UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 14-13180-RGS

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

v.

INVIVO THERAPEUTICS HOLDINGS CORP. and
FRANK REYNOLDS

MEMORANDUM AND ORDER
ON DEFENDANTS' MOTION TO DISMISS

April 3, 2015

STEARNS, D.J.

This is a federal securities class action brought on behalf of purchasers of common stock of defendant InVivo Therapeutics Holdings Corp. during the period from April 5, 2013, through August 26, 2013. Lead plaintiff Edmond Ganem alleges that InVivo intentionally misrepresented in a company press release the conditions imposed by the Food and Drug Administration (FDA) in approving a first-in-human clinical study of InVivo's biopolymer scaffold spinal injury repair product. The Amended Complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. InVivo and individual defendant Frank Reynolds

move to dismiss both counts pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state an actionable claim.

BACKGROUND

InVivo is a Massachusetts-based biotechnology company that seeks innovative treatments for spinal cord injuries. Defendant Frank Reynolds served as InVivo's Chairman, Chief Executive Officer, and Chief Financial Officer until August 22, 2013. On April 4, 2013, InVivo announced through a press release that FDA had designated its biopolymer Neuro-Spinal Scaffold as a Humanitarian Use Device.[1] By the end of the day, InVivo stock closed at $2.75 a share, up 16 percent from the previous day's closing price of $2.36. Trading volume rose to 683,500 shares, compared to an average 71,000 shares over the previous three trading days.

On April 5, 2013, prior to the market opening, InVivo issued a second press release announcing that the FDA had additionally approved an Investigational Device Exemption[2] for a five-patient pilot study of the

[1] The Humanitarian Use Device designation was created by the 1990 Safe Medical Devices Act to encourage the introduction to market of medical devices intended to treat or diagnose rare diseases manifested in populations of 4,000 or fewer individuals in the United States. 21 U.S.C. § 350j(m).

[2] According to the FDA: "An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data."

Neuro-Spinal Scaffold. The press release stated that InVivo "intend[ed] to commence a first-in-man clinical study in the next few months" and that it "expect[ed] the study to occur over approximately 15 months." Am. Compl. ¶ 22. Reynolds was quoted in the press release as saying that "we expect to have all data to the FDA by the end of 2014." *Id.* ¶ 23. InVivo stock closed at $2.80 a share on April 5, 2013, trading at a volume of 504,900 shares. On the following trading day, April 8, 2013, InVivo stock closed at $3.19 a share with a volume of 1,333,800 shares, and continued to rise over the next month.

On May 9, 2013, in a press release reporting InVivo's first quarter financial results, Reynolds announced that that because InVivo stock "has appreciated significantly since [obtaining FDA approval for the clinical study, InVivo will] call investor warrants that will provide up to $16.1 million of equity capital, but more importantly will remove an accounting liability that has been an impediment to up-listing to a national securities exchange." *Id.* ¶ 30. InVivo also iterated that "[it] expect[ed] to commence the study in mid-2013 and submit data to the FDA by end of 2014." *Id.* ¶ 31.

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http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/investigationaldeviceexemptionide/default.htm (accessed April 3, 2015).

On June 4, 2013, InVivo reported that the call period, which ended on June 3, 2013, had yielded the expected $16.1 million in additional capital. This combined with a warrant exchange offer completed on May 17, 2013, resulted in the elimination of a $24.6 million liability on InVivo's balance sheet. Reynolds was quoted in the press release as saying that "[w]ith the [] elimination of the $24.6 million warrant liability from our books, the last major obstacle to up-listing to a national securities exchange has been removed. We expect that an up-listing to a national security exchange will increase liquidity and unlock inherent value in our stock." *Id.* ¶ 33.

On August 27, 2013, before the market opened, InVivo's new management team[3] announced in a press release that it would be unable to complete the clinical trial within the originally contemplated 15 months.

> 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.

[3] Reynolds had resigned on August 22, 2013, ostensibly for medical reasons.

Id. ¶ 36. By the end of the day, InVivo stock fell from $3.45 to $2.07 a share, trading on a volume of 4,486,500 shares. The following day, the price fell further to $1.71 per share, with a volume of 3,658,000 shares.

In November of 2013, InVivo stated in a press release that it expected to enroll the first patient in the clinical trial during the first quarter of 2014. However, a month later, InVivo disclosed that it would need additional time to supply revised study protocols, supporting materials, and contracts to the six sites where the clinical study was to be undertaken, and that the chosen sites would require from 4 to 12 weeks to review and finalize the contracts. In March of 2014, the first patient enrollment was again deferred to the second quarter of 2014. In April of 2014, InVivo further disclosed that the host sites would require additional surgical training with the Neuro-Spinal Scaffold before patient enrollment could begin. InVivo ultimately enrolled its first clinical study patient in October of 2014.

In the Amended Complaint, Ganem alleges that InVivo in April and May of 2013 publicly embraced an impossibly optimistic timeframe in which to complete the clinical trial because the company was in dire financial straits and desperate for an infusion of capital. Ganem alleges that InVivo was bleeding cash in the Spring of 2013 and had so little in reserve that one analyst predicted it had only a year left on the clock before

depleting all of its available funds. Ganem also alleges that Reynolds was personally motivated to misrepresent the scope of the permission that the FDA had given for the clinical study to reap the profits of from InVivo's artificially inflated stock. Prior to April 5, 2013, and through June 13, 2013, with a two-day exception, Reynold sold 4,250 shares of InVivo common stock daily. After June 13, 2013, Reynold increased his sale of InVivo stock to 12,000 shares daily.

Battle Construction Co., Inc. brought this purported class action lawsuit on July 31, 2014. On October 7, 2014, the court appointed Ganem as the lead plaintiff. He filed the Amended Complaint on October 30, 2014. Defendants moved to dismiss under the Private Securities Litigation Reform Act of 1995 (PSLRA) on December 12, 2014. The court heard oral argument on the briefs on March 24, 2015.

DISCUSSION

Section 10(b) of the Securities Exchange Act forbids

> (1) the "use or employ[ment] . . . of any . . . deceptive device," (2) "in connection with the purchase or sale of any security," and (3) "in contravention of" Securities and Exchange Commission [(SEC)] "rules and regulations." 15 U.S.C. § 78j(b). Commission Rule 10b-5 forbids, among other things, the making of any "untrue statement of a material fact" or the omission of any material fact "necessary in order to make the statements made . . . not misleading." 17 CFR § 240.10b-5 (2004).

Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341 (2005). Under the PSLRA, to make out a section 10(b) claim, "plaintiffs [must] state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, *i.e.*, the defendant's intention 'to deceive, manipulate, or defraud.'" *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007), *quoting Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194, and n.12 (1976). "The effect of [PLSRA's pleading requirement] is to embody in the Act itself at least the standards of Rule 9(b), Fed. R. Civ. P." *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 193 (1st Cir. 1999). Under this heightened pleading standard, "[a] complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324.

Defendants contend that the challenged press releases contain non-actionable forward-looking statements falling under the protections of the "bespeaks caution" doctrine. The "bespeaks caution" doctrine "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). Defendants rely on the press releases' use of predictive verbs such as "intends to," "plan," and "expects," and the cautionary statements in the press releases themselves and in InVivo's Form 10-K Annual Reports to the SEC. The April 5 press release specifically cautions that statements relating 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 a HDE pathway, and the expected acceleration of commercialization of the Company's products resulting therefrom

are "based on current expectations, but are subject to a number of risks and uncertainties." Defs.' Ex. D at 2; *see also See Alt. Energy, Inc. v. St. Paul Fire and Marine Ins. Co.*, 267 F.3d 30, 33 (1st Cir. 2001) (In resolving a motion to dismiss, the court may properly consider "documents the authenticity of which are not disputed by the parties; [] official public records; [] documents central to plaintiffs' claim; or [] documents sufficiently referred to in the complaint."). The Safe Harbor Statement further warns that

> [t]he factors that could cause actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the Company's ability to obtain FDA approval to conduct human clinical trials;

> whether the human clinical trials produce acceptable results; the Company's ability to develop, market and sell products based on its technology; the expected benefits and efficacy of the Company's products and technology in connection with spinal cord injuries; the availability of substantial additional funding for the Company to continue its operations and to conduct research and development, clinical studies and future product commercialization; and, the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies.

Defs' Ex. D at 2; *see also Slayton v. Am. Exp. Co.*, 604 F.3d 758, 769 (2d Cir. 2010) ("[T]he use of linguistic cues like 'we expect' or 'we believe,' when combined with an explanatory description of the company's intention to thereby designate a statement as forward-looking, generally should be sufficient to put the reader on notice that the company is making a forward-looking statement.").

Plaintiff maintains that by concealing the provisional nature of the FDA approval letter and offering a timeline that would have been physically impossible to meet while satisfying the FDA's conditions, defendants misrepresented hard historical facts, and thereby forfeited their shelter under the safe harbor exception. *See Roeder v. Alpha Indus., Inc.*, 814 F.2d 22, 26 (1st Cir. 1987) ("When a corporation does make a disclosure – whether it be voluntary or required – there is a duty to make it complete and accurate. . . . If . . . a company chooses to reveal relevant, material information even though it had no duty to do so, it must disclose the whole

truth."). In particular, plaintiff argues that it would have been out of the question to begin the study "in the next few months," as suggested in the April 5 press release, given the pre-commencement requirements imposed by the FDA, and the bureaucratic process required to finalize arrangements with the investigational site partners (as experience proved). Plaintiff also asserts that the projected fifteen-month timeline was chimerical because it failed to factor in the time required to seek approval from the FDA to proceed with the next sequential human study subject, which would be forthcoming only after the prior patient had been safely followed for three months. (Plaintiff notes in this regard the August 27 corrective press release revising the 15-month study period to 21 months, which was also not achieved). According to plaintiff, these two alleged falsehoods rendered the assertion that InVivo would have study data to the FDA by the end of 2014 a complete no-go from the outset.

However, it is axiomatic that "a securities plaintiff does not satisfy the requirements of Rule 9(b) merely by pleading 'fraud by hindsight.'" *Gross v. Summa Four, Inc.*, 93 F.3d 987, 991 (1st Cir. 1996). "In other words, a general averment that defendants knew earlier what later turned out badly does not convey the necessary particularity that Rule 9(b) requires." *Id.* (internal quotation marks omitted). Plaintiff agrees that the court must

confine its enquiry to the FDA letter itself and what InVivo knew *at the time* it issued the contested press releases. Here is where plaintiff missed the mark. Although it is true that approval was granted "on the condition that, within 45 days from the date of this letter, [InVivo] submit[s] information correcting the following [thirteen] issues,"[4] the FDA also authorized "[InVivo] [to] begin [its] investigation, using a revised informed consent document . . . at an institution in accordance with the investigational site waiver granted below." Defs.' Ex. C. at 2. The approval letter went on to state that "[InVivo] should follow [the first] 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." *Id*.

Plaintiff faults the press releases for failing to make clear that the FDA's approval came with conditions. But any objective reading of the letter makes clear that the FDA erected no material barriers to an immediate enrollment of the first patient for the exploratory study. While 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

[4] Eight additional Study Design Considerations were suggested to support a future follow-up study that was not the subject of the press releases. Defs.' Ex. C. at 2, 7-8.

information. Indeed, the letter explicitly stated that "[InVivo] may enroll one subject *at this time*." *Id*. (emphasis added).

Plaintiff's next challenge is to the statement that the study would begin "in a few months," or "in mid-2013." In this regard, plaintiff objects to the failure of InVivo to own up to the time it would take to make an adequate response to the FDA, and to finalize arrangements (physical and contractual) with the host sites. With respect to the thirteen conditions, the FDA asked for a response within 45 days and plaintiff has alleged no facts that would suggest that InVivo believed *at the time* that it would be unable to conform to the FDA's target date. The site approval process proved prolonged only in retrospect. Plaintiff does not dispute InVivo's statement in the April 5 press release that "work to gain Institutional Review Board (IRB) approval at Massachusetts General Hospital in Boston [was] already underway." Defs.' Ex. D at 1. Nor does plaintiff (again) allege any facts that would suggest that InVivo knew in April of 2013 that it could not obtain site approval within a reasonable timeframe consistent with the necessary sequencing of the studies.

With respect to the duration of the study, plaintiff relies heavily on the assertion that the 15-month forecast was unrealistic. However, the estimate of the study length came from the FDA itself: "This [sequential

enrollment process] will result in a total of 5 subject[s] enrolled over a minimum of 15 month period." Defs.' Ex. C at 2. At best, the press release statements reflect an overly-optimistic opinion on the part of InVivo and Reynolds that they could meet the FDA's suggested timeline, or at worse a parroting of the FDA's own opinion as to the time that would be required.[5] *Cf. Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 2015 WL 1291916, at *7 (U.S. Mar. 24, 2015) ("[A] sincere statement of pure opinion is not an 'untrue statement of material fact,' regardless whether an investor can ultimately prove the belief wrong.").

Because the projected timeline set out in the April 5 and May 9 of 2013 press releases was not implausible (even in light of the conditions imposed by the FDA approval letter), there was no material misrepresentation supporting a claim under Section 10(b).[6] Having failed

[5] Plaintiff also contends that the projection that InVivo would have data in the hands of the FDA in 2014 was also false because it failed to account for the time that would be required to analyze the study data before its submission. However, nothing in the FDA approval letter mandated a particular quantity or duration of analysis.

[6] Without facts to establish that defendants knew the falsity of the statements in the April 5 and May 9 of 2013 press releases, plaintiff's allegations of scienter also miss the mark. *See Greebel*, 194 F.3d at 197 ("[M]erely pleading motive and opportunity, regardless of the strength of the inferences to be drawn of scienter, is not enough."). Moreover, as defendants point out, the desire to raise capital is possessed by virtually all corporations and is too generic to support a strong inference of motive. *See*

to plead a viable claim of a primary violation, plaintiff's control person claim against Reynolds under Section 20(a) must also be dismissed. *See Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 84 (1st Cir. 2002) ("[T]here must be a primary violation for liability under [S]ection 20(a).").

ORDER

For the foregoing reasons, defendants' motion to dismiss is ALLOWED. The Clerk will record the dismissal and close the case.

SO ORDERED.

/s/ Richard G. Stearns

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UNITED STATES DISTRICT JUDGE

Tabak v. Canadian Solar Inc., 549 F. App'x 24, 28-29 (2d Cir. 2013); *see also Cozzarelli v. Inspire Pharm. Inc.*, 549 F.3d 618, 627 (4th Cir. 2008) ("All investments carry risk, particularly in a field like biopharmaceuticals. If we inferred scienter from every bullish statement by a pharmaceutical company that was trying to raise funds, we would choke off the lifeblood of innovation in medicine by fueling frivolous litigation – exactly what Congress sought to avoid by enacting the PSLRA."). Finally, despite the small uptick in daily stock sales, Reynolds sold less than 7% of his InVivo stock during the class period, and his holdings lost more than $21 million in value between August 26 and August 28, 2013.