United States Court of Appeals
For the First Circuit

No. 11-2063

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.

John C. Dwyer, with whom Angela L. Dunning, Robert B. Lovett, Gilles R. Bissonnette, Karen L. Burhans, and Cooley LLP, were on brief for the AMAG appellees.

Tariq Mundiya, with whom Sameer Advani, Willkie Farr & Gallagher LLP, Kevin J. O'Connor, and Hinckley, Allen & Snyder LLP, were on brief for the Underwriter appellees.

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.

[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").

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 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

[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.

concerning "Serious Adverse Events" ("SAEs") that resulted during Feraheme's clinical trials.[3] For example, in a January 31, 2008 SEC 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]

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[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 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 . . .

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

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by injection of epinephrine." The FDA eventually concluded that Feraheme could cause anaphylaxis.

[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."

> 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 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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> . . . .
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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 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).

[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 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.

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 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

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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)).

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 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.

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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.

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 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.
>
> . . . .
>
> 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]

[9] The parties heavily relied on Matrixx in their briefs and oral arguments to the Court. Matrixx, however, addressed claims of

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

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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").

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]

[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

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 "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.

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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.

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.