UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

WILLIAM E. HATTAWAY,
individually and on behalf of all
others similarly situated,

Plaintiffs,

v. Case No. 8:22-cv-1298-WFJ-SPF

APYX MEDICAL CORPORATION;
CHARLES D. GOODWIN II; and
TARA SEMB,

Defendants.
_____/

ORDER

Before the Court is Defendants Apyx Medical Corporation ("Apyx"), Charles D. Goodwin II, and Tara Semb's Motion to Dismiss Plaintiff William E. Hattaway's Amended Complaint (Dkt. 45). Plaintiff, individually and on behalf of all others similarly situated, has responded in opposition (Dkt. 50). Defendants have replied (Dkt. 54). On June 1, 2023, the Court held a hearing on this matter. With the benefit of full briefing, the Court grants-in-part and denies-in-part Defendants' Motion.

BACKGROUND

Apyx is a publicly traded company that manufactures and sells medical devices. Mr. Goodwin is Apyx's Chief Executive Officer ("CEO"), and Ms. Semb

is Apyx's Chief Financial Officer ("CFO"). Plaintiff brings the instant securities class action against Defendants on behalf of himself and all others who purchased or acquired Apyx securities between May 12, 2021, and March 11, 2022 (the "Class Period"). Plaintiff alleges that, throughout the Class Period, Defendants engaged in a fraudulent scheme to artificially inflate the value of Apyx securities by making materially false statements and failing to disclose adverse information. The inflated value of Apyx securities allegedly vanished once the truth was revealed to the market, causing significant economic loss to Class Period investors such as Plaintiff.

I. Pre-Class Period Events

Sometime before 2012, Apyx began developing medical devices that employ "Helium Plasma Technology." Apyx would later market this as J-Plasma in the hospital surgical market and as Renuvion in the cosmetic surgery market. Dkt. 45 at 17. The systems Apex manufactures generally "consist of an electrosurgical generator unit, a handpiece, and a supply of helium gas, with energy delivered to the patient via a helium plasma beam" that is supposedly "precise and cooler in temperature compared to other surgical energy modalities." *Id.* at 17–18, 18 n.3. In short, Apyx's Helium Plasma Technology systems are supposed to offer surgeons and physicians a unique ability to provide controlled heat to tissue so as to "operate with a high level of precision and virtually eliminat[e] unintended tissue trauma" in certain procedures. Dkt. 45-5 at 2.

At some point during 2012, Apyx received from the United States Food and Drug Administration (the "FDA") a 510(k) clearance to market Renuvion for cutting, coagulation and ablation of soft tissue during open and laparoscopic surgical procedures. Dkt. 45 at 18. Other uses—such as the use of Renuvion for cosmetic dermal resurfacing procedures—were not cleared at this time and were therefore considered "off-label." Apyx, moreover, remained subject to numerous regulatory requirements as well as FDA monitoring of J-Plasma and Renuvion. *Id.* at 18–20.

In 2018, Apyx allegedly sold much of its non-advanced energy business to focus primarily on its development of Helium Plasma Technology. Dkt. 42 at 10. Plaintiff claims that Apyx invested the $97 million it received into broad marketing and sales initiatives that resulted in "rapid sales growth through December 31, 2021[,] and into the first quarter of 2022." *Id.* In addition, Apyx continued its efforts to gain FDA clearances related to dermal resurfacing and skin laxity procedures. *Id.*

II. Class Period Events

On May 12, 2021—the first day of the Class Period—Apyx released its Form 8-K for the first quarter of 2021 (the "21Q1 8-K"),[1] filed its quarterly Form 10-Q (the "21Q1 10-Q"),[2] and held an earnings call with investors (the "21Q1 Call").[3] The financial summary contained within the 21Q1 8-K was strong in relation to Apyx's

[1] The complete 21Q1 8-K can be found at Dkt. 45-2.
[2] The complete 21Q1 10-Q can be found at Dkt. 45-3.
[3] The complete 21Q1 Call transcript can be found at Dkt. 45-4.

advanced energy segment, and management's comments were optimistic concerning future growth. Dkt. 42 at 12–13. The 21Q1 10-Q, incorporating one of Apyx's 2020 10-K reports, nevertheless indicated a number of risk factors concerning "costly and complex laws and governmental regulations." *Id.* at 13. Apyx specifically warned that "[i]f the FDA were to conclude that we are not in compliance . . . or that any of our medical products are ineffective or pose a unreasonable health risk[,]" the FDA could take adverse action against Apyx. *Id.* Apyx further warned that "the FDA has taken the position that device manufactures are prohibited from promoting their products other than for the uses and indications set forth in the cleared product labeling" and that "[a]ny failure to comply could subject us to significant civil or criminal exposure, administrative obligations and costs, other potential penalties from, and/or agreements with, the federal government." *Id.* This latter concern was also raised by an investor in the 21Q1 Call: "our FDA on the dermal resurfacing, which we call facelift, now that's being done. Currently, we just don't have the regulatory approval, but that's been performed as we speak with our technology. Is that correct?" Dkt. 45-4 at 13. Mr. Goodwin acknowledged that this was true: "[y]es, it is an off-label procedure. We cannot promote it and we do not promote it. So it is being done. You're correct, because the clinician can decide to use the technology any way they want to . . . . it is something that we as an organization do not

promote[.]" *Id.* at 13–14. Mr. Goodwin remained optimistic about gaining FDA clearance for additional procedures in the near future. *Id.* at 14.

Plaintiff claims that portions of these statements were later proven to be "materially false and misleading." Dkt. 42 at 14. Plaintiff supports this claim by pointing to a May 12, 2022, conference call where Apyx disclosed that it had received a number of requests from the FDA concerning "changes to Apyx's messaging on its website labeling, and training materials with respect to the off-label use of its products[,]" "stronger statements in Apyx's labeling to warn of any specific procedure . . . which had not yet been reviewed or cleared" by the FDA, and the removal of "instances of language or imagery that might imply intended use outside the cleared general indications." *Id.* Plaintiff maintains that this later disclosure of FDA requests shows that "Defendants failed to disclose that they were aware that the growth in [Apyx's] products, including Renuvion and J-Plasma, was artificially inflated by off-label use, and that the risk posed by such use through FDA regulation severely impacted [Apyx's] financial condition." *Id.* Plaintiff also claims that said disclosures indicate that Apyx's 21Q1 10-Q was misleading "because the purported risks had already materialized and were greater in magnitude than Defendants portrayed." *Id.* at 15. Plaintiff buttresses these claims with the accounts of two confidential witnesses who assert that management figures were aware of off-label product use, supportive of them, and indifferent to the risks posed. *Id.* at 15–16.

On August 12, 2021, Apyx released its Form 8-K for the second quarter of 2021 (the "21Q2 8-K"),[4] filed its quarterly Form 10-Q (the "21Q2 10-Q"),[5] and held another earnings call with investors (the "21Q2 Call").[6] The financial summary contained within the 21Q2 8-K was of a similar nature to that found in the 21Q1 8-K, and management's comments were similarly optimistic concerning the growth of Apyx's advanced energy segment. Dkt. 42 at 16–17. Once again, however, Apyx indicated a number of risk factors by incorporating the same 2020 10-K report into its 21Q2 10-Q. When asked about the source of current growth during the 21Q2 Call, Mr. Goodwin claimed that:

> As far as the dermal resurfacing, which we submitted the 510(k) for on May 28th, that would be a new indication for us and if that is being done now in the U.S. and outside the United States, it is being done off-label by the physicians. And so that is – that would be a very small volume at this point. But getting the indication for dermal resurfacing would allow us to be able to go market that and sell that in the U.S. initially, and then we'd have to get registration outside the U.S. for dermal resurfacing. But right now, its almost all as a subdermal coagulator for body contouring procedures.

Dkt. 45-8 at 12. In addition, Mr. Goodwin discussed Apyx's regulatory strategy of "obtaining specific clinical indications for our targeted cosmetic surgery procedures . . . and the submission of a 510(k) premarket notification to the FDA" *Id.* at 6.

[4] The complete 21Q2 8-K can be found at Dkt. 45-6.
[5] The complete 21Q2 10-Q can be found at Dkt. 45-7.
[6] The complete 21Q2 Call transcript can be found at Dkt. 45-8.

As with Defendants' 2021, Quarter 1 claims, Plaintiff claims Defendants' 2021, Quarter 2 statements were later proven to be "materially false and misleading." Dkt. 42 at 19. Plaintiff supports his assertion with the same evidence discussed above. *Id.* at 19–21. Plaintiff maintains that Defendants' disclosures "were materially false and misleading because the purported risks had already materialized and were greater in magnitude than Defendants portrayed." *Id.* at 19.

On November 11, 2021, Apyx released its Form 8-K for the third quarter of 2021 (the "21Q3 8-K"),[7] filed its quarterly Form 10-Q (the "21Q3 10-Q"),[8] and held another earnings call with investors (the "21Q3 Call").[9] Then, on January 10, 2022, Apyx released its preliminary Form 8-K for the fourth quarter of 2021 (the "Preliminary 21Q4 8-K")[10] as well as its preliminary fiscal year 2021 financial results. Aside from specific growth figures, the financial summaries and management commentary contained therein were similar in nature to that discussed above. Management's optimism concerning advanced energy segment growth remained high. Once again, however, Plaintiff alleges that Defendants' claims were materially false and misleading. Plaintiff relies on the aforementioned post-Class

[7] The complete 21Q3 8-K can be found at Dkt. 45-9.
[8] The complete 21Q3 10-Q can be found at Dkt. 45-10.
[9] The complete 21Q3 Call transcript can be found at Dkt. 45-11.
[10] The complete Preliminary 21Q4 8-K can be found at Dkt. 45-12.

Period disclosures and confidential witness accounts to argue that Defendants failed to disclose that risks had materialized.

III. Post-Class Period Events

On March 14, 2022, Apyx issued a press release disclosing that the FDA would be posting a Medical Device Safety Communication ("MDSC") related to Apyx's advanced energy products (the "Press Release"). Dkt. 45-15 at 6–7. The Press Release stated that, "[b]ased on our initial interactions with the FDA, we believe that the [FDA's] MDSC will pertain to the use of our Advanced Energy products outside of their FDA-cleared indication for general use in cutting, coagulation, and ablation of soft tissue during open and laparoscopic surgical procedures." *Id.* at 6. The Press Release went on to state that, "[w]hile we are aware that some of our products are being used by physicians for dermal resurfacing procedures, for which our products do not have a cleared indication, we do not and will not promote the use of our products—or train physicians—for these procedures[.]" *Id.* The Press Release finally reiterated that, "[t]o be clear, our Advanced Energy products remain on the market, they continue to retain their existing FDA 510(k) clearances . . . . We also look forward to continuing to engage with the FDA in support of our two pending 510(k) premarket notifications, which remain under review by the [FDA]." *Id.* at 7.

Later the same day, the FDA issued the anticipated MDSC. Dkt. 45-16. The MDSC warned "consumers and health care providers against the use of the Renuvion/J-Plasma device by Apyx Medical for certain aesthetic procedures" including those "intended to improve the appearance of the skin through dermal resurfacing . . . or skin contraction[.]" *Id.* at 2. The MDSC went on to state that the "FDA has received reports describing serious adverse events when the Renuvion/J-Plasma device was used directly on the skin and potentially life-threatening adverse events when the Renuvion/J-Plasma device was used under the skin." *Id.* The MDSC concluded by stating that the "FDA is working with [Apyx] to evaluate all available information about the use of Renuvion/J-Plasma for aesthetic skin procedures and to inform patients and providers that the device has not been determined to be safe or effective for these procedures." *Id.* at 4. The FDA did not retract any clearances previously granted to Renuvion/J-Plasma devices or take further action against Apyx. Notwithstanding, on March 14, 2022, the same day that the Press Release and MDSC were issued, Apyx's stock price allegedly fell 40.6%. Dkt. 42 at 31.

On March 17, 2022, Apyx released its final Form 8-K for the fourth quarter of 2021 (the "21Q4 8-K"),[11] shared its overall fiscal year 2021 financial results, and

[11] The complete 21Q4 8-K can be found at Dkt. 45-17.

held a conference call with investors (the "21Q4 Call").[12] During the 21Q4 Call, Mr. Goodwin explained the following:

> As part of our program, we routinely submit medical device reports, or MDRs,[13] in order to report serious adverse events to the FDA. These MDRs are submitted when we receive an adverse event report that reasonably suggests one of our devices may have caused or contributed to a serious injury. These MDRs are often submitted before it is confirmed that our device caused or contributed the injury. They are also submitted in situations where the event was caused by user error and in situations where another device has been identified as a possible cause. With this backdrop, in February, we were contacted by the FDA. Through MDRs, they were requesting our assistance to complete an evaluation of post-market safety concerns with our Advanced Energy devices.
>
> After clarifying the request with a member of their team, we provided the FDA with data for adverse events, MDRs, promotional items and training for our Advanced Energy products for the requested last 5 years, beginning with 2017. On Friday, March 11, we were informed that they intended to publish a safety communication, which was posted to the FDA website on Monday, March 14. The FDA safety communication warns against the use of our Advanced Energy devices for procedures intended to improve the appearance of skin through dermal resurfacing or skin contraction. As a reminder, our products are cleared for general use in cutting, coagulation and ablation of soft tissue

[12] The complete 21Q4 Call transcript can be found at Dkt. 45-18.

[13] Under 21 C.F.R. § 803.50(a), a medical device manufacturer must submit a medical device report ("MDR") to the FDA:

> no later than 30 calendar days after the day that [the manufacturer] receive[s] or otherwise become[s] aware of information, from any source, that reasonably suggests that a device that [the manufacturer] market[s]: (1) May have caused or contributed to a death or serious injury or (2) Has malfunctioned and this device or a similar device . . . would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

MDRs are publicly available online at the FDA's Manufacturer and User Facility Device Experience database. *See* U.S. Food & Drug Admin., *MAUDE—Manufacturer and User Facility Device Experience*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

during open and laparoscopic surgical procedures, and we market them in accordance with this indication.

To be clear, all of our Advanced Energy products remain on the market, and we intend to continue marketing and selling them for their existing clinical indications for use, most commonly for subdermal coagulation. Importantly, we do not promote our products in the U.S. for dermal resurfacing or skin contraction and will not do so until we receive clearance from the FDA. Apyx Medical takes the safety of our customers and their patients very seriously. We understand that the FDA's decision to post the safety communication was based on an abundance of caution for patients, and we support the agency's focus on ensuring that clinicians and their patients understand the safe and proper use of our products. We believe that the decision to post this safety communication was due in part to the increase in the absolute number of MDRs reported for our Advanced Energy products in 2021 compared to 2020. Specifically, the MDR data that we provided to the FDA team showed that there were 90 MDRs involving the use of our Advanced Energy products for subdermal coagulation since the beginning of 2017, 32 of which occurred in 2021 as compared to 15 MDRs in 2020. In terms of the rate of occurrence of these MDRs, our products have been used for subdermal coagulation in over 150,000 procedures globally since 2017, which represents an MDR rate of 0.06%. Importantly, while the 0.06% MDR rate since 2017 is low, the rate of MDRs has declined over this period and represented approximately 0.04% of global procedures in 2021.

Looking more closely at the 32 MDRs reported for subdermal coagulation in 2021, investigation showed the events were either not attributable to the device or the events reported were within the scope of the existing clinical risk included in our product labeling. 14 of these 32 MDRs were performed by physicians that had not yet been trained by our global clinical team of skilled nursing staff. This, for us, underlines the importance of our continued outreach to all of our customers and that all surgeons receive our training and fully adhere to our safe and effective use guidelines, which were designed by our Medical Advisory Board to further ensure patient safety.

Dkt. 45-18 at 7. Mr. Goodwin went on to state that the FDA's decision to release an MDSC "was a surprise" and that "we are laser-focused on and always trying to improve." *Id.* at 15.

On May 12, 2022, Apyx held another call with investors (the "22Q1 Call").[14] During the 22Q1 Call, Mr. Goodwin disclosed the following:

> In our communication with the FDA on March 11, when we were notified about the intention to post the safety communication, it was our understanding that the FDA post-market team had not completed their review of this data. Following the FDA's safety communication, we requested a meeting with the FDA's post-market team to discuss the safety communication and our MDR data. I'm pleased to report that this meeting was held on March 29.
>
> During the meeting, our regulatory and clinical team presented a detailed analysis of our MDR data to clarify the reported adverse events and provide important context. On April 1, we received feedback from the FDA with requested revisions, including changes to certain messaging on our website, labeling, and training materials. The requested revisions reaffirmed our belief that the FDA is focused on the use by surgeons of our Advanced Energy products outside the general indications for use for which they are currently cleared. Surgeons may lawfully do so, but the FDA has requested stronger statements in our labeling to warn of any specific procedure intended to improve the appearance of skin which has not yet been reviewed or cleared by the agency. The FDA also asked us to remove instances of language or imagery that might imply intended use outside of the cleared general indications. We submitted our response to the FDA and have incorporated the requested revisions.
>
> Apyx Medical remains committed to product safety, patient safety, surgeon education and training, and customer support. We support the agency's focus on ensuring that clinicians and their patients understand the safe and proper use of our products for their current clinical

[14] The complete 22Q1 Call transcript can be found at Dkt. 45-20.

> indications for use. In addition to our engagement with the FDA's post-market team, we have remained focused on securing 510(k) clearances for new specific clinical indications, enabling us to market and sell our Advanced Energy products for use in target procedures.

Dkt. 45-20 at 6–7.

On May 26, 2022, Apyx announced that it had received from the FDA the 510(k) clearance it was seeking for use of Renuvion in limited dermal resurfacing procedures to treat moderate to severe wrinkles and rhytides. Dkt. 45-21. The FDA later updated the March 14 MDSC to reflect as much. Dkt. 45-22.[15] It is unclear whether this had any impact on the price of Apyx securities.

IV. The Instant Class Action

On December 13, 2022, Plaintiff filed his Amended Complaint in the instant securities class action. Dkt. 42. Plaintiff alleges that Defendants' statements (the 21Q1 8-K; the 21Q1 10-Q; the 21Q1 Call; the 21Q2 8-K; the 21Q2 10-Q; the 21Q2 Call; the 21Q3 8-K; the 21Q3 10-Q; the 21Q3 Call; and the Preliminary 21Q4 8-K) were materially false and misleading because Defendants: 1) "failed to disclose that they were aware that the growth in [Apyx's] products, including Renuvion and J-Plasma, was artificially inflated by off-label use, and that the risk posed by such use through FDA regulation severely impacted [Apyx's] financial condition[;]" and 2)

[15] Apyx received additional 510(k) clearance for loose skin treatments in the neck and submental region on July 18, 2022. Dkt. 45-23. The March 14 MDSC was again updated following this development. Dkt. 45-24.

"failed to disclose that [Apyx's] . . . purported risks had already materialized and were greater in magnitude than Defendants portrayed." Dkt. 42 at 14–15. Plaintiff essentially asserts misrepresentation through omission. Plaintiff brings two counts: Count I—violation of Section 10(b) of the Securities Exchange Act of 1934 ("the Exchange Act"), 15 U.S.C. §78j(b), and Securities Exchange Commission ("SEC") Rule 10b-5 against all Defendants; and Count II—violation of Section 20(a) of the Exchange Act, 15 U.S.C. §78t–1, against Mr. Goodwin and Ms. Semb. *Id.* at 42–45.

LEGAL STANDARD

A complaint withstands dismissal under Federal Rule of Procedure 12(b)(6) if the alleged facts state a claim for relief that is "plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This standard does not require detailed factual allegations but demands more than an unadorned accusation. *Id.* All facts are accepted as true and viewed in the light most favorable to the Plaintiff. *Pielage v. McConnell*, 516 F.3d 1282, 1284 (11th Cir. 2008).

At the dismissal stage, a court may consider matters judicially noticed, such as public records, without converting a defendant's motion to one for summary judgment. *See Universal Express, Inc. v. S.E.C.*, 177 F. App'x 52, 52 (11th Cir. 2006). Additionally, documents may be considered at the dismissal stage if they are central to, referenced in, or attached to the complaint. *LaGrasta v. First Union Sec.*,

Inc., 358 F.3d 840, 845 (11th Cir. 2004). Documents attached to a motion to dismiss may also be considered if the documents are (1) central to the plaintiff's claim, and (2) undisputed (if their authenticity is not challenged). *Horsley v. Feldt*, 304 F.3d 1125, 1134 (11th Cir. 2002).

Beyond these general Rule 12(b)(6) requirements, a plaintiff bringing private securities fraud claims must also satisfy Federal Rule of Civil Procedure 9(b)'s heightened pleading standards and the Private Securities Litigation Reform Act's ("PSLRA") particularity standards.

> Rule 9(b) is satisfied if the complaint sets forth: (1) precisely what statements were made in what documents or oral representations or what omissions were made; (2) the time and place of each such statement and the person responsible for making (or, in the case of omissions, not making) same; (3) the content of such statements and the manner in which they misled the plaintiff; and (4) what the defendants obtained as a consequence of the fraud.

Mizzaro v. Home Depot, Inc., 544 F.3d 1230, 1237 (11th Cir. 2008) (cleaned up) (citations and internal quotations omitted). The PSLRA's particularity standards are satisfied if the complaint: (1) "specif[ies] each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading," 15 U.S.C. § 78u–4(b)(1)(B); and (2) "state[s] with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Mizzaro*, 544 F.3d at 1238 (cleaned up) (quoting 15 U.S.C. § 78u–4(b)(2)).

DISCUSSION

As mentioned above, Plaintiff asserts one claim under § 10(b) of the Exchange Act as well as Rule 10(b)–5 promulgated thereunder (Count I) and one claim under § 20(a) (Count II). The Court will address each in turn.

I. § 10(b) and Rule 10(b)-5

To state a claim for securities fraud under § 10(b) and Rule 10b–5, a plaintiff must adequately plead: (1) a material misrepresentation or omission; (2) scienter; (3) a connection between the misrepresentation and the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. *Meyer v. Greene*, 710 F.3d 1189, 1194 (11th Cir. 2013); *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341–42 (2005). Defendants aver that Plaintiff's Amended Complaint is a "puzzle pleading" that fails to adequately plead an actionable misstatement or omission, scienter, and loss causation. Dkt. 45 at 28–44. The Court agrees.

i. Material Misrepresentation or Omission

The initial step in analyzing whether Plaintiff has adequately pled material misrepresentation through omission is identifying what statements Plaintiff's Amended Complaint seeks to challenge as misleading. This is an easy task at the general level. Plaintiff maintains that Defendants' statements concerning Apyx's financial position, future prospects, and current risks were materially misleading due to Defendants' omission of information concerning healthcare providers' off-label

use of Renuvion. Upon moving from the general to the specific, however, a number of issues become immediately clear. First, it is difficult to discern exactly which parts of Defendants' financial statements, growth projections, and risk assessments Plaintiff challenges and why. Second, much of the information Plaintiff claims to be "omitted" was disclosed by Defendants' or otherwise public. And third, Plaintiff has little, if anything, of import to say about materiality or falsity. These issues collectively represent a failure to adequately plead a material misrepresentation.

The most demonstrative example of this shortcoming is Plaintiff's challenge to the financial statements contained within the 21Q1 8-K, the 21Q2 8-K, the 21Q3 8-K, and the Preliminary 21Q4 8-K. These non-forward-looking financial statements include total revenue figures with year-over-year growth percentages, net loss figures, adjusted EBITDA figures, and liquidity figures. Due to Plaintiff's lack of specificity, the Court can only assume that Plaintiff challenges each one as materially false and misleading. *See* Dkt. 42 at 12, 16–17, 21–22, 25–26.

This broad challenge fails. As an initial matter, Plaintiff offers nothing to suggest that any of these figures are numerically incorrect. And even if growth in Apyx's products was being inflated by off-label use (a factor possibly influencing the challenged figures), this would not change the accuracy of Apyx's general accounting. As the Eleventh Circuit explained in *FindWhat Inv. Grp. v. FindWhat.com*, 658 F.3d 1282, 1306 (11th Cir. 2011), "[f]actual recitations of past

earnings, so long as they are accurate, do not create liability under Section 10(b)." What is more, Plaintiff nowhere specifies the level of "artificial inflation" he alleges—an essential materiality indicator in the instant context. While a "ridged test for materiality is inappropriate[,]" this much at least is required for the Court to make a threshold determination at the motion to dismiss stage. *In re Winn-Dixie Stores, Inc. Sec. Litig.*, 531 F. Supp. 2d 1334, 1343 (M.D. Fla. 2007). Plaintiff's challenge to Defendants' raw financial reporting is deficient under the PSLRA.

Plaintiff's challenge to Defendants' comments within the 21Q1 8-K, the 21Q2 8-K, the 21Q3 8-K, and the Preliminary 21Q4 8-K is similarly lacking. Plaintiff appears to focus on Defendants' statements concerning numerical growth and forward-looking optimism in relation to Apyx's advanced energy segment.[16] Plaintiff claims that these statements were materially false and misleading because Defendants omitted information about growth related to off-label use of Renuvion and J-Plasma. To being with, to the extent Plaintiff targets raw financial numbers,

[16] *See* Dkt. 42 at 12 (bolding the following comments: "we continued to see healthy utilization of our Helium Plasma Technology in the U.S. and key international markets, resulting in total handpiece growth in excess of 100% year-over-year"); *Id.* at 17 (bolding the following comments: "[w]e are pleased to deliver exceptional growth in sales of our Advanced Energy products . . . . we saw impressive growth in global sales of our Advanced Energy handpieces, which increased by over 270% year-over-year, driven by utilization demand both domestically and internationally"); *Id.* at 22 (bolding the following comments: "[w]e are excited by our team's impressive execution . . . . [w]e also saw global Advanced Energy sales increase by more than 70% year-over-year, primarily reflecting healthy adoption of our Renuvion technology in the U.S. cosmetic surgery market"); *Id.* at 26 (bolding the following comments: "[t]he impressive demand we have seen for our innovative Helium Plasma Technology reaffirms our conviction in the compelling long-term opportunity that remains ahead").

this claim fails for the same reasons explained above. Plaintiff does not dispute the numerical accuracy of the general financial figures provided by Defendants. Nor does Plaintiff specify the level of artificial inflation he alleges to have driven growth or otherwise explain why these figures themselves are materially misleading in the absence of "a detailed picture of every aspect of [Apyx's] operations" (which Apyx is not required to provide). *FindWhat*, 658 F.3d at 1306. Plaintiff's Amended Complaint fails to allege that Defendants' general financial reporting was materially misleading.

To the extent that Plaintiff targets Defendants' optimistic comments concerning future growth, Plaintiff's claim fails for different reasons. Most fundamentally, Defendants repeatedly disclosed that health care providers were using Apyx's products off-label. Dkt. 45-4 at 13–14; Dkt. 45-8 at 12. In fact, on the first day of the Class Period, during the 21Q1 Call, Mr. Goodwin stated that physicians were using Apyx's products off-label. Dkt. 45-4 at 13–14. The Court is aware of no authority that dictates the disclosure of this information with each and every comment Apyx makes about its future prospects or current position. Nor can the Court ascertain whether this information was inherently misleading when disclosed—Plaintiff fails to specifically allege just how prevalent off-label use was. It is important to recognize that "[s]ilence, absent a duty to disclose, is not misleading." *Basic v. Levinson*, 485 U.S. 224, 239 n.17 (1988). Further, while

Plaintiff is correct that an omission is material "if there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available," the further disclosure of off-label use of Apyx's products would not have altered the total mix of information available to Plaintiff—this information was already public. *S.E.C. v. Morgan Keegan & Co.*, 678 F.3d 1233, 1245 (11th Cir. 2012) (citation and internal quotations omitted).

Before moving forward, the Court also notes that "there are some kinds of talk which no sensible man takes seriously, and if he does, he suffers from his credulity." *Carvelli v. Ocwen Fin. Corp.*, 934 F.3d 1307, 1319 (11th Cir. 2019) (citation and internal quotations omitted). This kind of talk, comprising "generalized, vague, nonquantifiable statements of corporate optimism," is often referred to as "puffery." *Id.* at 1318. And this is essentially what Plaintiff complains of when he invokes statements such as "exceptional growth," "strong adaptation of our technology," and "impressive execution." This corporate puffery is not material or actionable. Plaintiff must plead actionable misrepresentation with more particularity.[17]

This brings the Court to Plaintiff's challenge of Defendants' risk disclosures contained within the 21Q1 10-Q, the 21Q2 10-Q; and the 21Q3 10-Q. Plaintiff

[17] The analysis contained within this paragraph is equally applicable to Plaintiff's challenge to the 21Q1 Call, the 21Q2 Call, and the 21Q3 Call. Accordingly, the Court will not address the statements made therein separately.

alleges that these risk disclosures were materially false and misleading because the purported risks had already materialized and were greater in magnitude than Defendants portrayed. This perhaps is Plaintiff's strongest argument for material misrepresentation through omission. Still, it fails for a number of reasons related to those addressed above.

Taking a step back, though, it is important to first contextualize the inherent risks attached to any company that operates within the medical device industry—risks that Defendants explicitly disclosed to their investors. As Defendants explained in the 21Q1 10-Q, the 21Q2 10-Q, and the 21Q3 10-Q (through incorporation of the same pre-Class Period 2020 10-K):

> **We are subject to costly and complex laws and governmental regulations and any adverse regulatory action may materially adversely affect our financial condition and business operations.**
>
> As a part of the regulatory process of obtaining marketing clearance for new products and new indications for existing products, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations, and trial endpoints. Unfavorable or inconsistent clinical data from existing or future clinical trials, or the market's or FDA's perception of this clinical data, may adversely impact our ability to obtain product approvals, our position in, and share of, the markets in which we participate. We cannot guarantee that we will be able to obtain or maintain marketing clearance for our new products or enhancements or modifications to existing products, and the failure to maintain approvals or obtain approval or clearance could have a material adverse effect on our business, results of operations, financial condition and cash flows. Even if we are able to obtain approval or clearance, it may:
>
> • take a significant amount of time;

• require the expenditure of considerable resources;
• involve rigorous clinical and pre-clinical testing, as well as increased post-market surveillance;
• involve modifications, repairs, corrections, or replacements of our products; and
• limit the proposed intended uses of our products.

Before and after a product is commercially released, we have ongoing responsibilities under the U.S. FDA, Health Canada, Australia, Brazil, EU, and other applicable world-wide government agency regulations. For instance, many of our processes and facilities, as well as those of our suppliers, are also subject to periodic audits to determine compliance with applicable regulations. The results of these audits can include major inspectional observations, warning letters, or other forms of enforcement.

If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical products are ineffective or pose an unreasonable health risk, they could ban such medical products, seize adulterated or misbranded medical products, order a recall, repair, replacement, correction, or refund of such products, refuse to grant pending pre-market approval applications, refuse to issue export certificates for foreign governments, or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health.

The FDA and other non-U.S. government agencies may also assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis. The FDA may also recommend prosecution to the Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future pre-market clearances or approvals, and could result in a substantial modification to our business practices and operations. These potential consequences, as well as any adverse outcome from government investigations, could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

In addition, the FDA has taken the position that device manufacturers are prohibited from promoting their products other than for the uses and

> indications set forth in the cleared product labeling. Any failure to comply could subject us to significant civil or criminal exposure, administrative obligations and costs, other potential penalties from, and/or agreements with, the federal government. Governmental regulations worldwide have, and may continue to become, increasingly stringent and customary.

Dkt. 45-1 at 13–14. This context is important not because it immunizes medical device companies (like Apyx) from committing securities fraud through risk disclosure omission, but because it informs a reasonable investors' risk assessment.

That said, Plaintiff cannot claim that Defendants' repeated disclosure of risk was materially false and misleading simply because risk later materialized in the form of the March 14 MDSC. At the time these risks were disclosed, it was publicly known that health care providers were using Apyx's products off-label, that the FDA arguably disapproved of such use, and that unfavorable results from off-label use in the marketplace could harm Apyx's financial position as explicitly explained by Defendants. Plaintiff, moreover, cannot support the notion that Defendants concealed materialized risk by pointing to the MDRs submitted to the FDA that the FDA later referenced in its March 14 MDSC. MDRs are available to the public. They were submitted by Defendants themselves. Simply put, Plaintiff had all of the information he needed to perform a viable risk assessment at the time Defendants made their risk disclosures. And, as the Court has previously held, Plaintiff cannot premise his omissions claim on risks and information that were previously disclosed. *See Bhatt v. Tech Data Corp.*, No. 8:17-CV-02185-T-02-AEP, 2018 WL 6504375,

at *5 (M.D. Fla. Dec. 11, 2018). Plaintiff must point to material information that was not disclosed or publicly available at the time Defendants released their challenged risk disclosures.

This availability of information is largely what differentiates the instant case from the omissions caselaw upon which Plaintiff relies. In *Findwhat*, for instance, the Eleventh Circuit disagreed with the lower court's finding that one of the defendants' Form 10-Ks was not misleading. 658 F.3d at 1299. The Eleventh Circuit explained that, notwithstanding the subject 10-Ks general risk-disclosing language, the 10-K "could mislead a reasonable investor into believing that the [d]efendants had systems in place that would detect and remove [certain fraudulent activity]." *Id.* at 1298. Accordingly, "[d]efendants' statements triggered a duty to disclose the grave defects that existed within the enforcement system [that defendants] voluntarily touted." *Id.* at 1298–99. Leaving aside the fact that Defendants have touted no system of preventing off-label use beyond a refusal to actively promote it, Defendants clearly disclosed that off-label use was happening and posed a real risk.

Finally, even accepting as true Plaintiff's confidential (and partly second-hand) witness accounts, it is not clear that off-label use was anything beyond (let alone materially beyond) what Defendants disclosed in combination with their general risk disclosures. Perhaps the Court's analysis would change at this early stage if Plaintiff's confidential witness accounts were more particularized. But they

are decidedly vague concerning the level of alleged off-label promotion and who was doing said promotion. Dkt. 42 at 15–16. No figures or names are provided. What is more, Confidential Witness 1 ("CW1")—the only confidential witness to speak to alleged promotion of off-label use—left Apyx over a year before the Class Period began. *Id.* at 15. CW1 would therefore have no insight into Apyx's operations during the Class Period. It follows that there are no allegations that Apyx was promoting off-label use at the time the challenged risk disclosures were made (or even a year prior to this time). It is also worth noting that "[s]everal cases have discussed the duty to disclose mismanagement and have determined that corporate officers do not have a duty to disclose internal management problems to shareholders." *In re Winn-Dixie Stores, Inc. Sec. Litig.*, 531 F. Supp. 2d at 1345 (citation omitted). The type of low-level to mid-level employee promotion of off-label use CW1 describes appears to fall within this category of internal management issues. Plaintiff has failed to adequately plead a material omission in Defendants' risk disclosures.

ii. Scienter

Plaintiff has also failed to adequately plead scienter. "Under the PSLRA's heightened pleading instructions, any private securities complaint alleging that the defendant made a false or misleading statement must . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 321 (2007) (citation

and internal quotations omitted). Specifically, Plaintiff's pleading must provide enough particularity to create "a strong inference that [Defendants] either intended to defraud investors or were severely reckless when they made the allegedly false or incomplete statements." *Mizzaro*, 544 F.3d at 1238 (internal quotations omitted). "[A] 'strong inference' of scienter means an inference that is 'cogent and at least as compelling as any opposing inference one could draw from the facts alleged.'" *Id.* (citation omitted).

> To determine whether the plaintiff has alleged facts that give rise to the requisite "strong inference" of scienter, a court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff. The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the "smoking-gun" genre, or even the "most plausible of competing inferences." ... Yet the inference of scienter must be more than merely "reasonable" or "permissible"—it must be cogent and compelling, thus strong in light of other explanations.

Tellabs, 551 U.S. at 324.

Here, Plaintiff primarily relies on three categories of support to create the inference that Defendants' intended to defraud investors or acted with severe recklessness: (1) Defendants' post-Class Period "admissions"; (2) Plaintiff's confidential witness accounts; and (3) the notion that "the facts alleged [in the Amended Complaint] relate to [Apyx's] core operations." Dkt. 50 at 27–30. The Court will consider each category separately to determine what support they lend Plaintiff's position before shifting to consider whether they collectively outweigh or

equal a number of inferences that can be made in Defendants' favor. *See Tellabs*, 551 U.S. at 322–23 ("The inquiry, as several Courts of Appeals have recognized, is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.").

The Court begins with Defendants' post-Class Period admissions, which include discussion of the March 14 MDSC, the FDA requested alterations to Apyx's materials, and the MDR data reported by Apyx to the FDA. By definition, these post-Class Period admissions came after Defendants' Class Period statements. Their import in relation to Defendants' scienter is therefore dependent on whether Defendants knew the underlying information throughout the Class Period and recognized it as a materialized risk, or otherwise acted with severe recklessness in failing to learn of this risk and inform investors.

Nothing in the admissions themselves suggests that any of this is the case. During the 22Q1 Call, Mr. Goodwin explained that Apyx had learned of the impending March 14 MDSC only on March 11, 2022. Dkt. 45-20 at 6. And it was not until April 1, 2022, that Defendants learned that the FDA desired alterations to Apyx's website, labeling, and training materials. *Id.* at 6. Plaintiff does not dispute these facts. This leaves all the inferential work (concerning retrospective knowledge) to Defendants' post-Class Period admissions concerning MDR data. But even

assuming that Defendants were fully aware of this data during the Class Period and even ignoring the fact that MDR's are publicly available, the most plausible inference concerning Defendants' failure to directly redisclose MDR data to investors during the Class Period is that Defendants did not consider the data to represent materialized risk. This does not constitute severe recklessness. As Mr. Goodwin made clear during the 21Q4 Call, the subject MDR data actually indicated that the overall percentage of adverse incidents involving Apyx's devices decreased in 2021 compared to 2020. Dkt. 45-18 at 7. This presumably explains why Mr. Goodwin considered the March 14 MDSC to be a "surprise." *Id.* at 11.

The Court recognizes that a defendant's later response to an issue (such as changing training materials or performing further compliance measures) can sometimes contribute to an inference of scienter. *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 708 (9th Cir. 2016) (finding that the defendants' later response contributed to an inference of scienter where the defendants hired an independent expert to affirm their earlier misrepresentations to investors concerning an animal study that the FDA had cast doubt on). But this is not the case here. Plaintiff does not allege that Defendants sought to cover up any prior misrepresentation to investors or to clarify any prior misleading statement. Accordingly, at most, Defendants' post-Class Period admissions and actions support the inference that

Defendants might have been aware that a handful of MDRs had been submitted in relation to off-label procedures.

Plaintiff's confidential witness accounts offer similarly weak support to Plaintiff's scienter argument. To summarize, CW1—a former Apyx employee who left Apyx over a year before the Class Period began—claims that physicians frequently used Apyx products without proper training and for off-label procedures. Dkt. 42 at 15. CW1 states that an Apyx regional director, as well as other sales specialists, were aware of such issues and did not care. *Id.* CW1 also states that "several members of Apyx's clinical team would discuss other territories where representatives would promote off-label use[.]" *Id.*

Confidential Witness 2 ("CW2")—a former Apyx employee who left Apyx approximately six months before the Class Period began—claims that Apyx's "sales representatives used DocMatter (an internet-enabled and human-supported collaboration [p]latform built by and for physicians) to monitor the use of [Apyx's] products." *Id.* at 16. DocMatter allegedly facilitated numerous conversations (between physicians) "regarding the use of Renuvion for dermal resurfacing." *Id.* "According to CW2, [Apyx's] salespeople viewed DocMatter as a great sales tool, and [Apyx] was aware that physicians posted on DocMatter regarding numerous instances" of off-label product use. *Id.*

Taken alone, these two accounts shed scant light on Defendants' state of mind and awareness of potentially materialized risk. Plaintiff does not allege that the information purportedly gathered by CW1 and CW2 was ever passed to Mr. Goodwin or Ms. Semb. Nor does Plaintiff allege that Mr. Goodwin or Ms. Semb were privy to what was going on in DocMatter forums. Plaintiff simply offers no direct connection between the information allegedly gathered by the confidential witnesses and Defendants.

This brings the Court to Plaintiff's final scienter argument—the notion that all the facts alleged "support a strong inference of scienter because they relate to the core operations of the company." Dkt. 50 at 28. In not wholly dissimilar circumstances, courts have found that where a plaintiff adequately pleads that a defendant's misrepresentation concerns core operations, "it is more likely that Defendants were aware of the alleged compliance issues posed by [that core segment of business]." *In re Flowers Foods, Inc. Sec. Litig.*, No. 7:16-CV-222 (WLS), 2018 WL 1558558, at *14 (M.D. Ga. Mar. 23, 2018) (relying on *Thorpe v. Walter Inv. Mgmt., Corp.*, 111 F. Supp. 3d 1336, 1376 (S.D. Fla. 2015)). The Court finds this to be a reasonable inference. Plaintiff has adequately alleged that the advanced energy segment is Apyx's core business. Plaintiff has also alleged that, "as senior executives . . . [Defendants] were privy to confidential and proprietary information concerning [Apyx]" and "its operations." Dkt. 42 at 7. Still, awareness of potential compliance

issues in the advanced energy segment cannot plausibly be equated to an intent to defraud investors where Defendants repeatedly disclosed said potential compliance issues to investors in official company statements. Further, without specific factual allegations indicating compliance issues greater that those disclosed, the Court cannot reasonably infer that Defendants were acting recklessly.

Given all of this, the facts on the record strongly support the inference that Defendants were not intentionally attempting to defraud or deceive investors during the Class Period. Defendants repeatedly disclosed that physicians were using Apyx products off-label. Defendants further disclosed, on multiple occasions, that off-label use of Apyx devices could lead to regulatory scrutiny from the FDA. And there are no particular allegations that indicate Defendants' direct or actual awareness of the widespread promotion of off-label device use CW1 suggests. Indeed, the undisputed MDR data, which was dropping as a percentage, does not indicate a substantial issue with off-label use that would lead to compliance issues.

The Court also reiterates that the MDR data was publicly filed. And even if Plaintiff had alleged some kind of information sharing system in Apyx, which Plaintiff did not, "[t]o impute knowledge of or extremely reckless disregard for the truth from the mere existence of an internal reporting system, and the mere active engagement of management, would allow almost any securities fraud case to proceed into discovery." *Mogensen v. Body Cent. Corp.*, 15 F. Supp. 3d 1191, 1220

(M.D. Fla. 2014). Plaintiff has failed to state with particularity facts giving rise to a strong inference that Defendants intended to deceive Class Period investors or acted with severe recklessness.

iii. Loss Causation

Notwithstanding Plaintiff's failure to establish material misrepresentation or scienter, the Court will also address loss causation. "[I]n a fraud-on-the-market case, the plaintiff must prove not only that a fraudulent misrepresentation artificially inflated the security's value but also that 'the fraud-induced inflation that was baked into the plaintiff's purchase price was subsequently removed from the stock's price, thereby causing losses to the plaintiff."[18] *Hubbard v. BankAtlantic Bancorp, Inc.*, 688 F.3d 713, 725 (11th Cir. 2012) (citation omitted). In such cases, plaintiffs often demonstrate loss causation circumstantially by:

> (1) identifying a "corrective disclosure" (a release of information that reveals to the market the pertinent truth that was previously concealed or obscured by the company's fraud); (2) showing that the stock price dropped soon after the corrective disclosure; and (3) eliminating other possible explanations for this price drop, so that the factfinder can infer that it is more probable than not that it was the corrective disclosure—

[18] As the Eleventh Circuit has explained, "[i]n securities claims . . . the Supreme Court has permitted a rebuttable presumption of reliance based on what is known as the fraud-on-the-market-theory." *Meyer*, 710 F.3d at 1195 (citation and internal quotations omitted). The fraud on-the-market theory derives from the efficient market hypothesis, which provides that "in an open and developed securities market, the price of a company's stock is determined by the available material information regarding the company and its business." *Id.* (citation and internal quotations omitted). Accordingly, courts can assume "that an investor relies on public misstatements whenever he buys or sells stock at the price set by the market[.]" *Id.* (citation and internal quotations omitted). Here, Plaintiff explicitly relies on the fraud-on-the-market theory to plead reliance. Dkt. 42 at 38.

> as opposed to other possible depressive factors—that caused at least a "substantial" amount of the price drop.

Meyer, 710 F.3d at 1196–97 (citation omitted). To qualify as corrective, "[a] disclosure need not 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 1197 (citation and internal quotations omitted). "[A] plaintiff need not rely on a single, complete corrective disclosure; rather, it is possible to show that the truth gradually leaked out into the marketplace through a series of partial disclosures." *Id.* (citation and internal quotations omitted). "Regardless of the theory upon which it is based," however, "loss causation analysis in a fraud-on-the-market case focuses on the following question: even if the plaintiffs paid an inflated price for the stock as a result of the fraud (i.e., even if the plaintiffs relied), did the relevant truth eventually come out and thereby cause the plaintiffs to suffer losses?" *Id.* (citation and internal quotations omitted).

In the instant case, Plaintiff appears to base his loss causation theory on four "corrective disclosures[:]" 1) the Press Release; 2) the March 14 MDSC; 3) the 21Q4 Call; and 4) the 22Q1 Call. Each fails to qualify as a corrective disclosure. To begin with, "[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" of a publicly traded company. *FindWhat*, 658 F.3d at 1310. This means that, at a minimum, "[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 (citations and internal quotations omitted). The March 14 MDSC and the 21Q4 Call presented nothing new to the market. Everything discussed therein was available (and known under the efficient market hypothesis) through Apyx's publicly available MDRs or the Press Release that preceded it and is itself the proper focus of a corrective disclosure analysis concerning Apyx's communications with the FDA. "The mere repackaging of already-public information . . . is simply insufficient to constitute a corrective disclosure." *Id.* at 1199.

The Press Release and the 22Q1 Call, on the other hand, fail to qualify as corrective disclosures for a different reason; namely, they fail to reveal to the market the falsity of a prior misstatement or misrepresentation. *See FindWhat*, 658 F.3d at 1311 n. 28 (finding that a corrective disclosure must "reveal to the market the falsity of the prior misstatements") (cleaned up) (citation and internal quotations omitted). Indeed, nothing in the Press Release or the 22Q1 Call reveals that Defendants had been avoiding regulatory compliance measures or concealing materialized risk. They demonstrate that Apyx was working with the FDA to remain in compliance and otherwise reiterate information that was already publicly available. Further, as the Eleventh Circuit has explained, "stock prices may fall upon the announcement of an SEC investigation" or the news of an impending FDA MDSC, "but that is because

the investigation can be seen to portend an added *risk* of future corrective action. That does not mean that the investigations, in and of themselves, reveal to the market that a company's previous statements were false or fraudulent." *Meyer*, 710 F.3d at 1201 (citation omitted). No future corrective action from the FDA ever came in this case. Plaintiff has failed to adequately plead that a fraudulent misrepresentation artificially inflated the value of Apyx securities or that any fraud induced inflation that was baked into Plaintiff's purchase price was subsequently removed by a corrective disclosure. In other words, Plaintiff has failed to plead loss causation.

II. § 20(a)

Plaintiff's Section 20(a) claim fails without a primary violation of Section 10(b) by Defendants. *See Mizzaro*, 544 F.3d at 1255.

CONCLUSION

Plaintiff has failed to adequately plead his case. Notwithstanding, because the Amended Complaint is the first operative complaint dismissed by the Court, Plaintiff will have a second and final opportunity to do so.

Accordingly, it is hereby **ORDERED** and **ADJUDGED**:

(1) Defendants' Motion to Dismiss (Dkt. 45) is **GRANTED-IN-PART and DENIED-IN-PART**.

(2) Plaintiff's Amended Complaint (Dkt. 42) is **DISMISSED WITHOUT PREJUDICE**.

(3) If Plaintiff so chooses, he may file a second amended complaint on or before July 3, 2023, in default of which the Court will close this case.

DONE AND ORDERED at Tampa, Florida, on June 15, 2023.

/s/ William F. Jung
WILLIAM F. JUNG
UNITED STATES DISTRICT JUDGE

COPIES FURNISHED TO:
Counsel of Record