UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

WANG YAN, individually and on behalf of all other similarly situated parties,	)	**Civil Action No. 17-10169-FDS**
Plaintiff,	)	
v.	)	
REWALK ROBOTICS LTD., LARRY JASINSKI, AMI KRAFT, AMIT GOFFER, JEFF DYKAN, HADAR RON, ASAF SHINAR, WAYNE B. WEISMAN, YASUSHI ICHIKI, ARYEH DAN, GLENN MUIR, BARCLAYS CAPITAL INC., JEFFERIES LLC, and CANACCORD GENUITY INC.,	)	
Defendants.	)	

MEMORANDUM AND ORDER ON DEFENDANTS' MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM

SAYLOR, J.

This is a putative class action alleging violations of Sections 11 and 15 of the Securities Act of 1933 and Sections 10(b) and 20(a) of the Exchange Act of 1934. The plaintiff class purchased common stock of ReWalk Robotics, Ltd. between September 12, 2014 (the date of its initial public offering ("IPO")) and February 29, 2016. The consolidated amended complaint alleges that ReWalk, its officers and directors, and the IPO underwriters concealed material information in its IPO registration statement about ReWalk's failure to comply with FDA regulations, in violation of the Securities Act. It also alleges that after the IPO, ReWalk and certain officers continued to make material false statements after the initial offering, in violation of the Exchange Act. It relies in part on statements by three former ReWalk employees acting as

confidential witnesses.

Defendants have moved to dismiss the complaint for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6) and the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. §§ 78u-4, 78u-5. Defendants contend that the complaint fails to set forth a Securities Act violation because it does not identify a misleading statement or omission in the registration statement. They also argue that the complaint fails to set forth an Exchange Act violation because the lead plaintiff lacks standing and the information allegedly omitted was not material and was in fact disclosed. In addition, they contend that the complaint fails to allege specific facts that give rise to a strong inference of scienter and that it fails to plead loss causation.

Because the complaint here fails to identify a false or misleading statement in the registration statement, to the extent it alleges violations of the Securities Act, it will be dismissed.

The claims under the Exchange Act, however, present different issues. As a threshold matter, the lead plaintiff in this case, Wang Yan, purchased shares only in September 2014, at the time of the initial public offering; he can therefore assert claims personally only under the Securities Act. Under normal circumstances, he would not have standing to assert claims under the Exchange Act, and those claims would accordingly be dismissed.

This case, however, is subject to the requirements of the PSLRA. That statute requires the appointment of a lead plaintiff, who may not be the party who actually filed the complaint (as here), but who normally has the largest financial interest in the litigation. Under some circumstances, courts have permitted lead plaintiffs appointed under the PSLRA to assert claims as to which they have no personal stake (and, therefore, would not have standing under a traditional legal framework).

The complicating factor here is that the lead plaintiff, Yan, has *no* valid claims remaining after dismissal of the Securities Act claims. Because standing has a constitutional dimension, in addition to the requirements of the PSLRA, it is at least somewhat unclear whether Yan can continue to act as lead plaintiff. Under the circumstances, and because the parties have not briefed or otherwise addressed the issue, the Court will not address the Exchange Act claims at this time. Instead, plaintiffs will be given an opportunity to persuade the Court that Yan remains an appropriate plaintiff; to seek the appointment of a substitute or supplemental lead plaintiff; or to take such other steps as they believe may be proper under the circumstances. In the meantime, the Court will grant the motion to dismiss as to the Securities Act claims, and deny it as to the Exchange Act claims without prejudice to its renewal once the standing issue has been resolved.

Accordingly, and for the reasons set forth below, defendants' motion to dismiss will be granted in part as to Counts One and Two, and denied in part without prejudice as to Counts Three and Four.

I. Background

A. Factual Background

The facts are set forth as described in the consolidated amended complaint.[1]

1. Overview

Defendant ReWalk Robotics, Ltd., formerly known as Argo Medical Technologies, Inc., is a medical device company. It designs and develops exoskeletons, which are devices that help persons with spinal-cord injuries walk. (CAC ¶ 2). The company is incorporated in Israel and

[1] Defendants' motion to dismiss is accompanied by certain exhibits, including communications with the FDA. While ordinarily "any consideration of documents not attached to the complaint, or not expressly incorporated therein, is forbidden . . . courts have made narrow exceptions for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiffs' claim; or for documents sufficiently referred to in the complaint." *Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993). Neither party disputes that the Court may properly consider these documents.

has its U.S. headquarters in Marlborough, Massachusetts. (*Id.* ¶ 26). It was founded by Amit Goffer, who served as CEO and Chief Technical Officer from 2001 until 2012. (*Id.* ¶ 30). Goffer resigned from the company on November 18, 2015. (*Id.*).

At the time of its IPO in September 2014, ReWalk's CEO was Larry Jasinski and its CFO was Ami Kraft. (*Id.* ¶¶ 27, 29). Hadar Ron, Jeff Dykan, Asaf Shinar, Wayne Weisman, Yasushi Ichiki, Glenn Muir, and Aryeh Dan were all members of ReWalk's Board of Directors. (*Id.* ¶¶ 31-37). In January 2015, Kevin Hershberger replaced Kraft as CFO. (*Id.* ¶ 28).

ReWalk currently sells two distinct products: ReWalk Personal, which is designed for everyday use, and ReWalk Rehabilitation, which is designed for clinical rehabilitation centers. (*Id.* ¶ 46). Both devices are regulated in various jurisdictions by the FDA, the European Union, or other governmental agencies. (*Id.* ¶ 94). This litigation concerns only the ReWalk Personal device, which the Court will refer to as the "device."

In 2014, ReWalk submitted the device to the FDA for "de novo" classification. (*Id.* ¶ 47). "De novo" classification allows manufacturers to market devices that are low to moderate risk and not substantially similar to devices that are already being marketed. (*Id.*).

On June 26, 2014, the FDA approved the ReWalk device for marketing. It designated the ReWalk device "Class II," requiring special controls. (*Id.* ¶¶ 48-49).[2] The FDA also ordered the company to conduct a "post-market surveillance" study to determine the product's risks, as required by Section 522 of the Food, Drug, and Cosmetic Act. (*Id.* ¶¶ 4, 48-49; 21 U.S.C. § 360L(a)(1)(A)). FDA regulations require manufacturers to report results of such studies, including important attributes such as the type of test subjects, methodology, data collection

[2] The FDA classifies medical devices into one of three classes—Class I, Class II, and Class III—depending on the risk associated with the device. (*Id.* ¶ 48). Class I devices are considered the safest, and Class III devices are considered the riskiest. (*Id.*).

plan, and patient follow-up. 21 C.F.R. 822.10. The FDA required the study due to concerns that a malfunction could result in serious injury or death. (CAC ¶¶ 4, 49).

The complaint alleges that defendants failed to disclose that ReWalk was either unprepared or unable to comply with the FDA's June 2014 directive that it perform post-market surveillance. (*Id.* ¶¶ 16, 68).

Prior to the IPO, ReWalk filed a registration statement with the SEC, stating that it had developed a "breakthrough product" that would "deliver a natural gait and functional walking speed." (*Id.* ¶ 90). The complaint alleges that the registration statement failed to disclose that the reason the FDA ordered the company to conduct a post-market surveillance study was that the ReWalk device posed a threat of serious injury or death. (*Id.* ¶¶ 85-95).

The initial public offering of ReWalk occurred on September 12, 2014. (*Id.* ¶ 5). The company issued 3 million shares of common stock. (*Id.*). The IPO was underwritten by defendants Barclays Capital Inc., Jefferies LLC, and Canaccord Genuity Inc. (*Id.* ¶¶ 38-40). Lead plaintiff Wang Yan purchased 3,600 shares of ReWalk in September 2014, shortly after the IPO. (Docket No. 7, Ex. C).

Two weeks after the IPO, on September 29, 2014, the FDA contacted ReWalk to inform the company that its proposed post-market surveillance study was deficient. (CAC ¶ 7). Notably, the FDA's letter stated that although the plan was deficient, because less than six months had elapsed since the issuance of the 522 order, the study status would be marked as "Plan Pending" on the FDA's website. (Feldman Decl. Ex. F at 3). The FDA granted ReWalk 30 days to file a response, which it failed to do in a timely fashion. (CAC ¶¶ 7-8). ReWalk eventually filed a response on November 6, 2014. (*Id.* ¶ 8). On February 13, 2015, the FDA found that the November 6 submission was also deficient. (*Id.*). The FDA granted ReWalk

another 30 days to file a further response, and ReWalk responded (late) on May 22, 2015. (*Id.* ¶¶ 8-10). ReWalk stated that it wanted to discuss an issue with the FDA before submitting a formal reply to the February 13 letter. (*Id.* ¶ 10).

According to the complaint, during that time, ReWalk officials held quarterly earnings calls, during which they failed to disclose the company's failure to comply with the FDA's requirement. Specifically, those calls were made on February 12, 2015 (Q4 2014), May 7, 2015 (Q1 2015), August 6, 2015 (Q2 2015), November 11, 2015 (Q3 2015), and February 25, 2016 (Q4 2015). (*Id.* ¶¶ 99-110).

On September 5, 2015, the FDA cautioned ReWalk that it still had not submitted a revised study plan addressing the deficiencies previously identified by the agency. (*Id.* ¶ 13). Having received no response, on September 30, 2015, the FDA issued a warning letter outlining the company's substantial failure to comply with the post-market surveillance requirement. (*Id.* ¶ 14). Specifically, the letter stated that under the 522 order, ReWalk was required to begin its surveillance study "not later than 15 months after the day on which [a 522 order] is issued." (Pl. Ex. C at 2). The 15-month time frame had closed on September 28, 2015. (*Id.*). The letter went on to state that ReWalk had "committed a prohibited act under section 301(q)(1)(C) of the [Food, Drug, and Cosmetic Act]" and that the ReWalk device was "currently misbranded." (*Id.*). The letter was eventually disclosed to the public by the FDA on March 1, 2016. (CAC ¶ 18).

ReWalk's closing stock price the day before the FDA released the letter was $10.48. (*Id.* ¶ 19). The closing price the following day, on March 1, 2016, was $9.07, reflecting a 13% decline in value. (*Id.*). The stock price has steadily declined since, and ReWalk shares are

currently trading at around $0.75 to $1.25.[3]

At the end of March 2016, the FDA exercised its enforcement discretion and allowed ReWalk to continue to market its device, provided that it would initiate the post-market surveillance study by June 1, 2016. (*Id.* ¶ 114). The FDA approved ReWalk's proposed protocol for the study on May 5, 2016. (*Id.* ¶ 115). However, ReWalk did not file timely monthly reports to the FDA in June and July 2016. (*Id.* ¶ 116). Although the approved protocol required 60 subjects from twelve U.S. clinical areas, according to CW-3, ReWalk had only recruited eight subjects from three areas by June 2017. (*Id.* ¶ 117-18).

2. Confidential Witness Allegations

As noted, the complaint alleges in substance that defendants failed to disclose ReWalk's failure to comply with various FDA regulations, both during and after the IPO. In support of those allegations, the complaint relies in part on statements from three confidential witnesses ("CWs"), who were formerly employed by ReWalk.[4]

CW-1 was the Executive Assistant to CEO Jasinski between April 2015 and December 2016. (CAC ¶ 70). She described Jasinski as "micromanaging" ReWalk's day-to-day operations and involving himself in "every single aspect of the business." (*Id.*). According to CW-1, ReWalk had a culture of procrastination, which was "exacerbated by Jasinski's

[3] The Court takes judicial notice of ReWalk's current stock price. *See* Fed. R. Evid. 201(b)(2). Because ReWalk common stock is publicly traded on NASDAQ, its stock price "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." (*Id.*).

[4] Under the PSLRA, a plaintiff may rely on a confidential witness and need not provide his or her name as long as the witness is "described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 51 (1st Cir. 2008) (internal quotation marks omitted). Courts must evaluate confidential witnesses based on factors such as "the level of detail provided by the confidential sources, the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia." *Id.* (internal quotation marks omitted).

micromanagement style." (*Id.* ¶ 71).

CW-1 sat in on weekly meetings between Jasinski and other high-ranking ReWalk officials. (*Id.* ¶ 72). She recalled a meeting where the FDA's September 30, 2015 warning letter was discussed. (*Id.*). Jasinski, CFO Hershberger, and other officials were concerned about possible consequences ReWalk could suffer if it failed to meet FDA requirements. (*Id.* ¶ 73). At some point, the warning letter was also brought to the attention of ReWalk's Board of Directors, chaired by defendant Dykan. (*Id.* ¶ 74).

CW-2 was a Clinical Training Manager at ReWalk from November 2015 to August 2016. (*Id.* ¶ 75). CW-2 reported to ReWalk's Worldwide Training Manager and trained physical therapists at hospitals and rehabilitation centers on how to use the ReWalk device. (*Id.*).[5]

In December 2015, Jasinski convened a company-wide teleconference to discuss ReWalk's plan for a post-market surveillance study. (*Id.* ¶ 76). At the teleconference, defendants "showed no sense of urgency at all to even start the post-market surveillance study before February 2016." (*Id.*). Two months later, the FDA sent another letter to ReWalk citing deficiencies in the company's proposed post-market surveillance study. (*Id.* ¶ 77). Around that time, ReWalk hosted a company-wide meeting in its Marlborough headquarters. (*Id.* ¶ 78). At that meeting, "CW-2 noticed for the first time that there appeared to be some urgency at [ReWalk] to start post-market surveillance." (*Id.*). The Worldwide Training Director instructed CW-2 to recruit subjects for such a study. (*Id.* ¶ 79). However, ReWalk did not recruit a sufficient number of subjects, in part because most insurance companies declined to reimburse users for the ReWalk device. (*Id.*).

CW-3 was the Associate Director of Clinical Operations at ReWalk from February 2016

[5] The complaint does not specify how many levels removed from the named defendants CW-2 was.

to June 2017. (*Id.* ¶ 80). CW-3 was hired to develop and execute ReWalk's post-market surveillance study. (*Id.* ¶ 81). CW-3 initially reported to John Hamilton, the Vice President of Regulatory and Clinical at ReWalk. (*Id.* ¶ 80). After Hamilton stepped down from his position in early 2017, CW-3 reported directly to Jasinski. (*Id.*).

CW-3 stated that before the IPO, ReWalk hired Clinivation, a third-party contract research organization, to prepare documents necessary for a post-market surveillance study. (*Id.* ¶ 82). However, upon joining ReWalk, CW-3 reviewed Clinivation's work and concluded that it was "quite garbage." (*Id.*). Eventually, CW-3 convinced Hamilton to terminate ReWalk's contract with Clinivation; however, Hamilton appeared to have "virtually no experience with clinical trials." (*Id.* ¶ 83). Like CW-2, CW-3 stated that ReWalk's attempt to conduct a post-market surveillance study was hampered by its failure to recruit a sufficient number of subjects after insurance companies refused to reimburse users for the ReWalk device. (*Id.* ¶ 84).

3. Defendants' Statements as to the Securities Act Claims

The complaint alleges that the following paragraphs in ReWalk's September 12, 2014 IPO registration statement were false and misleading:

> **Compelling Clinical Data.** We believe that ReWalk's clinical data differentiates us from our competitors. Clinical data published in established medical journals has demonstrated ReWalk's potential as a safe ambulatory device. We are not aware of any comparable clinical data generated in rigorous trials that has been published with respect to competing exoskeleton products. In addition, our interim analysis of an ongoing clinical study demonstrates improvements in secondary physical conditions, such as reduction in pain and spasticity and improvements in bowel and urinary tract function, body and bone composition, metabolism and physical fitness, as well as reduced hospitalizations and dependence on medications. We believe that continued results of this nature will greatly assist our ability to obtain regulatory clearances and third-party reimbursement.

(CAC ¶ 86).

> **Continue Clinical Studies to Further Demonstrate Health and Economic**

> **Benefits to Support Reimbursement.** We intend to continue to work with hospitals, rehabilitation centers, patient advocacy and support groups and individual users to generate additional data regarding functionality and that supports the health and economic benefits of ReWalk. We will continue to engage and fund researchers and organizations to conduct clinical studies to demonstrate the functionality and utilization of ReWalk and to highlight economic benefits of reductions in medical complications associated with spinal cord injury. We believe that this data will position us to pursue additional third-party reimbursement for our products.

(*Id.* ¶ 88).

> ReWalk is a breakthrough product that can fundamentally change the health and life experiences of users.
>
> . . .
>
> Published clinical studies demonstrate ReWalk's ability to deliver a natural gait and functional walking speed, which has not been shown in studies for any competing exoskeleton. In addition, our interim analysis of an ongoing clinical study and our experience working with health care practitioners and ReWalk users suggests that ReWalk has the potential to provide secondary health benefits. These benefits include reducing pain and spasticity and improving bowel and urinary tract function, body and bone composition, metabolism and physical fitness, as well as reducing hospitalizations and dependence on medications. Because of these secondary medical benefits, we believe that ReWalk has the ability to reduce the lifetime healthcare costs of individuals with spinal cord injuries, making it economically attractive for individuals and third-party payors.

(*Id.* ¶ 90).

The complaint alleges that all three paragraphs were materially false and misleading because defendants failed to disclose that in June 2014 the FDA had directed ReWalk to conduct a post-market surveillance study, and that it did so because the device posed a risk of serious injury or death. (*Id.* ¶¶ 87, 89, 91).

The registration statement included the following additional statements:

> In June 2014, the FDA granted our petition for "de novo" classification, which is a route to market for medical devices that are low to moderate risk, but are not substantially equivalent to a predicate device, and classified ReWalk as Class II subject to special controls. The special controls established in the de novo order include compliance with medical device consensus standards; performance of a

postmarket surveillance clinical study demonstrating a reasonable assurance of safety and effectiveness in urban terrain; non-clinical performance testing of the system's function and durability; a training program; and labeling related to device use and user training. The special controls of this de novo order will also apply to competing products seeking FDA clearance.

. . .

As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. If the FDA believes we or any of our contract manufacturers are not in compliance with the quality system requirements, or other postmarket requirements, it has significant enforcement authority. Specifically, if the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- refusal to grant export approvals for our products; or
- criminal prosecution.

Any such action by the FDA would have a material adverse effect on our business. In addition, these regulatory controls, as well as any changes in FDA policies, can affect the time and cost associated with the development, introduction and continued availability of new products. Where possible, we anticipate these factors in our product development processes.

(*Id.* ¶ 92).

In June 2014, the FDA granted our petition for "de novo" classification, which is a route to market for medical devices that are low to moderate risk, but are not substantially equivalent to a predicate device, and classified ReWalk as Class II subject to certain special controls. The special controls established in the de novo order include compliance with medical device consensus standards; performance of a post market surveillance clinical study demonstrating a reasonable assurance of safety and effectiveness in urban terrain; non-clinical performance testing of the system's function and durability; a training program; and labeling related to device use and user training. In order for us to market ReWalk, we must comply with both general controls, including controls related to quality, facility registration, reporting of adverse events and labeling, and the special controls

> established for the device. Failure to comply with the general and special controls could lead to removal of ReWalk from the market, which would have a material adverse effect on our business.
>
> . . .
>
> In addition, if we fail to comply with applicable regulatory requirements, it could result in fines, delays or suspensions of regulatory clearances, closure of manufacturing sites, seizures or recalls of products and damage to our reputation. Recent changes in enforcement practice by the FDA, European Union and other agencies have resulted in increased enforcement activity, which increases the compliance risk that we and other companies in our industry are facing. In addition, governmental agencies may impose new requirements regarding registration, labeling or prohibited materials that may require us to modify or reregister ReWalk once it is already on the market or otherwise impact our ability to market ReWalk in those countries. The process of complying with these governmental regulations can be costly and time consuming, and could delay or prevent the production, manufacturing or sale of ReWalk.

(*Id.* ¶ 94). The complaint alleges that those paragraphs were materially false and misleading because defendants failed to disclose the risk of "serious injury or death" to users of the device and ReWalk's "boilerplate recitation of potential adverse regulatory consequences" was "meaningless." (*Id.* ¶¶ 93, 95).

B. Procedural Background

Plaintiffs in this action initially filed suit in California state court on September 20, 2016. (Docket No. 37, Ex. 4 at 2). The California action was dismissed for lack of personal jurisdiction over the defendants. (*Id.*).[6]

On October 31, 2016, plaintiff Shane Vesey filed suit against defendants in the Massachusetts Superior Court. (*Id.* Ex. 1). On November 30, 2016, plaintiff Phanindra Chittavajhula also filed suit against defendants in the Superior Court. (*Id.* Ex. 2). Both cases were putative class actions alleging violations of the federal Securities Act relating to omissions

[6] According to defendants, there have been ten complaints brought by various plaintiffs against them arising from the same set of facts. Two were brought in federal court (one in California and the present case) and eight were brought in state court (five in California and three in Massachusetts). Docket No. 49 at 3.

in ReWalk's registration statement and final prospectus. The state court consolidated the two cases under the name *In re ReWalk Robotics Ltd. Stockholder Litigation* on January 10, 2017. (*Id.* at 1).

Three weeks later, on January 31, 2017, this action was filed in federal court. The original complaint in this case only alleged violations of the federal Securities Act.

On March 30, 2017, defendants moved in the Massachusetts Superior Court to stay the pending state action on the ground that the present case should be considered the first-filed because the federal complaint mirrored that of the earlier dismissed California state-court complaint. The court denied that motion, finding that the California action was a "nullity" and that the state-court plaintiffs "have made more progress in investigating the factual basis for their claims." (*Id.* Ex. 4 at 3). The court also concluded that there was concurrent state and federal jurisdiction for claims arising from violations of the Securities Act. (*Id.* at 4). Defendants filed a motion to dismiss the state action, and a hearing was held on October 18, 2017.

In the interim, on June 9, 2017, in this proceeding, the Court appointed a lead plaintiff, lead counsel, and liaison counsel. On July 6, 2017, defendants moved to stay this federal action based on the first-to-file rule, the *Colorado River* abstention doctrine, and the prior-pending-action doctrine. In their motion to stay, defendants also noted that the Supreme Court had granted a writ of certiorari in *Cyan, Inc. v. Beaver Cty. Emp. Ret. Fund*, which raised the question of whether the Securities Litigation Uniform Standards Act of 1998 ("SLUSA") stripped state courts of jurisdiction to adjudicate class actions brought under the Securities Act.[7]

Lead plaintiff then filed a consolidated amended complaint on August 9, 2017. That

[7] On March 20, 2018, the Supreme Court unanimously held that the SLUSA did not strip state courts of jurisdiction to adjudicate class actions brought under the Securities Act. *Cyan, Inc. v. Beaver Cty. Emp. Ret. Fund*, 138 S. Ct. 1061 (2018).

amended complaint added claims under the federal Exchange Act, 15 U.S.C. § 78a *et seq.*, over which federal courts have exclusive jurisdiction. On October 23, 2017, the Court denied without prejudice defendants' motion to stay.

Subsequently, on November 10, 2017, defendants filed a motion to dismiss. The motion sought to dismiss the action for failure to complete service of process on the individual domestic defendants pursuant to Rule 4(m), and for failure to state a claim pursuant to Rule 12(b)(6). Defendants then filed a renewed motion to stay in the Superior Court, which was granted on December 13, 2017. On February 23, 2018, the Court denied defendants' motion to dismiss for insufficient service of process.

II. Securities Act Claim

A. Relevant Pleading Standard

The parties first dispute the proper standard of review for analyzing plaintiffs' claims under the Securities Act. Defendants contend that the claims "sound in fraud" and are subject to the heightened pleading requirements of Fed. R. Civ. P. 9(b). *See Shaw v. Dig. Equip. Corp.*, 82 F.3d 1194, 1223 (1st Cir. 1994) ("It is the allegation of fraud, not the title of the claim that brings the policy concerns [underlying Rule 9(b)] . . . to the forefront.") (citation and internal quotation marks omitted). "Determining if allegations sound in fraud is not done by reference to a hard and fast rule." *Silverstrand Invs. v. AMAG Pharm., Inc.*, 12 F. Supp. 3d 241, 251 (D. Mass. 2014). However, "[b]ecause fraud is not an element of a Section 11 . . . claim, plaintiffs generally are not subjected to the heightened pleading requirements of Rule 9(b)." *Lenartz v. Am. Superconductor Corp.*, 879 F. Supp. 2d 167, 188 (D. Mass. 2012).

Here, the complaint segregates the factual allegations concerning the Securities Act claims from allegations relating to the Exchange Act claims. (*See* CAC ¶ 96) ("Lead Plaintiff

makes the additional allegations contained in paragraphs 96 to 111 below with respect to his claims under Sections 10(b) and 20(a) of the Exchange Act only. Lead Plaintiff disclaims any reliance upon these allegations or incorporation of these allegations in his Securities Act claims."). The paragraphs detailing the Securities Act allegations use the words "materially false and misleading" to describe the alleged omissions and misstatements in the registration statement. (CAC ¶¶ 85-95). Words such as "fraud" and "deceit" are not used, and there are no allegations of willful or intentional conduct. Arguably, at least, plaintiff has attempted to structure the complaint to avoid alleging fraud as to the Securities Act claim. *See Silverstrand Invs.*, 12 F. Supp. 3d at 252 (Gorton, J.); *Lenartz*, 879 F. Supp. 2d at 188-92 (Young, J.); *In re Refco, Inc. Sec. Litig.*, 503 F. Supp. 2d 611, 631-32 (S.D.N.Y. 2007) (holding that Securities Act allegations did not sound in fraud where complaint was "carefully structured so as to draw a clear distinction between negligence and fraud claims").

In any event, however, the issue appears to be immaterial. Because the claim is clearly brought under Section 11, and because fraud need not be proved to establish such a claim, Rule 9(b) does not apply. Any language in the complaint suggesting fraudulent conduct as to the registration statement is simply surplusage.

B. Legal Standard

On a motion to dismiss, the court "must assume the truth of all well-plead[ed] facts and give . . . plaintiff the benefit of all reasonable inferences therefrom." *Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir. 2007) (citing *Rogan v. Menino*, 175 F.3d 75, 77 (1st Cir. 1999)). To survive a motion to dismiss, the complaint must state a claim that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In other words, the "[f]actual allegations must be enough to raise a right to relief above the speculative level, . . . on the

assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (citations omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 556). Dismissal is appropriate if the complaint fails to set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." *Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir. 2008) (quoting *Centro Medico del Turabo, Inc. v. Feliciano de Melecio*, 406 F.3d 1, 6 (1st Cir. 2005)).

C. Analysis

Section 11 of the Securities Act "attaches liability to a registration statement that 'omit[s] to state a material fact . . . necessary to make the statements therein not misleading.'" *MAZ Partners LP v. Shear*, 218 F. Supp. 3d 132, 136 (D. Mass. 2016) (quoting 15 U.S.C. § 77k(a)). It essentially "imposes strict liability on issuers of a security, and any 'remaining [ ] defendants . . . may be liable for mere negligence.'" *Silverstrand Invs. v. AMAG Pharm., Inc.*, 707 F.3d 95, 102 (1st Cir. 2013). Notably, Section 11 does not include a scienter or reliance requirement. *Id.* Accordingly, the provision places a "relatively minimal burden on a plaintiff." *Id.* However, "Section 11's omissions clause . . . is not a general disclosure requirement; it affords a cause of action only when an issuer's failure to include a material fact has rendered a published statement misleading." *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318, 1332 (2015).

1. Claims Based on Regulation S-K Items 303 and 503

As an initial matter, in his opposition memorandum, plaintiff contends that defendants violated Items 303 and 503 of Regulation S-K.

"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." *Silverstrand Invs.*, 707 F.3d at 102 (citation and internal quotation marks omitted). Item 303 requires the disclosure of "any known . . . uncertainties that . . . the registrant reasonably expects will have a material . . . unfavorable impact on net sales or 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." *Silverstrand Invs.*, 707 F.3d at 103 (citing Mgmt.'s Discussion and Analysis of Fin. Conditions and Results of operations, SEC Release No. 6835, 1989 WL 1092885, at *4 (May 18, 1989)).

Similarly, Item 503 requires registrants 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). It requires that the issuer provide 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." *Silverstrand Invs.*, 707 F.3d at 103 (citation and internal quotation marks omitted). "[T]o 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." *Id.*

Here, the amended complaint does not mention either Regulation S-K or Items 303 and 503. Because plaintiff raised these claims for the first time in opposition to defendants' motion to dismiss, they will be disregarded. *See In re Hi-Crush Partners L.P. Sec. Litig.*, 2013 WL 6233561, at *11 n.6 (S.D.N.Y. Dec. 2, 2013) (disregarding mention of Item 503 in an opposition memorandum as an "improper attempt to amend the complaint through a brief.").

2. Allegedly Misleading Omissions in the Registration Statement

a. Failure to Disclose the ReWalk Device's Safety Profile

The complaint alleges that defendants failed to disclose in the registration statement that the ReWalk device was dangerous. Specifically, it alleges that defendants did not disclose that the device's "failure to prevent a fall would be reasonably likely to cause serious injury or death to the user and place individuals assisting the user at the risk of harm from a potential fall." (CAC ¶¶ 87, 89, 91, 93, 95).

That allegation is based on, and mischaracterizes, the FDA letters concerning the post-market surveillance requirement. For example, the June 26, 2014 letter from the FDA included the above-quoted text. (Feldman Decl. Ex. C at 1). However, the letter went on to state:

> The safety and effectiveness of the ReWalk has been demonstrated in an institutional environment (e.g. hospital, rehabilitation institution). However, there is limited information on use outside of the institutional setting (e.g. community and at home use) given that ARGO Medical Technologies, Inc. intends for the product's use in non-institutional settings.

(*Id.* at 1-2). The letter further stated that the post-market surveillance study would be useful to help determine the product's safety in non-institutional environments. (*Id.*). Nowhere did the FDA conclude that the ReWalk device was actually dangerous. The FDA referred to the study requirement in the context of the ReWalk product being a class

II device on *de novo* review. (*Id.*; Feldman Decl. Ex. B). The text of the registration statement accurately summarizes why the post-market surveillance requirement was imposed. (CAC ¶ 94) ("The special controls . . . include . . . performance of a post-market surveillance clinical study demonstrating a reasonable assurance of safety and effectiveness in urban terrain.").

In his opposition, plaintiff chiefly relies on the September 30, 2015 warning letter from the FDA. (Mem. in Opp. at 13-14; Pl. Ex. C).[8] He notes that the letter was issued "because the device's failure to prevent a fall would be reasonably likely to cause serious injury and/or death . . . ." (*Id.*). Again, however, the FDA never stated that the ReWalk device was dangerous; rather, the letter's language was conditional, warning that a defect could cause serious injury and that further study would help ensure the product's safety.[9]

b. Further Alleged Misstatements in the Registration Statement

The complaint also alleges that the registration statement included several statements that were misleading because they failed to disclose the nature of the post-market surveillance study requirement. Specifically, it alleges that the registration statement's representations concerning ReWalk's (1) "compelling clinical data," (2) intention to conduct further clinical studies, (3) characterization of the device as a "breakthrough product," (4) description of the post-market surveillance study requirement, and (5) discussion of regulatory risks were all materially false. (CAC ¶¶ 86, 88, 90, 92, 94).

First, the references to "compelling" clinical data, and to the ReWalk device as a

[8] The letter was issued more than one year after the IPO, and accordingly cannot be considered in the Securities Act claims analysis. *See Silverstrand Invs.*, 707 F.3d at 106-07.

[9] In any event, given the nature of the ReWalk device, it is self-evident that its malfunction could cause serious harm to users, most (if not all) of whom already had severe mobility impairments.

"breakthrough product," are mere puffery—that is, generic expressions of corporate optimism that are immaterial as a matter of law. It is well-established that "not every unfulfilled expression of corporate optimism, even if characterized as misstatement, can give rise to a genuine issue of materiality under the securities laws." *Shaw*, 82 F.3d at 1217.

> In particular, courts have demonstrated a willingness to find immaterial as a matter of law a certain kind of rosy affirmation commonly heard from corporate managers and numbingly familiar to the marketplace—loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker, that no reasonable investor could find them important to the total mix of information available.

Id. "The corporate puffery rule applies to loose optimism about both a company's current state of affairs and its future prospects." *In re Boston Sci. Sec. Litig.*, 2011 WL 4381889, at *11 (D. Mass. Sept. 19, 2011), *aff'd*, 686 F.3d 21 (1st Cir. 2012) (citation omitted). However, "[b]ecause 'the recent trend is to consider expressions of corporate optimism carefully' . . . claims of puffery now require a court to consider (1) 'whether the statement is so vague, so general, or so loosely optimistic that a reasonable investor would find it unimportant to the total mix of information' and (2) 'whether the statement was also considered unimportant to the total mix of information by the market as a whole.'" *Id.* (quoting *Brumbaugh v. Wave Sys. Corp.*, 416 F. Supp. 2d 239, 250 (D. Mass. 2006)). The references to clinical data as "compelling" and to the ReWalk device as a "breakthrough product" are unquestionably subjective, optimistic statements that a reasonable investor would not consider material.

Next, the reference to ReWalk's intent to conduct further clinical studies is a non-actionable "forward-looking" statement. The PSLRA provides, with certain limitations, that issuers of securities shall not be liable in any private action based on an untrue or misleading statement of a material fact "with respect to any forward-looking" statement if the statement is

> identified as a forward-looking statement, 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, . . . or . . . the plaintiff fails to prove that the forward-looking statement . . . [if made on behalf of a business entity by or with the approval of an executive officer was] made . . . with actual knowledge by that officer that the statement was false or misleading.

See 15 U.S.C. § 78u-5(c)(1); *In re Stone & Webster, Inc. Sec. Litig.*, 414 F.3d 187, 211-12 (1st Cir. 2005). The statute defines "forward-looking" statements to include

> (A) a statement containing a projection of revenues, income . . . earnings (including earnings loss) per share, . . . capital expenditures, dividends, . . . or other financial items; (B) a statement of the plans and objectives of management for future operations . . . ; (C) a statement of future economic performance . . . ; (D) any statement of the assumptions underlying or relating to [any of the above].

15 U.S.C. § 78u-5(i)(1); *accord In re Stone & Webster*, 414 F.3d at 212.

"Forward-looking statements are often contained in financial filings. Congress, in providing the limited safe harbor protection, sought to encourage market efficiency by encouraging companies to disclose future projections without fear that those projections, if they did not materialize, would result in an action for fraud." *In re Biogen IDEC, Inc. Sec. Litig.*, 2007 WL 9602250, at *10 (D. Mass. Oct. 25, 2007) (citations omitted), *aff'd sub nom. New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35 (1st Cir. 2008). "When faced with an arguably forward-looking statement, the future projections must be identified and separated from the present facts upon which those projections are based." *Id.* (citing *In re Stone & Webster*, 414 F.3d at 212-13). "The statutory protection will . . . apply [only] where the claim of fraud is based upon the future projection." *Id.*

Here, the statement that ReWalk intended to conduct further clinical studies squarely falls within the statutory safe harbor for "forward-looking" statements concerning "the plans and objectives of management for future operations." *See* 15 U.S.C. § 78u-5(i)(1)(B). It did not rely

on any representations of present facts.

Finally, as to the allegedly inadequate description of the post-market surveillance study requirement and the regulatory risks, the claim likewise fails. Paragraph 94 of the complaint specifically mentions that the FDA imposed such a requirement, and the possible consequences of failing to comply. There is no basis to conclude that the description was inadequate or misleading, particularly since the study had not yet even been designed, much less implemented. Similarly, the claim of inadequate description of regulatory risks was not misleading. Those risks are described in considerable detail at paragraphs 92 and 94 of the complaint; it was not necessary to set out every possible regulatory consequence of every possible contingent event.

Accordingly, the motion to dismiss will be granted as to Count One.

D. Count Two: Section 15 Liability

Count Two asserts a claim against the individual defendants under Section 15 of the Securities Act, which imposes joint and several liability on persons in control of entities that violate securities laws. 15 U.S.C. § 77o. However, violations of Section 15 depend on an underlying violation of the Securities Act. 15 U.S.C. § 77o-(a); *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 84-85 (1st Cir. 2002). Because the complaint fails to state a claim for an underlying violation of the Securities Act, Count Two will be dismissed.

III. Exchange Act Claims

Defendants contend that lead plaintiff Yan lacks standing to assert the Exchange Act claims because he purchased his shares "after the relevant statements were made and therefore could not have relied on the alleged misstatements." (Mem. in Supp. at 19). It is undisputed that Yan purchased his shares on September 15 and 17, 2014. (Docket No. 7, Ex. B at 3). And the statements alleged to have violated the Exchange Act were made between February 12, 2015,

and February 25, 2016. (CAC ¶¶ 99-110). The only statements, therefore, that Yan could have relied on were those made on or before September 17, 2014—that is, those in the registration statement, which the Court has found did not violate the Securities Act.

Normally, that would be sufficient to dispose of the Exchange Act claims for lack of standing. *See Gross v. Summa Four, Inc.*, 93 F.3d 987, 992-93 (1st Cir. 1996) (holding that a plaintiff was barred from relying on statements made after he purchased stock in support of his Exchange Act claims, reasoning that the statements "could not possibly have inflated the market price that he paid for those shares.").

There is a line of cases suggesting that class representatives may have standing to assert Exchange Act claims arising from statements made after the share purchase date "as long as the statements allegedly made were in furtherance of a common scheme to defraud." *Crowell v. Ionics, Inc.*, 343 F. Supp. 2d 1, 13-14 (D. Mass. 2004) (Young, J.); *see also Priest v. Zayre Corp.*, 118 F.R.D. 552, 556-57 (D. Mass. 1988) (Zobel, J.); *Kirby v. Cullinet Software, Inc.*, 116 F.R.D. 303, 311-12 (D. Mass. 1987) (Wolf, J.).

That argument, however, is undercut by the manner in which plaintiff structured his complaint. The complaint clearly alleges that the Securities Act claims are based on defendants' failure to disclose the reason the FDA required the post-market surveillance study, and that the Exchange Act claims are based on ReWalk's failure to disclose its difficulties in meeting that requirement. And, as noted, it states that plaintiff "disclaims any reliance upon [the Exchange Act allegations] or incorporation of these allegations in his Securities Act claims." (CAC ¶ 96). In addition, counsel for plaintiff explicitly argued that there were "two separate classes"—one for the Securities Act claims and one for the Exchange Act claims. (Mot. to Stay Hearing Tr. at 13, 16). Therefore, the alleged omissions may not be sufficiently similar to constitute a single

"common scheme" extending from September 12, 2014, through February 29, 2016. *See City of Bristol Pension Fund v. Vertex Pharm., Inc.*, 12 F. Supp. 3d 225, 235 (D. Mass. 2014).

There is also authority holding that a lead plaintiff in an action subject to the PSLRA need not have standing to bring every available claim under the securities laws. *See Hevesi v. Citigroup Inc.*, 366 F.3d 70, 82 (2d Cir. 2004) ("Nothing in the PSLRA indicates that district courts must choose a lead plaintiff with standing to sue on every available cause of action."). "[B]ecause the PSLRA mandates that courts must choose a party who has, among other things, the largest financial stake in the outcome of the case, it is inevitable that, in some cases, the lead plaintiff will not have standing to sue on every claim." *Id*. The alternative would require the Court to "cobble together a lead plaintiff group that has standing to sue on all possible causes of action." *In re IPO Sec. Litig.*, 214 F.R.D. 117, 123 (S.D.N.Y. 2002).

It is at least somewhat unclear how those principles should be applied in this context. Yan does not simply lack standing to sue on "every" claim; he lacks standing to sue on *any* remaining claim. Furthermore, standing is not merely an issue of statutory interpretation, but is a constitutional requirement, as well.[10] The parties have not briefed the issue, and it appears that the prudent course is to permit them to do so before the Court resolves it. Alternatively, it is possible that plaintiff may choose to seek the appointment of a substitute or supplemental lead

[10] Standing is a threshold question in every case; "[i]f a party lacks standing to bring a matter before the court, the court lacks jurisdiction to decide the merits of the underlying case." *United States v. AVX Corp.*, 962 F.2d 108, 113 (1st Cir. 1992). To satisfy the case-or-controversy requirement of Article III of the United States Constitution, plaintiffs bear the burden of establishing that they (1) have suffered an "injury-in-fact," (2) that the injury is "'fairly traceable' to the actions of the defendant[s]," and (3) that the injury will likely be redressed by a favorable decision. *Bennett v. Spear*, 520 U.S. 154, 162 (1997) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)).

"In addition to these Article III prerequisites, prudential concerns ordinarily require a plaintiff to show that his claim is premised on his own legal rights (as opposed to those of a third party), that his claim is not merely a generalized grievance, and that it falls within the zone of interests protected by the law invoked." *Pagan v. Calderon*, 448 F.3d 16, 27 (1st Cir. 2006) (internal citations omitted). Article III standing requirements are "both plaintiff-specific and claim-specific." *Id.* at 26.

plaintiff as a means of sidestepping the question. The Court will therefore deny the motion to dismiss as to Counts Three and Four, the Exchange Act claims, without prejudice, and permit plaintiff an opportunity to file a supplemental brief concerning the standing issue; to seek the appointment of a substitute or supplemental lead plaintiff; or to take such other steps as they believe may be proper under the circumstances.

Accordingly, the motion to dismiss will be denied without prejudice as to Counts Three and Four.

IV. Conclusion

For the foregoing reasons, defendants' motion to dismiss is GRANTED in part as to Counts One and Two, and DENIED in part without prejudice as to Counts Three and Four.

Plaintiff shall file any supplemental memorandum concerning standing, motion to appoint substitute or supplemental plaintiff, or other memorandum or motion responsive to this Memorandum and Order by September 10, 2018. Defendants shall file any opposition or response by September 24, 2018.

So Ordered.

/s/ F. Dennis Saylor
F. Dennis Saylor IV
United States District Judge

Dated: August 23, 2018