stock plunged by over $7.00, or more than 15% from $45.25 per share to close at $38.12 per share, damaging Lead Plaintiff and the Class, who purchased the Common Stock pursuant or traceable to the Offering.

12. The next day, on February 5, 2010, the Company issued a press release and held a conference call, in which it provided a "safety update" concerning Feraheme. The Company disclosed that it had received reports of forty (40) SAEs since the drug's launch, or an approximate rate of .1% per "patient exposure." However, the Company understated the SAEs that had occurred because it failed to calculate the rate *per patient* (the metric used during clinical trials) and instead used the different, more generous, *per patient exposure* metric.

13. On the following Monday, February 8, 2010, Summer Street issued another report in response to the Company's press release and conference call, recognizing that the metric used by AMAG in calculating SAEs post-marketing "is not a valid comparison" with the reported rate during clinical trials, and noting that the number of SAEs were likely higher than forty (40) because of reporting time lags and the recency of the events. The February 8th

Summer Street report further observed that Ferahemes primary competitor, Venofer®, has been associated with only one SAE and one death in the ten years that Venofer® has been on the market, according to Summer Streets conversations with clinicians.

14. Following the February 8th Summer Street report, the price of AMAG's stock fell once again to close at $36.67 per share, making for a decline of 19% in the value of the shares sold in the Offering.

15. Within months of the Offering, the FDA took action in response to the pattern of SAEs reported to AMAG, including the fatalities associated with Feraheme use, as set forth herein. In August 2010, the FDA created a "Tracked Safety Issue" (hereinafter sometimes referred to as "TSI") for Feraheme, and subsequently required AMAG to change Feraheme's label to include additional bolded warnings and precautions regarding SAEs caused by anaphylactic and cardiac related events, as well as an increase in the observation period for patients following a Feraheme injection.

16. The Offering Documents were materially false and misleading when made because they failed to disclose the true safety profile and commercial viability of Feraheme. Specifically, the Offering Documents failed to disclose that a significant number of reports of SAEs were made to the Company prior to the issuance of the Offering Documents, including at least one reported death that was suspected to have been caused by Feraheme and several incidents of anaphylaxis, including cardiac-related events, resulting in hospitalization. The occurrence and severity of these

SAEs, particularly in light of the FDA's stated concerns in approving Feraheme, were material to the commercial viability of Feraheme and thus the ability of AMAG to generate future revenues. In particular, these events could have, and did, trigger adverse action by the FDA in the form of stricter labeling warnings, and were likely to impact physicians' use of Feraheme as an alternative to competing treatments for iron deficiency in both dialysis and non-dialysis CKD patients.

17. On October 18, 2010, the FDA issued a Warning Letter to AMAG finding that the Company had, *inter alia*, misbranded Feraheme in violation of the Food, Drug and Cosmetic Act, 21 U.S.C. 352(a), (f)(1) & (n); 321(n), and FDA's implementing regulations by making materially misleading statements on the Company's website concerning the safety and approved use of Feraheme. The Warning Letter also stated that AMAG had failed to submit its labeling and advertising statements promoting GastroMARK and Feraheme on its website to the FDA as required by 21 C.F.R. §314.81(b)(3)(1).

18. The Offering Documents failed to disclose that a material portion of the Company's revenues were derived from the illegal and materially misleading marketing practices identified by the FDA in the Warning Letter, in that the Company's website made certain representations concerning Feraheme's safety and use approved by the FDA but failed to disclose risks associated with Feraheme use and included representations concerning unapproved uses.

19. The Offering Documents also failed to disclose that AMAG had not complied with 21 C.F.R. §314.81(b)(3)(1) in submitting the requisite documentation to the FDA regarding labeling and advertising statements promoting GastroMARK and Feraheme.

20. As a result of the disclosure of the pattern, frequency and severity of SAEs reported to the Company and the Company's misleading and illegal marketing practices and failure to comply with applicable FDA regulations as set forth herein, the price of AMAGs stock has fallen more than 71% from the Offering price.

II. JURISDICTION AND VENUE

21. The claims asserted herein arise under and are brought pursuant to Sections 11, 12(a)(2) and 15 of the Securities Act, 15 U.S.C. §§ 77k, 77l(a)(2), 77o.

22. This Court has jurisdiction of this action pursuant to Section 22 of the Securities Act, 15 U.S.C. § 77v.

23. Venue is properly laid in this District pursuant to Section 22 of the Securities Act, 15 U.S.C. § 77v, and 28 U.S.C. § 1331. At all relevant times, AMAG maintained its headquarters and principal place of business in this District. Many of the acts and conduct complained of herein occurred in this District, including the dissemination to the investing public of the materially false and misleading statements in the Offering Documents.

24. In connection with the acts alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mails, interstate telephone communications and the facilities of national securities exchanges.

III. PARTIES

A. Plaintiffs

25. Plaintiff Silverstrand Investments purchased AMAG Common Stock, as set forth in the certification previously submitted to the Court and incorporated herein by reference, pursuant to the Offering, and was damaged thereby.

26. Plaintiff Safron Capital Corporation purchased AMAG Common Stock, as set forth in the certification previously submitted to the Court and incorporated herein by reference, pursuant to the Offering, and was damaged thereby.

27. Plaintiff Briarwood Investments, Inc. purchased AMAG Common Stock, as set forth in the certification previously submitted to the Court and incorporated herein by reference, pursuant to the Offering, and was damaged thereby.

B. Defendants

AMAG

28. Defendant AMAG is a biopharmaceutical company formed under Delaware law and maintains its

principal executive offices at 100 Hayden Avenue, Lexington, Massachusetts 02421.

Individual Defendants

29. Defendant Dr. Brian J. G. Pereira ("Pereira") was, at all relevant times, President, Chief Executive Officer and Executive Director of AMAG. Pereira signed the Registration Statement and solicited the purchase of AMAG's registered Common Stock by the use of means or instruments of transport or communication in interstate commerce or of the mails and by means of the Prospectus and other oral and written communications, including road shows.

30. Defendant David A. Arkowitz ("Arkowitz") was, at all relevant times, Executive Vice President and Chief Financial Officer of AMAG. Arkowitz signed the Registration Statement and solicited the purchase of AMAG's registered Common Stock by the use of means or instruments of transport or communication in interstate commerce or of the mails and by means of the Prospectus and other oral and written communications, including road shows.

31. Defendant Joseph V. Bonventre, M.D. ("Bonventre") was, at all relevant times, a Director of AMAG. Bonventre signed the Registration Statement.

32. Defendant Michael Narachi ("Narachi") was, at all relevant times, a Director of AMAG. Narachi signed the Registration Statement.

33. Defendant Robert J. Perez ("Perez") was, at all relevant times, a Director of AMAG. Perez signed the Registration Statement.

34. Defendant Lesley Russell, M.D. ("Russell") was, at all relevant times, a Director of AMAG. Russell signed the Registration Statement.

35. Defendant Davey S. Scoon ("Scoon") was, at all relevant times, a Director of AMAG. Scoon signed the Registration Statement.

36. Defendant Ron Zwanziger ("Zwanziger") was, at all relevant times, a Director of AMAG. Zwanziger signed the Registration Statement.

37. Defendants Pereira, Arkowitz, Bonventre, Narachi, Perez, Russell, Scoon and Zwanziger are referred to herein as the "Individual Defendants."

Underwriter Defendants

38. Each of the Defendants listed in paragraphs 40 through 45, collectively referred to as the "Underwriter Defendants", provided underwriting services to AMAG for the Offering. The Underwriter Defendants collectively received $7.8 million in underwriting fees for services provided in the Offering.

39. As underwriters, the Underwriter Defendants, collectively and individually, are liable for material omissions and misstatements contained in the Offering Documents unless they can prove that they conducted, prior to the Offering, a reasonable investigation of the Company to ensure that the

statements contained in such documents contained no material misstatements or omissions of material fact. The Underwriter Defendants failed to fulfill their duty to the investing public in this regard and cannot bear their burden to show an adequate investigation under the circumstances.

40. Defendant Morgan Stanley & Co. Incorporated ("Morgan Stanley") is an investment bank with offices in Boston, Massachusetts. Morgan Stanley was a Lead Manager for the Offering. Pursuant to the Offering, Morgan Stanley sold and distributed 1,980,000 shares of AMAG Common Stock. Morgan Stanley was paid over $4.2 million for its underwriting services in connection with the Offering.

41. Defendant J.P. Morgan Securities Inc. ("J.P. Morgan") is an investment bank with offices in Boston, Massachusetts. J.P. Morgan was a Lead Manager for the Offering. Pursuant to the Offering, J.P. Morgan sold and distributed 720,000 shares of AMAG Common Stock. J.P. Morgan was paid over $1.5 million for its underwriting services in connection with the Offering.

42. Defendant Goldman, Sachs & Co., Inc. ("Goldman Sachs") is an investment bank with offices in Boston, Massachusetts. Goldman Sachs was a Lead Manager for the Offering. Pursuant to the Offering, Goldman Sachs sold and distributed 540,000 shares of AMAG Common Stock. Goldman Sachs was paid over $1.1 million for its underwriting services in connection with the Offering.

43. Defendant Leerink Swann LLC ("Leerink Swann") is an investment bank with offices in Boston,

Massachusetts. Leerink Swann was a Co-Manager for the Offering. Pursuant to the Offering, Leerink Swann sold and distributed 180,000 shares of AMAG Common Stock. Leerink Swann was paid over $390,000 for its underwriting services in connection with the Offering.

44. Defendant Robert W. Baird Co. Incorporated ("Robert Baird") is an investment bank with offices in Boston, Massachusetts. Robert Baird was a Co-Manager for the Offering. Pursuant to the Offering, Robert Baird sold and distributed 90,000 shares of AMAG Common Stock. Robert Baird was paid over $195,000 for its underwriting services in connection with the Offering.

45. Defendant Canaccord Genuity Inc. ("Canaccord Genuity"), formerly known as Canaccord Adams Inc., is an investment bank with offices in Boston, Massachusetts. Canaccord Genuity was a Co-Manager for the Offering. Pursuant to the Offering, Canaccord Genuity sold and distributed 90,000 shares of AMAG Common Stock. Canaccord Genuity was paid over $195,000 for its underwriting services in connection with the Offering.

IV. CLASS ACTION ALLEGATIONS

46. Lead Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of itself and all persons who purchased the Common Stock of AMAG pursuant to or traceable to the Offering. Excluded from the Class are Defendants herein, members of the immediate family of each of the Defendants, any person, firm, trust, corporation, officer, director, or other individual or

entity in which any Defendant has a controlling interest or which is related or affiliated with any of the Defendants, and the legal representatives, agents, affiliates, heirs, successors-in-interest, or assigns of any such excluded party.

47. The members of the Class are so numerous that joinder of all members is impracticable. AMAG sold 3.6 million shares in the Offering. The precise number of Class members is unknown to Lead Plaintiff at this time, but is believed to be in the thousands. In addition, the names and addresses of the Class members can be ascertained from the books and records of AMAG or its transfer agent or the underwriters to the Offering. Notice can be provided to such record owners by a combination of published notice and first-class mail, using techniques and a form of notice similar to those customarily used in class actions arising under the federal securities laws.

48. Common questions of law and fact exist as to all members of the Class and predominate over any question affecting solely individual members of the Class. Among the questions of law and fact common to the Class are:

> (a) Whether the Securities Act was violated by Defendants' acts as alleged herein;
>
> (b) Whether the Prospectus and Registration Statement (as defined herein) issued by Defendants to the investing public in connection with the Offering misrepresented or omitted to

state material facts about AMAG and its business; and

(c) The extent of injuries sustained by members of the Class and the appropriate measure of damages.

49. Lead Plaintiff's claims are typical of the claims of the other members of the Class because Lead Plaintiff's and all the Class members' damages arise from and were caused by the same false and misleading representations and omissions made by or chargeable to Defendants. Lead Plaintiff does not have any interests antagonistic to, or in conflict with, the Class.

50. The Court-appointed Lead Plaintiff will fairly and adequately represent and protect the interests of the members of the Class. Lead Plaintiff has retained competent counsel experienced in class action litigation under the federal securities laws to further ensure such protection and intends to prosecute this action vigorously.

51. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Since the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it virtually impossible for the Class members to seek redress for the wrongful conduct alleged. Lead Plaintiff knows of no difficulty that will be encountered in the management of this litigation that would preclude its maintenance as a class action.

V. FACTUAL ALLEGATIONS

52. Since it was founded in 1981, AMAG has marketed three drug products: Feridex I.V.® ("Feridex I.V."), GastroMARK and Feraheme. Feridex I.V., a liver contrast agent, was approved by the FDA in 1996. In November 2008, AMAG decided to cease manufacturing Feridex I.V. and subsequently terminated all of its licensing agreements for the drug.

53. GastroMARK, an oral contrast agent used for delineating the bowel in MRI, was approved by the FDA in 1996. GastroMARK is indicated in adult patients for oral use with MRI to enhance the delineation of the bowel to distinguish it from organs and tissues that are adjacent to the upper regions of the gastrointestinal tract.

54. Prior to the Offering, GastroMARK sales were the primary source of the Company's revenue. For example, as disclosed in AMAG's Form 10-K for the fiscal year ended December 31, 2008 incorporated by reference in the Offering Documents, in 2008, sales of GastroMARK constituted approximately 60% of AMAG's total revenues.

A. Numerous Serious Adverse Events and Deaths Are Associated with Feraheme Use

1. AMAG's New Drug Application for Feraheme Was Twice Rejected by the FDA, Citing the Occurrence of Serious Adverse Events During Clinical Trials

55. On December 18, 2007, AMAG submitted a new drug application ("NDA") to the FDA seeking approval for the marketing of Feraheme in the United States for the treatment of iron deficiency anemia in patients with CKD.

56. At the time AMAG submitted its NDA for Feraheme, there were two competing intravenous iron-replacement therapeutic agents, Venofer® and Ferrlecit®, already approved by the FDA for the same indicated use sought by AMAG. Unlike Feraheme, however, these drugs are not bolus, or rapid-injection, intravenous agents; rather, they are administered as a "slow push" or a 15 to 60-minute intravenous infusion at much lower dosages of 100 to 200 milligrams, and require five to ten physician visits for a complete course of treatment. By contrast, Feraheme is administered in bolus injections of 510 milligrams each, which take approximately 17 seconds to administer and can be accomplished in between two and four physician visits. According to the U.S. package insert, the recommended Feraheme dose (2 x 510 mg) may be re-administered to patients with persistent or recurrent iron deficiency anemia.

57. Notwithstanding the Companys submission of twenty (20) amendments to its Feraheme NDA, dated February 27, April 3, 14 and 28, May 20, June 5 and 23, July 16 and 24, August 4, 5 and 7, September 3(2), 5, 22, 23, and 25, October 1 and 3, 2008, the FDA declined to approve Feraheme, citing the occurrence of a "clinical pattern of serious adverse reactions" as well as several other safety concerns that had arisen during the clinical trials of Feraheme.

58. In particular, in an action letter sent to AMAG dated October 17, 2008, the FDA stated that it was ***declining to approve Feraheme*** due, in part, to a single occurrence of anaphylaxis among the 1,726 patients exposed to Feraheme. Anaphylaxis is a life-threatening whole-body allergic reaction to a drug or allergen. (For example, anaphylaxis may result from a severe allergy to bee venom or peanuts.) Within seconds or minutes of exposure to the drug or allergen, the immune system releases a flood of chemicals that can cause the body to go into shock, and causes, among other things, a sudden drop in blood pressure (hypotension) and a narrowing of airways that blocks normal breathing. Signs and symptoms of anaphylaxis include a rapid, weak pulse, hives, dizziness, syncope (loss of consciousness), fever, vomiting and nausea. The onset of anaphylaxis is rapid, and must be treated immediately, typically in a hospital emergency room, by an injection of epinephrine. If left untreated, anaphylaxis can result in death.

59. In addition to the single anaphylaxis event, the FDA stated that it was concerned by the occurrence of "serious hypotensive reactions" in approximately 0.3% of the exposed population.

60. The FDA further determined that AMAG had underreported and/or minimized the occurrence of SAEs as set forth in the FDA's October 17, 2008 letter to AMAG:

> ***The inspectors determined that adverse events, including serious adverse events, were not consistently reported.*** To illustrate, subject 554 appears to have experienced a serious hypotensive event that prompted the delay of a second dose of ferumoxytol. The adverse event report denoted this event as a "headache" and did not describe the other clinical problems. Additionally, ***drug disposition records were inaccurate*** for four subjects and our inspectional team recommended elimination of the clinical data from these four subjects, with respect to assessment of ferumoxytol safety and efficacy.
>
> The FDA also cited deficiencies discovered during a field inspection of AMAGs manufacturing facility for Feraheme, located in Cambridge, Massachusetts, as a reason for declining to approve Feraheme. (Emphases added.)

61. In response to the FDA's action letter dated October 17, 2008, AMAG sent the FDA an amended NDA dated October 30, 2008, seeking to address the safety issues raised by the FDA. Following its review of the October 30, 2008 amendment, the FDA again declined to approve the application for approval of Feraheme.

62. Following another round of amendments to its NDA, Feraheme was finally approved by the FDA on June 30, 2009. In July 2009, the Company launched the drug for sale in the U.S. market.

63. Despite the FDA approval of Feraheme, the safety and risk issues identified during the clinical trials increased in number and severity after Feraheme was approved. Following its approval in July 2009 and prior to the Offering, both the Company and the FDA received dozens of reports of SAEs related to Feraheme use, including several cases of anaphylaxis, cardiac-related events, and at least one death.

2. Information Obtained Through a FOIA Request to the FDA Confirms the Occurrence of at Least 11 Deaths and Dozens of Documented Cases of Anaphylaxis Since Feraheme's Launch in July 2009

64. On December 31, 2009, prior to the Offering, AMAG reported to the FDA the death of a 70-year-old female following one 510 mg injection of Feraheme. Feraheme was identified as the "Primary Suspect" in the fatality. Defendants did not disclose the occurrence of this fatality in the Offering Documents.

65. The fatality reported to the FDA was not publicly available information at the time of the Offering. Lead Counsel obtained this information through a recent request to the FDA pursuant to the FOIA.

66. Moreover, information obtained through Lead Counsel's FOIA request to the FDA reveal that AMAG has reported at least ***ten additional deaths*** associated with Feraheme use since the Offering was conducted. ***Defendants did not disclose any of the fatalities associated with Feraheme use until October 2010, nine months after the Offering.***

3. Defendants Received Numerous Reports of Serious Adverse Events Resulting from Feraheme Use Prior to the Offering

67. From the time of Ferahemes launch in July 2009 through January 21, 2010, the date the Offering was conducted, AMAG's customers, who include physicians, hematology clinics, dialysis centers and hospitals, were routinely reporting SAEs directly to AMAG sales representatives. Sales representatives then forwarded the reports to an internal "Medical Affairs" department, known and referred to as "Safety" among AMAG sales representatives. Indeed, sales representatives were required to forward all reported SAEs that they received from "the field" to the Medical Affairs department. The Medical Affairs department was responsible for following up on reported SAEs with the reporting person or entity.

68. CW1, a former sales representative who was employed by AMAG from March 2009 to May 2010, recalls that following Ferahemes launch in July 2009, all five sales representatives in his territory began receiving reports of SAEs on a routine basis. CW1 further states that some physicians were even reporting multiple cases of SAEs. CW1 recalls that he

received at least one report involving a case of anaphylaxis, reported to him directly by a physician in December 2009. As required by the Company, CW1 forwarded the report to the Medical Affairs department.

69. CW2, another former sales representative who was employed by AMAG from September 2008 to April 2010, confirmed that she received reports of at least five (5) SAEs from physicians including two in January 2010 prior to the Offering.

70. Both CW1 and CW2 forwarded the reported SAEs they received to the Medical Affairs department at AMAG for follow-up investigation and routinely discussed the reports with certain senior managers.

71. As of the date of the Offering, AMAG reported to the FDA (but failed to disclose to investors) twenty-three (23) SAEs associated with Feraheme use, including documented anaphylactic reactions in two female patients, ages 38 and 51, with a "life-threatening" outcome requiring hospitalization, as reported on October 18, 2009 and November 12, 2009 respectively. In fact, at least sixteen (16) of those twenty-three (23) SAEs exhibited one or more symptoms associated with anaphylaxis, such as cardiac arrest, shortness of breath, a reduction in blood pressure (hypotension), loss of consciousness, hives, dizziness, or vomiting, and resulted in hospitalization; yet, the Company did not report them to the FDA as anaphylactic reactions.

72. By February 5, 2010 — just two weeks after the Offering — the number of reported SAEs had

mysteriously increased by over 73.9%, from twenty-three (23) to forty (40), according to the Company's February 5, 2010 press release (described below). Among these were several more documented cases of anaphylaxis, along with numerous cases that presented multiple anaphylactic symptoms.

73. None of the above-referenced reported SAEs were publicly available information at the time of the Offering.

74. Coupled with the fatality, the reporting of at least twenty-three (23) SAEs, including at least two documented anaphylactic reactions and several cardiac-related events, all of which occurred within only a few months of Feraheme's launch and exposure to a relatively low patient population, established a clear and significant pattern of SAEs by the time the Offering was conducted. These events constituted material information that was likely to, and ultimately did affect, the safety profile and commercial viability of Feraheme, and should have been disclosed to investors. Specifically, the events could have, and did, trigger FDA action, in the form of stricter labeling warnings for Feraheme, and otherwise impact physicians' use of the drug, thereby affecting the commercial viability of Feraheme and thus future revenues of AMAG.

75. In total, at least one hundred forty-six (146) SAEs, including at least eleven (11) deaths, associated with Feraheme use have been reported through October 2010, a number that has grown in significance both in frequency and severity. Moreover, it is widely understood in the health care industry that the actual incidence of SAEs is likely much higher than reported,

since reporting to manufacturers and the FDA by physicians and consumers is strictly voluntary, resulting in incomplete or delayed reports, or avoidance of submitting reports because of the lengthy forms that must be filled out.

B. The FDA Requires AMAG to Change Feraheme's Labeling to Include Stricter Warnings Concerning, *Inter Alia*, the True Incidence of SAEs

76. On October 28, 2010, AMAG held an earnings call to discuss its third quarter results. During the call, the Company announced for the first time that (1) the FDA had created a Tracked Safety Issue for cardiac-related SAEs relating to Feraheme use in late August 2010; (2) the FDA had met with the Company in September to discuss the SAEs, and (3) the Company was "in discussions with the FDA concerning labeling changes." Prior to the Company's announcement, such information was not available to the public.

77. In its Form 10-Q for the period ended September 30, 2010, filed on November 8, 2010, AMAG reported:

> At our request, we met with the FDA in September 2010 regarding the FDA's creation of a Tracked Safety Issue for Feraheme in the FDA's Document Archiving, Reporting and Regulatory Tracking System related to potential safety signals of cardiac disorders in patients receiving Feraheme. Of the estimated more than 155,000 patient exposures through October 4,

2010 in the post-marketing environment, 146 cases of serious adverse events have been reported, an estimated reporting rate of less than 0.1%. The per patient serious adverse event rate contained in the U.S. package insert is 0.2%. We believe that the estimated reporting rate of serious adverse events by exposure in the post-marketing environment is consistent with the per patient serious adverse event rate contained in the U.S. package insert. ***However, life-threatening and fatal events, including hypersensitivity and cardiac events, have been reported after Feraheme administration in the post-marketing environment. We are currently in discussions with the FDA regarding potential changes to the Feraheme package insert. Specific changes being discussed include, a boxed warning to highlight the risks observed in the post-marketing environment and an extension of the observation period following Feraheme administration. Depending on the outcome of our discussions with the FDA, the potential changes to the Feraheme package insert could have an adverse impact on future sales of Feraheme.*** (Emphasis added.)

78. In the Form 10-Q for the period ended September 30, 2010, the Company discussed the potential impact of stricter labeling requirements by the FDA and their potential impact on the commercial viability of Feraheme:

Risk Factors

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

For example, the FDA recently created a Tracked Safety Issue for *Feraheme* in its Document Archiving, Reporting and Regulatory Tracking System related to potential safety signals of cardiac disorders in patients receiving *Feraheme*. We are currently in discussions with the FDA regarding potential changes to the *Feraheme* package insert which may include, among other things, a boxed warning to highlight risks observed in the post-marketing environment and an extension of the observation period following *Feraheme* administration. Depending on the exact nature of the changes to the *Feraheme* package insert, our ability to successfully compete in the IV iron market and potential sales of *Feraheme* may be adversely impacted. ***For example, if our discussions with the FDA result in a boxed warning in the Feraheme package insert, a recall or withdrawal of Feraheme from the market, or a requirement that we implement a REMS program, potential sales of Feraheme and our future business prospects could be significantly adversely impacted.*** (Emphasis added.)

79. On November 29, 2010, the FDA announced the imposition of the new warnings and precautions to be added to Ferahemes labeling regarding the drug's safety profile as well as a mandatory increase in the observation period for patients following Feraheme administration. In particular, the FDA required AMAG to include:

(1) Bolded warnings and precautions that describe events that have been reported after Feraheme administration in the post-marketing environment, including life-threatening hypersensitivity reactions and clinically significant hypotension, as follows:

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

- Feraheme may cause serious life-threatening hypersensitivity reactions including anaphylaxis and/or anaphylactoid reactions. Anaphylactic type reactions presenting with cardiac/ cardiorespiratory arrest, clinically significant hypotension, syncope, and unresponsiveness have been reported in the post-marketing experience.

Hypotension

- Severe adverse reactions of clinically significant hypotension have been reported.

(2) A new section of the label entitled Adverse Reactions from Post-marketing Spontaneous Reports, as follows:

ADVERSE REACTIONS

Postmarketing Experience

...The following serious adverse reactions have been reported from the post-marketing spontaneous reports with Feraheme: life-threatening anaphylactic/anaphylactoid reactions, cardiac/cardiorespiratory arrest, clinically significant hypotension, syncope, unresponsiveness, loss of consciousness, tachycardia/rhythm abnormalities, angioedema, ischemic myocardial events, congestive heart failure, pulse absent, and cyanosis....

(3) and, an increase in the observation period following Feraheme administration from 30 to 60 minutes to observe patients for signs and symptoms of hypersensitivity.

C. During the Relevant Time Period, AMAG Violated Federal Law and FDA Regulations by Making Materially Misleading Statements on its Website Concerning the Risks and Approved Use for Feraheme

80. On October 18, 2010, the FDA issued a Warning Letter to AMAG concerning material misrepresentations and omissions on AMAG's website regarding both GastroMARK and Feraheme and

specifically, *inter alia*, (1) the risks associated with Feraheme use; (2) unapproved uses for Feraheme.

81. Specifically, the FDA Warning Letter stated that:

> **The webpages [for GastroMARK and Feraheme] present numerous efficacy claims for GastroMARK and Feraheme, but fail to communicate any of the risks associated with the drugs** (see Background section above). By omitting the most serious and frequently occurring risks associated with these drugs, **the webpages misleadingly suggest that GastroMARK and Feraheme are safer than has been demonstrated and therefore place the public at risk**. For example, the GastroMARK webpage omits the drug contraindication in patients with known or suspected intestinal perforation or obstruction. We note that there are links to "Download the GastroMARK® Package Insert" at the bottom of the GastroMARK webpage and to "Download the Feraheme Package Insert" buried in the second sentence of the Feraheme webpage. However, these links do not mitigate the complete omission of risk information from the GastroMARK and Feraheme webpages . . . .
>
> **Promotion of Unapproved Uses**
>
> The Feraheme webpage includes the following claims:

- "Feraheme is indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease."

- "Feraheme is being developed to treat iron deficiency anemia associated with other conditions and disease states including women with abnormal uterine bleeding, and patients with cancer and gastrointestinal diseases."

- "Feraheme is also being developed as a diagnostic agent for vascular-enhanced magnetic resonance imaging to enhance peripheral arterial disease . . . ."

The presentation of both approved and unapproved product information for Feraheme together in this manner is misleading because it implies that Feraheme is effective for unapproved uses. However, Feraheme is not approved to treat iron deficiency anemia in women with abnormal uterine bleeding, or in patients with cancer and gastrointestinal diseases. In addition, Feraheme is not approved as a diagnostic agent for vascular-enhanced magnetic resonance imaging for the detection of clinically significant arterial stenosis or occlusion in subjects with peripheral arterial disease . . . .

The above statements thus misbrand Feraheme . . . . (Emphases added).

82. As a result of the material misstatements and omissions described in the preceding paragraph, the FDA found that AMAG had misbranded Feraheme in violation of the Food, Drug, And Cosmetic Act, 21 U.S.C. §§ 352(a),(f)(1) & (n), and FDA's implementing regulations, 21 C.F.R. §§ 201.100(c)(1), 201.128, 202.1(e)(3)(i), (e)(5) & (e)(6)(i).

83. The FDA Warning Letter also charged AMAG with violating 21 C.F.R. § 314.81(b)(3)(i) in failing to submit copies of the Feraheme and GastroMARK webpages on Form FDA-2253 to the FDA, which AMAG was required to do at the time of initial dissemination of the labeling and/or at the time of initial publication of the advertisement for Feraheme and GastroMARK.

VI. THE FALSE AND MISLEADING STATEMENTS IN THE REGISTRATION STATEMENT AND PROSPECTUS

84. On or about January 19, 2010, AMAG filed with the SEC a Form S-3/ASR, the Registration Statement for the Offering, using a "shelf" registration process. The Registration Statement became effective upon filing. Pursuant to the Registration Statement as amended by the accompanying Prospectus, dated January 21, 2010, AMAG sold 3,600,000 shares of Common Stock at a price of $48.25 per share for total offering proceeds of $173,700,000. AMAG granted the underwriters a right to purchase up to an additional 540,000 shares to cover potential over-allotments.

85. The Registration Statement and Prospectus incorporated by reference therein the following materially misleading AMAG public filings:

- AMAG's Form 10-K for the fiscal year ended December 31, 2008;
- AMAG's Form 10-Q for the fiscal quarter ended March 31, 2009;
- AMAG's Form 10-Q for the fiscal quarter ended June 30, 2009;
- AMAG's Form 10-Q for the fiscal quarter ended September 30, 2009;
- AMAG's Form 8-K filed with the SEC on December 22, 2009;
- AMAG's Form 8-K filed with the SEC on December 17, 2009;
- AMAG's Form 8-K filed with the SEC on October 8, 2009;
- AMAG's Form 8-K filed with the SEC on September 4, 2009;
- AMAG's Form 8-K filed with the SEC on July 1, 2009;
- AMAG's Form 8-K filed with the SEC on May 8, 2009;
- AMAG's Form 8-K filed with the SEC on April 30, 2009 (solely with respect to Item 8.01 therein); and

- AMAG's Form 8-K filed with the SEC on January 28, 2009.

As set forth in paragraph 1, *supra*, the Prospectus, Registration Statement, and all documents incorporated therein are collectively referred to herein as the "Offering Documents."

86. In a Form 10-K for the fiscal year ended December 31, 2008, which was signed by the Individual Defendants and incorporated by reference into the Offering Documents, Defendants stated:

> In December 2007, we submitted an NDA to the FDA for marketing approval of *Feraheme* for the treatment of IDA in CKD patients. ***In October 2008, we received a Complete Response letter from the FDA with respect to our NDA for Feraheme requesting certain additional clinical information, information regarding certain observations noted during a recent FDA inspection at one of our Phase III clinical sites, and resolution of certain deficiencies noted during a recent FDA inspection of our Cambridge, Massachusetts manufacturing facility. We submitted a response in October 2008, and in December 2008 we received a second Complete Response letter from the FDA requesting data to clarify a specific CMC question, resolution of the deficiencies observed during the FDA's recent inspection of our manufacturing facility, and finalization of labeling discussions for Feraheme. We will need to address the***

issues raised by the FDA with respect to our NDA in a timely and satisfactory manner in order to obtain approval to market and sell Feraheme in the U.S. We are working with the FDA to address the December 2008 Complete Response letter and believe that we will not need to conduct any additional clinical trials of *Feraheme* prior to FDA approval of *Feraheme*. ***Our NDA for Feraheme is supported by four pivotal Phase III clinical studies for Feraheme as an IV[intravenous] iron replacement therapeutic agent in patients with CKD.*** These trials have included patients with all stages of CKD, including patients with stages 1 through 5 CKD who are not on dialysis, patients with stage 5 CKD who are on hemodialysis or peritoneal dialysis, and kidney transplant recipients.

Two of our four pivotal Phase III studies were identically designed efficacy and safety studies in 304 and 303 non-dialysis patients with stages 1 through 5 CKD, respectively, who were randomized in a 3 to 1 ratio to receive either two rapid IV injections of 510 milligrams of *Feraheme* administered within a week or 200 milligrams of oral iron per day for three weeks. ***Both studies demonstrated a statistically significant achievement of all primary and secondary efficacy endpoints. The third pivotal Phase III trial was an efficacy and safety trial that included 230 CKD patients on hemodialysis and also demonstrated a statistically significant achievement of all primary and secondary efficacy endpoints.***

The fourth pivotal Phase III study was a double-blind, placebo-controlled, crossover safety study in 750 patients with all stages of CKD, comparing a single injection of 510 milligrams of *Feraheme* to normal saline placebo. Adverse events occurred in 21.3% of patients after *Feraheme* administration and in 16.7% of patients after placebo administration. On a blinded basis, meaning the physician was not aware whether the patient had received *Feraheme* or oral iron, these adverse events were deemed to be related to treatment by the investigator in 5.2% of patients after *Feraheme* administration and in 4.5% of patients after placebo administration. Serious adverse events, or SAEs, occurred in 2.9% of patients after *Feraheme* administration and in 1.8% of patients after placebo administration. On a blinded basis, these SAEs were deemed to be related to treatment by the investigator in one patient after *Feraheme* administration and in one patient after placebo administration. ***In this study, the single SAE attributed to the drug after Feraheme administration occurred in an 85 year-old male with non-dialysis dependent CKD, hypertension, coronary artery disease, cerebrovascular disease and a history of multiple drug allergies to ciprofloxacin, levofloxacin, and percocet. The patient experienced an anaphylactoid reaction with severe hypotension a few minutes after Feraheme administration, was treated with epinephrine and fully recovered. Across all phases of the Feraheme clinical development program***

> ***with approximately 2,800 total administered doses of Feraheme, there were no cases of anaphylaxis and no deaths determined by the investigator to be drug-related.*** Drug-related SAEs were reported in three, or 0.17%, of 1,726 patients treated with *Feraheme*, one, or 0.35%, of 289 patients treated with oral iron, and one, or 0.13%, of 781 patients treated with placebo. (Emphases added.)

87. Similar statements were made in the Form 10-Q for the fiscal quarter ended March 31, 2009, which was signed by Defendant Pereira and Defendant Arkowitz and incorporated by reference in the Offering Documents:

> In December 2007, we submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or the FDA, for marketing approval of Feraheme for the treatment of IDA in patients with chronic kidney disease, or CKD. ***In October 2008, we received a Complete Response letter from the FDA with respect to our NDA for Feraheme requesting certain additional clinical information, information regarding certain observations noted during an FDA inspection at one of our Phase III clinical sites, and resolution of certain observations noted during a recent FDA inspection of our Cambridge, Massachusetts manufacturing facility. We submitted a response to the Complete Response letter in October 2008, and in December 2008 we received a second Complete Response letter from the FDA***

> ***requesting data to clarify a specific chemistry, manufacturing and controls question, resolution of the observations noted during the recent FDA inspection of our manufacturing facility, and finalization of labeling discussions for Feraheme.*** We are working with the FDA to address the December 2008 Complete Response letter and believe that we will not need to conduct any additional clinical trials of Feraheme prior to FDA approval of Feraheme. In addition, we have been engaged in active dialogue with the FDA and have recently been informed that the observations noted during the recent FDA inspection of our manufacturing facility have been adequately addressed and that a re-inspection of our manufacturing facility will not be required as a condition to approval of Feraheme. We will need to resolve all of the issues raised by the FDA in the Complete Response letters in a timely manner in order to obtain approval to market and sell Feraheme in the U.S. (Emphasis added.)

88. The above-referenced statements in paragraphs 86 and 87 were materially false and misleading because Defendants failed to disclose that the FDA had in fact declined to approve Feraheme twice, on October 17, 2008 and on December 22, 2008, because (1) the occurrence of the case of anaphylaxis, contrary to Defendants' attempt to minimize it, was a cause of serious concern to the FDA because of its larger safety implications for the drug; and (2) the FDA found that the Company had underreported and/or minimized the occurrence of SAEs in patients. As a

result, investors remained unaware of material, adverse information concerning the true safety profile of Feraheme and its impact on Feraheme's commercial viability, including its ability to generate future revenue for the Company.

89. The Prospectus discussed the FDA approval process for Feraheme:

> On June 30, 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 both the dialysis and non-dialysis markets, including to nephrologists, hematologists, dialysis organizations, hospitals and other end-users.
>
> Our NDA [New Drug Application] for *Feraheme* was supported by four pivotal Phase III clinical studies for *Feraheme* as an IV iron replacement therapeutic agent in patients with CKD. These trials included patients with all stages of CKD, including patients with stages 1 through 5 CKD who were not on dialysis, patients with stage 5 CKD who were on hemodialysis or peritoneal dialysis, and kidney transplant recipients.

90. The statements made in the Prospectus referenced in paragraph 89 above were materially false and misleading when made because in discussing the FDA approval of Feraheme and the Phase III clinical trials, Defendants failed to disclose that the FDA had in fact declined to approve Feraheme on October 17, 2008 and on December 22, 2008, because (1) serious

safety concerns regarding Feraheme were raised during the Phase III clinical trials, including the occurrence of a case of anaphylaxis and (2) the Company had been determined by the FDA to have underreported and/or minimized the occurrence of SAEs in patients. As a result, investors remained unaware of material, adverse information concerning the true safety profile of Feraheme and its impact on Ferahemes commercial viability, including its ability to generate future revenue for the Company.

91. The Prospectus purported to warn about the risk factors in purchasing the Common Stock stating in pertinent part as follows:

> The degree of market acceptance of *Feraheme* depends on a number of factors, including but not limited to:
>
> - Our ability to demonstrate to the medical community, particularly nephrologists, hematologists, dialysis clinics and others who may purchase or prescribe *Feraheme*, the clinical efficacy and safety of *Feraheme* as an alternative to current treatments for iron deficiency anemia in both dialysis and non-dialysis chronic kidney disease patients;
>
> - The ability of physicians and other providers to be adequately reimbursed for *Feraheme* in a timely manner from payors, including government payors, such as Medicare and Medicaid, and private payors, particularly in light of the expected bundling of costs of providing care to dialysis patients;

- The relative price of *Feraheme* as compared to alternative iron replacement therapeutic agents;

- The actual or perceived convenience and ease of administration of *Feraheme* as compared to alternative iron replacement therapeutic agents;

- The effectiveness of our sales and marketing organizations and our distribution network; and

- ***The development of unanticipated adverse reactions to Feraheme resulting in safety concerns among prescribers.*** (Emphasis added.)

92. The statements made in the Prospectus referenced in paragraph 91 above were materially false or misleading because although they mentioned the risk of the development of SAEs, they failed to disclose the ***existing facts*** that (1) Feraheme use was linked to at least twenty-three (23) reported SAEs, including several potentially deadly anaphylactoid and cardiac-related events, and at least one fatality; and (2) such reports were occurring at a significant rate of incidence. As a result, investors remained unaware of material, adverse information concerning the true safety profile of Feraheme and its impact on Ferahemes commercial viability, including its ability to generate future revenue for the Company. The existence and severity of these SAEs could have, and did, trigger adverse action by the FDA in the form of

stricter labeling warnings, and were likely to, and did, impact physicians' use of Feraheme as an alternative to competing treatments for iron deficiency in both dialysis and non-dialysis CKD patients.

93. Additionally, the fatality that AMAG reported to the FDA on December 31, 2009 is a material fact bearing on the overall safety profile and commercial viability of Feraheme that should have been disclosed to investors in the Offering Documents in light of the following: (1) the Company claimed that no deaths had occurred as a result of Feraheme use during the clinical trials; therefore, a death, coupled with the pattern of SAEs associated with Feraheme use post-marketing, was significant; and (2) the FDA's stated concern regarding a single case of anaphylaxis during clinical trials resulted in the denial of FDA approval for Feraheme; therefore, a more severe event such as a fatality could have, and did, trigger FDA action, in the form of stricter labeling warnings, and otherwise affect physicians' use of the treatment, thereby impacting the commercial viability of Feraheme.

94. The Prospectus further stated in pertinent part as follows:

> ***Significant safety or drug interaction problems could arise with respect to Feraheme even after FDA approval, resulting in recalls, restrictions in Feraheme's label, or withdrawal of Feraheme from the market.***

Discovery of previously unknown problems with an approved product may result in recalls, restrictions on the product's permissible uses, or withdrawal of the product from the market. The data submitted to the FDA as part of our new drug application was obtained in controlled clinical trials of limited duration. ***New safety or drug interaction issues may arise as Feraheme is used over longer periods of time by a wider group of patients taking numerous other medicines and with additional underlying health problems.*** In addition, as we conduct additional clinical trials for *Feraheme*, new safety problems may be identified which could negatively impact both our ability to successfully complete these studies and the use and/or regulatory status of *Feraheme* for the treatment of iron deficiency anemia in patients with chronic kidney disease. ***These new safety or drug interaction issues may require us to provide additional warnings on the Feraheme label, directly alert healthcare providers of new safety information, or narrow our approved indications, any of which could reduce the market acceptance of Feraheme. In addition, if significant safety or drug interaction issues arise, FDA approval for Feraheme could be withdrawn, and the FDA could require the recall of all existing Feraheme in the marketplace.*** The FDA also has the authority to require the recall of our products if there is contamination or other problems with manufacturing, transport or storage of the product. A government-mandated

recall or a voluntary recall could divert managerial and financial resources, could be difficult and costly to correct, could result in the suspension of sales of Feraheme, and could have a severe adverse impact on our potential profitability and the future prospects of our business. (Emphases added.)

We may also be required to conduct certain post-approval clinical studies to assess known or suspected significant risks associated with *Feraheme*. The Food and Drug Administration Amendments Act of 2007 expanded the FDA's authority. Under the Food and Drug Administration Amendments Act, the FDA may: (i) require manufacturers to conduct post-approval clinical studies to assess known risks or signals of serious risks, or to identify unexpected serious risks; (ii) mandate labeling changes to a product based on new safety information; or (iii) require sponsors to implement a Risk Evaluation Management Strategy where necessary to assure safe use of the drug. If we are required to conduct post-approval clinical studies or implement a Risk Evaluation Management Strategy, or if the FDA changes the label for Feraheme to include additional discussion of potential safety issues, such requirements or restrictions could have a material adverse impact on our ability to generate revenues from sales of Feraheme, or require us to expend significant additional funds on clinical studies.

95. The statements made in the Prospectus referenced in paragraph 94 above concerning the possibility of new safety issues arising through continued marketing of Feraheme were materially false and misleading because although the Prospectus mentioned the risk of the development of SAEs, it failed to disclose the ***existing facts*** that (1) Feraheme use was linked to at least twenty-three (23) reported SAEs, including several potentially deadly anaphylactoid and cardiac-related events, and at least one fatality; and (2) such reports were occurring at a significant rate of incidence. As a result, investors remained unaware of material, adverse information concerning the true safety profile of Feraheme and its impact on Feraheme's commercial viability, including its ability to generate future revenue for the Company. The existence and severity of these SAEs could have, and did, trigger adverse action by the FDA in the form of stricter labeling warnings, and were likely to, and did, impact physicians' use of Feraheme as an alternative to competing treatments for iron deficiency in both dialysis and non-dialysis CKD patients.

96. The reported incidence of SAEs and fatalities linked to Feraheme use was particularly material in light of the fact that the FDA had ***twice*** declined to approve Feraheme due in large part to a ***single*** case of anaphylaxis reported during the clinical trials, and because the Company had been determined by the FDA to be underreporting and/or minimizing the occurrence of SAEs. Because the occurrence of the anaphylactic reaction and other serious adverse events or reactions were clearly of concern to the FDA in its approval process for Feraheme, any post-marketing reports of SAEs raised the risk that Feraheme's status as an

FDA-approved drug would be adversely impacted, potentially resulting in its removal from the market or the imposition of strict labeling warnings, or negatively impacting physicians' use of the treatment over competitors, thereby affecting the drug's commercial viability and the Company's future earnings. However, investors were not informed of Feraheme's post-marketing safety profile, including the existence, severity, or frequency of any SAEs reported to the Company.

97. The Offering Documents failed to disclose that a material portion of the Company's revenues were derived from the illegal and materially misleading marketing practices identified by the FDA in the Warning Letter, in that the Company's website made certain representations concerning Feraheme's safety and use approved by the FDA but failed to disclose risks associated with Feraheme use and included representations concerning unapproved uses. The full and accurate disclosure of these risks and uses would result in a material and adverse impact on the Company's stock price and the Company's revenues derived from sales of Feraheme.

98. The Offering Documents also failed to disclose that AMAG had not complied with 21 C.F.R. §314.81(b)(3)(1) in submitting the requisite documentation to the FDA regarding labeling and advertising statements promoting GastroMARK and Feraheme. The full and accurate disclosure of AMAG's failure to comply with applicable FDA regulations would result in a material and adverse impact on the Company's stock price and the Company's revenues derived from sales of Feraheme.

99. Under applicable SEC rules and regulations governing the preparation of the Registration Statement and Prospectus, the Registration Statement and Prospectus were required to disclose the safety profile of Feraheme, including the amount, nature, and severity of SAEs that had been reported to the Company. The Registration Statement and Prospectus failed to contain any such disclosures. Specifically:

(a) Under Item 303(a)(3)(ii) of Regulation S-K, an issuer is required to, among other things, "describe any known trends or uncertainties that have had or that the registrant reasonably expected will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." At the time of the Offering, SAEs were being reported, but not disclosed to the public. The amount, nature, and severity of SAEs related to Feraheme use would continue to have an unfavorable impact on the Company's revenues and income from continuing operations, and therefore, were required to be disclosed in the Prospectus, but were not; and

(b) Pursuant to Item 3 of Form S-1, the Registration Statement was required to furnish the information required by Item 503 of Regulation S-K. Under Item 503(c) of Regulation S-K, an issuer is required to, among other things, provide a "discussion of the most significant factors that make the offering risky or speculative." The material fact that safety issues existed as to Feraheme was a significant factor that made the Offering "risky or speculative" because the Company lacked critical in formation about the source of its revenues and the likelihood that those revenues would continue in the future. Thus, this

information was required to be disclosed in the Prospectus, but was not.

VII. THE TRUE SAFETY PROFILE AND COMMERCIAL VIABILITY OF FERAHEME IS REVEALED, CAUSING A 71% DECLINE IN AMAG'S STOCK PRICE

A. News of the SAEs Begins to Leak Out

100. The Offering Documents failed to disclose that the Company received ***any*** reports of SAEs from the use of Feraheme. The existence of SAEs was first disclosed in a Summer Street analyst report issued on February 4, 2010, which revealed two reported cases of anaphylaxis and one potentially related death among Feraheme users.

101. More particularly, on February 4, 2010, Summer Street analyst Carol Werther issued a report downgrading AMAG from buy to neutral. The report stated in pertinent part:

- ***Field checks reveal SAEs but exact incidence rate is unclear.*** [Original emphasis.] ***We are aware of several patients hospitalized with anaphylactoid reactions to Feraheme. We are aware of one death that may or may not be directly related to Feraheme.*** [Emphasis added.] Since we do not know how many patients have been treated since the July launch, it is impossible to know if it is within the labels' "In clinical studies serious hypersensitivity reactions were reported in

0.2% (3/1726) of subjects receiving Feraheme. While the incidence could be in line with the 0.2% in Ferahemes label, there is no way to know.

- ***Consultants are continuing to use Feraheme but adoption rate is slowing.*** [Original emphasis.] ***Specifically our consultants are: 1) delaying use in their dialysis unit; or 2) only administering Feraheme to patients without 1 or 2 drug allergies; or 3) only administering in outpatient clinics affiliated with hospitals*** - - the label states that physicians need[] [sic] to "Observe patients for signs and symptoms of hypersensitivity for at least 30 minutes following Feraheme injection and only administer the drug when personnel and therapies are readily available for the treatment of hypersensitivity reactions." While there was one SAE (ER visit in a patient with multiple drug allergies) despite the exclusion of these patients from the clinical trials, the label doesn't currently contain prominent warnings to exclude those with multiple allergies. ***These events could raise the risk of a more prominent labeled warning.*** [Emphases added.]

- ***We are reducing our Feraheme sales forecast.*** [Original emphasis.] Our model is highly dependant on the predialysis and ultimately other IDA treated in the clinician's office. Following resolution/ explanation of these reactions, we expect

> growth to pick up in H2:10. We are lowering our Feraheme estimates to $73MM in 2010, $126MM in 2011, $194MM in 2012, $286MM in 2013 and $374 in 2014 from $108MM, $172MM, $279MM, $381MM and $502MM respectively.
>
> - ***Downgrading to Neutral.*** [Original emphasis.] We understand that when Ferrlicit was launched a similar pattern of infusion reactions occurred that later were deemed unimportant. ***Nevertheless we expect the sales trajectory to slow near term and our model changes push out profitability to 2012 from 2011.*** [Emphasis added.] We do not necessarily believe that Feraheme's longer term potential will be negatively affected.

102. In response to the Summer Street report and downgrade, AMAG's shares fell by over $7.00, or more than 15% from $45.25 per share to $38.12 per share, on heavy trading volume of 8,573,900 shares, which had increased from an average trading volume of 547,500 shares.

103. Following the Summer Street report, the Company issued a press release on February 5, 2010, entitled, "AMAG Pharmaceuticals Provides Feraheme® Safety Update" in which the Company confirmed what was reported by Summer Street and revealed for the first time that it had received reports of forty (40) SAEs, including (at least) one death:

AMAG Pharmaceuticals, Inc. (NASDAQ: AMAG), a biopharmaceutical company focused on the development and commercialization of a therapeutic iron compound to treat anemia and novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease, today provided a safety update on Feraheme(R) (ferumoxytol) Injection for intravenous use. ***Since the commercial launch of Feraheme in July 2009, serious adverse events have been reported at a rate consistent with that contained in the U.S. package insert. Of the estimated 35,000 patient exposures to date, 40 serious adverse events have been reported, an approximate rate of 0.1 percent. No mortality signal has been observed. A single reported death occurred in a patient two days post-Feraheme treatment, which the Company does not believe was the result of Feraheme.***

Important Safety Information about *Feraheme*

Feraheme is indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease. Feraheme is contraindicated in patients with evidence of iron overload, known hypersensitivity to *Feraheme* or any of its components, and patients with anemia not caused by iron deficiency.

In clinical studies, hypotension was reported in 1.9% (33/1,726) of subjects receiving *Feraheme*, including three patients with serious

> hypotensive reactions. Serious hypersensitivity reactions were reported in 0.2% (3/1726) of patients. Patients should be observed for signs and symptoms of hypersensitivity for at least 30 minutes following *Feraheme* injection and the drug should only be administered when treatment for hypersensitivity reactions is readily available. Excessive therapy with parenteral iron can lead to excess storage of iron with the possibility of iatrogenic hemosiderosis. Patients should be regularly monitored for hematologic response during parenteral iron therapy. As a superparamagnetic iron oxide, *Feraheme* may transiently affect magnetic resonance diagnostic imaging but will not affect X-ray, CT, PET, SPECT, ultrasound, or nuclear imaging.
>
> In clinical trials, the most commonly occurring adverse reactions in *Feraheme* treated patients versus oral iron treated patients were diarrhea, nausea, dizziness, hypotension, constipation and peripheral edema. (Emphasis added.)

104. On that same day, Defendants conducted a conference call to discuss the press release. Defendant Pereira stated in pertinent part as follows:

> Our top priority at AMAG is patient safety and as such we have a robust pharmacovigilance program in place. Since the commercial launch of Feraheme in July 2009, serious adverse events have been reported at a rate consistent with that contained in the U.S. package insert. Of the estimated 35,000 patient exposures

to-date, 40 serious adverse events have been reported, an approximate rate of 0.1%. ***These include cases of hypertension and some cases of allergic reactions, including anaphylactoid or anaphylactic events.*** These events are known to occur with intravenous iron administration as a class.

I'd like to remind you that in post marketing adverse event reporting, all reported events are captured irrespective of causality. ***To-date, no mortality signal has been observed. The single reported death occurred in a patient two days post-Feraheme treatment, which we do not believe was a result of Feraheme.*** Like most patients with chronic kidney disease, this patient had significant comorbidities.

As you know, the morbidity and mortality rates among non-dialysis dependent and dialysis dependent CKD patients in general have been shown to be high, largely due to the underlying disease. ***I'd like to remind you that in the ferumoxytol registrational program submitted as part of our NDA, there were a total of 2,074 subjects and 31 deaths were observed. The mortality rate was 1.1% among ferumoxytol treated subjects compared to 2.8% among subjects treated with oral iron.*** None of these deaths were considered to be related to study treatment. We have provided as much granularity on this subject as we are able to at this time. (Emphases added.)

105. Following the Company's press release and conference call, AMAG's stock price once again declined, this time from $38.12 per share to $37.77 per share.

106. The February 5, 2010 press release misleadingly calculated the reported incidence rate of SAEs post-marketing as approximately .1% based upon "the estimated 35,000 patient ***exposures*** to date." (Emphasis added.) The Company inaccurately claimed that this rate was "consistent with that contained in the U.S. package insert" which was disclosed as occurring in "0.2% (3/1726) ***patients***" during clinical trials. (Emphasis added.) By calculating the post-marketing incidence rate based upon patient exposures rather than number of patients as calculated during clinical trials, the Company used a different metric that effectively lowered the incidence rate. In other words, AMAG's new metric counted every *injection* of Feraheme post-marketing, and incorrectly compared it to an incidence rate calculated based upon the number of *patients* that used Feraheme during clinical trials, regardless of number of exposures. Since Feraheme is a drug that is administered in a minimum of two and as many as four injections, the number of *exposures* is much higher than the number of *patients* who have used Feraheme, making any comparison between the two numbers deceptive and effectively understating the post-marketing incidence rate by as much as .35%, from a post-marketing rate that is potentially as high as .45%.

107. Moreover, allergic reactions are far more likely to occur initially on the first injection rather than

on a subsequent injection; thus, counting a subsequent exposure as a non-adverse event is misleading.

108. The table below calculates a true comparison of SAE rates, based upon the per patient metric used and reported during clinical trials. These calculations are based on the forty (40) reported SAEs disclosed by the Company in the February 5, 2010 press release and take into account the various doses in which Feraheme may have been administered:

Number of Patients/Exposures	Actual Rate of Incidence
35,000 patient exposures	0.11% (40/35,000 x 100)
17,500 patients (2 injections each, for a total of 35,000 patient exposures)	0.23% (40/17,500 x 100)
11,666 patients (3 injections each, for a total of 35,000 patient exposures)	0.34% (40/11,666 x 100)
8,750 patients (4 injections each, for a total of 35,000 patient exposures)	0.45% (40/8,750 x 100)

109. The next business day after AMAG's press release, on February 8, 2010, Summer Street issued a follow-up report entitled "Feraheme Safety Update

Raises more Questions than Answers." In the report, the analyst questioned management's calculated rate of SAEs and noted that notwithstanding the fact that the number of SAEs most likely *exceeded* forty (40) because of the recency of the reports and time lag in reporting by health care professionals, there has been only one reported SAE and one death associated with use of Venofer®, Feraheme's primary competitor, in the ten years that Venofer® had been on the market:

> AMAG's safety update reveals 40 SAEs in 35K patient exposures. Their calculated rate is 0.1% and the labels is 0.2%. ***However the two rates are calculated differently: 3/1726 patients vs 40/35,000 exposures, thus is not a valid comparison.*** Exposures count patients that safely received multiple feraheme doses. ***The rate we really want to know is the number of SAEs/ the number of patients.***
>
> - ***Our consultants are not reassured as they believe neither the numerator nor the denominator is known. First, they know that not all SAEs have been reported to AMAG or the FDA as some of these events are very recent. It can take 2-3 weeks to file a report. We knew of only one SAE in mid December NY, now we have confirmed four and two of those have not been reported yet. Therefore there are more than 40. Second, perhaps AMAG knows how many doses have been sold or [are] at distributors, however there is no way they can know how many doses have been administered. Our***

consultants have not used all of the Feraheme they have purchased and we know some of Q4's $12-13MM is in inventory. Third, they would like to know the definition of SAE and if it is the same as in the clinical trials (to insure a true comparison to the label). If it is the same definition, our understanding is that it was death, hospitalization for any cause or an unexpected event. Our clinicians were clear to say that a blood pressure drop that is treatable quickly with saline is not an SAE and they would not report it as such. The label is for 1.9% hypotension rates which are similar to Ferliccit's label.

- We still think some of the SAEs may be in patients with multiple drug allergies. We have spoken to several doctors that were involved with the clinical trials that have acknowledged that these patients were excluded and should not be treated. We think the four NY cases were in patients with multiple drug allergies. If this is a common factor, this is quite simple to address.

- Fereheme's [sic] perceived safety profile is key. Many predialysis patients are not treated with IV iron due to the multiple doses necessary and the risk of adverse events in the out patient setting. ***Our conversations with clinicians reveal their experience with Venofer is excellent: we have heard of one SAE and one death in 10 years of Venefor [sic] use.***

> It is in best interest of AMAG and Feraheme to be accurate and proactive in providing details surrounding the SAEs to the medical community. (Emphases added.)

110. Following this report, AMAG's stock price dropped once again, from $37.77 per share on Friday, February 5, 2010 to close at $36.67 per share on Monday, February 8th, on heavy trading volume of 3,120,600 shares. In total, between February 3, 2010 and February 8, 2010, AMAG's stock price dropped by $8.58 per share, a decline of 19%.

B. The FDA Mandates Stricter Warnings Concerning SAEs on Feraheme's Label

111. As set forth herein, during the third quarter earnings call held on October 28, 2010, the Company announced for the first time that the FDA had created a Tracked Safety Issue regarding Feraheme, that the Company was meeting with the FDA to discuss the cardiac-related SAEs and changes to be made to Feraheme's labeling as mandated by the FDA, including the potential for a boxed warning, the most serious warning imposed by the FDA that is designed to alert patients and health care providers to SAEs resulting from a product's use. Questions from analysts during the earnings call focused on the true rate of incidence and severity of the SAEs and their impact on the Company's business, including the effect on future sales and revenues of any labeling changes, the impact on clinical trials to broaden the indications for Feraheme use, as well as the impact on the approval process in Europe. For example, the following exchange occurred between a Citi analyst and Defendant Pereira:

Q: Where, how—the most obvious question is how realistic is it, do you think, that you will get a black box?

A: This is Brian, Yaron. We are in discussions with the agency on the broad issues regarding updating the label. As I said in my call, there are several post-marketing events that have occurred that will come into the label. These are events which are similar to those that already exist in the labels of the other IV iron on the market.

However, based on our evaluation of the post-marketing safety data, we do not believe that a boxed warning is warranted for Feraheme. At this point, we are in discussions with the agency so it's hard to handicap what the outcome is.

Q: And if you do get a black box warning, what do you think the outlook for the brand is? So this is really a question of—in many ways it's going to be a question of existence for the brand at that point. The whole convenience benefit at that point is going to be dramatically damaged. Do you agree with that?

A: Well, not quite, Yaron, Feraheme has, as you know, unique characteristics. Its two doses of 500 milligrams each can be given in 17 seconds. Obviously, if Feraheme does receive a boxed warning, it will make the commercial effort more challenging. But I must remind you that in some segments of the IV iron market, the

> dominant IV iron used even today is Dextran, which has a boxed warning. So I would say that we need to wait until this plays out, at which time we'll be in a better position to assess the U.S. opportunity and our strategy going forward.

112. The following exchange took place between a Morgan Stanley analyst and Defendant Pereira concerning the severity and frequency of cardiac-related SAEs:

> Q: Yes, hey guys. Thanks for taking the question. So the first one is I know this got asked, but I'm still not clear on what the answer is. So is what the FDA's concerned about in terms of the error safety database, is it the absolute number of events, that there are serious cardiac events that they're seeing? Or has there been a change in the pacing not just from the beginning of the year to now, but from 1Q to 2Q into 3Q in terms of the number of events that they are seeing and specifically is that what's concerning them?
>
> A: If you'd note, FDA put us on the TSI in the DARRTS system in late August, but we were informed about this decision much earlier. We would suggest that this was based on their analysis of the first quarter data this year. Again, this is speculative. We can't say with absolute certainty what prompted the FDA to list Feraheme.

113. In an exchange between Defendant Pereira and an analyst with Robert Baird, the analyst

challenged the Company's assessment that th e SAEs reported were in line with SAEs reported in Feraheme's packaging insert. The Company further acknowledged the significance of the creation of a TSI by the FDA both with regard to physicians' prescribing practices for Feraheme and with regard to investors:

> Q: Just one question. I'm a little confused about one of the things you mentioned in your commentary about one of the primary drivers of decreased use utilization being safety concerns. Knowing, obviously, that you've got a surveillance system that's showing essentially issues that are in line with the label. Yet, you do have this issue with the FDA. What is really the mechanism of that or what's the genesis of the concern among physicians? Are they aware of the FDA AERS database is that really the driver, or was there maybe sort of a word of mouth thing going on between docs. Thanks.
>
> A: Marshall, I think that both Gary and I will offer pieces of color in this. I'll take the first shot. As you know, in 2010 the separation between the investor community and the prescribing community has continued to narrow. Physicians today read their medical business journals more often than they did in the past. **And when events such as listing of the drug on the TSI or a company withdrawing from an investor conference because of ongoing discussions with the agency, it tends to I would say go viral.** And many physicians are well in tune with what's happening on the investors side.

And hence that does contribute to prescribing patterns. Now again as I said, I hope that with the label being finalized, with us being able to speak more freely with prescribing docs and in the not too distant future once we have comparative data for Feraheme versus the other IV irons, well be able to provide folks far more clarity. And Gary has a couple of comments as well to give you a more complete picture.

<A - Gary J. Zieziula, Chief Commercial Officer & Executive Vice President: So, Chris, **from a business perspective, safety we feel definitely played a role in our performance in the third quarter particularly in the Nephrology segment. And there were two large Nephrology clinics that actually decided to stop using Feraheme in the third quarter, relatively early in the third quarter, and we felt almost the immediate impact of that. Now that was either the result of having an adverse event occur in the clinic or hearing about an adverse event occurring in a neighboring clinic.**

As you can well imagine, **it's a close-knit community and when nephrologists have an experience, a bad experience and maybe have not had a significant experience up to that point in time using a relatively new product, they become concerned and in several cases clinics stopped using Feraheme and moved to other products.**

> We haven't seen that occur in other segments as much as in the Nephrology segment. So to your question, **we do have specific examples where safety played a role in impacting the business in the third quarter** as was stated in our remarks. (Emphases added.)

114. An analyst with Jefferies queried Defendant Pereira about the impact on enrollment rates in clinical trials to expand the indication for Feraheme:

> Q: Okay. And then given this safety concern, how do you think that this may impact your current ongoing phases of your trials in IDA?
>
> A: Our IDA trials are ongoing. They're enrolling well and they have not been a subject of discussion with the Agency.
>
> Q: But how about the enrollment rate? Do you think that it could slow down?
>
> A: We have not seen any change in the enrollment rate. They are on track.

115. Another analyst with Leerink Swann expressed concern about the fatalities linked with Feraheme use post-marketing:

> Q: Thanks. I had a question similar to the last. I was curious about the 10 deaths, because on the surface it wouldn't seem like the overall level of SAE would justify this amount of concern but perhaps the severity is what the FDA detected. So, how does the 10 deaths

amongst 146 SAE and 155,000 exposures, how does that mortality rate compare to the overall death rate in the CKD population? And also what you know about other IV irons?

A: Well, I think, Joe, that's an important question that can bring all the pieces of information into context. So let's start from the highest level. Overall, the mortality rate in Dialysis patients is 23% per year. In CKD patients it varies based on the stage of disease. Those who have more advanced stages of disease, that's stages three and four, it is closer to the mortality rate in Dialysis and, as you'd expect, its lower.

As a frame of reference, you will recall two and half years ago in February of 2008, we provided you information on our clinical development program. In our clinical development program among 2,000-plus patients, subjects who were enrolled, who had received about 2,800 doses, there were 31 deaths and the mortality rate was 1.1% in Feraheme-exposed patients and 2.8% in oral iron-exposed patients. This provides you a context that these are sick patients.

The 10 deaths in patients who were exposed to Feraheme have occurred from the same day to several weeks after administration. So again as I said earlier, in the post-marketing environment both for SAEs and deaths, it's very hard to ascribe causality. With respect what is the state of affairs with other IV irons, we have

> no direct head-to-head studies and so it's hard to address this. But similar events are highlighted in the package inserts of all the existing IV irons on the market.

116. Summer Street analyst Carol Werther asked the following question concerning the FDA's concerns regarding Feraheme's safety:

> Q: Thank you. Brian, I'm still trying to understand, I mean if these serious adverse events are within your label I'm having a hard time trying to figure out how you might end up with a black box. The other, I mean, can you help me out a little bit, like what is the FDA seeing that they're concerned about?
>
> A: Well, we can't speak for the FDA, but **we believe that their concern was that some of the events that we have seen in the post-marketing environment haven't been explicitly listed in our label.** And as to how the FDA is going to approach IV irons as a class, it's not ours to speculate. (Emphasis added.)

117. A Citi analyst asked about the impact on approval of Feraheme in Europe:

> Q: Yes, hi, thanks for taking my follow-up. Guys, if I may, I just wanted to get your thoughts as to how do you think these new events or these new occurrences, which were not known at the time in which you filed and got approved, any sense as to how would that

impact the potential for approval and outlook in Europe?

A: Well, Yaron, a couple of comments I'd like to make. **One is that many of the types of events that we observed in clinical trials have been observed in the post-marketing environment but were not explicitly listed in our labels** and we plan to update that, our label, to reflect that.

With respect to Europe, the review is ongoing and I don't believe it's appropriate to speculate. First let's see how the resolution of our discussions with the U.S. FDA pans out before trying to answer that question. At this point in time that's where it is.

118. A JP Morgan analyst posed a question about the pattern of cardiac-related SAEs:

Q: Hi guys. Thanks for the follow-up. So, a little bit different way to ask the previous question, when you look at the SAEs, I know it's exploratory but is there any defining feature among the patients who've had a cardiac event?

A: To be honest, Geoff, we have cut it every which way to identify-- with the data that we have. As you would expect, as any responsible organization will try and see if there is any particular patient type, any particular dosing paradigm, any site of care and we don't see any specific pattern. These are sick patients in

general. So, it's very hard and we've tried our best.

119. The JP Morgan analyst also asked about the relationship between a TSI and a boxed warning:

Q: Okay. And then last question, do you have a sense of the drugs that made the docs list, which ones don't have a black box?

A: We haven't done that analysis. There have been many products which have been on the TSI list for a long while. I think different organizations approach this differently. As I said earlier, for us safety is our priority. When we got listed, we reached out to the agency to find out what is the basis.

120. Another question was posed by a Jefferies analyst regarding the Company's claimed rate of incidence for cardiac-related SAEs:

Q: Thanks for taking the follow-up question. Regarding the cardiac disorder event, in the clinical trials the instance rate, instance was less than 1%. So, now these events keep coming up and it sounds like they could be reflected in the label. Should we assume that the cardiac events that you are seeing in post-marketing is approaching 1% or over 1%?

A: Well, in the post-marketing environment there is no percentage cutoff, Eun. When you observe events in the post-marketing environment you list them. If you look at labels

> of the other IV irons in the market, all of these events are listed in their— many of these events are listed in their labels.

121. Although AMAG and Defendants Pereira and Arkowitz sought to downplay both the incidence of SAE's and the Company's discussions with the FDA, the news concerning the true rate of incidence of SAEs post-marketing, their severity, and the fatalities reported caused an immediate negative reaction in the market. The following day, October 29, 2010, AMAG's stock price fell from the previous day's close of $ 20.01 per share to close at $15.91 per share, on heavy trading volume of 4,619,600, an increase from the average volume of 683,500 the previous day.

122. The stock price continued to decline precipitously as investors awaited news of the labeling changes to be imposed by the FDA. Between October 29, 2010 and November 26, 2010, when the labeling changes were announced by AMAG, the stock fell to $14.05 per share, on extremely low trading volume of just 142,500, representing a price decline of ***71%*** from the Offering price of $48.25 per share.

123. The resulting low level of investor confidence in the Company's performance is reflected in an article posted on TheStreet.com on December 1, 2010, entitled "Vote for the Worst Biotech CEO" listing Defendant Pereira as one of four contenders for the title:

> Pereira [] deserves inclusion on this list of worst biotech CEOs nominees because he promised way too much and delivered far too little throughout 2010. ***Almost everything Pereira***

promised about the Feraheme launch failed to materialize, while the critics with questions he somewhat arrogantly brushed aside in the early days of the launch have been proven right.

Feraheme today fights an uphill battle. Changes to the way kidney disease drugs and services are reimbursed have made Feraheme's convenience factor irrelevant and its premium price a liability. A new FDA-mandated Feraheme label warns doctors to watch patients for potentially life-threatening allergic reactions. Quarterly sales of the drug have fallen consistently below expectations, forcing the company to restructure and retool its marketing approach, which still seems to have no clear direction.

Pereira is a nephrologist who repeatedly told investors to trust his hands-on expertise in the chronic kidney disease market. He, better than most, knew how to make Feraheme a commercial success, he said. Well, one year later, ***Feraheme borders on failure, and whatever reservoir of trust Pereira built with Wall Street is gone. Amag shares are down 71% this year from their peak in mid-January. Shareholders are angry, and some are starting to push the company's board to make significant changes.*** (Emphases added.)

C. Feraheme Sales Plummet As Health Care Providers Become Aware of the Safety Issues Related To Feraheme Use

124. In December 2009, the last full month reported prior to the Offering, AMAG reported provider demand for Feraheme at approximately 8,700 grams (excluding sales due the Company's Launch Incentive Program). In January 2010, as physicians were increasingly reporting SAEs to AMAG sales representatives, provider demand for Feraheme dropped to approximately 3,200 grams (excluding sales due to the Company's Launch Incentive Program), as reported in the Company's fourth quarter 2009 ("4Q09") earnings slides presented to analysts during an earnings call. In February 2010, provider demand for Feraheme remained significantly below December 2009 levels, equaling approximately 4,100 grams, as reported in the Company's 4Q09 earnings slides. When reporting its results for the second quarter 2010, AMAG revealed in a conference call with analysts that it would no longer present end-to-end monthly figures. The Company reported that approximately 8,200 grams were in provider inventory in the second quarter 2010.

125. During the third quarter 2010, in what was referred to as a "challenging period" by Defendant Pereira, the Company reported a net loss of approximately $17 million. Feraheme sales declined sharply in the third quarter, reporting $15.1 million in Feraheme net product revenues, which was $900,000 lower than the second quarter. Overall provider demand dropped by 11%, with demand dropping more than 20% in certain segments, and a large customer returned $1.9 million of Feraheme inventory to the

Company. Two large customers stopped using Feraheme entirely as set forth in paragraph 113 herein. During the Q3 earnings call held on October 28, 2010, the Company attributed the sharp decline in sales of Feraheme in large part to safety concerns regarding Feraheme.

VIII. CAUSES OF ACTION

COUNT I

For Violations of Section 11 of the Securities Act Against All Defendants

126. Lead Plaintiff repeats and realleges each and every allegation contained above.

127. This cause of action is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of the Class, against all Defendants.

128. The Registration Statement for the Offering was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and concealed and failed to adequately disclose material facts as alleged herein.

129. AMAG is the registrant for the Offering. As issuer of the shares, AMAG is strictly liable to Lead Plaintiff and the Class who acquired Common Stock pursuant to and traceable to the Registration Statement and incorporated Offering Documents for the misstatements and omissions contained therein in violation of Section 11 of the Securities Act.

130. The Individual Defendants each signed the Registration Statement. In addition, Defendants Bonventre, Narachi, Perez, Russell, Scoon and Zwanziger were directors of AMAG at the time the Registration Statement and Offering Documents were issued.

131. Each of the Underwriter Defendants was an underwriter for the Offering.

132. The Individual Defendants and the Underwriter Defendants are unable to establish an affirmative defense based on a reasonable and diligent investigation of the statements contained in the Registration Statement and Offering Documents. The Individual Defendants and the Underwriter Defendants did not make a reasonable investigation or possess reasonable grounds to believe that those statements were true and that there were no omissions of any material fact. Therefore, the Individual Defendants and the Underwriter Defendants acted negligently and are liable to Lead Plaintiff and other members of the Class who acquired AMAG Common Stock pursuant to or traceable to the Registration Statement and Offering Documents.

133. Lead Plaintiff and the Class have sustained damages. The value of AMAG shares declined substantially subsequent to and due to Defendants' violations.

134. At the times they purchased AMAG shares, Lead Plaintiff and other members of the Class were without knowledge of the facts concerning the wrongful

conduct alleged herein and could not have reasonably discovered those facts prior to January 21, 2010.

135. Less than one year has elapsed from the time that Lead Plaintiff discovered or reasonably could have discovered the facts upon which this Complaint is based to the time that Lead Plaintiff filed this Complaint. Less than three years has elapsed between the time that the securities upon which this Count is brought were offered to the public and the time Lead Plaintiff filed this Complaint.

COUNT II

For Violations of Section 12(a)(2) of the Securities Act Against Defendant AMAG, Defendant Pereira, Defendant Arkowitz, and the Underwriter Defendants

136. Lead Plaintiff repeats and realleges each and every allegation contained above. This cause of action is brought pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. § 771(a)(2), against Defendant AMAG, Defendant Pereira, Defendant Arkowitz and the Underwriter Defendants on behalf of Lead Plaintiff and members of the Class who purchased or acquired registered shares of AMAG Common Stock pursuant to the Prospectus and Offering Documents and any other oral or written communications used to solicit the Offering, including free writing prospectuses and road shows, and were damaged by the acts alleged herein.

137. Defendant AMAG sold, offered for sale, and solicited the sale of the Common Stock by the use of means or instruments of transport or communication

in interstate commerce or of the mails, by means of the Prospectus or oral or other written communications, including the Offering Documents. The Prospectus and Offering Documents contained untrue statements of material fact and omitted other facts necessary to make the statements not misleading, and failed to disclose material facts, as alleged herein.

138. Defendant Pereira and Defendant Arkowitz solicited the sale of the Common Stock by the use of means or instruments of transport or communication in interstate commerce or of the mails, by means of the Prospectus or oral or other written communications, including the Offering Documents and road shows. The Prospectus and Offering Documents contained untrue statements of material fact and omitted other facts necessary to make the statements not misleading, and failed to disclose material facts, as alleged herein.

139. The Underwriter Defendants committed to and purchased AMAG's registered Common Stock from AMAG and sold the registered Common Stock to Lead Plaintiff and members of the Class by the use of means or instruments of transport or communication in interstate commerce or of the mails, by means of the Prospectus or oral or other written communications, including the Offering Documents.

140. The Defendants named in this Count actively solicited the sale of the Common Stock to serve their own financial interests through, among other things, the preparation and dissemination of the Prospectus, participating in road shows, and the planning and orchestrating of all activities necessary to promote the sale of the Common Stock.

141. The Prospectus and Offering Documents contained untrue statements of material fact and omitted other facts necessary to make the statements not misleading, and failed to disclose material facts, as alleged herein.

142. The Defendants named in this Count knew or in the exercise of reasonable care should have known that the Prospectus and Offering Documents contained statements of material fact that were misleading as alleged herein or that material facts necessary to make the statements not misleading should have been disclosed, as alleged herein. None of the Defendants made a reasonable investigation or had reasonable grounds to believe that the statements in the Prospectus were accurate and complete in all material respects.

143. Lead Plaintiff and members of the Class purchased registered shares of AMAG Common Stock in the Offering and were damaged thereby.

144. Lead Plaintiff and the Class did not know, nor in the exercise of reasonable diligence could they have known, of the untrue statements of material fact or omissions of material facts in the Prospectus, Offering Documents and other oral and written communications when they purchased or acquired the shares.

145. This action is commenced within one year after the discovery of the misstatements and omissions contained in the Prospectus, Offering Documents and other oral and written communications and within three years of the Offering.

146. By reason of the foregoing, the Defendants named in this Count are liable to Lead Plaintiff and members of the Class for violations of Section 12(a)(2) of the Securities Act. Lead Plaintiff and Class members hereby tender their registered shares of AMAG common stock to the Section 12 Defendants and seek rescission of their purchases to the extent that they continue to own such securities. Lead Plaintiff and Class members who have sold their AMAG Common Stock are entitled to rescissisory damages.

COUNT III

For Violations of Section 15 of the Securities Act for Control Person Liability Based on Section 11 and 12(a)(2) Violations by AMAG Against Defendant Pereira and Defendant Arkowitz

147. Lead Plaintiff repeats and realleges each and every allegation contained above.

148. This cause of action is brought pursuant to Section 15 of the Securities Act, 15 U.S.C. § 77o, against Defendants Pereira and Arkowitz on behalf of Lead Plaintiff and members of the Class who purchased or acquired registered shares of AMAG Common Stock pursuant to and/or traceable to the Offering Documents and were damaged by acts alleged therein.

149. As alleged herein, Defendant AMAG violated Sections 11 and 12(a)(2) of the Securities Act by issuing the Offering Documents, which included materially untrue statements of fact and omitted to state material

facts required to be stated therein or necessary to make the statements therein not misleading. Defendants Pereira and Arkowitz were controlling persons of Defendant AMAG when the Offering Documents were filed and became effective, due to their senior executive positions therewith; their direct involvement in the Company's day to day operations; and their participation in, and preparation of, the Offering Documents. Moreover, Defendant Pereira was a controlling person of Defendant Arkowitz when the Offering Documents were filed and became effective, due to his senior executive position as CEO and his direct supervision over Defendant Arkowitz in the preparation of the Offering Documents.

150. By virtue of their exercise of control over the Company, these Defendants each had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of AMAG, including the content of its public statements and of the Offering Documents. These Defendants did not make a reasonable investigation or possess reasonable grounds for the belief that the Offering Documents were accurate and complete in all material respects. Had they exercised reasonable care, they would have known of the material misstatements and omissions alleged herein.

151. This claim is brought within one year after the discovery of the materially untrue statements and omissions in the Offering Documents and within three years after AMAG's registered Common Stock was offered to the public.

152. By reason of the misconduct alleged herein, Defendants Pereira and Arkowitz are liable to Lead Plaintiff and the members of the Class for violations of Section 15 of the Securities Act.

IX. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff, on behalf of itself and the Class, prays for judgment as follows:

(a) Declaring this action to be a class action properly maintainable pursuant to Rule 23 of the Federal Rules of Civil Procedure, and declaring Lead Plaintiff to be a proper Class representative;

(b) Awarding all damages and other remedies set forth in the Securities Act in favor of Lead Plaintiff and all members of the Class against Defendants, jointly and severally, in an amount to be proven at trial, including interest thereon;

(c) Awarding Lead Plaintiff and other members of the Class their costs and expenses of this litigation, including reasonable attorneys' fees, accountants' fees and experts' fees and other costs and disbursements; and

(d) Awarding Lead Plaintiff and other members of the Class such other and further relief as may be just and proper under the circumstances.

X. JURY TRIAL DEMANDED

Lead Plaintiff hereby demands a trial by jury.

DATED: December 17, 2010

By /s/ *Mitchell M.Z. Twersky*
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* * *

[Certificate of Service Omitted for Purposes of this Appendix.]

APPENDIX G

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No.: 11-2063

[Filed March 5, 2012]

SILVERSTRAND INVESTMENTS; BRIARWOOD INVESTMENTS, INC.; SAFRON CAPITAL CORPORATION, on behalf of themselves and all others similarly situated,	)
Plaintiffs-Appellants,	)
v.	)
AMAG PHARMACEUTICALS, INC.; BRIAN J.G. PEREIRA, M.D.; DAVID A. ARKOWITZ; JOSEPH V. BONVENTRE, M.D.; MICHAEL NARACHI; ROBERT J. PEREZ; LESLEY RUSSELL, M.D.; DAVEY S. SCOON; RON ZWANZIGER; MORGAN STANLEY & CO. INCORPORATED; J.P. MORGAN SECURITIES INC.; GOLDMAN, SACHS & CO.; LEERINK SWANN LLC; ROBERT W. BAIRD & CO.	)

INCORPORATED; CANACCORD GENUITY INC.,

Defendants-Appellees.

On Appeal from an Order Entered by the United States District Court for the District of Massachusetts, Boston
Case No.: 10-cv-10470-NMG
The Honorable Nathaniel M. Gorton

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure ("FRAP"), Defendant-Appellee AMAG Pharmaceuticals, Inc. certifies, through its undersigned counsel, that it has no parent corporation and that no publicly-held corporation owns 10 percent or more of its stock.

Respectfully submitted,

AMAG PHARMACEUTICALS, INC.

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Dated: March 5, 2012

INTRODUCTION

AMAG Pharmaceuticals, Inc. ("AMAG" or the "Company") manufactures an FDA-approved intravenous iron therapy known as *Feraheme*. Although patients in Phase III clinical trials experienced serious adverse events (or "SAEs"), including anaphylactic reactions and death, the FDA approved *Feraheme* in June 2009 based on a determination that its safety risks were outweighed by the substantial benefits it provided as a treatment for anemia in adult patients suffering from chronic kidney disease. The SAEs associated with *Feraheme* were repeatedly disclosed in AMAG's public filings, the FDA-approved product insert, and the registration statement and prospectus ("Offering Documents") filed in connection with AMAG's January 2010 secondary public offering (the "Offering"). Nevertheless, Plaintiffs-Appellants seek by this action to hold AMAG, its officers and directors, and the underwriters of the Offering liable under the Securities Act for omitting to state in the Offering Documents that 23 SAEs of the same nature and frequency observed in the clinical trials also occurred, as one would expect, in the six-month period between FDA approval and the Offering. The district court held that Plaintiffs' allegations fail to state a claim, dismissed the Second Amended Class Action Complaint ("SAC") and declined to grant Plaintiffs a third opportunity to amend. This Court should affirm.

Plaintiffs focus much of their Opening Brief on the Supreme Court's recent decision in *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011). While *Matrixx* holds that adverse event reports may be

material in certain cases absent statistical significance, the district court's dismissal order was not predicated on an absence of statistical significance as Plaintiffs misleadingly suggest. Further, *Matrixx* holds that adverse event reports, like any other allegedly omitted information, must be disclosed only if they would "significantly alter[] the total mix of information" available to investors. 131 S. Ct. at 1321 (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988)). That is, there must be "something more" than the mere occurrence of the adverse events in question to trigger a disclosure obligation. *Id*. Here, the nature and frequency of the 23 SAEs that Plaintiffs claim were omitted were fully consistent with the extensive disclosures AMAG made both before the Offering and in the Offering Documents regarding *Feraheme's* safety risks. As a result, the SAC lacks the "something more" the Supreme Court held is required to state a claim.

Plaintiffs attempt to circumvent this fundamental defect in their pleading by devoting a substantial portion of the SAC and their Opening Brief to events that occurred long after the Offering. By doing so, they attempt to create the false impression that AMAG concealed from investors important safety information about *Feraheme* which should have been disclosed in the Offering. However, it is well settled that to state a claim under either Section 11 or Section 12(a)(2) of the Securities Act based on the alleged omission of material information, the allegedly omitted information must have existed at the time of the Offering. The securities laws simply do not impose liability where, as here, the allegedly omitted information was not available to the Company at the time of the Offering.

Like all investors in a drug company with essentially one product, Plaintiffs invested in AMAG fully aware that their investments would be worth far more if *Feraheme* achieved commercial success and far less if it did not. That is the very risk/reward calculus that attracted them in the first place. The securities laws do not "provide investors with broad insurance against market losses, but . . . protect them against those economic losses that misrepresentations actually cause." *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 345 (2005). As Plaintiffs do not allege any misstatements or actionable omissions in this case, Defendants respectfully request that the Court affirm the district court's Order dismissing the SAC with prejudice.

ISSUES PRESENTED

1. Was Plaintiffs' Section 11 claim properly dismissed where AMAG publicly disclosed, both before the Offering and in the Offering Documents, all of the risk and safety information that Plaintiffs allege was omitted?

2. Was Plaintiffs' Section 12(a)(2) claim properly dismissed where Plaintiffs failed to plead any actionable omission or that any of the AMAG Defendants was a "seller" within the meaning of the statute?

3. Was Plaintiffs' Section 15 claim properly dismissed where Plaintiffs failed to plead a primary violation of Sections 11 or 12(a)(2)?

4. Did the district court abuse its discretion in denying Plaintiffs a third opportunity to amend their complaint where Plaintiffs: (i) did not move for leave to amend; (ii) failed to assert that leave to amend was warranted under *Matrixx*, 131 Ct. 1309, and (iii) have never identified any additional facts they might allege to cure the fundamental defects in their pleading?

STATEMENT OF THE CASE

This is a putative securities class action brought under Sections 11, 12(a)(2), and 15 of the Securities Act of 1933 ("Securities Act"). 15 U.S.C. §§ 77k, 771(a)(2), and 77o. Plaintiffs allege that the Offering Documents related to AMAG's January 21, 2010 secondary stock Offering improperly omitted material facts regarding the safety profile and commercial viability of *Feraheme*. Plaintiffs seek to recover damages against AMAG, certain of its officers and directors, and the underwriters of the Offering, on behalf of all persons who acquired AMAG common stock pursuant to the Offering.

STATEMENT OF RELEVANT FACTS

I. THE PARTIES

Plaintiffs are three investment funds who allegedly purchased AMAG stock pursuant to the Offering. (A66 (¶ 139).)[1] Defendant AMAG is a publicly-traded

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[1] The Appendix and Addendum to Plaintiffs' Opening Brief are cited herein as "A__" and "ADD__," respectively. Unless otherwise specified, citations to "¶ __" are to the SAC.

biopharmaceutical company based in Massachusetts that currently sells two FDA-approved products, *Feraheme* and *GastroMARK*. (A19 (¶ 2).) This appeal focuses exclusively on disclosures relating to *Feraheme*. The individual defendants are the Chief Executive Officer and Chief Financial Officer of AMAG and each member of its board of directors at the time of the offering (collectively with AMAG, the "AMAG Defendants"). (A25–26 (¶¶ 29–37).)[2]

II. *FERAHEME*

Feraheme is an FDA-approved intravenous iron-replacement therapy for the treatment of anemia in adult patients with chronic kidney disease or "CKD." (A19 (¶ 3).) CKD is an irreversibly progressive and debilitating condition characterized by persistent kidney dysfunction. Morbidity and mortality rates among CKD patients are high, and they often suffer from other serious health problems, including high blood pressure, anemia, nerve damage, and heart and blood vessel disease. (*See* A183–84 (Jan. 31, 2008 Form 8-K (hereinafter, "01/31/08 8-K")); A190 (Feb. 27, 2009 Form 10-K (hereinafter, "2008 10-K")); A212 (Feb. 27, 2008 Form 10-K (hereinafter, "2007 10-K")); www.kidney.org/kidneydisease/ckd/index.cfm.)

Although other intravenous iron therapies have been approved by the FDA, they are typically administered as a "slow push," i.e., a 15- to 30-minute

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[2] Plaintiffs also name as defendants the six firms that underwrote the Offering (the "Underwriters"). (A26–28 (¶¶ 38–45).) They have filed a separate brief.

infusion of doses of either 100 or 200 milligrams, and require up to ten physician visits for patients to receive a standard one-gram therapeutic course. (A31 (¶ 56); A194 (2008 10-K).) In contrast, *Feraheme* is typically administered as two 510 milligram injections, each of which can be administered in less than a minute during a regular office visit or dialysis treatment without the use of infusion equipment or prolonged medical intervention. (A31 (¶ 56); A194 (2008 10-K); A246 (July 1, 2009 Form 8-K (hereinafter, "07/01/09 8-K")).)

III. THE FDA APPROVES *FERAHEME* AND PUBLICLY DISCLOSES ITS SAFETY RISKS

A. AMAG Conducts Rigorous Clinical Trials for *Feraheme*

Before a drug may be approved for sale in the United States, the manufacturer must demonstrate to experts at the FDA that it is "safe and effective" for its intended use. 21 U.S.C. § 355. (*See also* A30, 32, 41–43 (¶¶ 55, 62, 86–87).) "No drug is absolutely safe; all drugs have side effects." (A203 (*The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective* (hereinafter, "FDA Review Guidelines")).) Pursuant to FDA regulations, a drug is "safe" if its "benefits appear to outweigh the risks." 21 C.F.R. §§ 312.84, 314.105.

Feraheme went through three rigorous phases of clinical trials, during which its safety was thoroughly tested and all adverse reactions noted. *See* 21 C.F.R. § 312.21. (*See also* A191 (2008 10-K); A211–16 (2007 10-K).) These trials included four Phase III clinical studies of *Feraheme* in adult patients with all stages of

CKD. (A191 (2008 10-K); A211–16 (2007 10-K).) Three of the Phase III studies were open-label, randomized efficacy and safety studies. (*Id.*) The fourth was a double-blind, placebo-controlled safety study comparing the safety of *Feraheme* to normal saline placebo. (*Id.*)

B. AMAG Submits a New Drug Application for *Feraheme*

On December 17, 2007, AMAG submitted a new drug application ("NDA") for *Feraheme* to the FDA. (A30 (¶ 55); A211 (2007 10-K).) The materials submitted with the NDA included detailed information from AMAG's clinical studies. (A211–16.) Of particular relevance, the NDA provided detailed data regarding the safety profile of *Feraheme*, including extensive data pertaining to deaths and other adverse events associated with *Feraheme's* administration. (*Id.*)

Among other things, the NDA disclosed that 31 participants in the Phase III studies died. (A212; *see also* A183 (01/31/08 8-K).) Of the 1,726 patients who received *Feraheme* injections across all four studies, 19 patients, or 1.1 percent, died during the study in which they were enrolled. (*Id.*)[3] The death rate across the first three open-label studies was higher. Roughly 1.3 percent of patients participating in those studies died after receiving *Feraheme*. (*Id.*)

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[3] The remaining 12 study participants who died received oral iron or placebo. (A212 (2007 10-K).) Of those patients receiving oral iron, 2.8 percent died. (*Id.*)

AMAG's NDA also disclosed serious adverse events, or SAEs, occurring over the course of the Phase III clinical program. SAEs are "[a]ny adverse drug experience occurring at any dose that results in . . . [d]eath, a life-threatening adverse drug experience [or] inpatient hospitalization . . . , a persistent or significant disability/incapacity, or a congenital anomaly/birth defect." 21 C.F.R. § 310.305(b). AMAG disclosed that, across the first three studies, 9.8 percent of *Feraheme*-treated patients experienced SAEs. (A212 (2007 10-K); A184 (01/31/08 8-K).) AMAG also disclosed an SAE rate of 2.9 percent among *Feraheme*-treated patients in the fourth Phase III study, including one patient who suffered an immediate anaphylactoid reaction[4] involving severe hypotension (low blood pressure) that was determined by the study investigator to be drug-related. (A216 (2007 10-K); A191 (2008 10-K).)

C. The FDA Determines That *Feraheme* Is Safe and Effective

Upon receipt of the NDA, an FDA review team comprised of medical doctors, chemists, statisticians, microbiologists, pharmacologists and other experts evaluated whether the clinical study data and other

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[4] Anaphylaxis is "a life-threatening whole-body allergic reaction to a drug or allergen . . . . Within seconds or minutes of exposure . . . , the immune system releases a flood of chemicals that can cause . . . , among other things, a sudden drop in blood pressure (hypotension) and a narrowing of airways that blocks normal breathing . . . . The onset of anaphylaxis is rapid, and must be treated immediately, typically . . . by injection of epinephrine." (A31–32 (¶ 58).)

materials submitted by AMAG demonstrated that *Feraheme* was safe and effective for its proposed use. *See* 21 C.F.R. § 312.84; (A203 (FDA Review Guidelines).) During this lengthy review process, AMAG was in frequent communication with the FDA to address and resolve questions and concerns raised by the agency, including those raised in Complete Response Letters in October and December 2008.[5] (A31–32 (¶¶ 57– 62).) Ultimately, after reviewing the data disclosed in the NDA and AMAG's amendments thereto, the FDA review team concluded that the risks associated with *Feraheme* were manageable:

> The risks outlined by [AMAG] are well-known to healthcare providers who treat patients with [CKD] . . . . [I]t does not appear that the adverse reactions are substantially more frequent or severe with [*Feraheme*] in comparison to other intravenous iron products. These risks are currently managed through labeling and routine pharmacovigilance activities . . .

(A238 (FDA Risk Assessment and Risk Mitigation Review(s), Sept. 19, 2008); *see also* A229 (FDA Summary Review, June 23, 2009) (noting that the rate of serious hypotensive reactions, including anaphylaxis, during *Feraheme* trials was 0.5% versus 0.4% for oral iron).)

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[5] Complete Response Letters are issued when FDA review of an NDA is complete but questions remain that preclude approval at that time. *See* 21 C.F.R. § 314.110.

Based on these and other assessments, the FDA approved *Feraheme* for sale in the United States on June 30, 2009. (A32 (¶ 62); A246 (07/01/09 8-K).) FDA approval does not mean that *Feraheme* has no risks. Rather, the FDA granted approval based on its determination that the risks associated with *Feraheme* are acceptable when weighed against its benefits. (*See* A204 (FDA Review Guidelines); A231 (Summary Review).)

D. The FDA Publicly Discloses Its Analysis of *Feraheme's* Safety

After the FDA approves a drug, regulations require that it publish the information described above, including "all safety and effectiveness data" and "adverse reaction reports." 21 C.F.R. § 314.430. Accordingly, the FDA made its "Drug Approval Package" for *Feraheme* publicly available on its website on November 25, 2009, two months before the Offering. (*See* A242 (FDA Drug Approval Package Cover Page).) The Drug Approval Package included the FDA's approval letter for *Feraheme*, its summary and medical reviews of *Feraheme*, other FDA action letters (including its October and December 2008 Complete Response Letters, specifically identifying the FDA "concern[s]" discussed at pages 7–8 of Plaintiffs' Brief), and the FDA's Risk Assessment for *Feraheme*. (*Id.*)

E. The FDA-Approved Product Insert For *Feraheme* Explicitly Warns of the Risk of Anaphylaxis and Other SAEs

On July 1, 2009, AMAG issued a press release and filed a Form 8-K with the SEC, announcing the FDA's

approval of *Feraheme*. (A249–51.) The press release included a link to the FDA-approved product insert for the drug (commonly known as the "label") and alerted investors that it was also publicly available at www.amagpharma.com. (A251; A253–62 (Product Insert).) The product insert explicitly identified the safety risks associated with *Feraheme*, including the risk of hypotension and serious hypersensitivity reactions, such as anaphylaxis:

> **5 WARNINGS AND PRECAUTIONS**
>
> **5.1 HYPERSENSITIVITY REACTIONS**
>
> Feraheme may cause **serious hypersensitivity reactions, including anaphylaxis and/or anaphylactoid reactions. In clinical studies, serious hypersensitivity reactions were reported in 0.2% (3/1,726) of subjects receiving Feraheme**. Other adverse reactions potentially associated with hypersensitivity (e.g., pruritus, rash, urticaria or wheezing) were reported in 3.7% (63/1,726) of these subjects. **Observe patients for signs and symptoms of hypersensitivity for at least 30 minutes** following Feraheme injection and only administer the drug when personnel and therapies are readily available for the treatment of hypersensitivity reactions. [*see Adverse Reactions (6.1)*].
>
> **5.2 HYPOTENSION**
>
> Hypotension may follow Feraheme administration. In clinical studies, hypotension

> was reported in 1.9% (33/1,726) of subjects, including three patients with serious hypotensive reactions. Monitor patients for signs and symptoms of hypotension following *Feraheme* [injection].
>
> **6 ADVERSE REACTIONS**
>
> **Feraheme injection may cause serious hypersensitivity reactions and hypotension** [*see Warnings and Precautions (5.1)(5.2)*] . . . .

(A255–56 (emphasis added).)

IV. AMAG REPEATEDLY DISCLOSES THE SAFETY RISKS ASSOCIATED WITH *FERAHEME* IN ITS SEC FILINGS

AMAG repeatedly disclosed to investors the results of its Phase III clinical trials, including both efficacy and safety data, as well as the risks that certain safety issues might pose to its financial success. For example, in its 2008 10-K, publicly filed on February 27, 2009, AMAG stated:

> Serious adverse events, or **SAEs, occurred in 2.9% of patients after *Feraheme* administration** . . . . On a blinded basis, these SAEs were deemed to be related to treatment by the investigator in one patient after *Feraheme* administration . . . . The single SAE attributed to the drug . . . occurred in an 85 year-old male with non-dialysis dependent CKD, hypertension, coronary artery disease, cerebrovascular disease and a history of multiple drug allergies . . . . [H]e

> experienced an **anaphylactoid reaction with severe hypotension a few minutes after *Feraheme* administration**, was treated with epinephrine, and fully recovered.

(A191 (emphasis added).)

Similarly, in its July 1, 2009 Form 8-K announcing FDA approval, AMAG warned:

> In clinical studies, **hypotension was reported in 1.9% (33/1,726) of subjects receiving *Feraheme***, including three patients with serious hypotensive reactions. Adverse reactions potentially associated with hypersensitivity (e.g., pruritus, rash, urticaria or wheezing) were reported in 3.7% (63/1,726) of these subjects **including 0.2% (3/1,726) with serious hypersensitivity reactions.** Patients should be observed for signs and symptoms of hypersensitivity for at least 30 minutes following *Feraheme* injection and the **drug should only be administered when treatment of hypersensitivity reactions is readily available**.

(A250 (emphasis added).)

Thus, as of July 1, 2009, more than six months before the Offering, AMAG had disclosed to investors that, in clinical trials of *Feraheme*: (1) SAEs had been reported in **2.9 percent** of *Feraheme*-treated patients; (2) hypotension, including three patients with serious hypotensive reactions, had been reported in **1.9 percent** of *Feraheme*-treated patients; (3) "serious

hypersensitivity reactions, including anaphylaxis and/or anaphylactoid reactions" had been reported in **0.2 percent** of *Feraheme*-treated patients; and (4) **3.7 percent** of patients treated with *Feraheme* had experienced symptoms associated with hypersensitivity. (A255–56 (Product Insert); A250 (07/01/09 8-K).)

AMAG also repeatedly warned investors that these safety issues could impact its financial performance. For example, in its 2008 10-K, AMAG warned that SAEs occurring after FDA approval could significantly affect *Feraheme's* commercial viability:

> The FDA also requires all companies with approved products to submit reports on adverse drug experiences that occur after marketing approval. These requirements include specific and timely notification of certain serious, unexpected and/or frequent adverse events, as well as regular periodic reports summarizing adverse drug experiences . . . . [T]he FDA could place additional limitations on a product's use, such as labeling changes and, potentially, withdrawal or suspension of the product from the market.

(A195.) The 2008 10-K went on to identify a number of specific factors that could affect *Feraheme's* success in the market, including:

> Our ability to demonstrate to the medical community . . . the clinical efficacy and safety of *Feraheme* as an alternative to current treatments . . . ; [t]he actual or perceived safety

> profile of *Feraheme* relative to alternative iron therapeutic agents; [and t]he *Feraheme* labeling and product insert required by the FDA . . . .

(A196.)

In its Form 10-Q publicly filed on November 5, 2009, just eleven weeks before the Offering, AMAG stated:

> *Feraheme* may not receive the same level of market acceptance as . . . competing iron replacement therapy products [Ferrlecit and Venofer], especially since these products have been on the market longer and are currently widely used by physicians . . . . The iron replacement therapy market is highly sensitive to several factors including . . . the perceived safety profile of the available products . . . .

(A270 (Nov. 5, 2009 Form 10-Q (hereinafter, "3Q2009 10-Q")).)

Due to these and other fully disclosed uncertainties respecting *Feraheme,* AMAG specifically cautioned that its stock price could be affected: "[t]he 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." (A273 (3Q2009 10-Q).)

V. THE OFFERING DOCUMENTS FULLY DISCLOSE THE SAFETY RISKS ASSOCIATED WITH *FERAHEME*

In anticipation of the Offering, AMAG filed its registration statement and prospectus with the SEC on January 19 and 20, 2010, respectively. (A127–38 (Reg. Stmt.); A140–76 (Prospectus).) The prospectus included detailed disclosures regarding *Feraheme's* safety profile. (A145–66.) In fact, the Offering Documents specifically incorporated by reference each of AMAG's public filings identified in Section IV above. (A173 (Prospectus) (incorporating by reference, among other documents, AMAG's 2008 10-K and 07/01/09 8-K, which in turn incorporated by reference the *Feraheme* product insert); A134 (Reg. Stmt.) (same).) Thus, as of the Offering date, investors had been fully apprised of the clinical trials results, the nature and frequency of SAEs reported therein, the FDA's risk assessment of *Feraheme*, the possibility of additional adverse events being reported post-marketing, and the potential impact of each of these factors on AMAG's commercial success.

The risks to potential investors were also made clear in the prospectus: "Factors which may affect the market price of our common stock include . . . [s]afety concerns related to *Feraheme* . . . ." (A164.) The prospectus also stated that the "degree of market acceptance of *Feraheme* depends on a number of factors, including . . . [t]he development of unanticipated adverse reactions to *Feraheme* resulting in safety concerns among prescribers." (A146–47.) And it identified other risks that could negatively impact any investment in AMAG:

- "We are subject to ongoing FDA regulatory requirements and review pertaining to *Feraheme's* manufacture, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. Failure to comply with such regulatory requirements or the later discovery of previously unknown problems with *Feraheme* . . . may result in restrictions on our ability to market and sell *Feraheme* . . . [;] FDA warning letters; . . . [and] FDA-imposed label changes . . . . Any of these sanctions would have a material adverse impact on our ability to generate revenues and to achieve profitability." (A156.)

- "Significant safety or drug interaction problems could arise . . . resulting in recalls, restrictions in *Feraheme's* label, or withdrawal of *Feraheme* from the market." (A157.)

- "[N]ew safety or drug interaction issues may require us to provide additional warnings on the *Feraheme* label or narrow our approved indications, any of which could reduce the market acceptance of *Feraheme*." (*Id*.)

- "[I]f the FDA changes the label for *Feraheme* to include additional discussion of potential safety issues . . . [, this] could have a material adverse impact on our ability to generate revenues from sales of *Feraheme* . . . ." (A158.)

VI. *FERAHEME* IS SUBJECT TO ADVERSE EVENT REPORTING REGARDLESS OF WHETHER ADVERSE EVENTS ARE CAUSED BY *FERAHEME*

In light of Plaintiffs' allegations in this litigation, one other aspect of the applicable regulatory framework is worth noting. The FDA encourages healthcare providers to notify drug makers and the FDA of all adverse events occurring in patients receiving FDA-approved drugs. Drug makers, in turn, are required to report all adverse events of which they become aware, even though such events may have nothing to do with the drug at issue. *See* FDA, *Guidance for Industry, Good Pharmacovigilance Practice and Good Pharmacoepidemiologic Assessment*, 2005 WL 3628217, at *4 (Mar. 2005).

Notably, SAE reports do not establish or reflect any causal relationship between administration of the drug and the SAE. *See Matrixx*, 131 S. Ct. at 1321 ("[T]he mere existence of reports of adverse events . . . says nothing in and of itself about whether the drug is causing the adverse events . . . ."). Indeed, adverse events should be reported even if the reporting person does not believe there is any causal relationship. 21 C.F.R. § 314.80(a), (k). Accordingly, the FDA has specifically instructed that post-marketing SAE reports are not reliable as a measure of drug safety:

> There are some important things to remember when reviewing or analyzing data from [the FDA's Adverse Event Reporting System] . . .

2. The **information contained in the reports has not been scientifically or otherwise verified.**

3. For any given report, there is no certainty that the suspected drug caused the reaction . . . . **The event may have been related to the underlying disease for which the drug was given, to concurrent drugs being taken or may have occurred by chance at the same time the suspected drug was taken.**

4. **Accumulated case reports cannot be used to calculate incidence or estimates of drug risk.**

5. Numbers from these data must be carefully interpreted as **reporting rates and not occurrence rates**. True incidence rates cannot be determined from this database.

(A304 (Adverse Event Reporting System (AERS) – Background, Report Definitions, and Caveats, Aug. 1, 2006) (emphasis added).)

VII. AMAG'S SECONDARY OFFERING

On January 21, 2010, AMAG successfully completed a secondary Offering of approximately 3.6 million shares of common stock at a price to the public of $48.25 per share. (A20 (¶ 8).) The Offering was a firm commitment offering, meaning that AMAG sold the shares to the Underwriters, who then sold shares to investors. (A66 (¶ 139); A167 (Prospectus).)

VIII. PLAINTIFFS FILE THIS ACTION FOLLOWING ISSUANCE OF AN ANALYST'S REPORT DOWNGRADING AMAG'S STOCK

Despite AMAG's detailed disclosures, Plaintiffs allege that *Feraheme's* "true safety profile" began to emerge two weeks after the Offering, when an analyst with Summer Street Research Partners issued a report downgrading AMAG from "buy" to "neutral." (A50–51 (¶¶ 100–101).) According to the SAC, the February 4, 2010 analyst report revealed that there were "several patients hospitalized with anaphylactoid reactions to *Feraheme* . . . [and] one death that may or may not be directly related to *Feraheme*." (A21 (¶ 10).) Notably, the analyst conceded in her report that she did not know whether these SAEs were consistent with the SAE rates observed during clinical trials and publicly disclosed by AMAG and the FDA:

> In clinical studies serious hypersensitivity reactions were reported in 0.2% (3/1726) of subjects receiving *Feraheme*.[] While the incidence [of the SAEs identified in this report] could be in line with the 0.2% in *Feraheme's* label, there is no way to know.

(A306 (Summer Street Report, dated Feb. 4, 2010).) The analyst further stated:

- The [serious adverse] events may well be . . . within label. They may even be over reported due to patient counseling information in the label . . . . [I]t may be that all of the reactions were in patients with multiple drug allergies, which is fairly simple to address.

> • We understand that when Ferrlicit [a competing product] was launched a similar pattern of infusion reactions occurred that later were deemed unimportant . . . . We do not necessarily believe that *Feraheme's* longer term potential will be negatively affected.

(*Id.*) Based on discussions with unidentified "consultants" and her conclusion that the "adoption rate" of *Feraheme* was "slowing," the analyst reduced her sales forecast for *Feraheme* and downgraded AMAG. (A307.) The same day, AMAG's stock price fell $7.13, or 15 percent, to close at $38.12. (A312–13 (AMAG Stock Chart).)[6]

The following day, AMAG issued a press release, stating that post-marketing SAEs had been reported "at a rate consistent with that contained in the U.S. package insert." (A51 (¶ 103).) More specifically, AMAG reported that, "[o]f the estimated 35,000 patient exposures to date, 40 serious adverse events have been reported, an approximate rate of 0.1 percent. (*Id.*) In an analyst call later that day, AMAG was asked about the circumstances of the single reported death, and a Company representative stated:

> [A]s typically seen with intravenous iron, many infusion reactions happen immediately. The

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[6] The prospectus expressly warned investors of this risk as well: "If any of the analysts who cover us downgrade our stock or issue commentary or observations that are perceived by the market to be adverse to us or our stock, our stock price would likely decline rapidly." (A165.)

> patient did not have an infusion reaction like that. And given the comorbidities of the patient, given the fact that the infusion was well tolerated, we do not believe that this was related to the drug in fact. He had no AEs on the day of administration.

(A328 (Feb. 5, 2010 Transcript of AMAG Conf. Call).)

Plaintiffs filed this action six weeks later on March 18, 2010.[7] Plaintiffs filed an amended complaint on September 15, 2010, and a Second Amended Complaint ("SAC") on December 17, 2010.

At its crux, the SAC alleges that AMAG should have disclosed in the Offering Documents that it had received reports of 23 SAEs, including two anaphylactic reactions and one death, during the six-month period between FDA approval and the Offering (collectively, the "23 SAEs"). (A33–35 (¶¶ 64–74); Pls.' Br. at 8–10, 15.) Plaintiffs allege that the "actual rate of incidence" of these 23 SAEs (i.e., the percentage of *Feraheme*-treated patients who experienced SAEs) was at most 0.45 percent. (A54 (¶ 108).)[8] Plaintiffs further

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[7] On that date, AMAG's stock closed at $36.60, 24 percent less than the Offering price. (A312–13 (AMAG Stock Chart).)

[8] "Feraheme is administered in a minimum of two and as many as four injections," so Plaintiffs calculate that the 35,000 post-marketing patient exposures (i.e., *Feraheme* injections) that had occurred as of February 5, 2010 translate to a minimum of 8,750 patients (assuming all patients received four injections) and a maximum of 35,000 patients (assuming all patients received only one injection). (A53 (¶ 106); *see also* A54 (¶ 108).) Dividing the total

allege that 16 of the reported SAEs (or 0.18 percent of patients) "exhibited one or more symptoms associated with anaphylaxis." (A34, 54 (¶¶ 71, 108).)[9] According to the SAC, Defendants had a duty to disclose these 23 SAEs in the Offering Documents pursuant to Items 303 and 503 of Regulation S-K and to make other statements in the Offering Documents not misleading. (A35, 47 (¶¶ 74, 95).)[10]

IX. THE DISTRICT COURT DISMISSES ALL CLAIMS

On August 11, 2011, the district court granted Defendants' motion to dismiss the SAC. (ADD1–19.) The district court began by noting that, pursuant to *Matrixx*, the mere existence of reports of SAEs is insufficient to give rise to a duty of disclosure;

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number of post-marketing SAEs reported as of that date (40) by 35,000 and 8,750, respectively, yields, according to the SAC, a true post-marketing SAE incidence rate of between 0.11 and 0.45 percent. (*Id.*) On appeal, Defendants accept as true Plaintiffs' most aggressive alleged SAE incidence rate of 0.45 percent.

[9] Dividing the number of patients who allegedly reported SAEs involving symptoms of anaphylaxis (16) by the minimum number of patients Plaintiffs allege had received the drug (8,750) yields a maximum incidence rate of 0.18 percent.

[10] The SAC also asserted that Defendants should have disclosed the FDA's Complete Response Letters issued in October and December 2008 (A31, 43 (¶¶ 57, 88)), but the district court rejected this argument (ADD16–17), and Plaintiffs have apparently abandoned it on appeal. *See United States v. Benavente Gomez*, 921 F.2d 378, 386 (1st Cir. 1990) (arguments not raised in opening brief are waived). Defendants object to any attempt by Plaintiffs to raise in their Reply Brief this or any other issue not specifically raised in their Opening Brief.

"something more is needed." (ADD15 (quoting *Matrixx*, 131 S. Ct. at 1321).) The district court went on to find, however, that Plaintiffs' claims would fail "[e]ven if the Court assumes that the 23 SAEs are material." (*Id.*) The district court reasoned that AMAG was under no duty to disclose the 23 SAEs because it had "repeatedly disclosed in its Offering Documents and other public filings the safety information for Feraheme, including the fact that SAEs were observed during the clinical trials." (*Id.*) Indeed, the rate of incidence of post-approval SAEs alleged by Plaintiffs was significantly lower than and, thus, "consistent with the previously and publicly-disclosed rates [of SAEs] observed in the clinical trial[s]." (*Id.*; *compare* A54 (¶ 108) (alleging a post-marketing SAE incidence rate of at most 0.45%) *with* A255 (Product Insert), A191 (2008 10-K), A211–216 (2007 10-K) *and* A183 (01/31/08 8-K) (collectively disclosing that 2.9% of *Feraheme*-treated patients experienced SAEs, including serious anaphylactic and anaphylactoid reactions, and 1.1% of *Feraheme*-treated patients died).) Thus, disclosure of the 23 SAEs was not required under Items 303 or 503 of Regulation S-K or to make other disclosures in the Offering Documents not misleading. (ADD11–16.)

The district court also rejected Plaintiffs' allegations that the Offering Documents should have disclosed concerns raised by the FDA in a Warning Letter dated October 18, 2010. Section 11 imposes liability "only if the registration statement contains material misstatements or omissions as of its effective date," and the SAC established no "connection between the Warning Letter or the allegations contained therein and the time of the Offering" nine months earlier. (ADD18.)

Accordingly, the district court concluded that Plaintiffs had failed to identify a material omission that could support a claim and dismissed the SAC with prejudice. (ADD19–20.)

SUMMARY OF THE ARGUMENT

The SAC was properly dismissed. Each of Plaintiffs' claims therein is based on alleged omissions only, not affirmative misrepresentations. Plaintiffs claim that the registration statement should have disclosed that, during the six-month period between FDA approval and the Offering, 23 patients experienced SAEs after receiving *Feraheme*. However, these allegations, even if true, fail to articulate an actionable omission under Section 11 for at least three reasons.

First, the 23 SAEs that Plaintiffs assert should have been disclosed were consistent in rate and kind with the SAEs observed during clinical trials and publicly disclosed both before the Offering and in the Offering Documents. *Feraheme's* product insert specifically warns that *Feraheme* may cause serious hypersensitivity reactions, including anaphylaxis and anaphylactoid reactions, and AMAG repeatedly informed the public that such reactions had, in fact, occurred. Moreover, it is a matter of simple math that the rate of post-marketing SAEs alleged by Plaintiffs in the SAC (at most 0.45%) is dramatically less than the SAE rate observed during clinical trials and disclosed to the public (2.9%). Finally, the fact that one patient died two days after receiving *Feraheme* should have come as no surprise to investors given the very sick patient population to whom *Feraheme* is administered and the fact that, as disclosed by AMAG, 19 patients

(or 1.1%) died during clinical trials after receiving *Feraheme*. In short, under the materiality standard articulated by the Supreme Court in *Basic*, 485 U.S. at 231–32, and reaffirmed in *Matrixx*, 131 S. Ct. at 1321, the 23 SAEs were immaterial as a matter of law as they did not alter the total mix of information available to investors.

Second, even if the 23 SAEs were material, AMAG had no duty to disclose them. As this Court has repeatedly emphasized, mere possession of material information does not create a duty to disclose. Rather, in the Section 11 context, a duty to disclose may only be triggered by a specific statute or regulation or by inaccurate or misleading disclosures in the registration statement. Here, contrary to Plaintiffs' assertion, AMAG was under no duty to disclose the 23 SAEs under Items 303 and 503 of Regulation S-K because, in light of prior disclosures, they did not give rise to an undisclosed trend, risk or uncertainty. Similarly, disclosure was not required to make other statements in the registration statement not misleading because the documents incorporated by reference therein (including *Feraheme's* product insert) made clear that the very same SAEs had occurred in clinical trials at even higher rates.

Third, implicitly conceding – as they must – that the mere occurrence of the 23 SAEs is insufficient to give rise to a duty of disclosure, Plaintiffs resort to pleading in their SAC and arguing in this Court that events occurring many months after the Offering somehow provide the "something more" required under *Matrixx*. 131 S. Ct. at 1321. But Section 11 claims cannot be based on facts occurring after the offering in

question. To the contrary, to state a Section 11 claim, Plaintiffs must identify allegedly omitted material information that existed at the time the registration statement became effective. Plaintiffs have not done so, and it is abundantly clear, after three versions of their pleading, that they cannot cure this fundamental defect.

In sum, Plaintiffs have failed to allege a material omission actionable under Section 11. Plaintiffs' Section 12(a)(2) claim fails for the same reasons and because the AMAG Defendants were not "sellers" within the meaning of that statute. Finally, as Plaintiffs have failed to plead a primary violation of Section 11 or 12(a)(2), their Section 15 claim fails as well. The district court's Order dismissing the SAC with prejudice was proper and should be affirmed.

ARGUMENT

I. STANDARD OF REVIEW

This Court reviews *de novo* a dismissal under Federal Rule of Civil Procedure 12(b)(6). *Cooperman v. Indiv., Inc.*, 171 F.3d 43, 46 (1st Cir. 1999). The Court may affirm a dismissal on any basis fairly supported by the record, even if the district court did not reach the issue or relied on different grounds or reasoning. *Haley v. City of Boston*, 657 F.3d 39, 46 (1st Cir. 2011). A district court's refusal to grant leave to amend is reviewed for an abuse of discretion. *Epstein v. C.R. Bard, Inc.*, 460 F.3d 183, 191 (1st Cir. 2006).

II. LEGAL STANDARDS GOVERNING DEFENDANTS' MOTION TO DISMISS

A. Rule 12(b)(6) of the Federal Rules of Civil Procedure

Dismissal is proper under Rule 12(b)(6) where a complaint fails to allege facts to support a claim for relief. *Cooperman*, 171 F.3d at 47 (affirming dismissal of Section 11 and 15 claims under Rule 12(b)(6)). A complaint must allege "a plausible entitlement to relief" in order to withstand a motion to dismiss. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949 (2009). Moreover, the Court is not required to accept as true those facts that are contradicted by documents incorporated by reference into the SAC or subject to judicial notice. *Clorox Co. Puerto Rico v. Procter & Gamble Commercial Co.*, 228 F.3d 24, 32 (1st Cir. 2000); *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1120 (1st Cir. 1996) (on a motion to dismiss, district court may consider the text of documents referenced in the complaint, matters subject to judicial notice and documents "integral" to plaintiff's claim).

B. Sections 11, 12(a)(2) and 15 of the Securities Act

Section 11 imposes liability where "a registration statement, as of its effective date: (1) contained an untrue statement of material fact; (2) omitted to state a material fact required to be stated therein; or (3) omitted to state a material fact necessary to make

statements therein not misleading." *Shaw*, 82 F.3d at 1204 (quoting 15 U.S.C. § 77k(a)) (internal quotations omitted). Similarly, Section 12(a)(2) imposes liability on any person who offers or sells a security "by means of a prospectus . . . which includes an untrue statement of a material fact or omits to state a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading." 15 U.S.C. § 771(a)(2). The test for whether an alleged misstatement or omission is material under Section 11 or 12(a)(2) is identical to that under Section 10(b) of the Securities and Exchange Act of 1934 ("Exchange Act"), namely: whether there is a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." *Basic*, 485 U.S. at 231–32 (citation and internal quotations omitted).

To plead control person liability under Section 15, Plaintiffs must allege: (1) a primary violation of the Securities Act by the controlled person or entity, and (2) that the defendant controlled the violator. *Cooperman*, 171 F.3d at 52.[11]

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[11] In their motion to dismiss, the AMAG Defendants argued that the SAC sounds in fraud, thereby triggering the heightened pleading requirements of Fed. R. Civ. P. 9(b) and the PSLRA. (A107–08, 465-66.) The district court, however, declined to reach this argument, concluding that Plaintiffs had failed to state a claim even under Rule 8. (ADD9.) Because affirmance is appropriate for the reasons set forth below, this Court also need not address this issue. However, if this Court concludes that the SAC adequately states a claim under Rule 8, it should remand to the district court for a determination of whether Rule 9(b) applies

III. PLAINTIFFS' SECTION 11 CLAIM WAS PROPERLY DISMISSED

Plaintiffs do not allege that the registration statement contained any affirmative misstatements; they allege omissions only. (Pls.' Br. at 8–10, 22–23.) Accordingly, to state a Section 11 claim, Plaintiffs were required to allege that: (1) the registration statement contained a material omission; (2) Defendants had a duty to disclose the omitted information; and (3) the omitted information existed at the time the registration statement became effective. *See Cooperman*, 171 F.3d at 47. Plaintiffs fail to satisfy any of these requirements.

A. AMAG's Disclosures Were Entirely Appropriate Under *Matrixx*

Plaintiffs devote more than ten pages of their Brief to a discussion of the Supreme Court's recent decision in *Matrixx*, 131 S. Ct. 1309. (*See* Pls.' Br. at 1, 30–39.) Plaintiffs assert, among other things, that the district court erred by: (i) failing to apply the materiality standard enunciated in *Matrixx*, (ii) concluding that the 23 SAEs "were immaterial[] simply because they were not statistically significant"; (iii) deciding "a disputed issue of fact" in determining that the rate of post-marketing SAEs was consistent with the clinical trial rate; and (iv) failing to consider the source, content or context of the 23 SAEs in concluding that

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and, if so, whether the SAC meets that heightened standard. *See U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 384 n.8 (1st Cir. 2011).

disclosure was not required. (*Id.* at 1, 20, 26–31, 41.) The record readily shows, however, that the district court did none of those things.

Contrary to Plaintiffs' repeated assertion, the district court did not discuss or make any findings as to whether the 23 post-marketing SAEs were "statistically significant." Those words do not appear anywhere in the district court's Order. Nor, as Plaintiffs claim, did the district court decide disputed issues of fact. Rather, accepting as true Plaintiffs' allegations that 23 post-marketing SAEs (including two anaphylactoid reactions and one death) had been reported prior to the Offering and that these SAEs affected at most 0.45 percent of patients treated with *Feraheme*, the district court concluded – correctly – that such facts could not give rise to a duty of disclosure because they were consistent in rate and kind with the SAEs that had already been repeatedly disclosed to the public by AMAG and the FDA. (ADD13–16.) In so doing, the district court engaged in precisely the kind of "contextual" analysis called for by *Matrixx* and reached the only conclusion consistent with its principles. 131 S. Ct. at 1321.

1. The *Matrixx* decision

In *Matrixx*, the plaintiffs alleged that Matrixx Initiatives, Inc. had committed securities fraud under Section 10(b) of the Exchange Act by making false and misleading statements about Zicam – an over-the-counter nasal spray. 131 S. Ct. at 1315–16. Among other things, plaintiffs alleged that Matrixx had received "information that plausibly indicated a reliable causal link between Zicam and anosmia [the

loss of smell]," including reports from medical professionals presented at an industry conference. *Id.* at 1322. In addition, nine product liability lawsuits had been filed against Matrixx asserting a causal link between Zicam and anosmia. *Id.* Nevertheless, the company, without disclosing any of this information, made unabashedly positive statements that it expected revenues from Zicam "to rise 50 and then 80 percent." *Id.* at 1323. Thereafter, when the anosmia data was publicized by others, Matrixx characterized it as "completely unfounded and misleading" and stated that Zicam's safety was "well established," even though, as Matrixx later conceded, the scientific evidence was "insufficient . . . to determine if [Zicam] . . . affects a person's ability to smell." *Id.* The Supreme Court held that the complaint adequately alleged a claim for securities fraud. *Id.* at 1317–23.

In so holding, the Court reaffirmed the "total mix" standard for materiality enunciated in *Basic*. *Id.* at 1321–22 ("The question remains whether a *reasonable* investor would have viewed the nondisclosed information 'as having *significantly* altered the 'total mix' of information made available.'") (emphasis in original) (quoting *Basic*, 485 U.S. at 231–32). The Court then rejected the bright-line rule advocated by defendants that adverse event reports need only be disclosed if they establish a statistically significant causal link between the adverse event and the product. *Id*. at 1321.

Importantly, however, the Court also clarified that the mere existence of adverse event reports is not sufficient to trigger a duty to disclose:

> **Application of *Basic*'s "total mix" standard does not mean that pharmaceutical manufacturers must disclose all reports of adverse events**. Adverse event reports are daily events in the pharmaceutical industry . . . . [T]he mere existence of reports of adverse events – which says nothing in and of itself about whether the drug is causing the adverse events – will not satisfy this standard. **Something more is needed**, but that something more is not limited to statistical significance . . .

Id. (emphasis added). Further, the Court reaffirmed that "[s]ilence, absent a duty to disclose, is not misleading," and emphasized that the principles in *Matrixx* "do not create an affirmative duty to disclose any and all material information." *Id.* at 1321–22; *see also Hill v. Gozani*, 651 F.3d 151, 152 (1st Cir. 2011) ("In *Matrixx*, the Court specifically reaffirmed the long-standing rule that the possession of material, non-public information does not create an automatic duty to disclose.").

Applying these standards, the Court concluded that plaintiffs had adequately pled a Section 10(b) claim based on the company's failure to disclose the risk that Zicam may cause anosmia. 131 S. Ct. at 1322-23. Among other things, *Matrixx* had attacked reports that Zicam caused anosmia as "unfounded and misleading" and falsely asserted that the safety of Zicam was "well established," when, in fact, "Matrixx had evidence of a biological link between Zicam's key ingredient and anosmia, and it had not conducted any studies of its own to disprove that link." *Id*. at 1323.

2. *Matrixx* requires dismissal of the SAC

This case is readily distinguishable from *Matrixx*. First, Zicam was an over-the-counter product. Accordingly, it had not been subjected to the rigorous clinical trials and adverse event reporting that *Feraheme* and other controlled drugs must undergo. Second, *Matrixx* involved entirely undisclosed risks. The company had *never disclosed* a potential link to anosmia or that even one user had reported experiencing such an event. In contrast, as detailed below, AMAG provided repeated and extensive disclosures in the FDA-approved product insert for *Feraheme*, in public filings, and in the Offering Documents regarding *Feraheme's* safety risks. And third, not only did Matrixx fail to disclose the anosmia risk, when reports began to surface that users were suffering from anosmia, it affirmatively represented that Zicam was safe even though it lacked the scientific evidence to support that claim. 131 S. Ct. at 1316. The SAC contains no comparable allegations. Rather, AMAG marketed and sold *Feraheme* only after (i) all of its safety risks were disclosed to the FDA and the public; and (ii) the FDA's own experts concluded that its benefits to adult CKD patients outweighed those risks. Accordingly, rather than lending any support to Plaintiffs' claims, *Matrixx* supports dismissal of the SAC as AMAG provided extensive disclosures regarding the very safety risks that form the basis of Plaintiffs' claims. The "something more" required by *Matrixx* is simply absent here. *See id.* at 1316.

3. The 23 SAEs did not alter the safety profile for *Feraheme*

Notwithstanding AMAG's extensive prior disclosures, Plaintiffs claim that the "reported occurrences of anaphylaxis and a death materially changed the safety profile of Feraheme" and that the district court was required to decide a disputed issue of fact in order to conclude otherwise. (Pls.' Br. at 28; *see also id.* at 18.) Plaintiffs are wrong.

In the SAC, Plaintiffs assert that the post-marketing incidence rate of SAEs was at most 0.45 percent of all patients who received *Feraheme*. (A53–54 (¶¶ 106–108).) Even assuming the SAE rate was that high (it was not), it pales in comparison to the SAE incidence rate of 2.9 percent observed in the fourth Phase III clinical trial and disclosed in the Offering Documents. (A191 (2008 10-K); A134 (Reg. Stmt.); A173 (Prospectus).)[12] In addition, Plaintiffs allege that 16 of the 23 patients who reported SAEs experienced "one or more symptoms associated with anaphylaxis." (A34 (¶ 71).) Even using Plaintiffs' most aggressive assumption that only 8,750 patients had received *Feraheme* as of February 5, 2010, this amounts to a serious hypersensitivity rate of at most 0.18 percent, which is also entirely consistent with (and below) the expected incidence rate of 0.2 percent disclosed in the FDA-approved product insert. (A34–35, 53–54 (¶¶ 71–74, 106– 108); A250 (07/01/09 8-K); A255

[12] The publicly reported rate of incidence of SAEs in the first three Phase III trials was 9.8 percent, or *twenty times higher*. (A211 (2007 10-K).)

(Product Insert).)[13] As such, Plaintiffs' assertion that the 23 SAEs were somehow more "serious" or frequent than those previously disclosed by AMAG (Pls.' Br. at 34) is belied by Plaintiffs' own allegations.

Plaintiffs also make much of the fact that a single death was reported. (*See* Pls.' Br. at 19–20, 28.) But the fact that a single patient died after receiving *Feraheme* should have come as no surprise to investors given that AMAG repeatedly disclosed in its SEC filings prior to the Offering that "mortality rates among . . . CKD patients are high" and that 19 patients (or roughly 1.1%) died in clinical trials after receiving the drug. (*See* A212 (2007 10-K); A183 (01/31/08 8-K).)[14] Moreover, Plaintiffs concede that AMAG evaluated the circumstances of the death and determined that it was not caused by *Feraheme*. (A52-53 (¶ 104); *see also* A328 (02/05/10 Tr.).) Plaintiffs have never challenged that determination, much less attempted to explain how a single death unrelated to *Feraheme* among at least 8,750 very sick CKD patients might have factored into a reasonable investor's decision to participate in the Offering.

In sum, disclosure of the 23 SAEs was not required, as they were consistent in rate and kind with those previously disclosed by AMAG and, therefore,

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[13] In fact, the product insert discloses that 3.7 percent (or 63/1,726) of *Feraheme* patients in clinical trials experienced adverse reactions potentially associated with hypersensitivity.

[14] At that rate, one might have expected at least 96 patients treated with *Feraheme* (1.1 percent of 8,750) to have died by the time Plaintiffs filed suit.

immaterial as a matter of law. *Matrixx*, 131 S. Ct. at 1321–22. To conclude otherwise would be tantamount to adopting a bright line rule that post-marketing SAEs are always material, regardless of whether a *reasonable* investor would view them as *significantly* altering the total mix of information. *Matrixx* explicitly rejects such a rule and mandates dismissal of Plaintiffs' Section 11 claim for failure to plead a material omission.

4. That AMAG's stock price dropped following an analyst downgrade does not transform previously disclosed SAEs into material non-public information

Plaintiffs' final materiality argument is that materiality can be inferred from the fact that AMAG's stock price dropped 15 percent following publication of the Summer Street report and a total of 24 percent by the time Plaintiffs filed suit. (Pls.' Br. at 37–39.) This argument fails, too. As one court has succinctly put it: "[w]hat is important to the materiality inquiry is what Defendants said in the statements challenged by Plaintiffs, not what happened to the price of [defendant's] stock." *In re Daktronics, Inc.*, No. 08-4176, 2010 WL 2332730, at *14 (D.S.D. June 9, 2010). Accordingly, this Court and others routinely find omissions immaterial notwithstanding significant stock price declines. *See e.g.*, *Glassman v. Computervision Corp.*, 90 F.3d 617, 619–21 (1st Cir. 1996) (no materiality despite 30 percent decline in share price); *Pyramid Holdings, Inc. v. Inverness Med. Innovations, Inc.*, 638 F. Supp. 2d 120, 126–27 (D. Mass. 2009)

(allegedly omitted disclosures were immaterial despite a "significant[]" decline in the defendants' share price).

Markets move for all sorts of reasons. *See, e.g., Pyramid Holdings*, 638 F. Supp. 2d at 126 ("[N]ot every market reaction necessarily bespeaks a prior omission or misrepresentation . . . .") Here, the decline in AMAG's stock price followed the downgrade of AMAG's stock by the Summer Street analyst, a risk that AMAG explicitly disclosed in the prospectus. (A164–65.) But whether the stock price decline was a reaction to the downgrade, or the analyst's characterization of reported SAEs, or the fact that the analyst claimed that the "adoption rate" for *Feraheme* was slowing, or any number of other possibilities, is unknown and beside the point. *See Geiger v. Solomon-Page Group, Ltd.*, 933 F. Supp. 1180, 1188 (S.D.N.Y. 1996) (decline in stock price did not evince materiality of omission where stock price might have fallen for many other reasons). The 23 SAEs at issue were consistent with AMAG's prior disclosures and, thus, immaterial under *Basic* and *Matrixx*.

B. AMAG Had No Duty To Disclose the 23 SAEs

Even if the 23 SAEs constituted material, nonpublic information, the Section 11 claim would still fail. AMAG had no affirmative duty to disclose the 23 SAEs in the registration statement pursuant to any statute or regulation; nor was disclosure required to make other statements in that document not misleading.

1. The 23 SAEs were not "required to be stated" pursuant to Regulation S-K

Section 11 liability arises where a registration statement fails "to state a material fact required to be stated therein." *Shaw*, 82 F.3d at 1204 (quoting 15 U.S.C. § 77k(a)). Information is not "required to be stated" merely because it is material. Rather, to trigger this prong of Section 11, there must be a specific statutory or regulatory obligation requiring disclosure. *See id.*; *Cooperman*, 171 F.3d at 49–52 (board level conflict regarding corporate strategy was material, but no Section 11 liability existed because there was no affirmative duty to disclose pursuant to statute or regulation).

Here, Plaintiffs identify two regulatory provisions – Items 303 and 503 of Regulation S-K – that they assert created an affirmative duty on the part of AMAG to disclose the 23 SAEs. (A49–50 (¶ 99); Pls.' Br. at 25.) As the district court correctly held, neither is availing to Plaintiffs. (ADD15–16.)

a. AMAG did not violate Item 303

Item 303 requires a company to "[d]escribe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." 17 C.F.R. § 229.303(a)(3)(ii). A trend or uncertainty must be "both presently known to management and reasonably likely to have material effects on the registrant's financial condition or results of operation." Sec. Act Release No. 6835, 1989 WL 1092885, at *4

(May 18, 1989). Thus, Item 303 only requires disclosure where information known by a defendant indicates there is a "substantial likelihood that [actual events will] turn out to be an *extreme departure* from publicly known trends and uncertainties." *Glassman*, 90 F.3d at 631 (emphasis added) (quoting *Shaw,* 82 F.3d at 1194).

Here, Plaintiffs allege that AMAG violated Item 303 because, "[a]t the time of the Offering, SAEs were being reported, but [were] not disclosed to the public." (A49 (¶ 99(a)); *see also* Pls.' Br. at 39–43.) Plaintiffs allege that these SAEs "established a clear and significant pattern . . . by the time the Offering was conducted," and argue that the unfavorable impact that this pattern of SAEs was likely to have on AMAG's financial performance necessitated disclosure. (A35 (¶ 74); *see also* A49 (¶ 99(a)); Pls.' Br. at 39–43.) Plaintiffs' allegations fail for at least three reasons.

First, Item 303 is inapplicable. AMAG filed an SEC Form S-3 registration statement, not an S-1. (A40 (¶ 84); A127–38 (Reg. Stmt.).) Item 303 does not apply to Forms S-3, and "a Form S-3 registrant is not required separately to furnish in the prospectus the information required by Item 303(a) . . . ." *Shaw*, 82 F.3d at 1205; *see also* SEC Form S-3 (available at http://www.sec.gov/about/forms/forms-3.pdf) (requiring the registrant to provide, *inter alia*, the information required by Items 202, 401–03, 407, 502–12, 601, 702, but not Item 303). Although the district court found it unnecessary to address this issue, this Court can and should reject Plaintiffs' Item 303 claim in light of this obvious and incurable defect. *See Haley*, 657 F.3d at 46 (affirmance appropriate on any ground evident in record).

Second, AMAG disclosed in its registration statement and elsewhere that SAEs were observed in clinical trials, the frequency of those SAEs and their attendant risks to investors in the Offering. Moreover, the 23 SAEs alleged by Plaintiffs were entirely consistent in rate and kind with those previously disclosed by the Company. (*See* ARGUMENT, Section III.A., *supra*, at 28–35.)[15] Accordingly, disclosure of the 23 post-approval SAEs was not required under Item 303 (even assuming it applied) as they were not an "extreme departure from publicly known trends and uncertainties." *Glassman*, 90 F.3d at 631 (quoting *Shaw,* 82 F.3d at 1194). And the single post-approval death was not a "trend" at all. (ADD16 ("[O]ne death does not a trend make.").) Rather, these SAEs merely *continued* a known trend or uncertainty that had already been disclosed.[16] *See, e.g.*, *In re IAC/InterActiveCorp Sec. Litig.*, 695 F. Supp. 2d 109, 117-118 (S.D.N.Y. 2010) (holding that Item 303 did not require disclosure of fact that hotel suppliers were improving their own online capacities as this trend had

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[15] Investors are presumed to be familiar with the Company's prior disclosures. *See, e.g., Garber v. Legg Mason, Inc.*, 537 F. Supp. 2d 597, 611–12 (S.D.N.Y. 2008), *aff'd*, 347 F. App'x 665 (2d Cir. 2009) (no duty to disclose in prospectus where allegedly omitted information was already publicly reported in SEC filings); *Wielgos v. Comm. Edison Co.*, 892 F.2d 509, 517 (7th Cir. 1989) (rejecting Section 11 claim based on omission of public information as "[i]t would be pointless and costly to compel firms to reprint information already in the public domain).

[16] Even the analyst who downgraded AMAG in February 2010 conceded that she could not conclude that the reported SAEs were of a greater frequency or severity than those observed in the clinical trials. (A306.)

been disclosed in earlier filings); *City of Roseville Employees' Ret. Sys. v. EnergySolutions, Inc.*, No. 09-8633, 2011 WL 4527328, at *26 (S.D.N.Y. Sept., 30, 2011) (dismissing Item 303 claim where plaintiffs did "not allege that the negative incentives of the LOP contracts or the infirmities in the market for the License Stewardship Initiative were uncertain or changed over time, but rather that they were always present"). Conversely, it would indeed have been an extreme departure from expectations if, following the Offering, the very ill CKD patients receiving *Feraheme* suddenly stopped experiencing the SAEs that occurred in clinical trials. No reasonable investor (or drug company) could have expected such a result.

Third, Item 303 is concerned with trends and uncertainties that "the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." 17 C.F.R. § 229.303(a)(3)(ii). Notably, AMAG's revenues from the sale of *Feraheme* actually increased from $13,056,000 in the first quarter of 2010 (the quarter during which the Offering took place) to $16,014,000 in the second quarter of 2010. (A341 (May 6, 2010 Form 10-Q); A349 (Aug. 5, 2010 Form 10-Q).) Thus, the "trend" or "uncertainty" that Plaintiffs assert AMAG should have reasonably expected (and, thus, disclosed) as of the January 21, 2010 Offering did not even materialize during the relevant period.

b. AMAG did not violate Item 503

Plaintiffs also allege that the Offering Documents failed to comply with Item 503(c) of Regulation S-K, 17 C.F.R. § 229.503(c) (hereinafter, "Item 503"). Item 503

requires a "discussion of the most significant factors that make the offering risky or speculative." *Id.* Plaintiffs assert that "[t]he material fact that safety issues existed as to *Feraheme* was a significant factor that made the Offering 'risky or speculative.'" (A49–50 (¶ 99(b)); *see also* Pls.' Br. at 45–47.) This argument fails as well.

As discussed above, AMAG fully disclosed to investors the safety issues and SAEs associated with *Feraheme* as well as the risks they posed to AMAG's business. Indeed, one of the explicit risk factors cited in AMAG's prospectus was "safety concerns related to *Feraheme*." (A164.) AMAG also warned of the possibility that "[s]ignificant safety . . . problems could arise . . . resulting in recalls, restrictions in *Feraheme's* label, or withdrawal of *Feraheme* from the market." (A157) Accordingly, Plaintiffs' assertion that AMAG violated Item 503 by failing to disclose *Feraheme's* safety issues in the Offering Documents simply is not credible. *See Panther Partners, Inc. v. Ikanos Commc'n, Inc.*, 538 F. Supp. 2d 662, 672–74 (S.D.N.Y. 2008) (manufacturer's disclosure of general risk of defects and bugs was sufficient; disclosure of specific defect not required by Item 503); *Lin v. Interactive Brokers Group, Inc.*, 574 F. Supp. 2d 408, 419-20 (S.D.N.Y. 2008) (Item 503 not violated as cautionary language concerning the company's technology was sufficient to put reasonable investors on notice regarding risks).

2. Disclosure of the 23 SAEs was not necessary to make statements in the Offering Documents not misleading

Plaintiffs also argue that disclosure of the 23 SAEs was required because the Offering Documents were materially misleading without it. (Pls.' Br. at 41–43.) More specifically, Plaintiffs claim that the risk disclosures in the Offering Documents were mere "boilerplate . . . concerning the *potential* impact of adverse safety events that may occur, and failed to disclose that those risks had already materialized and would impact the Company's business." (*Id.* at 42.) This argument finds no support in the record.

First, the FDA-approved product insert specifically warns that: "Feraheme may cause serious hypersensitivity reactions, including anaphylaxis and/or anaphylactoid reactions. In clinical studies, serious hypersensitivity reactions were reported in 0.2% (3/1,726) of subjects receiving Feraheme." (A255.) This language makes clear both that hypersensitivity reactions *may* occur, and that they *had already occurred*. (*See also* A191 (2008 10-K) (describing severe anaphylactoid reaction that was determined to be drug-related).) Indeed, the label specifically warns physicians to monitor patients for 30 minutes to be sure that such events do not occur. (A255.) Thus, the only reasonable interpretation of the *Feraheme* label is that the risk of anaphylaxis and other SAEs is present and real.[17]

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[17] Plaintiffs repeatedly point to AMAG's statement in its 2008 10-K that "[a]cross all phases of the *Feraheme* clinical development

Second, AMAG specifically identified "[s]afety concerns related to *Feraheme*" as a risk factor affecting the Offering. (A164 (Prospectus).) As Plaintiffs point out, the prospectus also identified risk factors pertaining to safety issues that could arise in the future. (*See* Pls.' Br. at 42; A157 (disclosing, among other things, that: (1) "Significant safety . . . problems could arise with respect to *Feraheme* even after FDA approval . . . ."; and (2) "New safety . . . issues may arise as *Feraheme* is used over longer periods of time . . . ."; and (3) "if significant safety . . . issues arise, FDA approval for *Feraheme* could be withdrawn . . . .").) But AMAG did not warn of these potential risks *in lieu* of present risks; it disclosed both. Indeed, in light of

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program . . . , there were no cases of anaphylaxis and no deaths *determined by the investigator to be drug-related*" as evidence that investors were misled into believing that these SAEs had never been reported, but that is demonstrably false. (Pls.' Br. at 9, 44; A42 (¶ 86) (emphasis added).) First, AMAG repeatedly reported the death rate among *Feraheme*-treated patients in clinical trials. (*See* A212 (2007 10-K); A183 (01/31/08 8-K).) Moreover, the 2008 10-K, itself, discusses an anaphylactoid reaction caused by the drug. (A191.) Finally, the product insert – publicly disclosed three months later – confirms that anaphylaxis and anaphylactoid reactions had been reported and may occur post-approval. (A255.) The point of the statement in the 2008 10-K was not that these events had not been reported (as Plaintiffs misleadingly suggest), but that, aside from a single case of anaphylactoid reaction, the clinical trial investigators had not concluded that the events were *caused by the drug*. The 23 SAEs are no different, in this sense, from the SAEs reported during clinical trials, as Plaintiffs have never asserted that any of the 23 SAEs were "drug-related" or causally linked to *Feraheme*; nor could they under *Matrixx*. 131 S. Ct. at 1321. The mere existence of adverse event reports (which is all Plaintiffs have ever alleged) does not reflect any causal relationship between the drug and the SAE. *Id.*

Feraheme's label, no reasonable investor could have interpreted the identification of potential future risks as suggesting that serious safety issues relating to *Feraheme* had not already arisen.

The Eleventh Circuit's decision in *Oxford Asset Mgmt., Ltd. v. Jaharis*, 297 F.3d 1182, 1193 (11th Cir. 2002), illustrates the point. In *Oxford*, plaintiffs argued that the offering documents were false and misleading as they failed to disclose the high percentage (88%) of patients who would experience a side effect after using the company's only drug, Niaspan. However, the company had disclosed:

> Although most patients taking Niaspan® will sometimes flush, the formulation and dosing regimen for Niaspan® have been designed to maximize patient acceptance and minimize the occurrence of flushing. There can be no assurance, however, that patients using Niaspan® will not suffer episodes of flushing that they consider intolerable.

Id. Although the disclosure did not contain the level of detail sought by plaintiffs, the court held: "In view of this and other candid statements about the side effect of flushing that appear in the prospectus, we hold that the prospectus was not misleading in this respect." *Id.*

This Court's recent decision in *Hill v. Gozani* is also instructive. 651 F.3d at 151. There, plaintiff asserted that NeuroMetrix violated Section 10(b) by failing to disclose that the billing codes used to obtain reimbursement from insurers and Medicare for its neurological medical device were improper. The district

court dismissed the complaint, and this Court affirmed. Its rationale was simple: after examining "the statements actually made by NeuroMetrix during the period," it concluded that, unlike in *Matrixx*, "NeuroMetrix's statements acknowledged a risk to its business posed by nonreimbursement for its customers." *Id.* at 152–53.

Here, as in *Oxford* and *Hill*, the Offering Documents fully and fairly disclosed the risks posed by *Feraheme's* safety profile and its unproven track record. They disclosed that serious hypersensitivity reactions had occurred, and warned that such reactions could occur in the future. Indeed, unlike in *Oxford*, the Offering Documents here actually disclosed the clinical rate of incidence of the precise SAEs at issue. As such, disclosing the 23 SAEs would not have changed the safety profile, and their omission from the Offering Documents was in no way misleading. *See Pyramid Holdings*, 638 F. Supp. 2d at 125 ("Defendant's explicit disclosure of the precise risk upon which Lead Plaintiff rests its claim is ground for dismissal."); *In re Bausch & Lomb, Inc. Sec. Litig.*, 592 F. Supp. 2d 323, 354 (W.D.N.Y. 2008) (dismissing Section 11 claim as eye products' risks were disclosed in public filings).

C. Facts Arising After the Offering Should Be Disregarded

Unable to identify material facts existing at the time of the Offering that were improperly omitted from the Offering Documents, Plaintiffs resort to pleading facts that occurred long after the Offering in an attempt to establish actionable omissions. Plaintiffs allege that: (i) the FDA implemented a Tracked Safety

Issue protocol regarding *Feraheme* in August 2010, seven months after the Offering (A22, 55–58, 60 (¶¶ 15, 111–13, 119); Pls.' Br. at 13–14, 35); (ii) two clinics ceased using *Feraheme* in response to safety concerns, and demand for the drug declined in the third quarter of 2010, six to eight months after the Offering (A58, 63 (¶ 113, 125); Pls.' Br. at 7, 26, 35–37, 40); (iii) additional SAEs had been reported as of October 2010, nine months after the Offering (A20, 33, 35–36 (¶¶ 7, 66, 75)); (iv) the FDA issued a Warning Letter on October 18, 2010, nine months after the Offering (A23, 38–40, 48–49 (¶¶ 17–18, 80–83, 97–98); Pls.' Br. at 14, 45–47); and (v) the FDA announced new warnings to be included in *Feraheme's* label on November 29, 2010, nine months after the Offering (A37, 55–62 (¶¶ 79, 111–123); Pls.' Br. at 14–15, 20, 35.) These post-Offering allegations are irrelevant in the Section 11 context and do nothing to cure the SAC's fatal defects.

Omissions are not actionable under Section 11 unless the allegedly omitted information existed at the time the registration statement became effective. *Cooperman*, 171 F.3d at 47; *Shaw*, 82 F.2d at 1204. Plaintiffs make no effort – nor could they – to establish that any of these events occurring many months after the Offering were known to Defendants (or even knowable) at the time of the Offering in January 2010. *See Zucker v. Quasha*, 891 F. Supp. 1010, 1017 (D.N.J. 1995) ("'Even Section 11 . . . does not impose liability for the omission of material information which was unknown to . . . defendants.'") (citation omitted); *Panther*, 538 F. Supp. 2d at 672 (dismissing omission claim concerning development revealed four months later and rejecting attempts to reverse-engineer facts

based on hindsight). Moreover, as the public disclosures related to these events (and the events themselves) all occurred months after this lawsuit was filed, they could not possibly have caused the losses that Plaintiffs seek to recover.[18]

1. Plaintiffs badly distort the record in discussing post-Offering events

Although it is clear that Plaintiffs' post-Offering allegations need not and should not be considered, Plaintiffs' flagrant efforts to distort and conflate those allegations to give the false impression that they existed at the time of the Offering necessitate limited, additional discussion. For example, on page 19 of their Brief, Plaintiffs argue that the 23 SAEs "were far more serious than the safety profile of Feraheme indicated in the Offering Documents," "were of particular concern to the close-knit community of nephrologists targeted by AMAG," and "had an immediate impact on the Company's financial performance" when two large nephrology clinics decided to stop using *Feraheme* in light of safety concerns. (Pls.' Br. at 19 (emphasis added) (citing A58 (¶ 113)).) However, the cited paragraph of the SAC makes clear that the clinics at issue "decided to stop using Feraheme in the third quarter" of 2010 – six months after the Offering. (A58

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[18] Although loss causation is an affirmative defense and not part of the prima facie case in a Section 11 or 12(a)(2) action, dismissal is nevertheless appropriate where, as here, the absence of loss causation is apparent from the face of the complaint. *See Stumpf v. Garvey*, No. 03-1352, 02-MDL-1335, 2006 WL 39237, at *1 (D.N.H. Jan. 6, 2006); *In re McKesson HBOC, Inc. Sec. Litig.,* 126 F. Supp. 2d 1248, 1262 (N.D. Cal. 2000).

(¶ 113).) Plaintiffs do not allege that there was any similar reaction, immediate or otherwise, to the 23 SAEs, and, indeed, the record reflects that demand for *Feraheme* grew in the first two quarters of 2010. (*See* ARGUMENT, Section III.B.1.a., *supra*, at 39-40.)

Similarly, on page 18 of their Brief, Plaintiffs assert that AMAG's disclosure on February 5, 2010 of the SAE rate across the 35,000 *Feraheme* injections administered post-marketing "was questioned by analysts, and the FDA later found that AMAG had 'inconsistently and inaccurately' reported SAEs." In fact, the FDA concerns that Plaintiffs allude to (and mischaracterize) did not come "later" (*see* Pls.' Br. at 18); they were identified in the FDA's October 17, 2008 Complete Response Letter and resolved to the FDA's satisfaction prior to approval. (A32 (¶¶ 60–62).)

As a final example, Plaintiffs repeatedly refer to discussions between the FDA and AMAG that ultimately led to changes to *Feraheme's* label. For instance, on pages 31–32 of their Brief, Plaintiffs assert that the "materiality of [the 23 SAEs] was affirmed when, based on [those] reports, the FDA later mandated that AMAG relabel Feraheme to include stricter warnings regarding Feraheme's link to anaphylaxis and serious adverse events." (*See also* Pls.' Br. at 13–14, 20, 35.) As the SAC and Plaintiffs' own papers make clear, however, discussions with the FDA about *Feraheme*'s label took place in late September 2010, eight months after the Offering, and the label change did not occur until two months after that. (A416 (Skovron Aff., Ex. 2); A37 (¶ 79).) Moreover, the FDA's decision to require stricter labeling for *Feraheme* was based, not on the 23 SAEs as Plaintiffs misleadingly

suggest, but on SAE reports received in "the 13 month period since *Feraheme's* approval" and in new clinical trials that were "ongoing" as of September 2010. (A416 (Skovron Aff., Ex. 2).) The notion that Defendants could have anticipated a label change in January 2010, months before these new SAE reports occurred or the FDA raised any concerns, is disingenuous at best.

2. Nothing in the FDA's Warning Letter necessitated further disclosure in the Offering Documents

In a last ditch effort to manufacture a viable Section 11 claim, Plaintiffs point to an October 2010 FDA Warning Letter purportedly "charging the Company with making material misrepresentations and omissions on its website regarding the risks associated with Feraheme use and unapproved uses for Feraheme." (*See* Pls.' Br. at 45–46 (citing A23, 38–40 (¶¶ 17, 80–83)).) Plaintiffs assert that "a material portion of the Company's revenues" as of the time of the Offering was traceable to the allegedly problematic website materials, thereby triggering a duty to disclose under Item 503. (*Id*.) This argument, too, is baseless.

As an initial matter, Plaintiffs badly mischaracterize the Warning Letter. (A23 (¶ 17) (alleging that the Warning Letter contained a "finding that the Company had . . . misbranded Feraheme" in violation of applicable law).) A warning letter is not, as Plaintiffs allege, a "finding" of regulatory non-compliance, and it did not "charge" AMAG with anything; rather, it is "informal and advisory . . . [and i]t communicates the agency's position on a matter, but it does not commit [the] FDA to taking enforcement

action." FDA Regulatory Procedures Manual, 2004 WL 3363386, at *2 (March 2010); *see also Anderson v. Abbott Labs.*, 140 F. Supp. 2d 894, 902 (N.D. Ill. 2001) ("There is nothing magical about the warning letter. Although the language sounds ominous, it really is rather boilerplate.").

Moreover, as the district court properly noted, the SAC fails to tie the Warning Letter to any specific time period pre-dating the Offering. (ADD18); *In re Discovery Labs. Sec. Litig.*, No. 06-1820, 2006 WL 3227767, at *9 (E.D. Pa. Nov. 1, 2006) (dismissing securities claims where no allegation that defendants knew about warning letters at the time of the challenged statements). Plaintiffs have never asserted (and do not assert in their Brief) that the allegedly problematic content giving rise to the Warning Letter was on AMAG's website at the time of the Offering, nine months before the letter was sent, much less that Defendants could reasonably have anticipated at that time that the FDA would ultimately raise the concerns it did. Nor, for that matter, does the SAC or Warning Letter provide any support for Plaintiffs' bald proposition that a material portion of AMAG's revenues as of January 2010 derived from the allegedly problematic language. Thus, there is no reason to believe – and it simply is not alleged – that the Offering Documents were misleading as of their effective date with respect to any matters raised in the Warning Letter.

Finally, Plaintiffs' assertion that Defendants violated Section 11 by failing to warn investors of the risk that the FDA might issue a warning letter or take other actions adverse to AMAG's business fails for the

simple reason that those precise risks were, in fact, disclosed in the prospectus:

> We are subject to ongoing FDA regulatory requirements and review pertaining to *Feraheme's* . . . labeling, . . . advertising, [and] promotion . . . . Failure to comply with such regulatory requirements or the later discovery of previously unknown problems with *Feraheme* . . . may result in restrictions on our ability to market and sell *Feraheme* . . . . We may also be subject to additional sanctions, including but not limited to: **FDA warning letters**; . . . [and] FDA-imposed label changes . . . . **Any of these sanctions would have a material adverse impact on our ability to generate revenues and to achieve profitability.**

(A156 (emphasis added).) Thus, the Warning Letter is incapable of establishing an actionable omission.

IV. PLAINTIFFS' SECTION 12 CLAIM WAS PROPERLY DISMISSED

To state a claim under Section 12(a)(2), a plaintiff must adequately allege that: (1) each defendant was a "seller" of the securities sold in the Offering; (2) the prospectus contained a misstatement of fact or failed to state a fact necessary to make a statement not misleading; and (3) the false or misleading statement was material. *See* 15 U.S.C. § 771(a)(2). Plaintiffs' Section 12(a)(2) claims were properly dismissed as to the AMAG Defendants for two reasons.

First, because the second and third prongs of Section 12(a)(2) mirror the elements of Section 11, dismissal of Plaintiffs' Section 12(a)(2) claim was appropriate for all of the reasons discussed above.

Second, none of the AMAG Defendants was a statutory "seller." Under Section 12(a)(2), only a statutory "seller" (i.e., a person who "offers or sells a security") may be held liable, and then only to persons who "purchas[ed] such security from him." 15 U.S.C. § 771(a)(2). In *Shaw*, this Court held that, in a firm-commitment underwriting – where the issuer sells its stock to the underwriters, rather than to individual investors – the company is not a statutory seller and will only be held liable if it actively "solicited" the Plaintiffs' purchases "in the manner of a broker or vendor's agent." 82 F.3d at 1215–16.

Here, Plaintiffs acknowledge that the Offering was a firm-commitment offering and that they bought their stock from the Underwriters, not AMAG. (A66 (¶ 139); A167 (Prospectus).) Accordingly, Plaintiffs do not assert in their Brief that the AMAG Defendants are statutory "sellers"; rather, they focus exclusively on whether the Underwriter Defendants satisfy this standard. (*See* Pls.' Br. at 47–50.) Moreover, the SAC alleges merely that the AMAG Defendants "actively solicited" the sale of AMAG stock through "the preparation and dissemination of the Prospectus, participating in road shows, and the planning and orchestrating of all [necessary] activities" (A66 (¶ 140)), which is plainly insufficient. *See Shaw*, 82 F.3d at 1216 ("[n]either involvement in preparation of a registration statement or prospectus nor participation in 'activities' relating to the sale of securities, standing alone,

demonstrates the kind of *relationship between defendant and plaintiff* that could establish statutory seller status.") (emphasis in original). As such, the Section 12(a) claim was properly dismissed.

V. PLAINTIFFS' SECTION 15 CLAIM WAS PROPERLY DISMISSED

The SAC asserts a Section 15 claim against AMAG officers Pereira and Arkowitz based solely on AMAG's alleged violations of Sections 11 and 12(a)(2). (A67–68 (¶¶ 148–52).) "[B]ecause plaintiffs have failed to state a claim for a primary violation of either § 11 and § 12(a)(2), they have fallen short of stating a claim under § 15" as well. (ADD 19); *see also Cooperman*, 171 F.3d at 52.

VI. THE DISTRICT COURT PROPERLY DENIED LEAVE TO AMEND

"Although a court's denial of a motion to amend is typically reviewed for an abuse of discretion, in this case the district court neither granted nor denied a motion to amend." *Gray v. Evercore Restructuring LLC*, 544 F.3d 320, 327 (1st Cir. 2008). This is because Plaintiffs never moved the district court under Rule 15(a) of the Federal Rules of Civil Procedure for leave to file a third amended complaint. Rather, Plaintiffs' opposition to Defendants' motion to dismiss merely included legal boilerplate and a one-sentence request for leave to replead "if any aspect of the complaint has been inadequately pled." (A409-10.) A request of that nature does not constitute a Rule 15(a) motion, and "the district court cannot be faulted for failing to grant such leave *sua sponte*." *Gray*, 544 F.3d at 327; *see also*

Confederate Mem'l Ass'n v. Hines, 995 F.2d 295, 299 (D.C. Cir. 1993) (same) (internal citations omitted); *Royal Bus. Group, Inc. v. Realist, Inc.*, 933 F.2d 1056, 1066 (1st Cir. 1991) ("[I]t is the practice in this circuit that, when a plaintiff, rather than amending, chooses to appeal from a judgment of dismissal, the court of appeals, if the order of dismissal is affirmed, will not permit an amended complaint to be filed.")

Even if Plaintiffs' request were deemed a motion to amend, the district court's implicit denial was well within its discretion. While Rule 15(a) requires that leave be "freely given when justice so requires," district courts "need not grant every request to amend, come what may." *Epstein*, 460 F.3d at 191 (describing as an "uphill battle" an effort to reverse a district court judge's refusal to permit amendment). "Reasons for denying leave include . . . repeated failure to cure deficiencies . . . and futility of amendment." *U.S. ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 48 (1st Cir. 2009).

Here, Plaintiffs concede in the SAC that they have had access to a tremendous amount of material, including AMAG's public documents, FDA materials obtained via FOIA request and otherwise, and interviews with former AMAG employees. Further, the SAC is the third iteration of the allegations submitted by Plaintiffs. Accordingly, it is clear that Plaintiffs' failure to state a claim is not from a lack of information or opportunity, but rather because no claims exist. Under these circumstances, further amendment would be futile, and "[c]onsiderations of fairness, judicial economy, and congressional purpose in enacting the Securities Laws all point to a denial of discovery and to

dismissal of [Plaintiffs'] complaint with prejudice." *Carney v. Cambridge Tech. Partners, Inc.*, 135 F. Supp. 2d 235, 257 (D. Mass. 2001) (quotations omitted); *see also Powers v. Boston Cooper Corp.*, 926 F.2d 109, 111 (1st Cir. 1991) ("[T]he district court gave Powers three chances to plead his case. That should have been ample. Though hope may spring eternal, a trial judge need not allow a litigant – particularly a counselled litigant – an infinite number of chances to state an actionable claim.").

Plaintiffs argue for the first time on appeal that amendment is warranted insofar as *Matrixx* was decided three months after the SAC was filed, and leave to amend will permit Plaintiffs "to include additional contextual facts available to them in accordance with the new Supreme Court rule." (Pls.' Br. at 54.) This argument fails for at least three reasons.

First, although *Matrixx* was decided before Plaintiffs filed their opposition brief, they never argued in the district court that amendment was warranted under *Matrixx*. (A409-10.) By failing to raise this argument below, Plaintiffs have waived it on appeal. *Rocafort v. IBM Corp.,* 334 F.3d 115, 121 (1st Cir. 2003) ("The law in this circuit is crystalline: a litigant's failure to explicitly raise an issue before the district court forecloses that party from raising the issue for the first time on appeal.") (citation omitted).

Second, Plaintiffs insist that they should be permitted to add additional facts regarding the "source, content and context" of the 23 SAEs in light of the "new" rule announced in *Matrixx*. (Pls.' Br. at 53, 54.)

However, as discussed above, *Matrixx* did not create a new rule; rather the Court simply reaffirmed the context-based "total mix" standard articulated in *Basic*. *Matrixx*, 131 S. Ct. at 1320. Plaintiffs fail to explain, because they cannot, why any additional facts they might add were not included in the SAC in the first place. *See Epstein*, 460 F.3d at 190– 91 (district court did not abuse its discretion in refusing to grant leave to amend when matters in amendment could have been stated in prior complaint).

Third, Plaintiffs have never attempted to articulate what new facts they might allege to cure the deficiencies in their pleading. This is not surprising. All the "context" in the world will not change the fact that AMAG repeatedly disclosed the very SAEs about which Plaintiffs now complain. Accordingly, granting Plaintiffs leave to file a fourth complaint would still be futile after *Matrixx*. *Id.* at 191.

Finally, Plaintiffs claim that, "[a]t the very least, the District Court should have granted leave to replead with respect to Plaintiffs' allegation regarding AMAG's misrepresentations on its website." (Pls.' Br. at 54.) As discussed above, however, even if Plaintiffs could allege a temporal connection between the October 2010 Warning Letter and the January 2010 Offering nine months earlier (they cannot), the risk of a warning letter was specifically disclosed to investors in the Offering Documents. (*See* ARGUMENT, Section III.C.2., *supra*, at 48-50.) Accordingly, amendment of these allegations would also be futile.

CONCLUSION

For the foregoing reasons, the AMAG Defendants respectfully request that the Court affirm the order of the district court dismissing the SAC with prejudice.

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Respectfully submitted,

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[Certificate of Compliance Omitted for Purposes of this Appendix]

[Certificate of Service Omitted for Purposes of this Appendix.]

APPENDIX H

15 U.S.C. § 77l. Civil liabilities arising in connection with prospectuses and communications

(Effective: December 21, 2000)

(a) In general

Any person who--

* * *

(2) offers or sells a security (whether or not exempted by the provisions of section 77c of this title, other than paragraphs (2) and (14) of subsection (a) of said section), by the use of any means or instruments of transportation or communication in interstate commerce or of the mails, by means of a prospectus or oral communication, which includes an untrue statement of a material fact or omits to state a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading (the purchaser not knowing of such untruth or omission), and who shall not sustain the burden of proof that he did not know, and in the exercise of reasonable care could not have known, of such untruth or omission,

shall be liable, subject to subsection (b) of this section, to the person purchasing such security from him, who may sue either at law or in equity in any court of competent jurisdiction, to recover the consideration paid for such security with interest thereon, less the amount of any income received thereon, upon the tender of such security, or for damages if he no longer owns the security.

* * *

15 U.S.C. § 77o. Liability of controlling persons

(Effective: July 22, 2010)

(a) Controlling persons

Every person who, by or through stock ownership, agency, or otherwise, or who, pursuant to or in connection with an agreement or understanding with one or more other persons by or through stock ownership, agency, or otherwise, controls any person liable under sections 77k or 77l of this title, shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person had no knowledge of or reasonable ground to believe in the existence of the facts by reason of which the liability of the controlled person is alleged to exist.

* * *

15 U.S.C. § 78j. Manipulative and deceptive devices

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange--

* * *

(b) To use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, or any securities-based swap agreement any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

* * *

17 C.F.R. § 240.10b-5. Employment of manipulative and deceptive devices.

It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,

* * *

(b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to

make the statements made, in the light of the circumstances under which they were made, not misleading, or

* * *