UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

NICHOLAS LUONGO, Individually and on Behalf of All Others Similarly Situated,	*	
	*	Civil Action No. 1:21-cv-12099-IT
Plaintiff,	*	Consolidated Action
	*	
v.	*	Consolidated with:
	*	No. 1:22-cv-10059-IT
DESKTOP METAL, INC., RIC FULOP,	*	No. 1:22-cv-10173-IT
ALI EL-SIBLANI, and MICHAEL JAFAR,	*	No. 1:22-cv-10297-IT
	*	
Defendants.	*	

MEMORANDUM AND ORDER

September 20, 2023

TALWANI, D.J.

Lead Plaintiffs Sophia Zhou and Yichun Xie bring this securities fraud putative class action against Defendants Desktop Metal, Inc. ("Desktop Metal") and its executives Ric Fulop, Michael Jafar, and Ali El-Siblani. Plaintiffs allege Defendants misled investors about the company's compliance with U.S. Food and Drug Administration ("FDA") regulations and the quality of one of its products, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act. Pending before the court is Defendants' Motion to Dismiss [Doc. No. 109] Plaintiff's Amended Corrected Consolidated Class Action Complaint [Doc. No. 107]. For the reasons set forth herein, the Motion is GRANTED.

I. Standard of Review

In evaluating a motion to dismiss for failure to state a claim, the court assumes "the truth of all well-pleaded facts" and draws "all reasonable inferences in the plaintiff's favor." Nisselson v. Lernout, 469 F.3d 143, 150 (1st Cir. 2006). To survive dismissal, a complaint must contain

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sufficient factual material to "state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations . . . [f]actual allegations must be enough to raise a right to relief above the speculative level . . . ." Id. at 555 (internal citations omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). In addition, "an adequate complaint must include not only a plausible claim but also a plausible defendant." See Peñalbert-Rosa v. Fortuño-Burset, 631 F.3d 592, 594 (1st Cir. 2011).

When a plaintiff brings claims sounding in fraud, there is an exception to Rule 12(b)(6)'s general plausibility pleading standard. See N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale, 567 F.3d 8, 15 (1st Cir. 2009) (holding that the particularity requirement applies not only to actual fraud claims but also to "associated claims where the core allegations effectively charge fraud"). Pursuant to Rule 9(b) of the Federal Rules of Civil Procedure, a party must state "with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Rule 9(b) requires that a plaintiff's averments of fraud specifically "plead 'the time, place, and content of the alleged false representation.'" Mulder v. Kohl's Dep't Stores, Inc., 865 F.3d 17, 22 (1st Cir. 2017) (citing United States ex rel. Heineman-Guta v. Guidant Corp., 718 F.3d 28, 34 (1st Cir. 2013)). The purpose of this requirement is to "give notice to defendants of the plaintiffs' claim, to protect defendants whose reputation may be harmed by meritless claims of fraud, to discourage 'strike suits,' and to prevent the filing of suits that simply hope to uncover relevant information during discovery." Doyle v. Hasbro, Inc., 103 F.3d 186, 194 (1st Cir. 1996).

The First Circuit has interpreted this rule to require that beyond pleading "the false statements and by whom they were made," a plaintiff must also identify "the basis for inferring scienter." N. Am. Catholic Educ. Programming Found, 567 F.3d at 13. In application, this renders a "general averment of the defendant's 'knowledge' of material falsity" insufficient. Id. (quoting Greenstone v. Cambex Corp., 975 F.2d 22, 25 (1st Cir. 1992), superseded by statute on other grounds by, Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737). Instead, plaintiffs must put forth "specific facts that make it reasonable to believe that defendant knew that a statement was materially false or misleading." Id.

II. Procedural Background

Nicholas Luongo initiated this action individually and on behalf of all others similarly situated against Desktop Metal, Ric Fulop, James Haley, and Ali El-Siblani. Complaint [Doc. No. 1]. The court consolidated the action with the three other above-captioned actions. Order Consolidating Actions [Doc. No. 5]; Elec. Order [Doc. No. 63].

After disputes arose between the plaintiffs regarding the length of the proposed class period, the court severed Xie v. Desktop Metal, Inc., et al., No. 1:22-cv-10297, from the consolidated proceedings. Memorandum and Order [Doc. No. 73]. The court further determined that the Xie proposed class period ran from January 15, 2021, to February 16, 2021 (inclusive of both dates), id., and approved Xie as lead plaintiff in the Xie action, No. 22-cv-10297 [Doc. No. 20]. The court appointed Sophia Zhou lead plaintiff for the consolidated action and determined that the Zhou proposed class period ran from February 17, 2021, up to and including November 15, 2021. Mem. and Order [Doc. No. 73].

On September 29, 2022, on the parties' Joint Motion [Doc. No. 97], the court re-consolidated the actions for pretrial proceedings. Order Consolidating Cases [Doc. No. 98].

Plaintiffs subsequently filed their operative Amended Consolidated Corrected Class Action Complaint ("Complaint") [Doc. No. 107], alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. Lead Plaintiff Zhou brings claims against Desktop Metal, Inc., Ric Fulop, Ali El-Siblani, and Michael Jafar for a proposed class period of March 15, 2021, through November 15, 2021. Lead Plaintiff Xie brings claims against Desktop Metal, Inc., and Ric Fulop only and for the proposed class period January 15, 2021, through March 14, 2021.[1]

Defendants responded with the pending Motion to Dismiss [Doc. No. 109] the claims alleged by both Lead Plaintiffs. [Doc. No. 109]. Lead Plaintiffs opposed. Plaintiffs' Opposition to Defendants' Motion to Dismiss [Doc. No. 113].

III. Factual Background as Alleged in the Complaint

A. Desktop Metal

Desktop Metal is a Massachusetts-based 3D-printing company. Cons. Am. Compl. ¶ 28 [Doc. No. 107]. Its "core business segment" consists of a metal 3D printing technology. Id. at ¶¶ 2, 29. In 2019 and 2020, Desktop Metal was operating at a loss. Id. at ¶ 50. On August 26, 2020, Desktop Metal restructured and went public; after going public, Desktop Metal was valued at $2.5 billion. Id. at ¶¶ 52, 54-55.

At all times relevant to this dispute, Desktop Metal's CEO was Defendant Ric Fulop. Id. ¶ 33.

B. EnvisionTEC

EnvisionTEC is also a 3D printing company and was a competitor to Desktop Metal. Id. at ¶ 4. EnvisionTEC's focus was photopolymer additive manufacturing, a 3D printing process

[1] Both Plaintiffs also brought claims against James Haley but have stipulated to his dismissal from this action. Pl. Opp. to Mot. to Dismiss 4 n.4 [Doc. No. 113].

that uses light-activated polymerization to cure liquid resin into a final form, and EnvisionTEC was credited as the "original inventor" of Digital Light Printing (DLP) technology. Id. at ¶ 4. EnvisionTEC's DLP printing system uses a three-step procedure for printing custom medical devices. Id. at ¶ 64. In step one, a 3D printer uses a biocompatible material to print the desired object based on a custom set of printing instructions. Id. In step two, excess material is cleaned away from the printed object. Id. In step three, a curing unit (analogous to an oven) is used to solidify the printed object into its final, hardened form. Id. All told, EnvisionTEC's printing system allows a dental office or a medical lab to print a custom set of permanent dental implants in approximately an hour. Id. at ¶¶ 60, 64.

EnvisionTEC sold the materials necessary for each step of the above-described process. Id. at ¶ 65. In particular, EnvisionTEC boasted a "comprehensive library of biocompatible 3D printing materials—including multiple FDA-listed and 510(k)-cleared resins for the manufacturing of FDA-regulated medical devices." Id. at ¶ 4. Part of EnvisionTEC's suite of available resin products was Flexcera. Id. at ¶¶ 67-68. Flexcera is "a light-curable brand of resin developed for the fabrication of high-impact and removable denture bases formulated exclusively for use with EnvisionTEC 3D printers." Id. at ¶ 5. EnvisionTEC also offered curing boxes to harden the resin after it was printed and cleaned. Id. at ¶ 76. EnvisionTEC sold the Otoflash, which was the "gold standard" of curing boxes due to its use of intense light radiation and broad range of light frequency. Id. at ¶ 78. However, EnvisionTEC did not manufacture the Otoflash—instead, the company purchased it from a third-party competitor, re-branded it, and upsold it for profit. Id. at ¶ 80. EnvisionTEC sold the Otoflash for approximately $4,000. Id. EnvisionTEC also manufactured its own line of curing boxes called PCA (Parts Curing

Apparatus) Series. Id. at ¶¶ 6, 81. In late 2020/early 2021, EnvisionTEC began to market its newest curing box, the PCA 4000, as a direct competitor with the Otoflash. Id. at ¶ 82.

Defendant Ali El-Siblani was EnvisionTEC's CEO until one week before the end of the Zhou proposed class period. Id. at ¶¶ 8, 17.

C. Desktop Metal Acquires EnvisionTEC[2]

On January 15, 2021, Desktop Metal announced its plan to acquire EnvisionTEC. Id. at ¶ 8. The EnvisionTEC acquisition was finalized on February 17, 2021. Id. at ¶ 198. At the time of the acquisition, EnvisionTEC was still awaiting clearance with FDA for the Flexcera products. Id. at ¶ 5. EnvisionTEC CEO El-Siblani continued to head the company after the acquisition and also became a member of Desktop Metal's board of directors. Id. at ¶ 8.

D. As a Result of the EnvisionTEC Acquisition, Desktop Metal Launches Desktop Health[3]

Analysists viewed the EnvisionTEC acquisition as an opportunity for Desktop Metal to break into the lucrative dental market, valued to reach nearly $10 billion by 2030. Id. at ¶¶ 4, 58. On March 15, 2021, Desktop Metal launched a new division of the company, Desktop Health. Id. at ¶ 57. Desktop Health would cover the 3D-printed medical and dental device portfolio of Desktop Metal, including the recently acquired EnvisionTEC's dental channel business. Id. at ¶ 115. Defendant Michael Jafar, a relative of El-Siblani, was appointed as President and CEO of Desktop Health. Id. at ¶ 37. Also on March 15, 2021, El-Siblani and Fulop signed Desktop

[2] This Subsection describes the factual background for the Xie proposed Class Period. The allegedly false or misleading statements made during this period are discussed in detail in Section IV.A.1.

[3] Subsections D-H describe the factual background that occurred during the Zhou proposed Class Period. The allegedly false or misleading statements made during this period are discussed in detail in Sections IV.A.2 and IV.A.3.

Metal's annual report form for the period ending December 31, 2020, which discussed the EnvisionTEC acquisition. Id. at ¶ 203.[4]

E. Desktop Metal Receives FDA Clearance on EnvisionTEC's Flexcera Resin

Medical devices that are "substantially equivalent" to an existing "legally marketed device" must also be registered with FDA through a premarket clearance process, also known as a 510(k) submission. Id. at ¶ 93. Once FDA determines that the premarket medical device meets the substantial equivalence standard, it can be marketed in the United States. Id. at ¶ 93. FDA has published guidance to industry regarding medical devices that are 3D-printed. Id. at ¶ 95. In that guidance, FDA recommends—but does not require—that manufacturers "describe the type of [additive manufacturing] technology used to build your device." FDA, "Technical Considerations for Additive Manufactured Medical Devices – Guidance for Industry," Dec. 05, 2017. FDA also recommends that "[p]erformance testing should be conducted on final finished devices subjected to all post-processing, cleaning, and sterilization steps." Id.

On March 29, 2021, Desktop Metal submitted a Form 510(k) to the FDA for regulatory approval to market Flexcera. Cons. Am. Compl. ¶ 73 [Doc. No. 107]. To acquire the data used in its submissions to FDA, the company used the Otoflash curing box, not the PCA 4000, to produce the final hardened resin product. Id. at ¶¶ 121, 124.

On May 12, 2021, Desktop Metal announced that it had obtained FDA clearance for Flexcera. Id. at ¶ 73. Because Flexcera cost between $500-$750 a bottle, id. at ¶ 71, and large-scale users could consume several bottles per week, Desktop Metal employees believed that the product would "provid[e] a large recurring revenue source," id. at ¶ 5.

[4] This communication, discussed further below, was the only allegedly misleading communication by El-Siblani identified in the Complaint.

F. EnvisionTEC Manufactures Flexcera in Non-FDA Compliant Facility

Several FDA regulatory requirements applied to EnvisionTEC's production of Flexcera resin. First, manufacturing facilities must be authorized to produce the medical device in question. Id. at ¶¶ 86-87. EnvisionTEC maintained three manufacturing facilities: one in Dearborn, Michigan; one in Montreal, Canada; and one in Gladbeck, Germany. Id. at ¶¶ 88, 89. Only the Gladbeck facility was registered with FDA to make Flexcera dental resin. Id. at ¶ 88. Second, medical devices must be properly labeled, which (among other things) requires that the label "specify conspicuously the name and place of business of the manufacturer, packer, or distributor." Id. at ¶ 91. If a label does not include this information (or includes "misleading" information), a manufacturer can be subject to civil and criminal liability. Id. at ¶ 92.

Sometime between March and April 2021, EnvisionTEC began manufacturing Flexcera resin at its Montreal facility, despite that facility not being registered with FDA for such production. Id. at ¶ 128. Sometime in April or May 2021, El-Siblani called the director of the Montreal facility and told him to "up his production" of Flexcera resin. Id. at ¶ 131. The Montreal facility then shipped the resin to the Dearborn, Michigan facility, where the resin was bottled and improperly labeled as having been manufactured at the Gladbeck, Germany facility. Id. at ¶¶ 135, 137. As a result, non-FDA compliant Flexcera resin was sold to customers from approximately April 1, 2021, until October 2021. Id. at ¶ 142. The non-FDA compliant Flexcera resin comprised approximately 10% of the total Flexcera resin sales during that time. Id.

G. El-Siblani Pushes the Sale of the PCA 4000

Shortly after the launch of Desktop Health, EnvisionTEC CEO El-Siblani began pushing aggressive sales quotas on the dental sales team. Id. at ¶¶ 120, 125-126. El-Siblani also pressured the team to sell the new PCA 4000 over other curing boxes for use with the Flexcera line, even

though the company had not used the PCA 4000 to cure the Flexcera resin in its FDA application. Id. at ¶¶ 121, 124. At the time, Flexcera marketing materials referenced the Otoflash as the only curing unit for finalizing Flexcera-printed dental products. Id. at ¶ 159. Dental sales team members pushed back on El-Siblani's instruction. Id. at ¶ 167. In a private conversation, one sales team member told another team member that he and other employees did not believe the PCA 4000 was capable of curing Flexcera properly, i.e., in a manner that would result in a fully hardened product. Id.

Sometime after El-Siblani increased the push to sell the PCA 4000, customers expressed dissatisfaction with the Flexcera product when it was cured by the PCA 4000, calling it "gummy." Id. at ¶ 171. Thereafter, the company more than doubled its previous 15-minute recommended curing time in the PCA 4000. Id. German staff also recommended a much longer curing time of 30-60 minutes. Id. at ¶ 172.

H. Jafar Is Alerted About PCA 4000 Performance Issues When Curing Flexcera Resin

Sometime during 2021, a materials research expert and then-EnvisionTEC employee sent the Flexcera product to an independent laboratory for validation testing. Id. at ¶ 174. The employee instructed the laboratory to follow EnvisionTEC's Instructions for Use ("IFU") for making the Flexcera dentures, which at the time included instructions to use the PCA 4000 for curing. Id. at ¶ 175. The lab reported that the resulting product was significantly weaker than EnvisionTEC was advertising: "though the Company claimed that Flexcera-printed dentures had a flexural strength of about 90 megapascals (MPa), [the] validation tests using the Company's IFU found a strength of only 72 MPa." Id. at ¶ 176.

As a result of these tests, the employee concluded that the Flexcera resin, when cured by the PCA 4000, did not qualify as a "rigid dental material." Id. at ¶ 178. In September 2021, the employee emailed Defendant Jafar to alert him to the problem. Id. at ¶ 179.

I. November 2021 Whistleblower Complaint and the Fall-Out

In November 2021, a then-employee emailed "several, high-level people in different departments across Desktop Metal, including Human Resources," to raise concerns regarding the improper manufacturing of Flexcera resin in non-FDA compliant facilities. Id. at ¶ 180. Thereafter, the employee was contacted by Desktop Metal's corporate headquarters. Id. at ¶ 182.

On November 4, 2021, Desktop Metal hired a third party to conduct an independent internal investigation into "manufacturing and product compliance practices and procedures with respect to a subset of its photopolymer equipment and materials at its EnvisionTEC US LLC facility." Id. at ¶ 183. On November 5, 2021, El-Siblani resigned as Chief Executive Officer of EnvisionTEC and as a director of Desktop Metal. Id. at ¶ 184. On November 8, 2021, Desktop Metal filed a Form 8-K with the SEC reporting the investigation and El-Siblani's resignation. Id. at ¶¶ 183, 184. Desktop Metal's stock fell $1.02 over the next two trading days, dropping 9.2% from November 8, 2021, to November 10, 2021. Id. at ¶ 186.

On November 15, 2021, Desktop Metal published its Quarterly Report that stated in part: "[B]ased on compliance issues with certain shipments of EnvisionTEC's Flexcera dental resins and its PCA 4000 curing box, the Company has determined that it will notify the FDA and consult with them on the appropriate voluntary market action with respect to these products. The Company does not expect the costs of any such market action to have a material impact on its financial statements." Id. at ¶ 187. After this announcement, Desktop Metal's stock fell $1.19, or 15%, from November 15, 2021, to close of trading on November 16, 2021. Id. at ¶ 188.

Two months later, in January 2022, Desktop Metal initiated two voluntary recalls with the FDA: one for Flexcera resin manufactured between April 1, 2021, to September 15, 2021, and the other for PCA 4000 curing boxes sold to non-industrial users. Id. at ¶¶ 190-191.

J. False and Misleading Statements

Plaintiffs have identified twenty-five statements by the Defendants as false and misleading. The statements are set forth in detail below.

IV. Discussion

To state a claim for securities fraud under Section 10(b) and Rule 10b–5, a plaintiff must sufficiently allege "(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 Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 27 (1st Cir. 2012) (quoting Miss. Pub. Empls.' Ret. Sys. v. Bos. Sci. Corp., 523 F.3d 75, 85 (1st Cir. 2008)). Defendants challenge the sufficiency of the allegations as to the first, second, and sixth elements.

A. Material Misrepresentation or Omission

For a Section 10(b) complaint to survive a motion to dismiss, it must allege a materially "false, or misleadingly omitted, statement of [material] fact." Constr. Indus. & Laborers Joint Pension Tr. v. Carbonite, Inc., 22 F.4th 1, 7 (1st Cir. 2021). To plead a misleading statement under the PSLRA, a plaintiff must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." Hill v. Gozani, 638 F.3d 40, 55 (1st Cir. 2011) (alteration in original) (quoting 15 U.S.C. § 78u-4(b)(1)). A fact or omission is material where "there is a substantial likelihood that a reasonable investor would have viewed it as significantly alter[ing] the total mix of information made available." Fire and Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 240 (1st Cir. 2015) (internal quotations omitted)

(alteration in original); see Operating Local 649 Annuity Tr. Fund v. Smith Barney Fund Mgmt. LLC, 595 F.3d 86, 92-93 (2d Cir. 2010) ("Put another way, '[a] fact is to be considered material if there is a substantial likelihood that a reasonable person would consider it important in deciding whether to buy or sell shares [of stock].'").

But even where the omitted "information is material, there is no liability . . . unless there was a duty to disclose it." Roeder v. Alpha Indus., Inc., 814 F.2d 22, 26 (1st Cir. 1987). Section 10(b) "do[es] not create an affirmative duty to disclose any and all material information," just what is necessary to prevent statements, when viewed "in the light of the circumstances under which they were made," from being "so incomplete as to mislead." In re Bos. Sci. Corp., 686 F.3d at 27 (quoting Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011)); Thant v. Karyopharm Therapeutics Inc., 43 F.4th 214, 226 (1st Cir. 2022) ("[W]e have conclusively established that a company is not, by virtue of making some disclosures about its products, obligated to disclose all potentially interesting information."); City of Bristol Pension Fund v. Vertex Pharms. Inc., 12 F. Supp. 3d 225, 236 (D. Mass. 2014) ("A disclosure of certain facts may trigger a duty to disclose others where necessary to avoid making a misleading statement.").

1. Statements by Desktop Metal and Fulop Prior to Desktop Metal's Acquisition of EnvisionTEC

Plaintiffs point to four allegedly misleading public statements by Desktop Metal or Fulop prior to the acquisition of EnvisionTEC. The first is a four-paragraph press release from January 15, 2021, announcing the impending acquisition of EnvisionTEC. Cons. Am. Compl. ¶ 194 [Doc. No. 107]. Although Plaintiffs do not specify, their main concern seems to stem from the final paragraph of the statement, which reads:

> Today, EnvisionTEC has over 5,000 customers across a broad range of industries, including medical devices, jewelry, automotive, aerospace, and biofabrication. In addition, the company is a leader in the dental market, more than tripling the number of Envision One dental shipments from 2019 to 2020 and with over 1,000

> dental customers now using its printers for end-use parts. . . . EnvisionTEC has a broad library of over 190 materials, featuring photopolymer resins with material properties in-line with or exceeding those of thermoplastics and multiple FDA-listed and 510(K)-cleared resins for the manufacturing of medical devices. The company augments its robust proprietary material development efforts with a selectively open business model, leveraging relationships with major chemical companies . . . to sell third-party, industry-validated resins for use with its additive manufacturing platforms.

Id. at ¶ 194.

The second statement is also from January 15, 2021. During a management call, Defendant Fulop stated that:

> In addition to engineering resins, EnvisionTEC has a number of biocompatible and medical materials including many FDA-listed and 510(k) cleared resins. * * * The company has over 60 qualified dental materials that are best-in class. I do just want to highlight for a second two very exciting ones that are undergoing 510(k) clearance with the FDA. The first one is the new E-Dent 1000 material, and the second one is the new EDenture Pro, both are incredibly fantastic materials with industry leading performance. Compared to NextDent and carbon materials, these can achieve higher performance like Flexural Strength in our features.

Id. at ¶ 196.

In that same meeting, Defendants provided a formal presentation on the upcoming acquisition. The presentation reiterated the potential benefits of EnvisionTEC's dental channel. Id. at ¶ 197, F.23.

The final statement prior to the acquisition is a six-paragraph press release issued on February 17, 2021. Id. at ¶ 198. The press release, like the January presentation, mentions EnvisionTEC's portfolio of "190 qualified materials" and its position as a "leader in the dental market, with over 1,000 dental customers now using its printers for pre-production and end-use parts in this segment." Id. at ¶ 198.

Plaintiffs provide the same reasons why each of the above statements is false and/or misleading: (1) they "conveyed to investors that Desktop Metal had conducted due diligence sufficient to identify the issues surrounding EnvisionTEC's manufacturing and product

compliance practices and procedures"; (2) those procedures were deficient; and (3) the deficiencies presented a "material risk to the commercialization of EnvisionTEC's products." Id. at ¶¶ 195, 197-198 [Doc. No. 107]. The court finds that these general allegations are insufficient to support a claim under the PSLRA.

To start, nothing in these statements can be read to suggest anything about Desktop Metal's due diligence procedures. And even if the statements could be read to assert such due diligence, Plaintiffs have not alleged anything to suggest that Desktop Metal's due diligence procedure was, in fact, inadequate at the time it was conducted. See id. at ¶¶ 106-110 (alleging only that: a "senior financial advisor" was not provided with a copy of a due diligence report; Desktop Metal had below-average mergers and acquisitions department; and Fulop visited "notoriously dirty" Dearborn facility but still signed deal). In any event, Desktop Metal's generalized statements about its impending acquisition of EnvisionTEC do not impose upon the company an "obligat[ion] to disclose all potentially interesting information" about that acquisition. See Thant, 43 F.4th at 226.

Further, none of the "deficiencies" Plaintiffs allege were concealed had yet materialized at the time of the challenged statements. The thrust of Plaintiffs' allegations is that Desktop Metal's optimistic statements about the acquisition were misleading because of issues with EnvisionTEC's manufacturing and product quality. Plaintiffs have not alleged that those issues were present when the acquisition-related statements were made. In light of that timing, Plaintiffs have not sufficiently alleged that any pre-March 2021 statement could possibly be fraudulent or misleading. See ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 62 (1st Cir. 2008) ("fraud by hindsight" is untenable claim when not accompanied by allegations that

Defendants had actual inconsistent knowledge at the time the contested statement was made); accord Ganem v. InVivo Therapeutics Holding Corp., 845 F.3d 447, 457 (1st Cir. 2017).

2. Statements By Desktop Metal, Fulop and El-Siblani After Desktop Metal Acquired EnvisionTEC

Plaintiffs identify one statement made by Fulop and El-Siblani after Desktop Metal acquired EnvisionTEC. On March 15, 2021, Defendants Fulop and El-Siblani signed Desktop Metal's FY 2020 Annual Report Form for the period ending December 31, 2020. Cons. Am. Compl. ¶ 203 [Doc. No. 107]. The report stated that the company "may experience difficulties in integrating the operations of EnvisionTEC into our business and in realizing the expected benefits of the EnvisionTEC acquisition." Id. at ¶ 203.

Plaintiffs contend that this statement was misleading by implying that Desktop Metal had done due diligence. Id. ¶ 204. The due diligence argument fails here for the same reasons as discussed with respect to the earlier statements, see supra Section IV.A.1. The additional argument—that Defendants knew by March 15, 2021, but failed to disclose to investors that EnvisionTEC's manufacturing standards and controls were deficient—fails for the reasons the remaining post-acquisition statements are not sufficient, as discussed in the next section.

3. Statements By Desktop Metal, Fulop or Jafar After Desktop Metal Acquired EnvisionTEC

Plaintiffs allege that twenty additional statements made after Desktop Metal acquired EnvisionTEC were fraudulent and/or misleading. Cons. Am. Compl. ¶¶ 203, 205-206, 208, 210, 212-213, 215, 217-218, 220-221, 223, 225, 227, 229, 231, 233-234, 236-237 [Doc. No. 107]. None of these statements were made by El-Siblani. The court focuses on the particular aspects of longer statements that Plaintiffs have highlighted.

4Q20 Earnings Call and Investor Presentation: On March 15, 2021, Defendant Fulop stated that Desktop Metal had "several materials that have either received FDA 510(k) clearance

or are in process….” Id. at ¶ 206. He presented a slide that referenced Flexcera Smile and Flexcera Base (then known as E-Dent 1000 and E-Denture Pro) as “[m]aterials pending 510(k) clearance.” Id.

Launch of Desktop Health: Also on March 15, 2021, Defendants Fulop and Jafar were quoted in a Desktop Metal press release announcing the launch of Desktop Health. Id. at ¶ 208. The statement referenced EnvisionTEC’s “proprietary technology infrastructure…including Digital Light Processing (DLP), [and] Continuous Digital Light Manufacturing (cDLM),” and stated that “regulatory requirements will apply to Desktop Health’s technology, products, materials and applications, including by the U.S. Food and Drug Administration and comparable agencies in other countries.” Id.

FDA Clearance Announcement: On May 12, 2021, Defendant Jafar was quoted in a Desktop Metal press release announcing that Desktop Metal had “received U.S. Food and Drug Administration (FDA) 510(k) clearance of Flexcera Base, a proprietary resin for use in 3D fabrication of high-quality dental prosthetics.” Id. at ¶ 210. The statement also referenced Flexcera’s “superior strength, aesthetics, and function for patients.” Id.

Twitter Promotional Video: Also around May 12, 2021, Desktop Metal posted a Twitter video promoting the Flexcera product line. Id. at ¶ 212. The video headline stated that Flexcera was “a new FDA cleared resin for the fabrication of beautiful, functional dentures with ceramic-like strength.” Id. at ¶ 213. Defendant Jafar appeared in the video stating that Flexcera could “provide the flexibility of plastic and the strength of ceramic.” Id. at ¶ 213.

1Q21 Quarterly Report: On May 17, 2021, Desktop Metal filed its quarterly report for the period ending March 31, 2021. Id. at ¶ 215. In the report, Desktop Metal stated that:

> “[T]his business and its technology, products, materials and applications may be subject to strict regulatory requirements in the United States and other countries.

> The success of this business will also depend on our ability to attract, hire and retain qualified personnel, establish sales, marketing and distribution infrastructure, and establish and maintain supply and manufacturing relationships." Id.

1Q21 Earnings Call and Investor Presentation: Also on May 17, 2021, Defendant Fulop stated in an earnings call that "Flexcera Smile is a Class I medical device and Flexcera Base is a Class 2 device recently cleared by the FDA," and a slide in the investor presentation stated that Flexcera Base was "3x [m]ore resistant to fracture" and "2x [m]ore resistant to water." Id. at ¶¶ 217-218.

S-1 Registration Statement: On May 26, 2021, Desktop Metal filed an amendment to its February Registration Statement that stated its "extensive library of materials also includes biocompatible resins as well as several Food and Drug Administration- (FDA) cleared resins for us[e] in medical and dental applications." Id. at ¶ 220. It also stated that the "PCA-2000 and PCA 4000 are solutions for curing parts printed using our CDLM or DLP platforms and utilize a unique system . . . to achieve smooth surface on each part." Id. These statements were repeated in each monthly Registration Statement from June through October. Id. at ¶ 221.

CE Mark Certification and International Launch: On June 10, 2021, Desktop Metal published a press release announcing the international launch of Flexcera. Id. at ¶ 223. The press release reiterated that Flexcera Base had received FDA 510(k) clearance. Id. Defendant Jafar is quoted as stating: "The introduction of Flexcera marks the inception of a remarkable new era in dentistry, combining advanced Flexcera science with 3D printing technology to deliver superior strength, aesthetics, and function for patients." Id.

Stifel Cross Section Insight Conference: Also on June 10, 2021, Defendant Fulop participated in a conference question-and-answer session in which he stated that the Flexcera products had received FDA approval. Id. at ¶ 225.

Inside Dental Technology Interview: In June 2021, Defendant Jafar participated in a question-and-answer interview. During the interview, Jafar stated: (1) that Flexcera was "three times stronger than one of the most popular denture base materials on the market, and two times more resistant to water"; (2) that EnvisionTEC was a "leader" in the dental space; and (3) that "the FDA provides a very clear path for approval" of dental products. Id. at ¶ 227.

California Business Journal Interview: That same month, Defendant Jafar gave an interview to the California Business Journal. Id. at ¶ 229. The article includes two quotes from Jafar. In the first, Jafar states: "The beauty of Flexera [sic] is that when we tested it against the market leader, it showed improved strength and water absorption." Id. In the second, he states: "When the consumer really begins to see the speed and efficiency of this ecosystem [EnvisionTEC's printing system], people will start to realize the power of the manufacturing component." Id.

2Q21 Quarterly Report: On August 11, 2021, Defendant Fulop signed the 2Q21 Quarterly Report for the period ending June 30, 2021. Id. at ¶ 231. Similar to the 1Q21 Report, it stated:

> "The healthcare market overall is highly regulated and subject to frequent and sudden change. Our failure to secure clearances or approvals or comply with regulations could have an adverse impact on our business and reputation and subject us to lost research and development costs, withdrawal of clearance/approval, operating restrictions, liabilities, fines, penalties and/or litigation." Id.

Desktop Metal repeated this statement in its September 15, October 7, and October 8 Prospectuses. Id. at ¶ 231 n. 59.

2Q21 Earnings Call and Press Release: Also on August 11, 2021, Desktop Metal published a press release describing Flexcera Base as "FDA-cleared." Id. at ¶ 233. That same day, Defendant Fulop stated on an earnings call that:

> "Desktop Health completed CE certification for our Flexcera™ Base and Smile resins and received FDA clearance for Class II permanent indications with Flexcera™ Base. Together, Flexcera™ Base and Smile enable next-generation digital dentures and same day full arch implant procedures. Flexcera™ solutions sold out within the first four weeks of launch, and we're adding capacity to meet the robust demand." Id.

Desktop Metal repeated that statement in its August 20, 2021 Prospectus. Id. at ¶ 234.

EnvisionTEC Website Statements: Throughout the proposed Zhou Class Period, EnvisionTEC published statements on its website regarding the Flexcera product line. Id. at ¶ 236. Plaintiffs highlight the following assertions: (1) that Flexcera Smile is a "light-curable resin" that is "[c]ompatible and validated for use with EnvisionTEC™ systems"; (2) that Flexcera smile was three times more resistant to fracture as compared to competing brands; (3) that "Flexcera is expected to ship in the U.S. and Canada by the end of June 2021. Pre-order today while supplies last. Flexcera Base is an FDA 510(k) Cleared Class 2 Medical Device indicated for the fabrication of denture bases in dental laboratories for full removable dentures; Flexcera Smile is an FDA Class 1 Medical Device for the fabrication of artificial teeth for dental prostheses." Id. at ¶ 237.

The challenged statements fall into three general buckets: (1) statements about Flexcera's FDA approval status; (2) statements about EnvisionTEC's overall regulatory compliance; and (3) statements about the PCA 4000's capabilities, including statements about Flexcera's product quality when cured with the PCA 4000. As to all of these statements, Plaintiffs contend:

> [S]tatements regarding Flexcera's physical and regulatory characteristics, the PCA 4000's ability to cure Flexcera, and the manufacturing and product compliance practices and procedures at the Company's EnvisionTEC facilities were false and misleading for the following reasons, both together and individually: (a) though Defendants' statements suggested that the Company's Flexcera resin complied with FDA regulations, the Company did not manufacture certain lots of Flexcera resin in an FDA-registered facility (Montreal), in contravention to FDA regulations; (b) though Defendants' statements suggested that the Company's Flexcera resin complied with FDA regulations, the Company

> repackaged in to bottles nonconforming FDA resin in a non-FDA registered facility (Dearborn), in contravention to FDA regulations; (c) though Defendants' statements suggested that the Company's Flexcera resin complied with FDA regulations, the Company mislabeled Flexcera resin manufactured in Canada and repackaged in the United States as being of German origin, in part, to disguise their fraudulent conduct; (d) the Company sold and included in its order counts sales of Flexcera resin prior to obtaining FDA premarket clearance even though the Company knew or recklessly disregarded the fact that purchasers were likely using non-FDA cleared resin as a Class II medical device (i.e., for permanent patient use); (e) despite the Company's claims to consumers, as instructed by Defendant El-Siblani, the PCA 4000 had not been sufficiently internally tested and was not FDA-certified for use with Flexcera; (f) despite the Company's claims to consumers, as instructed by Defendant El-Siblani, the PCA 4000's technology was not strong enough to sufficiently cure Flexcera resin for permanent human use; and (g) despite the Company's claims regarding Flexcera's physical characteristics (fracture resistance, moisture resistance, etc.), the Company's Flexcera could not meet claimed/required characteristics if cured with the PCA 4000.

Id. ¶ 202; see also id. at ¶¶ 207, 209, 211, 214, 216, 219, 222, 224, 226, 228, 230, 232, 235, and 238 (referencing "the reasons set forth" in ¶ 202 to support each paragraph).

None of these statements is sufficient to support a Rule 10b-5 claim. Despite the allegations of violations of FDA regulations, "this case is not about whether or not defendants violated the [Food, Drug, and Cosmetic Act] or FDA regulations. It concerns alleged violations of securities law." See Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 246 (1st Cir. 2015). And, while Desktop Metal's activities surrounding Flexcera and the PCA 4000 "might have been a risky course in terms of its likelihood of prompting sanctions from the FDA . . . . '[a]llegations of corporate mismanagement are not actionable under Rule 10b-5'" where statements are not otherwise misleading. Id. (quoting City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp., 632 F.3d 751, 760 (1st Cir. 2011)); accord Hill v. Gozani, 638 F.3d 40, 59 (1st Cir. 2011) ("questionable"—and even "illegal"—business practices are not equivalent to allegations that "the principals were engaged in a comprehensive scheme to disguise negative information 'to keep the house of cards standing'") (quoting In re Cabletron

Systems, Inc., 311 F.3d 11, 24 (1st Cir. 2002)). For the reasons detailed below, Plaintiffs fail as a matter of law to state a Section 10b-5 claim.

First, as Plaintiffs acknowledge, Defendants applied for FDA approval for the Flexcera product, and Flexcera was actually approved by FDA in May 2021. Plaintiffs do not allege that Defendants falsified the data in their FDA application or that the agency's ultimate approval of the Flexcera product was otherwise invalid. That a small percentage of the product was manufactured for several months in facilities that were not FDA compliant does not negate the fact of Flexcera's approval status. Nor does it render the reference to that approval status misleading; indeed, given that 90% of the Flexcera resin manufactured between the time of the acquisition and the end of the proposed Zhou Class Period fully complied with FDA regulations, and that the issue was solved without FDA's intervention, it would have been more misleading to assert that the product was *not* FDA-compliant. See Abiomed, Inc., 778 F.3d at 244 (requiring company to "affirmatively admit[] widespread wrongdoing" would have been "a perverse result … since the [compliance] issues had the potential to be resolved with no adverse action from the FDA").

Second, as to the FY 2020 Annual Report Form, March 2021 FY 2020 Annual Report Form, 4Q20 Earnings Call, and Desktop Health Launch statements, Plaintiffs fail to demonstrate that any risk of regulatory non-compliance "had already begun to materialize," and thus have provided no basis for finding the statements misleading. See City of Miami Fire Fighters' and Police Officers' Ret. Trust v. CVS Health Corp., 46 F.4th 22, 35 (1st Cir. 2022); see also Section IV.A.1. So too with the May 2021 1Q21 earnings statement, which only covered Company activity through the end of March. As to the August 2021 statement by Defendant Fulop, even assuming Plaintiffs are correct that general statements about regulatory requirements could be

misleading because a small fraction of one product is being manufactured in a non-compliant manner, Plaintiffs have failed to demonstrate that Fulop had the requisite scienter with respect to any of the alleged misrepresentations, as discussed infra Section IV.B.

Third, to the extent Plaintiffs' primary argument is that Defendants made misleading statements about the FDA's approval of their products in a bid to artificially raise stock prices, "that argument is undercut by the fact that [the Company] explicitly warned investors" about the potential costs and consequences of FDA regulation. See Abiomed, Inc., 778 F.3d at 243 (company statement "(a) that the FDA might disagree with the company's assessment of the legality of its … practices, and (b) that, if the FDA took enforcement action against it, that 'could result in reduced demand for our products and would have a material adverse effect on our operations and prospects'" negated the misleading nature of other related claims). In fact, Defendants warned investors about this risk repeatedly. Cons. Am. Compl. ¶ 231 [Doc. No. 107] (cautionary statement that "failure to obtain or maintain approvals, clearances, or compliance could impact financial projections and/or subject us to penalties or liabilities" repeated August 11, September 15, October 7, and October 8, 2021). And in November 2021, when an employee blew the whistle on the improper Flexcera manufacturing process, the company did *not* re-issue this general warning: it instead specifically told investors that it was investigating a manufacturing issue. Id. at ¶ 185. All told, Defendants' disclosures with respect to the company's regulatory compliance requirements were not misleading.

Finally, Plaintiffs do not dispute that dentures produced with Flexcera resin were generally capable of achieving the quality specifications Defendants advertised. Instead, they allege that when cured with one of EnvisionTEC's products—the PCA 4000—the resultant Flexcera dentures did not meet those standards. But Plaintiffs do not point to a single statement

suggesting that the PCA 4000 was actually responsible for achieving or optimizing Flexcera's touted qualities. In fact, Plaintiffs do not point to a single statement that expressly links Flexcera resin and the PCA 4000 at all. As such, the statements about Flexcera's superior characteristics are best characterized as "immaterial expressions of corporate optimism or puffery," which cannot serve as the basis for securities fraud. See In re Biogen Inc. Sec. Litig., 193. F. Supp. 3d 5, 42-43 (D. Mass. 2016) (statements that product is "compelling treatment," "terrific product," and "a major business driver" not actionable).

Plaintiffs have pointed to one statement made on May 26, 2021, and repeated in subsequent SEC registration filings, that arguably makes a representation about the PCA 4000's ability to cure any EnvisionTEC dental resin.[5] Cons. Am. Compl. ¶ 220 [Doc. No. 107]. However, Plaintiffs have not alleged that the PCA 4000 was incapable of curing *all* "parts printed using [EnvisionTEC's] CDLM or DLP platforms," see id. at ¶ 220—just parts made with Flexcera resin. And the statement does not make any reference to Flexcera specifically.[6] Nor have Plaintiffs alleged any facts that would make this statement, even if it were a misrepresentation, a material one.[7] For instance, Plaintiffs have not alleged that sales of the PCA

[5] Even if the S-1 registration statement constituted a misrepresentation about the PCA 4000, Plaintiffs have failed to show that (a) the defendant with actual knowledge of wrongdoing, El-Siblani, was a "maker" of that statement, and (b) either of the other two defendants, Fulop and Jafar, acted with the requisite scienter. See Section IV.B., infra.

[6] In fact, Defendants did not issue a total recall of the PCA 4000; it recalled the device only as to "non-industrial users." Id. at ¶ 191.

[7] Plaintiffs make two discrete claims about the PCA 4000's lackluster performance. First, Plaintiffs allege that because the Company was not following the German team's recommendation about curing times with the PCA 4000, customers were experiencing poor product results. But Plaintiffs fail to reconcile their allegation that the Company had recently "more than doubled" its prior curing time recommendation of 15 minutes in response to customer complaints with their allegation that the Company was not complying with the German team's recommendation of a 30-60 minute curing time for the PCA 4000. Id. at ¶ 171. Second, Plaintiffs allege that an independent investigator confirmed that the PCA 4000 was not capable

4000 contributed in any significant way to Desktop Metal's overall revenue, or that the PCA 4000 was a product that sparked investor interest and attention such that information about it would have caused a change in Desktop Metal's overall valuation.[8] See CVS, 46 F.4th at 31 (complaint failed to show that "alleged misstatements contradicted the state of that business as it then stood"). As such, "Plaintiffs' contention that the omission would have mattered to a reasonable investor depends on a long chain of inferences, most of which are not sufficiently substantiated by the allegations in the complaint." See Abiomed, Inc., 778 F.3d at 242.

As a result, Plaintiffs have not alleged any statement that constitutes material fraud and/or misrepresentation under the PSLRA.

B. Scienter

Scienter is a "mental state embracing [an] intent to deceive, manipulate, or defraud." Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976). The First Circuit has interpreted "scienter" to encompass both a "conscious intent to defraud" and/or a "high degree of recklessness." ACA Fin. Guar. Corp., 512 F.3d at 58 (quoting Aldridge v. A.T. Cross. Corp., 284 F.3d 72, 82 (1st Cir. 2002)). At the pleading stage, Plaintiffs must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). A "strong" inference "must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of

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of producing the results reported to FDA in the Flexcera approval application. But the investigation's findings were not reported to any of the Defendants until September 2021, when an employee presented them to Defendant Jafar. Id. at ¶ 179. And two months later, the Company undertook an independent investigation of the PCA 4000 line (followed, two months after that, by a recall). Id. at ¶ 190.

[8] Plaintiffs allege that El-Siblani pushed sales of the PCA 4000 over the Otoflash, but do not allege that PCA 4000 sales actually increased. Id. at ¶¶ 164-166. Additionally, Plaintiffs also allege elsewhere that EnvisionTEC continued to promote the Otoflash over the PCA 4000 in EnvisionTEC's public-facing materials. Id. at ¶ 159, F.19.

nonfraudulent intent." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 314 (2007). This pleading standard is "rigorous." ACA Fin. Guar. Corp., 512 F.3d at 58. To satisfy it, Plaintiffs must set forth "'clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendants were aware that they were withholding vital information or at least were warned by others that this was so.'" Brennan v. Zafgen, Inc., 853 F.3d 606, 613-614 (1st Cir. 2017) (quoting In re Bos. Sci. Corp. Sec. Litig., 686 F.3d 21, 31 (1st Cir. 2012)).

1. Core Operations Theory

As a threshold issue, Plaintiffs often do not specify which individual Defendant is responsible for the allegedly misleading statement. E.g., Cons. Am. Compl. ¶¶ 215, 220, 236-237 [Doc. No. 107]. Instead, Plaintiffs rely on the theory of "imputed knowledge about core operations," asserting that "because dental channel sales were core to the Company's short-term profitability and longer-term success, the materially false statements and omissions detailed herein could not have occurred without the Individual Defendants' knowledge and approval." Id. at ¶¶ 246-247. Defendants counter by noting that the First Circuit has not adopted a "core operations" theory, and in any event, Plaintiffs have not alleged that Flexcera and/or the PCA 4000 were "central to [the Company's] continued survival" as required by the test. Def. Mem. Mot. to Dismiss 17 [Doc. No. 111] (emphasis omitted) (quoting Lenartz v. Am. Superconductor Corp., 879 F. Supp. 2d 167, 183 n. 9 (D. Mass. 2012)).

The court finds that Plaintiffs have sufficiently alleged that Flexcera was a major revenue source for EnvisionTEC, and EnvisionTEC itself could eventually total 40% of Desktop Metal's total revenue. But the allegations are insufficient to show that Flexcera and/or the PCA 4000 was

central to Desktop Metal's core survival. As such, even if this court were to adopt the core operations theory, it would not succeed here.

2. Defendant El-Siblani

Plaintiffs allege only one statement made directly by El-Siblani. Cons. Am. Compl. ¶ 203 [Doc. No. 107] (Desktop Metal's FY 2020 Annual Report Form for the period ending December 31, 2020, signed March 15, 2021, by Fulop and El-Siblani). Plaintiffs argue that El-Siblani can nevertheless be considered a "maker" of the other twenty statements because as CEO of EnvisionTEC, he had "ultimate authority" over all statements insofar as they related to the subsidiary's activities. Pl. Oppo. Mot. to Dismiss 13 n. 22 [Doc. No. 113] ("After Desktop acquired EnvisionTEC, El-Siblani not only joined Desktop's Board but also 'continue[d] to le[ad]' the wholly owned EnvisionTEC subsidiary and 'serve[d] as Chief Executive Officer of the EnvisionTEC business.' In those capacities, he 'continued to have the same responsibilities, duties, and authority over EnvisionTEC's business activities,' which necessarily included statements concerning EnvisionTEC manufacturing and compliance procedures."). In response, Defendants argue that El-Siblani did not have "ultimate authority" over statements made by the parent company, Desktop Metal, because he did not have the final say or responsibility over the contents of those statements. Def. Mem. Motion to Dismiss 14-15 [Doc. No. 111]. Defendants also correctly note that Plaintiffs' only factual allegation regarding El-Siblani's involvement in statements made by Desktop Metal as a company was that he and the other Defendants "possessed the power and authority to control the contents of the Company's reports to the SEC" and other statements because they were all "provided with copies of the Company's reports and press releases…prior to, or shortly after, their issuance." Def. Reply MTD 14 [Doc. No. 114]; see Cons. Am. Compl. ¶ 38.

"For purposes of [a private action under] Rule 10b-5, the maker of a statement is the person or entity with ultimate authority over the statement." Janus Capital Grp., Inc. v. First Derivative Traders, 564 U.S. 135, 142 (2011). The First Circuit has not addressed whether a subsidiary can ever be considered the "maker of a statement" on behalf of a parent company. See In re Boston Scientific Co. Sec. Litig., No. 20-12225-DPW, 2022 WL 17823837, at *15 n. 29 (D. Mass. Dec. 20, 2022). Regardless of whether that may occur in some circumstances, Plaintiffs' allegations are insufficient here. To start, Plaintiffs have not sufficiently alleged that El-Siblani had actual control over statements made by Desktop Metal regarding its EnvisionTEC subsidiary. Plaintiffs do not allege that El-Siblani signed the Quarterly Reports that mentioned EnvisionTEC, that El-Siblani was ever specifically consulted about the Reports' contents where they mentioned EnvisionTEC, that El-Siblani ever led or was present for the Investor Presentations or Earnings Calls, or that El-Siblani publicly spoke on behalf of Desktop Metal regarding EnvisionTEC. Even if that were not the case, Plaintiffs have also not sufficiently alleged that El-Siblani was "uniquely" vested with such control. E.g., Cons. Am. Compl. ¶ 33 [Doc. No. 107] ("Fulop"—and only Fulop— "regularly signed, approved of, or had the power to exercise control over Company public statements and regulatory filings").

3. Defendants Fulop and Jafar

Plaintiffs do not allege sufficient facts for this court to conclude that either Defendant Fulop or Defendant Jafar acted with knowledge of any underlying misconduct or with an intent to defraud investors when making their public statements. Plaintiffs allege that Defendants were involved in the day-to-day operations of the company. Id. at ¶ 249 (Fulop "involved in all aspects of operations"); ¶ 252 (Fulop and Jafar "aware of the status of all material matters"). That is insufficient to show scienter. See, e.g., In re Wayfair, Inc. Sec. Litig., 471 F. Supp. 3d 332, 345

(D. Mass. 2020) ("[A] vague assertion that Defendants must have known something by virtue of their position of authority does not suffice to adequately allege a strong inference of scienter.") (quoting Sousa v. Sonus Networks, Inc., 261 F. Supp. 3d 112, 120 (D. Mass. 2017)). Other than generalized statements about Defendant Fulop's involvement in managing his various business operations, Plaintiffs do not allege that Fulop had any firsthand knowledge of the Flexcera product manufacturing process or PCA 4000 product performance. None of the seven confidential informants Plaintiffs rely upon, Cons. Am. Compl. ¶¶ 40-46 [Doc. No. 107], allege that they spoke directly to Defendant Fulop, or that they ever attended a meeting or presentation where Defendant Fulop was present and information about Flexcera manufacturing or PCA 4000 product performance was discussed.

Plaintiffs also attempt to extrapolate from the fact that Defendant Jafar "frequently attended and/or ran" sales meetings that he was privy to information about manufacturing practices and product quality. Id. at ¶ 37. But Plaintiffs never allege that such information was expressly presented at *any* sales meeting,[9] let alone a sales meeting that Jafar actually attended. Plaintiffs do not allege that Jafar had knowledge of any issues with either the Flexcera manufacturing or the PCA 4000's performance until September 2021, when a former employee presented the results of the independent study to Jafar. Id. at ¶ 179. But all of the allegedly false or misleading statements attributable to Jafar occurred before that date. Plaintiffs also claim that Jafar's June 2022 resignation—six months after the manufacturing violations and product quality issues were discovered—"strongly suggest[s] that Jafar too was pushed out for knowingly or

[9] The closest Plaintiffs come is detailing one salesman's concerns about the PCA 4000 in a dental channel sales meeting. Cons. Am. Compl. at ¶¶ 164, 167 [Doc. No. 107]. But Plaintiffs do not allege that Defendant Jafar was present at that particular meeting. Nor do Plaintiffs allege that Dillon (the salesman) specified the basis for his concerns to anyone other than with another employee in a private conversation following the conclusion of the sales meeting. Id. at ¶ 167.

recklessly engaging in misconduct." Id. at ¶ 256. That kind of nonspecific inferential reasoning does not suffice to allege scienter. See City of Dearborn Heights, 632 F.3d at 760 ("mere suspicion is not enough" to allege scienter).

In sum, Plaintiffs have failed to allege that Defendants Fulop and Jafar acted with scienter when making any public statements about Flexcera's FDA approval status or about EnvisionTEC's product quality.

4. The Non-Fraudulent Inference

Finally, Plaintiffs must sufficiently allege that the fraudulent inference is at least as compelling as the non-fraudulent inference in order to meet the pleading standard for scienter. Tellabs, 551 U.S. at 324. Here, they have not done so. For the reasons described above, Plaintiffs' narrative—that Defendants were engaged in a monthslong coverup of manufacturing violations that affected 10% of one product produced by a subsidiary, when the parent company's revenue stream did not depend on that product—relies more heavily on speculation than on plausible factual allegations. The competing narrative—that Defendants reacted quickly and responsibly to a whistleblower complaint and voluntarily recalled the offending products without FDA intervention—is both supported by the allegations Plaintiffs have put forward and free of inferential guesswork. See City of Dearborn Heights Act 345 Police & Fire Ret. Syst. v. Waters Corp., 632 F.3d 751, 758 (1st Cir. 2011) (even where defendants had actual knowledge of undisclosed facts, "the inference of a nonculpable explanation for the lack of disclosure is much stronger than the inference of scienter"). As such, Plaintiffs have not satisfied the standard for demonstrating scienter.

C. Loss Causation

Because the court finds that the statements are not materially misleading, and that none of the individual Defendants had the requisite scienter when making and/or authority to make the statements, the court need not address the issue of loss causation.

D. Section 20 Claims

Section 20 allows claims to be brought against persons who "control[] any person liable" under a different provision of the Act. 15 U.S.C. § 78t(a). But, as discussed above, Plaintiffs have failed to allege such a predicate violation. As a result, Plaintiffs' claims under Section 20(a) also fail. See Mehta v. Ocular Therapeutix, Inc., 955 F.3d 194, 211 (1st Cir. 2020) ("A claim brought under Section 20(a) is thus derivative of a claim alleging an underlying securities law violation.").

E. Leave to Amend

Plaintiffs requested in their briefing that if the court is inclined to grant Defendants' motion, that they be allowed to amend their complaint. Pl. Opp. 21 [Doc. No. 113]. Here, Plaintiffs did not promptly seek leave to amend their complaint to address any deficiencies after reviewing Defendants' Motion to Dismiss and have not suggested any basis for waiting to amend their complaint until after that Motion is decided. See ACA Financial Guaranty Corp. v. Advest, 512 F.3d 46, 56 (1st Cir. 2008) ("Plaintiffs may not…wait in the wings" to see whether the district court finds their first complaint adequate); see also City of Miami Fire Fighters' and Police Officers' Ret. Trust v. CVS, 46 F.4th 22, 38 (1st Cir. 2022) ("[T]here is no basis for contending that in this case the grounds for dismissal were somehow a surprise."). Nor did they submit a proposed second amended complaint with their request, or articulate what additional

facts would be alleged in a proposed amendment. As a result, Plaintiffs' request for leave to amend is denied.

V. Conclusion

For the reasons stated herein, Defendants' Motion to Dismiss is GRANTED.

IT IS SO ORDERED.

Dated: September 20, 2023

/s/ Indira Talwani
United States District Judge