IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF UTAH

In Re PolarityTE, Inc., Securities Litigation	**MEMORANDUM DECISION AND ORDER GRANTING DEFENDANTS' MOTIONS TO DISMISS AND RESOLVING PENDING MOTIONS** Case No. 2:18-cv-00510 Howard C. Nielson, Jr. United States District Judge

Plaintiffs Jose Moreno and Yedid Lawi each sued Defendants PolarityTE, Inc., Denver Lough, and John Stetson under the Securities Exchange Act and regulations promulgated thereunder. Plaintiffs sued on their own behalf and on behalf of a proposed class of investors. After Judge Parrish consolidated the two actions and appointed Mr. Lawi as lead Plaintiff, Defendants filed two motions to dismiss. The court grants these motions.

I.

PolarityTE is "a commercial-stage biotechnology and regenerative biomaterials company" founded by Denver Lough and Edward Swanson that designs and develops regenerative skin tissue products.[1] Dkt. No. 45 ¶ 2; *see id.* ¶ 44. John Stetson "served as

[1] In deciding this motion, the court considers various documents submitted by both parties. *See* Dkt. Nos. 61, 70, 80, 81; *cf.* Dkt. No. 59 (ruling that Dkt. No. 53 will be considered). At this stage of the proceedings, the court may consider not only the "facts . . . alleged in the complaint itself," but also "documents referred to in the complaint if the documents are central to the plaintiff's claim and the parties do not dispute the documents' authenticity and matters of which a court may take judicial notice." *Employees' Retirement System of R.I. v. Williams Cos., Inc.*, 889 F.3d 1153, 1158 (10th Cir. 2018) (cleaned up). The court may take judicial notice of

PolarityTE's CFO until June 20, 2018, when he was appointed as Chief Investment Officer and President of the Company's newly formed strategic development office." *Id.* ¶ 46. He served in this position until he was fired on September 7, 2018. *Id.*

PolarityTE's "leading product," designed by Dr. Lough, is SkinTE, which is intended to repurpose a patient's own skin to heal damaged or lost skin tissue. *Id.* ¶ 2. After developing the technology behind SkinTE, Dr. Lough filed several applications to patent this technology with the United States Patent and Trademark Office ("USPTO") between December 2014 and July 2017. *Id.* ¶¶ 258, 260.

A.

In order to raise the capital needed to turn this invention into a fully commercialized product, PolarityTE engaged in a reverse merger with Majesco Entertainment Holdings in December 2016. This transaction "involved the acquisition of a public company [a Majesco subsidiary] by a private company (PolarityTE) so that the private company could bypass the lengthy and complex process of going public." *Id.* ¶ 145. PolarityTE then gave "over $104 million of PolarityTE stock" to Dr. Lough in exchange for his pending patent applications. *Id.* ¶ 6.

During the merger, Majesco stated that investing in PolarityTE "involve[d] a high degree of risk," and that "Polarity[TE]'s business is subject to continuing regulatory compliance" by the Food and Drug Administration ("FDA"), including the FDA's "requirements for registration and listing of products . . . and inspection and enforcement." Dkt. No. 53-3 at 7, 9. The Form 8-K

---

adjudicative facts that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." FED. R. EVID. 201. Publicly available government records are a classic example of such sources. All of the exhibits provided by the parties are either publicly available government documents or are referred to in the Amended Complaint and central to Plaintiffs' claims.

filed by Majesco on December 7, 2016, further stated that PolarityTE's technology was "not currently protected by issued patents," and that PolarityTE could not "ensure that any of its pending patent applications [would] result in issued patents." *Id.* at 8.

B.

On March 31, 2017, a week before the merger closed, the USPTO "posted on the . . . SkinTE Patent Application's website its decision to issue a Non-Final Rejection of the patent." Dkt. No. 45 ¶ 6. The USPTO concluded that the patent application "failed the written description requirement" and was also "'obvious' in light of three prior publications." *Id.* ¶ 49. A letter notifying PolarityTE of this decision was mailed on "the same day [as] the [m]erger." *Id.* ¶ 6. After this Non-Final Rejection, PolarityTE made several conflicting statements, sometimes stating that Dr. Lough had patented the SkinTE technology, and sometimes indicating that the patent was pending.[2] PolarityTE clearly indicated in at least three SEC filings, however, that PolarityTE "do[es] not currently own any issued patents" and that PolarityTE "cannot ensure that any of the pending patent applications we acquire, have acquired, or may file will result in issued patents." Dkt. Nos. 70-1 at 3, 70-2 at 5, 70-3 at 4.

In June 2018, USPTO posted a "Final Rejection of the November 2015 SkinTE Patent Application." Dkt. No. 45 ¶ 92. "The USPTO determined that 'no claim is allowed' because [the patent applications] were 'obvious' as defined by 35 U.S.C. 103." *Id.* PolarityTE never directly addressed this Final Rejection, but it did make a few statements that were more cautious regarding the patent applications, indicating, for example, that "[s]ome of the factors that may

[2] *Compare, e.g.*, Dkt. No. 45 ¶ 51 (PolarityTE "is the owner of a novel regenerative medicine and tissue engineering platform developed and patented by Dr. Lough") (emphasis omitted), *with, e.g., id.* ¶ 62 ("Dr. Lough is the named inventor under a pending patent application") (emphasis omitted).

cause the market price of our common stock to fluctuate" include "developments or disputes concerning patents." *Id.* ¶ 94 (emphasis omitted).

In October 2017, several months after the USPTO's initial rejection of the patent, *Seeking Alpha* published an article "exposing PolarityTE's contradictory, misleading and flipflopping statements" in which the Company had "at times" stated that it had "patented technology" and at other times stated that it had a "patent application." *Id.* ¶ 9. This article acknowledged, however, that PolarityTE's SEC filings "clearly indicate[] that the company's asset is a patent application that has not yet been granted by the USPTO." Dkt. No. 53-12 at 19 (emphasis omitted). After this article was published, PolarityTE's stock price fell by 3.94%. *See* Dkt. No. 45 ¶ 112.

In June 2018, after the USPTO's final rejection, *Citron Research* issued an article "exposing the Defendants' failure to disclose" this rejection or the previous non-final rejection. *Id.* ¶ 113. An article published in *Seeking Alpha*'s the next month, however, argued that the *Citron Research* article "greatly exaggerated the significance of [PolarityTE's] initial patent application rejection." Dkt. No. 53-14 at 2. Following the release of the *Citron Research* article, PolarityTE's stock price fell by 31.81%. *See* Dkt. No. 45 ¶ 114.

PolarityTE then issued a press release that in part addressed the *Citron Research* article, stating that PolarityTE "is actively pursuing a variety of claims within multiple published non-provisional patent applications in the U.S." and that it "is common for a first office action [from the USPTO] to be referred to as a 'non-final rejection,' and for a second office action to be referred to as a 'final rejection.'" *Id.* ¶ 115. And indeed, the USPTO itself recognizes that a "Final Rejection" does not in fact terminate a patent application: "there is no such thing as a terminal rejection. Prosecution terminates with either an issued patent or an abandonment" of the

application. Dkt. No. 53-19 at 5. "PolarityTE's share price fell another . . . 12.68%" after this press release. Dkt. No. 45 ¶ 116.

C.

Meanwhile, on October 3, 2017, PolarityTE announced that it had registered SkinTE with the FDA "as an HCT/P solely under Section 361 of the Public Health Service Act and 21 CFR 1271." *Id.* ¶ 66 (emphasis omitted). An HCT/P is a human cells and tissue-based product. *Id.* The Public Health Service Act provides two avenues for registering HCT/Ps—Section 351 and Section 361.

For an HCT/P to be qualified for registration under Section 361, it must meet the following criteria:

> (1) The HCT/P is minimally manipulated;
>
> (2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
>
> (3) The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and
>
> (4) Either:
>
> (i) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
>
> (ii) The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
>
> (a) Is for autologous use;
>
> (b) Is for allogeneic use in a first-degree or second-degree blood relative; or
>
> (c) Is for reproductive use.

21 C.F.R. § 1271.10(a).

Unlike HCT/Ps registered under Section 351, HCT/Ps registered "under Section 361 are not required to obtain premarket approval/clearance from the FDA and do not require the extensive registration, manufacturing, and reporting steps required [for registration] under Section 351 since the marketers of HCT/Ps are permitted to self-designate." *Id.* ¶ 253. "The time to market for a Section 361 HCT/P is typically one to two years and the development costs run around $1 million," while for a product registered under Section 351, "time to market from first development is typically over 10 years and development costs can run well into the billions." *Id.* ¶¶ 252–53.

Before and after registering SkinTE under Section 361, PolarityTE made several statements representing that SkinTE was "appropriately" registered under Section 361 because it is an "autologous, homologous" product. *See, e.g.*, *id.* ¶ 55 (PolarityTE June 8, 2017, Form 8-K and attached press release "announc[ing] pre-clinical results for the SkinTE product and claim[ing] that it is an autologous homologous SkinTE^{TM} construct" (cleaned up)); *Id.* ¶ 85 (PolarityTE's March 19, 2018, 10-Q stating that PolarityTE "believe[s] that our current product candidates are appropriately regulated under Section 361" (cleaned up)).

In July 2018, *Seeking Alpha* published an article arguing "that the SkinTE product did not meet the requirements for regulation under Section 361 because the product did not meet the 'minimally manipulated' and 'not combined with another article' prongs*." Id*. ¶ 117. The article opined that SkinTE "obviously meets the other requirements for" Section 361 registration, however. Dkt. No. 53-14 at 3. The article acknowledged that its conclusions were not based upon "any statements by management" or the FDA, and it warned readers to "not take our word as gospel" as the authors were "far from lawyers or specialists in regenerative medicine." *Id*. at 4–5. The same month, *Ozgur Ogut* also published an article, likewise maintaining that SkinTE "did

not meet the 'homologous use'" requirement for Section 361 registration. Dkt. No. 45 ¶ 119. More broadly, this article questioned *"*how SkinTE meets the first, second, and third criteria" for Section 361 registration. Dkt. No. 53-15 at 9. After these articles were published, PolarityTE's share price fell 12.41%. Dkt. No. 45 ¶ 120.

Two years later, on August 6, 2020, PolarityTE filed a Form 10-Q reporting that after "informal, voluntary discussions between [PolarityTE] and the FDA . . . [the FDA's] preliminary assessment is that SkinTE does not meet the requirements to be regulated" under Section 361, and that SkinTE "should be regulated under Section 351" instead. Dkt. No. 81 at 3. PolarityTE stated that it had "re-evaluated [its] regulatory approach and determined it is prudent to submit an investigational new drug application (IND), and thereafter a biologics license application (BLA) for SkinTE, and to adjust the focus of [its] commercial effort for SkinTE." *Id.*

D.

In the first half of 2018, PolarityTE moved its manufacturing to an approximately 200,000-square-foot facility in Salt Lake City, Utah. *See* Dkt. No. 45 ¶ 104. Soon after, "FDA inspectors conducted an examination of PolarityTE's" new facility. *Id.* ¶ 225; *see id.* ¶ 212. During such inspections, FDA "[i]nvestigators note facts that, in their judgment, constitute violations of FDA standards" and use "[a] Form 483 . . . [to] notify[] the inspected establishment's top management in writing of significant objectionable conditions" relating to FDA-regulated products at the location. *Id.* ¶ 213 (emphasis omitted). A Form 483 identifies the FDA's "inspectional observations," but does "not represent a final Agency determination regarding [the company's] compliance" with FDA regulations. Dkt. No. 53-16 at 2. After the inspection of PolarityTE's facility, the FDA issued a Form 483 documenting "eight separate observed violations of [FDA] regulations." Dkt. No. 45 ¶¶ 226–27. In September and October of

2018, two investing websites, *The Capitol Forum* and *Citron Research*, published articles reporting that PolarityTE had received a Form 483, and PolarityTE's stock fell by 12.87% and 17.05%, respectively, after the articles were published. *See id.* ¶¶ 123–26.

E.

"Following *The Capitol Forum* article, Polarity[TE] announced that it had notified governmental authorities of 'suspected significant illegal trading in [PolarityTE's] securities,' which appeared 'to be in strategic coordination with the publication of misleading materials,' including the [articles] discussed above." Dkt. No. 49 at 18 (quoting Dkt. No. 53-17 at 2). A few days later, "PolarityTE received a document request and inquiries from the SEC relating to subjects addressed in the short seller reports published by *Citron Research* and others." Dkt. No. 45 ¶ 170. While PolarityTE did not disclose this document request from the SEC in the Form 10-K that covered this period, the Form noted that

> [t]he market price for our common stock may be influenced by many factors, including: . . . announcement[s] of investigations or regulatory scrutiny of our operations or lawsuits filed against us. . . . Except as noted above, at October 31, 2018, we were not a party to any legal or arbitration proceedings that may have significant effects on our financial position or results of operations. No governmental proceedings are pending or, to our knowledge, contemplated against us.

Id. ¶ 109 (cleaned up).

II.

Section 10(b) of the Securities Exchange Act prohibits the use of "any manipulative or deceptive device" "in connection with the purchase or sale of any security." 15 U.S.C. § 78j(b). This statute also empowers the SEC to "prescribe [such rules] as necessary or appropriate [to protect] the public interest . . . [and] investors" from the use of such "manipulative or deceptive device[s]." *Id.* The SEC did so in Rule 10b-5, which makes it

> unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,
>
> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,
>
> in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

"Section 10(b) and Rule 10b-5 [together] create an implied private cause of action arising from fraud in the purchase or sale of securities." *Hampton v. root9B Techs., Inc.*, 897 F.3d 1291, 1298 (10th Cir. 2018); *see also Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 730 (1975). To properly state a claim, a plaintiff's complaint must allege:

> (1) a material misrepresentation (or omission),
>
> (2) scienter, *i.e.*, a wrongful state of mind,
>
> (3) in connection with the purchase or sale of a security,
>
> (4) reliance, often referred to in cases involving public securities markets (fraud-on-the-market cases) as "transaction causation,"
>
> (5) economic loss, and
>
> (6) "loss causation," *i.e.*, a causal connection between the material misrepresentation and the loss.

Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341–42 (2005) (cleaned up). The parties here dispute whether Plaintiffs have adequately alleged material misrepresentations or omissions, scienter, and loss causation.[3]

A.

"Information is material only if a reasonable investor would consider it important in determining whether to buy or sell stock." *Employees' Retirement System of R.I. v. Williams Cos., Inc.*, 889 F.3d 1153, 1167 (10th Cir. 2018) (internal quotations omitted). The court must also consider "other information already available to the market [because] unless the statement significantly alter[s] the 'total mix' of information available, it will not be considered material." *Grossman v. Novell, Inc.*, 120 F.3d 1112, 1119 (10th Cir. 1997) (cleaned up). As a general matter, "Rule 10b-5 does not create an affirmative duty to disclose any and all material information." *Williams Cos.*, 889 F.3d at 1164 (internal quotations omitted). Rather, "a duty to disclose arises only where both the statement made is material, and the omitted fact is material to the statement in that it alters the meaning of the statement." *Id*. (cleaned up)

Courts have identified several categories of statements that are generally not considered materially misleading. Two such categories recognized by the 10th Circuit are "pure statements of opinion" and "statements of optimism that are not capable of objective verification." *Hampton*, 897 F.3d at 1299 (cleaned up).

Pure statements of opinion are not materially misleading if they accurately represent "the speakers' beliefs concerning then-present factual conditions" and "rest on a factual basis that justifies them as accurate, the absence of which renders them misleading." *Id.* (internal

[3] The court does not reach the question whether Plaintiffs have adequately alleged scienter because it concludes that Plaintiffs have failed adequately to allege materiality, loss causation, or both, for each of the misrepresentations or omissions they allege.

quotations omitted). This does not mean that "[a]n opinion statement . . . [is] necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way" because "[r]easonable investors understand that opinions sometimes rest on a weighing of competing facts." *Omnicare, Inc. v. Laborers Dist. Council Const. Industry Pension Fund*, 575 U.S. 175, 189–90 (2015). Whether this kind of omission is "misleading always depends on context." *Id.* at 190. For example, a reasonable investor analyzing a formal SEC document "reads each statement . . . in light of all its surrounding text, including hedges, disclaimers, and apparently conflicting information . . . [and] an omission that renders misleading a statement of opinion when viewed in a vacuum may not do so once that statement is considered . . . in a broader frame." *Id.*

Statements of "corporate optimism" or "mere puffing" are "forward-looking statements" or "generalized statements of optimism." *Grossman*, 120 F.3d at 1119. Such statements "are not capable of objective verification" and are generally "not actionable because reasonable investors do not rely on them in making investment decisions." *Id.* They may, however, constitute material misstatements if "they inaccurately represent the speakers' beliefs concerning then-present factual conditions." *Hampton*, 897 F.3d at 1299 (internal quotations omitted).

B.

To adequately plead "loss causation," a complaint must allege "that a [material] misrepresentation that affected the integrity of the market price *also* caused a subsequent economic loss." *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804, 812 (2011) (emphasis in original). Even if a plaintiff can show that the "price on the date of purchase was inflated because of [a] misrepresentation . . . [a] drop [in stock price] could instead be the result of other intervening causes, such as changed economic circumstances, changed investor

expectations, new industry-specific or firm-specific facts, conditions, or other events." *Id.* at 812–13 (cleaned up). If any factor other than the misrepresentation is "responsible for the loss . . . a plaintiff would not be able to prove loss causation." *Id.* at 813. "The plaintiff bears the burden of showing that his losses were attributable to the revelation of the fraud and not the myriad [of] other factors that affect a company's stock price" and "[w]ithout showing a causal connection that specifically links losses to misrepresentations, [the plaintiff] cannot succeed." *In re Williams Secs. Litig.-WCG Subclass*, 558 F.3d 1130, 1137 (10th Cir. 2009).

"Loss causation is easiest to show when a corrective disclosure reveals the fraud to the public and the price subsequently drops—assuming, of course, that the plaintiff could isolate the effects from any other intervening causes that could have contributed to the decline." *Id*. For a disclosure to be corrective, it does "not [need to] precisely mirror the earlier misrepresentation, but it must at least relate back to the misrepresentation and not to some other negative information about the company." *Id.* at 1140.

Although the Tenth Circuit appears not to have squarely addressed the issue, various other circuits have held that a corrective disclosure must disclose nonpublic information. *See, e.g.*, *Meyer v. Green*, 710 F.3d 1189, 1198 (11th Cir. 2013) ("a corrective disclosure obviously must disclose new information" (cleaned up)); *In re Omnicom Grp., Inc. Secs. Litig*., 597 F.3d 501, 511 (2d Cir. 2010) (finding the alleged corrective disclosures failed because "none . . . purported to reveal some then-undisclosed fact"); *cf. Hampton v. Root9B Techs., Inc.*, No. 15-cv-02152-MSK-MEH, 2016 WL 9735744, at *6 n.6 (D. Colo. Sept. 21, 2016), aff'd, 897 F.3d 1291 (10th Cir. 2018) (expressing doubt that a "publication . . . which relied exclusively on publicly-available information . . . can constitute the type of corrective disclosure" sufficient to demonstrate loss causation (cleaned up)).

This is especially true under an efficient market theory, such as that alleged by Plaintiffs here, *see* Dkt. No. 45 ¶ 312, where courts presume that "all publicly available information about a security is reflected in the market price of the security." *Meyer*, 710 F.3d at 1197. In an efficient market, any information "released to the public is immediately digested and incorporated into the price of a security." *Id*. "A corollary of the efficient market hypothesis is that disclosure of confirmatory information—or information already known by the market—will not cause a change in the stock price." *Id*. (quoting *FindWhat Investor Grp. v. FindWhat.com*, 658 F.3d 1282, 1310 (11th Cir. 2011)); *see also Bricklayers and Trowel Trades Int'l Pension Fund v. Credit Suisse Secs. (USA) LLC*, 752 F.3d 82, 95 (1st Cir. 2014) ("disclosures . . . [that] did no more than to provide gloss on public information . . . [do] not [move a company's] share price in an efficient market"). It follows that "[c]orrective disclosures must present facts to the market that are new, that is, publicly revealed for the first time." *Meyer*, 710 F.3d at 1197–98.

C.

To survive a motion to dismiss, a complaint typically must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "[P]laintiff must offer specific factual allegations to support each claim" and "mere 'labels and conclusions'" or "a formulaic recitation of the elements of a cause of action will not suffice." *Kansas Penn Gaming, LLC v. Collins*, 656 F.3d 1210, 1214 (10th Cir. 2011). "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 making this determination, the court "must accept all the well-pleaded allegations of the complaint as true and must construe them in the light most favorable to the plaintiff." *Sylvia v. Wisler*, 875 F.3d 1307, 1313 (10th Cir. 2017).

The Private Securities Litigation Reform Act of 1995, however, "created a heightened pleading standard applicable to the first . . . element[]" of Plaintiffs' claim. *In re Gold Res. Corp. Secs. Litig.*, 776 F.3d 1103, 1108–09 (10th Cir. 2015). For a complaint to survive a motion to dismiss under this statute, it must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1)(B). In addition, if the alleged misleading statement is one of opinion, the "plaintiff [must] meet a higher pleading standard," adequately alleging that the opinion "inaccurately represent[ed] the speakers' belief concerning then-present factual conditions." *Hampton*, 897 F.3d at 1299 (cleaned up).

III.

Plaintiffs allege that Defendants made numerous actionable misrepresentations. The parties agree that Dkt. No. 49-1 accurately catalogs these alleged misrepresentations. *See* Oral Argument at 1:03:19–01:03:34. The alleged misrepresentations fall into four categories: (A) statements relating to SkinTE's Section 361 registration; (B) statements relating to PolarityTE's manufacturing facilities; (C) statements relating to PolarityTE's patents or patent applications; and (D) a statement relating to pending or contemplated government proceedings against PolarityTE. *See* Dkt. No. 45; 49-1. The court concludes that Plaintiffs have failed to state a claim under Section 10(b) and Rule 10b-5 with regard to any of these statements.

A.

Plaintiffs allege that various statements regarding SkinTE's Section 361 registration violated the statute and rule. Some of these statements appear to be statements of fact. Examples include PolarityTE's October 3, 2017, press release, its February 2, 2018, press release, and its

March 14, 2018, Form S-3 filing. These statements all take some form of "SkinTE [] is registered with the United States Food and Drug Administration . . . under Section 361." Dkt. No. 49-1 at 6 (emphasis omitted). Other statements, such as the ones made in PolarityTE's January 30, 2018, Form 10-K, or March 19, 2018, Form 10-Q, appear to be statements of opinion. Some of these take some form of PolarityTE "believe[s] . . . SkinTE [to be] appropriately regulated by the FDA as 361 HCT/Ps." *Id.* at 4. Others address the specific requirements of Section 361.[4] The court concludes that the statements of fact were true when made and that Plaintiffs have likely failed to allege facts supporting a reasonable inference that the statements of opinion amounted to material misrepresentations. In all events, the court concludes that Plaintiffs have failed adequately to allege loss causation with regard to any of these statements.

1.

The statements that SkinTE was registered under Section 361, all of which were published before the most recent Form 10-Q filing and SkinTE's deregistration, were true. *See* Dkt. No. 45 ¶ 83. SkinTE was registered under Section 361 during the time when all these statements were made. *See* Dkt. Nos. 53-14; 53-15. These statements thus do not constitute material misrepresentations.[5]

[4] These include statements that SkinTE was "autologous," "minimally manipulated" and "intended for homologous use." Dkt. No. 45 ¶¶ 43, 66. For purposes of this opinion, the court groups such statements with PolarityTE's more general assertions that SkinTE was appropriately registered under Section 361.

[5] To the extent Plaintiffs argue that these statements were misleading because they were not accompanied by disclosures that SkinTE was not appropriately registered under Section 361, this argument fails for essentially the same reasons set forth in Parts III.A.2 and III.A.3.

2.

Plaintiffs contend that statements opining that SkinTE was appropriately registered under Section 361 registration were misleading "because they lacked any factual basis to justify the claim" that SkinTE "was appropriately registered and regulated under Section 361." Dkt. No. 60 at 21. But the court concludes that Plaintiffs have likely failed adequately to allege that these statements of opinion were materially false or misleading.

As discussed, when alleging that a statement of opinion amounts to a material misrepresentation, Plaintiffs must "meet a higher pleading standard," alleging facts supporting a reasonable inference that the statement "inaccurately represent[ed] the speakers' belief concerning then-present factual conditions." *Hampton*, 897 F.3d at 1299. To the extent Plaintiffs offer any allegations that would support this conclusion, those allegations are conclusory. *See, e.g.*, Dkt. No. 45 ¶¶ 78, 84 (alleging why the statements were "materially false and/or misleading" but making no attempt to allege why the statements did not accurately reflect the speaker's belief).

In addition, Plaintiffs likely fail to allege facts supporting a reasonable inference that PolarityTE lacked any "factual basis" for these opinions. *Hampton*, 897 F.3d at 1299. Neither Plaintiffs nor the authors of the investor research articles on which Plaintiffs rely claim to know the actual processes by which SkinTE is made. *See, e.g.*, Dkt. No. 45 ¶ 258 (Two of Dr. Lough's patent applications "*appear* to address the technology and *purported* invention underlying the SkinTE product" (emphasis added)); Dkt. No. 53-14 at 4 (*Seeking Alpha* July 2018 article admitting its authors "cannot find any statements by management describing what is done to a skin sample to turn it into the paste which is applied to wounds"). Although Plaintiffs and the articles base their assertions that SkinTE's registration was improper on "patent application[s],

the Lough Papers . . . [and] description[s] of the SkinTE product in [PolarityTE's] SEC filing[s] and business presentation," Dkt. No. 45 ¶ 268, they acknowledge that they do not in fact know "[w]hat is [in] the final SkinTE product." Dkt. No. 53-15 at 14. Furthermore, the articles on which Plaintiffs rely at least partially disagreed with each other. *Compare* Dkt. No. 53-14 at 4, 5 (*Seeking Alpha* article opining that although SkinTE "violates the minimal manipulation" and "not combined with another article" requirements for Section 361 registration, it "obviously meets the other requirements [since] the skin is not applied in the same surgical procedure, is intended for homologous use only, and does not have systemic or metabolic effects" (cleaned up)), *with* Dkt. No. 53-15 at 9 (*Ozgur Ogut* article questioning "how SkinTE meets the first, second, and third criteria" for Section 361 registration). Given that neither Plaintiffs nor the articles on which they rely can identify the processes used to create SkinTE, and that the articles disagreed in their analysis of whether SkinTE satisfied certain requirements for Section 361 registration, it is difficult to conclude that Plaintiffs have plausibly alleged that PolarityTE lacked any factual basis for its opinion statements that SkinTE was appropriately registered under Section 361.

To be sure, in its Form 10-Q for the quarterly period ending June 30, 2020, PolarityTE disclosed that after "informal, voluntary discussions between [PolarityTE] and the FDA," the FDA's "preliminary assessment is that SkinTE does not meet the requirements to be regulated" under Section 361, and that SkinTE "should be regulated under Section 351" instead. Dkt. No. 81 at 3. Following these discussions, PolarityTE "re-evaluated [its] regulatory approach and determined it is prudent to submit an investigational new drug application (IND), and thereafter a biologics license application (BLA) for SkinTE, and to adjust the focus of [its] commercial effort for SkinTE." *Id.* Plaintiffs argue that this is evidence that "Defendants misled investors during

the Class Period by claiming that SkinTE was appropriately registered and regulated under Section 361 . . . when, in fact, SkinTE did not meet the Section 361 registration criteria." Dkt. No. 80 at 1–2. This new filing does not change the court's assessment, however. It still seems likely that Plaintiffs have failed to allege facts supporting the reasonable inference that the opinion statements "inaccurately represent[ed] [PolarityTE's] belief concerning then-present factual conditions" at the time these statements were made and that PolarityTE lacked any "factual basis" for these opinions. *Hampton*, 897 F.3d at 1299.

3.

The court need not definitively determine whether Plaintiffs have adequately alleged that PolarityTE's statements regarding SkinTE's registration were material misrepresentations, however, because it concludes that Plaintiffs have failed adequately to allege loss causation through a corrective disclosure. (They have not attempted to allege loss causation in any other way.) The *Seeking Alpha* and *Ozgur Ogut* articles are not corrective disclosures because they do not reveal "some-then undisclosed fact." *In re Omnicom Grp.*, 597 F.3d at 511; *see also Meyer*, 710 F.3d at 1198 (to be corrective, a disclosure "obviously must disclose new information."). Indeed, Plaintiffs appear to admit that the information contained in the two articles was "widely disseminated" before publication. Dkt. No. 60 at 36. In addition, all of the sources on which these articles base their conclusions were publicly available: the *Seeking Alpha* article based its conclusion that the SkinTE "process violates the minimal manipulation requirement" on PolarityTE's publicly available patent applications, Dkt. 53-14 at 4–5, and the *Ozgur Ogut* article rested its assertion that "PolarityTE's technology raise[s] the question of how SkinTE meets the first, second, and third criteria" for Section 361 registration on PolarityTE's 2017 10K SEC filing, patent applications, and Dr. Lough's published scientific papers, Dkt. 53-15. Given these

articles' exclusive reliance on information gleaned from public filings and other publicly available sources, they do not constitute corrective disclosures and thus fail to establish loss causation. *See Meyer*, 710 F.3d at 1198.

To be sure, some cases have held that expert analysis of publicly available information can constitute a corrective disclosure. For example, in *Public Employees' Retirement System of Mississippi, Puerto Rico Teachers' Retirement System v. Amedisys*, the Fifth Circuit held that a Yale professor's article "analyz[ing] Medicare records to determine how often between 2005 and 2008 various home health companies sent therapists to patients' homes during a 60 day treatment period and whether such visits coincided with Medicare financial incentives" constituted a corrective disclosure even though it relied on publicly available data because the data was "complex" and "understandable only through expert analysis." 769 F.3d 313, 318, 323 (5th Cir. 2014). Here, by contrast, there is no indication that the anonymous authors of the articles on which Plaintiffs rely had any expertise beyond that of careful investors. *See* Dkt. No. 53-14; 53-15. Indeed, the authors of the *Seeking Alpha* article candidly acknowledged that they were "far from lawyers or specialists in regenerative medicine" and accordingly cautioned readers to "not take our word as gospel." Dkt. No. 53-14 at 5. Under these circumstances, the court concludes that these articles do not present the sort of expert analysis that might constitute corrective disclosures despite their reliance on publicly available information. *See Miller v. PCM, Inc.*, 2018 WL 5099722, at *11–12 (C.D. Cal. Jan. 3, 2018) (finding the *Seeking Alpha* article failed to qualify as a corrective disclosure in part because the author possessed no expertise).

B.

Plaintiffs also allege that two statements made by Dr. Lough regarding PolarityTE's manufacturing facilities are actionable. First, Dr. Lough stated on a September 12, 2018,

conference call that PolarityTE had "designed and built [its] first scalable biomedical manufacturing facility" and "moved [its] manufacturing headquarters to a new 200,000-square-foot facility in Salt Lake City . . . which [was] designed [to] support the manufacturing of SkinTE." Dkt. No. 49-1 at 8–9 (emphasis omitted). The next day Dr. Lough stated on another conference call that PolarityTE's new manufacturing headquarters had

> very large clean rooms . . . [that] contain essentially smaller clean rooms or . . . laminar flow glow lights that are boxes that are in them, which allows us to turnover products much more quickly and efficiently, and sort of creating a little bit more of . . . an assembly mechanism in order for us to maintain the absolute utmost aseptic technique, the best quality checks and assessment possible.

Id. Plaintiffs allege that these statements were materially false or misleading because in July 2018, FDA inspectors had issued a Form 483 after inspecting the new facilities listing eight "violations relating to the manufacture of SkinTE." Dkt. No. 60 at 23; *see also* Dkt. No. 45 ¶ 24. The court, however, concludes that the first statement was true when made and that Plaintiffs have failed to allege facts supporting a reasonable inference that the second statement was materially false or misleading.

1.

The statement that PolarityTE had moved its manufacturing headquarters to a new 200,000-square-foot facility in Salt Lake City appears true on its face, and Plaintiffs have not alleged any facts to the contrary. Nor do Plaintiffs allege that this facility was not PolarityTE's "first scalable biomedical manufacturing facility" or that it was not "designed [to] support the manufacturing of SkinTE." Dkt. No. 45 ¶ 104 (emphasis omitted).

Plaintiffs have failed to allege how PolarityTE's receipt of a Form 483 would render these materially false or misleading, since a Form 483 notes only possible "violations of FDA standards," *id.* ¶ 213—there is no allegation that, for example, the Form somehow indicated that

PolarityTE had not in fact moved or that the new facility was not designed to manufacture SkinTE. Plaintiffs have likewise failed plausibly to allege that Dr. Lough had any duty to disclose the receipt of the Form 483 in connection with this statement, since there is no plausible basis to think that receipt of the Form somehow "alters the meaning of the statement" made. *Williams Cos.* 889 F.3d at 1164 (emphasis omitted).

2.

The statements made on the second conference call are best characterized as statements of "corporate optimism," "mere puffing," or "generalized statements of optimism." *Grossman*, 120 F.3d at 1119. Such statements are generally "not actionable," *id.*, unless "they inaccurately represent the speakers' beliefs concerning then-present factual conditions." *Hampton*, 897 F.3d at 1299 (internal quotations omitted). Plaintiffs only allegation that could conceivably support an inference that Dr. Lough did not believe what he said is that PolarityTE had received the Form 483 two months earlier. And while Dr. Lough did not mention PolarityTE's receipt of this form, such an omission is itself actionable "only where both the statement made is material, and the omitted fact is material to the statement in that it alters the meaning of the statement." *Williams Cos.*, 889 F.3d at 1164 (cleaned up).

A Form 483, however, does "not represent a final Agency determination regarding compliance" but rather "lists observations made by the FDA representative(s) during the inspection." Dkt. No. 53-16 at 1. Indeed, in this case it appears that the FDA ultimately "closed the inspection with a Voluntary Action Indicated classification," reflecting an agency

determination that "the allegedly objectionable conditions [did] not meet the threshold of regulatory significance." Dkt. No. 49 at 23 n.11 (cleaned up).[6]

In addition, two months had passed between the inspection and Dr. Lough's statements, and it appears that PolarityTE had made at least some improvements to its processes in response to the Form 483. To be sure, Plaintiffs argue that "a letter from the FDA shows that [the FDA] was not satisfied with Defendants' response." Dkt. No. 60 at 25. But PolarityTE had not yet received this letter at the time of Dr. Lough's statements. *See* Dkt. No. 49-1 at 9. Nor did the letter suggest that PolarityTE had not attempted to address the concerns raised in the Form 483. Rather, it provides "concerns and comments regarding [PolarityTE's] responses designed to assist" PolarityTE moving forward. Dkt. No. 61-4 at 3. Among other things, the letter acknowledged that PolarityTE had "made some improvements to [its] environmental monitoring system" though it found that its "procedure still allow[ed] for high microbiological action levels." *Id.*

In light of these considerations, the court concludes that PolarityTE's receipt of the Form 483 does not support a reasonable inference that Dr. Lough did not believe the "puffing" statements of "corporate optimism" that he made on the second conference call and that, even assuming these "generalized statements of optimism" were somehow material, the receipt of the Form 483 did not "alte[r] the meaning" of these statements.

[6] To be sure, the FDA had not yet closed the inspection at the time the statement was made and did not do so until after the proposed class period. *See* Dkt. No. 60 at 10. But this outcome does underscore that a Form 483 is not a final agency determination and does not necessarily evidence material regulatory violations.

C.

Plaintiffs also allege that various statements regarding PolarityTE's patent applications violated Section 10(b) and Rule 10(b)(5). Some of these statements simply stated that Dr. Lough or PolarityTE had "pending patent applications." *E.g.*, Dkt. No. 49-1 at 3. Others, however, represented that PolarityTE's technology was "patented." *E.g.*, Dkt. No. 45 ¶ 7 (PolarityTE is the "owner of a novel regenerative medicine and tissue engineering platform developed and patented by Dr. Lough" (emphasis omitted)). Plaintiffs allege these statements constituted material misrepresentations because none of PolarityTE's technology was in fact patented. In addition, Plaintiffs allege that Defendants failed to disclose prior USPTO Non-Final and Final rejections of Dr. Lough's patent applications. *See, e.g.*, Dkt. No. 45 ¶¶ 6–8. The court, however, concludes that the statements regarding "pending patent applications" were true and that Plaintiffs have likely failed adequately to allege that the false statements that PolarityTE's technology was "patented" were material. In all events, Plaintiffs have again failed adequately to allege loss causation.

1.

As an initial matter, the statements that PolarityTE and Dr. Lough had "pending patent applications" were true. As explained earlier, neither the USPTO's Non-Final nor its Final rejection terminated these applications: "there is no such thing as a terminal rejection. Prosecution terminates with either an issued patent or an abandonment of the application." Dkt. No. 53-19 at 5. These statements thus do not constitute material misrepresentations. For the same reason, Defendants had no duty to disclose the rejections in connection with these statements, since the rejections did not "alte[r] the meaning of the statement[s]." *Williams Cos.*, 889 F.3d at 1164 (cleaned up).

2.

To be sure, Plaintiffs allege that on several occasions PolarityTE and Dr. Lough falsely described their technology as "patented." *See* Dkt. No. 45 ¶¶ 51, 53, 57, 68. When considered as part of the "total mix" of information readily available to a reasonable investor, however, the court concludes that these false statements were likely not material. *Grossman*, 120 F.3d at 1119.

The "total mix" of available information included, for example, Majesco's December 7, 2016, Form 8-K, which disclosed that PolarityTE's technology was "not currently protected by issued patents," and that PolarityTE could not "ensure that any of its pending patent applications [would] result in issued patents." Dkt. No. 53-3 at 8; *see also United Food & Commercial Workers Union Local 880 Pension Fund v. Chesapeake Energy Corp.*, 774 F.3d 1229, 1238 (10th Cir. 2014) (explaining that a reasonable investor would consider "public documents" as part of the "total mix" of available information). It also included PolarityTE's January 30, 2018, Form 10-K and its March 19, 2018, Form 10-Q, both of which likewise explicitly cautioned investors that the company could not "ensure that any of the pending patent applications we acquire, have acquired, or may file will result in issued patents," Dkt. No. 49-1 at 5–6, as well as information readily available on the USPTO website, from which a reasonable investor could confirm the status of these patent applications.[7]

Indeed, the conflicting statements made by PolarityTE and Dr. Lough regarding the status of the patent applications would likely give a reasonable investor sufficient pause to warrant independent verification. As the Tenth Circuit has explained, "a 'reasonable investor' is neither an ostrich, hiding her head in the sand from relevant information, nor a child, unable to

[7] Using an internet search engine, the court was able to ascertain the status of Dr. Lough's patent application within a matter of minutes.

understand the facts and risks of investing." *Chesapeake Energy Corp.*, 774 F.3d at 1238 (cleaned up). And given the wealth of public information regarding the status of PolarityTE and Dr. Lough's patent applications "already available to the market," the false statements that PolarityTE's technology was "patented" likely failed to "significantly alte[r] the 'total mix' of information available." *Grossman*, 120 F.3d at 1119; *see also Phillips v. LCI Int'l, Inc.*, 190 F.3d 609, 617 (4th Cir. 1999) ("even lies are not actionable when an investor possesses information sufficient to call the misrepresentation into question" (quoting *Teamsters Local 282 Pension Trust Fund v. Angelos*, 762 F.2d 522, 529 (7th Cir. 1985) (cleaned up)).

The cases cited by Plaintiffs in opposing this conclusion are distinguishable and unpersuasive. The decision in *Litwin v. Blackstone Group, L.P.*, for example, is factually distinguishable. There, the court found that publicly available information, the "potential future impact" of which was completely unknown by investors and "not even mentioned in Blackstone's Registration Statement," could not be "considered part of the 'total mix' of information already available to investors." 634 F.3d 706, 718–19 (2d Cir. 2011). Here, by contrast, PolarityTE's corporate disclosures repeatedly addressed the pendency of the company's patent applications, explaining how different potential outcomes could affect the company's success. *See, e.g.*, Dkt. No. 49-1 at 5–6. Plaintiffs also quote from the decision in *United Paperworkers Int'l Union v. International Paper Co.*, in support of their argument that because "the [patent] Rejections were not 'widely reported,'" information found on USPTO's website cannot be "part of the total mix" of information available to investors. Dkt. No. 60 at 21 (quoting 985 F.2d 1190, 1199 (2d Cir. 1993)). But the court in that case actually held that "[t]he 'total mix' of information may also include 'information already in the public domain *and* facts known *or* reasonably available to the shareholders.'" *United Paperworkers*, 985 F.2d at 1199 (emphasis

added). As discussed, information on the USPTO website was reasonably available to investors. And the court finds the decision in *Kronfeld v. Trans World Airlines, Inc.* not only distinguishable, but unpersuasive given its outdated assumptions and the absence of a fraud-on-the market theory in that case. *See* 832 F.2d 726, 736 (2d Cir. 1987). More generally, the court notes that all of these decisions are from the Second Circuit, which reads § 10(b) and Rule 10b-5 "broadly" compared to other Circuits. *PPM America, Inc. v. Marriott Corp*, 875 F. Supp. 289, 299 (D. Md. 1995).

3.

Regardless of whether these false statements were material, moreover, Plaintiffs once again fail adequately to allege loss causation. Plaintiffs allege that the October 2017 *Seeking Alpha* and June 2018 *Citron* articles were corrective disclosures because "[t]he market was alerted to Defendants' misrepresentations regarding SkinTE's patent status." Dkt. No. 60 at 35. But the October 2017 *Seeking Alpha* article simply reiterated information from PolarityTE's *publicly available* SEC filings. *See* Dkt. No. 45 ¶ 111; Dkt. No. 53-12. And the *Citron* article acknowledged that it "cut and pasted" the information on which it relied "from the USPTO website." Dkt. No. 53-13. Because these internet articles merely repackaged publicly available information without technical, expert, or authoritative analysis, they revealed no new information to the market and thus were not corrective disclosures. *See, e.g.*, *Meyer*, 710 F.3d at 1198 (no loss causation where the alleged corrective disclosure relied on information gleaned from public filings and other publicly available sources). Plaintiffs have alleged no other theory of loss causation.

D.

Finally, Plaintiffs allege that PolarityTE's statement on January 14, 2019, that no "governmental proceedings are pending against us or, to our knowledge, contemplated against us," Dkt. No. 45 ¶ 109 (emphasis omitted), was materially false or misleading because PolarityTE did not disclose that it had previously received a document request from the SEC, a fact that Plaintiffs claim made it "obvious that an investigation was being contemplated." Dkt. No. 60 at 26. The court rejects this contention and concludes that Plaintiffs have failed to allege facts supporting a reasonable inference that this statement was materially false.

At the time this statement was made, the only alleged action taken by the SEC was an inquiry and request for documents "relating to subjects addressed in the [investment research] reports." Dkt. No. 45 ¶ 109. This document request occurred immediately after PolarityTE "notified [multiple regulatory bodies] of suspected significant illegal trading in [PolarityTE's] securities" that "appear[ed] to be in strategic coordination with the publication of" the investment research articles. Dkt. No. 53-17 at 2. But an isolated document request is not an investigation, and it seems unreasonable to infer that Defendants expected an SEC investigation based solely on the alleged document request. *Cf.*, *e.g.*, *Home Ins. Co. of Ill. v. Spectrum Info. Techs.*, 930 F. Supp. 825, 839 (E.D.N.Y. 1996) ("[Plaintiff] implausibly argues that [Defendant] failed to disclose the SEC Inquiry . . . [as] any other litigation. . . . Plainly, the SEC Inquiry did not constitute any type of litigation." (cleaned up).

Even accepting Plaintiffs' claim that an investigation was obviously contemplated, however, PolarityTE did not represent that no *investigation* was pending or contemplated. Rather, it stated that no "governmental *proceedings* are pending against us or, to our knowledge, contemplated against us." Dkt. No. 45 ¶ 109 (cleaned up). But "[a]n investigation on its own is

not a 'pending legal proceeding' until it reaches a stage when the agency or prosecutorial authority makes known that it is contemplating filing suit or bringing charges." *Plymouth County Retirement System v. Patterson Companies, Inc.*, No. 18-cv-871 (MJD/SER), 2019 WL 3336119, at *14 (D. Minn. July 25, 2019) (quoting *Richman v. Goldman Sachs Grp., Inc.*, 868 F. Supp. 2d 261, 272 (S.D.N.Y. 2012)); *see also In Re Lions Gate Entertainment Corp. Secs. Litig.*, 165 F. Supp. 3d 1, 18 (S.D.N.Y. 2016) (an SEC "investigation [is only] a 'pending legal proceeding' or one 'known to be contemplated by governmental authorities'" when the SEC "decide[s] whether it [will] charge . . . [defendants] with securities violations"). Since the SEC had not informed PolarityTE that it was "contemplating filing suit or bringing charges," there was no reason for PolarityTE to assume that any proceeding was contemplated against it.

* * *

Plaintiffs have thus failed to state a claim under Section 10(b) and Rule 10(b)-5 based on any of the misrepresentations they allege.

IV.

Because Plaintiffs have failed to state a claim under Section 10(b) and Rule 10(b)-5, they have also failed to state a claim for control-person liability under Section 20(a), and the court accordingly dismisses their claims for violations of that provision as well. *See City of Philadelphia v. Fleming Companies, Inc.*, 264 F.3d 1245, 1270 (10th Cir. 2001) ("To state a prima facie case [under Section 20(a)], the plaintiff must establish (1) a primary violation of the securities law" (cleaned up)).

* * *

For the foregoing reasons, the court **GRANTS** Plaintiffs' motion for judicial notice and **GRANTS** Defendants' motions to dismiss. Because Plaintiffs have not filed a motion seeking leave to amend their complaint, this action will be dismissed with prejudice.[8]

IT IS SO ORDERED.

DATED this 22nd day of November, 2020.

BY THE COURT:

Howard C. Nielson, Jr.
United States District Judge

[8] *See* DUCivR 7-1(b)(1); *Calderon v. Kansas Dep't of Social & Rehabilitation Servs.*, 181 F.3d 1180, 1185–87 (10th Cir. 1999); *cf.* FED. R. CIV. P. 15 notes (2009 amendment) (explaining that amendment "will force the pleader to consider carefully and promptly the wisdom of amending to meet the arguments in the motion" to dismiss and "expedite determination of issues that otherwise might be raised seriatim").