United States Court of Appeals
For the First Circuit

No. 15-1544

EDMOND GANEM,

Plaintiff, Appellant,

BATTLE CONSTRUCTION CO., INC., individually and on behalf of all others similarly situated; STEVE ADAMS,

Plaintiffs,

v.

INVIVO THERAPEUTICS HOLDINGS CORP.; FRANK REYNOLDS,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Richard G. Stearns, U.S. District Judge]

Before

Howard, Chief Judge,
Selya and Lipez, Circuit Judges.

Thomas G. Shapiro, with whom Patrick J. Vallely and Shapiro Haber & Urmy LLP were on brief, for appellant.

Michael G. Bongiorno, with whom James W. Prendergast, Andrew S. Dulberg, Wilmer Cutler Pickering Hale and Dorr LLP, Richard J. Rosensweig, Paul F. Beckwith, Derek B. Domian, and Goulston & Storrs PC were on brief, for appellee InVivo Therapeutics Holdings Corp.

Richard J. Rosensweig for appellee Frank Reynolds.

January 9, 2017

LIPEZ, **Circuit Judge**. Following a drop in the share price of InVivo Therapeutics Holdings Corporation's ("InVivo") common stock, investors filed suit against the company and its former chief executive officer ("CEO"), Frank Reynolds, alleging securities fraud in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), as well as the Securities and Exchange Commission's ("SEC") Rule 10b-5, 17 C.F.R. § 240.10b-5. On behalf of himself and a putative class of shareholders, lead plaintiff Edmond Ganem ("Ganem") alleges that InVivo and Reynolds inflated the value of InVivo's common stock for about five months in 2013 by issuing false or materially misleading press releases concerning the approval of human clinical trials for a new medical device the company was developing, by, inter alia, failing to identify the caveats and conditions imposed by the Food and Drug Administration ("FDA") for the clinical trials. The district court, in a well-reasoned opinion, granted defendants' motion to dismiss the complaint. We affirm, agreeing with the district court that Ganem has failed to allege false or misleading statements sufficient to state a claim under Section 10(b) and Rule 10b-5, and, having failed to plead a viable claim of a primary violation, Ganem's control person claim against Reynolds under Section 20(a) was also properly dismissed.

I.

A. Factual Background

According to InVivo's 2012 annual report to the SEC ("Form 10-K"), which was filed in early March 2013, the company focuses on "develop[ing] and commercializ[ing] new technologies for the treatment of spinal cord injuries." The report identified InVivo's "Lead Product Under Development" as "biopolymer scaffolding," a device that would attach to a patient's body at the point of a spinal injury to prevent additional damage to the spinal cord. The report outlined the company's strategy for marketing the device, including the steps for securing the required approval from the FDA.

The report explained that InVivo would first need to obtain an Investigational Device Exception ("IDE") to permit it to conduct human clinical trials. Such a clinical study was a prerequisite for obtaining either Pre-Market Approval ("PMA") or a Humanitarian Device Exemption ("HDE"), either of which would permit the company to sell the product in the United States. InVivo stated that it "plan[ned] to conduct an initial clinical study to evaluate the device in five spinal cord injury patients with acute thoracic injuries. We are also planning a larger follow-on human study in acute spinal cord injury patients after the initial study is completed."

In the report, InVivo qualified the above statements, noting that "forward-looking statements" -- such as "statements about our plan to conduct an initial clinical study to evaluate our product" -- are necessarily contingent because they "involve substantial known and unknown risks." InVivo stated that "[t]he start of clinical trials can be delayed or take longer than anticipated for many and varied reasons, many of which would be outside of our control."

On March 29, 2013, the Acting Director of the FDA's Office of Device Evaluation sent an eleven-page letter to InVivo. Because Ganem's claims rely on the proposition that InVivo later misrepresented the content of the letter, we quote from it at some length:

> The [FDA] has reviewed your amendment to your [IDE] application to conduct an early feasibility study . . . . Your application to begin your study is approved with conditions . . . . You may begin your investigation, using a revised informed consent document which corrects deficiency number 1 and 3, at an institution in accordance with the investigational site waiver granted below. Your investigation is limited to 3 institutions and 1 subject.
>
> Your IDE application has been approved with conditions as a staged study; you may enroll one subject at this time. You should follow this subject for 3 months before requesting approval for an additional subject, who should also be followed for three months before requesting another subject. This will result in a total of 5 subject[s] enrolled over a minimum 15 month period. . . .

> A feasibility study is a preliminary study which is not expected to provide the primary support for the safety and effectiveness evaluation of a medical device for the purposes of a marketing application. . . . FDA believes that additional modifications, as outlined in "Study Design Considerations" below, are needed for your study design to support a future study.
>
> This approval is being granted on the condition that, within 45 days from the date of this letter, you submit information correcting the following issues[.]

The FDA listed thirteen issues for which it required further information before the initial study could begin.[1] Then, under "Study Design Considerations," the FDA stated that "[w]e recommend, but do not require, that you modify your study to address the following issues" so that it could support a future study, listing eight specific issues.[2]

The following week, on April 5, 2013, InVivo issued the three-page press release at the heart of Ganem's complaint:

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[1] These thirteen issues required InVivo to, among other things: make revisions to its draft informed consent document, provide results from preclinical animal testing, provide certain test protocols and reports for FDA review, and remove specified language from product labeling.

[2] These modifications included, for example: a recommendation to include a randomized control group; a recommendation that InVivo "pre-specify . . . effectiveness and safety endpoints"; a recommendation that InVivo "include the age range of the study population" in the "Indications for Use"; and a recommendation that InVivo accompany all symbols on its "carton labeling" (such as "Rx") with descriptive text.

> InVivo Therapeutics Receives Approval from FDA for First Human Trial Using Biomaterials for Traumatic Spinal Cord Injury
>
> . . . InVivo Therapeutics Holdings Corp. . . . today announced that the U.S. Food and Drug Administration (FDA) has approved the Company's Investigational Device Exemption (IDE) to begin human studies to test its biopolymer scaffold product, a technology developed to treat patients with acute, traumatic SCI.
>
> With this approval, InVivo intends to commence a first-in-man clinical study in the next few months that will test safety and performance of its biopolymer scaffold in five patients. The Company expects the study to occur over approximately 15 months. There are currently no treatment options approved by the FDA, or in clinical trials, to intervene directly in the spinal cord following SCI. The trial will be conducted at multiple U.S. hospitals, and work to gain Institutional Review Board (IRB) approval at Massachusetts General Hospital in Boston is already underway.
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> " . . . [W]hen conducting a first-in-man study, it is imperative to take the time to get it right, because any mistakes can lead to years of lost time for the scientists and patients that follow," said Frank Reynolds, InVivo Chief Executive Officer.
>
> . . .
>
> Continued Reynolds, "Over the next month or so, we plan to finalize the details of our study, and we expect to have all data to the FDA by the end of 2014. We will be conducting an open label study, and so we look forward to keeping the public aware of its progress. . . ."

The press release did not reveal that FDA approval was conditional, or list any of the conditions, or explain that the FDA had recommended changes to the study protocol in order to allow

the staged study to support future studies. The release did, however, contain a "Safe Harbor Statement" indicating that certain statements in the press release were covered by the Exchange Act's statutory safe harbor for "forward-looking statements."[3] The safe harbor statement explained that the covered statements included "those related to the expected approval of the FDA to conduct human clinical trials for the Company's products, the expected commencement date of any approved human clinical trials, the expected size of the pilot study, the expectation that the scaffold product will be regulated under an HDE pathway, and the expected acceleration of commercialization of the Company's products resulting therefrom[,]" which were "subject to a number of risks and uncertainties[,]" including "risks and uncertainties relating to the Company's ability to obtain FDA approval to conduct human clinical trials[.]" The release also referred to InVivo's Form 10-K, which described the potential risks in more detail.

Ganem alleges that the price of InVivo stock increased as a result of the apparent good news contained in the press

[3] The Exchange Act's safe harbor provision is found in 15 U.S.C. § 78u-5. Under this provision, a person "shall not be liable" with respect to any "forward-looking statements when not made with knowledge of falsity or when the statement itself is identified as forward-looking and is accompanied by 'meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement.'" Hill v. Gozani, 638 F.3d 40, 54 (1st Cir. 2011) (quoting 15 U.S.C. § 78u–5(c)(1)(A)(i)).

release. Historical stock prices cited by both parties indicate that there was a relatively high volume of trading on Monday, April 8, 2013, after the press release the previous Friday. That day, the stock price rose from $2.85 per share to $3.19 per share.

Ganem also points to alleged misrepresentations in another press release from May 9, 2013. In that release, Reynolds was quoted as saying "[w]e are off to a great start for 2013 and continue to successfully accelerate our plans[.]" It also reiterated some of the statements made a month earlier: "In April 2013, the FDA approved InVivo's Investigational Device Exemption (IDE) application to begin human studies to evaluate its biopolymer scaffold product for acute traumatic SCI. . . . [T]he product will be evaluated in five patients. The Company expects to commence the study in mid-2013 and submit data to the FDA by the end of 2014." The May 9 release contained a safe harbor statement similar to the one in the April 5 release. Ganem does not allege any change in InVivo's stock price resulting from the May 9 release.

Finally, on August 27, 2013, before regular trading hours, InVivo issued a press release titled "InVivo Therapeutics Updates Clinical Plan." That release said:

> The Company now expects that, based on the judgment of new management, it will enroll the first patient during the first quarter of 2014.

> Under the conditions of the FDA's approval of the Investigational Device Exemption, the five-person pilot trial will be staggered such that each patient will be followed for three months prior to requesting approval to enroll the next patient. Because the Company must obtain FDA approval to enroll each subsequent patient, the Company anticipates that from the date of the first enrolled patient, it will take at least 21 months to complete enrollment. Consistent with FDA guidance, the Company then expects to conduct a pivotal study with a control group to obtain FDA approval to commence commercialization under a Humanitarian Device Exemption.

Interim CEO Michael Astrue was quoted as saying: "While the study will take additional time, we look forward to bringing this important therapy into the clinic."

Ganem alleges that InVivo's stock price dropped in reaction to the revised 2014 start date and estimated 21-month time for completion of the clinical trial revealed in this press release. Historical stock prices show that an unusually high volume of trading started on Friday, August 23, 2013, and continued from Monday, August 26 through the end of the class period on August 28. The stock price fluctuated during those four trading days, ultimately dropping from $4.00 per share at the opening of trading on August 23 to $2.07 at the close of trading on August 28.

B. Procedural Background

Ganem brought this action against InVivo and its former CEO, Reynolds, on behalf of a putative class "consisting of all persons and entities who purchased the common stock of [InVivo]

from April 5, 2013, through August 26, 2013, inclusive" -- i.e., all purchasers of stock between the dates of the initial announcement of the clinical trial and the press release nearly five months later that revealed problems with the timeline for the trial. The operative amended complaint asserted two claims: first, that InVivo and Reynolds deceived investors into buying common stock at high prices, artificially boosted by the false or misleading press releases, in violation of § 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5; and, second, that Reynolds is liable as a "controlling person" under § 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

The district court rejected both claims, concluding that Ganem had failed adequately to plead material misrepresentations or scienter supporting a claim under § 10(b) and Rule 10b-5, and that, absent a primary violation under § 10(b), Ganem's derivative control person claim against Reynolds must be dismissed. Battle Constr. Co., Inc. v. InVivo Therapeutics Holdings Corp., 101 F. Supp. 3d 135, 141-42 & n.6 (D. Mass. 2015). We focus on the claim under § 10(b) and Rule 10-b5 (the "10(b) claim").[4] We review a

[4] Because, as we explain, the district court properly dismissed the § 10(b) claim, the derivative control person claim under § 20(a) was also properly dismissed. Automotive Indus. Pension Tr. Fund v. Textron Inc., 682 F.3d 34, 36 n.2 (1st Cir. 2012).

dismissal for failure to state a claim de novo. SEC v. Tambone, 597 F.3d 436, 441 (1st Cir. 2010) (en banc). We accept as true all well-pleaded allegations in the complaint and make all reasonable inferences in favor of the pleader. Id.

II.

A. The Exchange Act and Rule 10-b5.

Section 10(b) of the Exchange Act "forbids the 'use or employ, in connection with the purchase or sale of any security . . . , [of] any manipulative or deceptive device . . . .'" Tellabs Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 318 (2007) (alteration in original) (quoting 15 U.S.C. § 78j(b)). The SEC has implemented this provision via Rule 10b-5, which proscribes, among other things, "any untrue statement of a material fact" or omission of any "material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5. To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must plead the following elements: (1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. In re Ariad Pharm., Inc. Sec. Litig., 842 F.3d 744, 750 (1st Cir. 2016)(citing ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008)).

Only the first two elements -- a material misrepresentation or omission and scienter -- are implicated by this appeal. Though Ganem contests the district court's conclusions as to both, we begin and end with the first.[5] To establish a material misrepresentation or omission, Ganem must show "that defendants made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading." Geffon v. Micrion Corp., 249 F.3d 29, 34 (1st Cir. 2001). "[M]ere possession of material, nonpublic information does not create a duty to disclose it," Hill, 638 F.3d at 57 (internal punctuation omitted), but "when a company speaks, it cannot omit any facts 'necessary in order to make the statements made, in the light of the circumstances under which

[5] InVivo also argues that its forward-looking statements are protected by the bespeaks caution doctrine, which "embodies the principle that when statements of 'soft' information such as forecasts, estimates, opinions, or projections are accompanied by cautionary disclosures that adequately warn of the possibility that actual results or events may turn out differently, the 'soft' statements may not be materially misleading under the securities laws." Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1213 (1st Cir. 1996); see also id. at 1213 n.23. InVivo does not, however, invoke the statutory safe harbor codifying the bespeaks caution doctrine, 15 U.S.C. § 78u-5(c)(1), because, it explains, "arguably, the [statutory] safe harbor does not apply to the challenged statements because, while InVivo is now listed on the NASDAQ, the Company could have been, at the time, considered an issuer of 'penny stock.'" See id. § 77z-2(b)(1)(C) (excluding issuers of "penny stock" from the statutory safe harbor). Because the absence of a material misrepresentation or omission is determinative, we need not decide the applicability of either the bespeaks caution doctrine or the statutory safe harbor to InVivo's statements.

they were made, not misleading.'" Id. (quoting 17 C.F.R. § 240.10b-5); see also Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 37 (2011)

Finally, "[a]s with all allegations of fraud, a plaintiff must plead the circumstances of the fraud with particularity, pursuant to Rule 9(b)." Hill, 638 F.3d at 55. Moreover, under the additional pleading requirements imposed by the Private Securities Litigation Reform Act ("PSLRA"), in order to survive a motion to dismiss, the plaintiff must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." ACA Fin. Guar. Corp., 512 F.3d at 58 (modification in original) (quoting 15 U.S.C. § 78u–4(b)(1)); see also Hill, 638 F.3d at 54-56 (discussing the history and purpose of the PSLRA). As we have previously noted, although "the PSLRA does not require plaintiffs to plead evidence . . . a significant amount of 'meat' is needed on the 'bones' of the complaint." Id. at 56 (citation omitted).

B. Analysis of the Claims.

Ganem claims that the statements in InVivo's April 5 and May 9 press releases about the projected timeline for the preliminary study were materially false or misleading. Specifically, with regard to the start date of the study, the April 5 release expressed the intention that the study begin "in the next few months," and the May 9 release predicted it would start

"in mid-2013." Regarding the duration of the study, the April 5 release said that InVivo "expects the study to occur over approximately 15 months." As for the end date of the study, the April 5 release said "we expect to have all data to the FDA by the end of 2014," and the May 9 release predicted that InVivo would "submit data to the FDA by the end of 2014."

Ganem claims that InVivo's failure to mention the details of the FDA approval letter rendered these statements materially false or misleading. He cites three allegedly material omissions: (1) the FDA's requirement that InVivo satisfy a number of conditions within 45 days (including correcting the informed consent form before testing could begin on the first human subject); (2) the FDA's recommendation that InVivo modify its study design so that the preliminary study could serve as the basis for approval of a larger follow-on study; and (3) the FDA requirement of a staged study, in which separate FDA approval was required for each of five stages.

According to Ganem, the FDA's conditions, recommendations, and requirement of a staged study inevitably prevented InVivo from following through on its stated timeline. He alleges that "Defendants failed to disclose in the April 5 and May 9 press releases that the FDA's approval of the clinical study included conditions that made it impossible to complete the study in 15 months or to submit data to the FDA by the end of 2014, as

represented." Am. Compl. ¶ 34. In short, Ganem's theory of material misrepresentation is that InVivo's omissions about the content of the FDA approval letter rendered the company's temporal predictions materially misleading.

Like the district court, however, we readily conclude that none of the challenged statements is false or misleading. We discuss each of the allegedly false or misleading statements in turn.

1. Commencement of the Clinical Trial.

Ganem contends that InVivo misrepresented the imminence of the commencement of the study when the company reported in April that it would begin "in the next few months" and in May that it was expected to begin "in mid-2013." According to Ganem, the "mid-2013" start date provided by InVivo would be impossible to achieve given the conditions imposed by the FDA, thus making InVivo's optimistic statements materially misleading. However, as the district court found, "any objective reading of the [approval] letter makes clear that the FDA erected no material barriers to an immediate enrollment of the first patient for the exploratory study." Although the FDA required particular changes to the informed consent form before the first human was tested, Ganem understandably does not argue that simply changing a form could have delayed the beginning of the study. Also, as the district court found, "[w]hile the FDA did require additional information

of a corrective nature from InVivo, it did not condition the first enrollment on the prior receipt of this information." In fact, the FDA's letter explicitly permits a start date in the near future: "[InVivo] may enroll one subject at this time." Further, although the FDA required additional information within 45 days, Ganem alleges no facts suggesting that InVivo would fail to meet that deadline. And, though InVivo needed to obtain Institutional Review Board approval to use each testing site, Ganem alleges no facts suggesting that this would delay the beginning of the study beyond the "few months" InVivo projected. Indeed, InVivo represented in the April 5 press release that it was already "work[ing] to gain Institutional Review Board (IRB) approval at Massachusetts General Hospital," making clear that the approval had not yet been obtained.

Ganem also alleges that InVivo's statements regarding commencement of the study were misleading because the FDA letter required InVivo to make eight specific modifications to its initial feasibility study for that study to support a future, separate study, and implementing such modifications would make InVivo's proposed timeline impossible to meet. As an initial matter, this argument fails for the simple reason that Ganem alleges no facts suggesting that InVivo could not make these eight changes within the proposed timeline, a necessary showing for the statements to have been misleading when made. See 15 U.S.C. § 78u–4(b)(1); ACA

Fin. Guar. Corp., 512 F.3d at 62 ("The PSLRA requires plaintiffs' complaint to 'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading.'") (alteration in original). Moreover, the FDA did not require InVivo to make these eight changes before commencing its initial feasibility study. The FDA, in fact, stated that "[w]e recommend, but do not require, that you modify your study to address the following issues." Although Ganem alleges that going forward without the recommended changes would have made "no sense" and would serve "no purpose," Ganem's own speculation and conjecture about InVivo's business decisions cannot substitute for well-pleaded facts.

2. Duration of the Clinical Trial

In alleging that InVivo's statements regarding the estimated duration of the study were false or misleading, Ganem relies on the proposition that a fifteen-month duration was impossible, particularly in light of the sequential patient enrollment process that the FDA required, which InVivo did not disclose in its April 5 and May 9 press releases.[6] Ganem

[6] Ganem similarly argues that "[InVivo's] statement that the FDA 'has approved' a study to evaluate 'five patients' was false." This claim is without merit. InVivo's April 5 release says that the FDA approved InVivo's plan "to begin human studies," and that "InVivo intends to commence a . . . study . . . in five patients," and its May 9 release repeats that the approval was "to begin human studies," adding that "the product will be evaluated in five patients." These statements are not "literally false" as Ganem

acknowledges, however, that the FDA itself wrote that the staged study "will result in a total of 5 subject[s] enrolled over a minimum of [a] 15 month period." Ganem also acknowledges, as he must, that if each subject was observed for the required three months and then the next subject was enrolled almost immediately, observing five subjects would take approximately fifteen months.

Ganem insists, however, that it would be impossible to do this study in these fifteen months because of the steps necessary after each patient was observed for the requisite three months -- at a minimum, reviewing the data, preparing a report for the FDA, and waiting for FDA approval to proceed with the next patient. As with Ganem's other claims, however, this timing allegation is not supported by any well-pleaded facts. We have no basis on which to conclude that it would take a significant length of time to complete the steps for each patient, and the only available evidence -- the FDA's own letter suggesting a fifteen-month minimum testing period -- suggests the opposite.

3. Submitting data to the FDA

As for the timing of InVivo's submission of data to the FDA at the end of the study, Ganem relies on the assumption that analyzing the data from the study would take a significant amount

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claims. InVivo correctly stated that the FDA had approved a clinical trial expected to ultimately include five patients. InVivo did not say that the FDA had already approved the enrollment of all five patients.

of time after all five patients had been observed for three months each. Again, Ganem provides no facts supporting this assertion. Ganem does not explain why he believes that the analysis and preparation of the data could only begin after all the data is collected, nor does he point to any FDA requirement that InVivo actually analyze the data at all before submitting it. Ganem's allegations amount to nothing more than unsupported speculation.

Thus, to support a claim that InVivo's statements were false or misleading, Ganem is left only with the inference that because, in retrospect, the test lagged significantly behind the proposed timeline, the timeline must have always been impossible to achieve. Yet, as the district court properly recognized, "fraud by hindsight" does not satisfy the pleading requirements in a securities fraud case. See ACA Fin. Guar. Corp. 512 F.3d at 62 ("A plaintiff may not plead 'fraud by hindsight'; i.e., a complaint 'may not simply contrast a defendant's past optimism with less favorable actual results' in support of a claim of securities fraud." (quoting Shaw 82 F.3d at 1223)); Gross v. Summa Four, Inc., 93 F.3d 987, 991 (1st Cir. 1996). The securities laws do not make it unlawful for a company to publicize an aggressive timeline or estimate for a proposed action without disclosing every conceivable stumbling block to realizing those plans. Hence, while "greater clairvoyance" might have led InVivo to propose a more conservative timeline, "failure to make such perceptions does not

constitute fraud." Denny v. Barber, 576 F.2d 465, 470 (2d Cir. 1978) (Friendly, J.).

III.

In sum, Ganem has failed to allege any material misrepresentation or omission sufficient to state a claim under § 10(b) and Rule 10b-5. Hence, the district court properly dismissed the complaint.

Affirmed.