UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

CITY OF HOLLYWOOD FIREFIGHTERS' PENSION FUND, individually and on behalf of those similarly situated, Plaintiff, v. INSPIRE MEDICAL SYSTEMS, INC.; TIMOTHY P. HERBERT; and RICHARD J. BUCHHOLZ, Defendants.	Case No. 23-CV-3884 (NEB/DJF) ORDER ON DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT

This putative class action alleges claims under Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") and SEC Rule 10b-5 against Inspire Medical Systems, Inc. ("Inspire"), its CEO Timothy P. Herbert, and its CFO Richard J. Buchholz, and claims under Section 20(a) of the Exchange Act against Herbert and Buchholz. Defendants move to dismiss the amended complaint. (ECF No. 38.) For the reasons below, the motion to dismiss is granted.

BACKGROUND

I. Complaint Allegations[1]

A. The Device and Prior Authorization Approval Process

Inspire is a medical-device company headquartered in Golden Valley, Minnesota. (ECF No. 28 ("Am. Compl.") ¶¶ 1, 16.) Inspire became a publicly traded company in May 2018. (*Id.* ¶ 24.) Timothy Herbert is Inspire's President and Chief Executive Officer, and Richard Buchholz is its Chief Financial Officer. (*Id.* ¶¶ 17–18.)

Inspire produces an implanted device designed to treat obstructive sleep apnea in patients who have difficulties with traditional Continuous Positive Airway Pressure ("CPAP") machine therapy.[2] (*Id.* ¶ 23.) Third-party medical providers implant Inspire's devices. (*See id.* ¶ 26.) Historically, about seventy percent of Inspire's revenue has come from commercial insurance reimbursements for its device. (*Id.* ¶ 25.) The other thirty percent comes from Medicare and other sources.[3] (*Id.*)

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[1] The Court sets forth the facts and events drawn from the amended complaint, which it takes as true in ruling on the motion to dismiss. *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322 (2007). It also considers "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice," such as public SEC filings and stock price history. *Id.*

[2] Traditional CPAP therapy requires wearing a mask while sleeping. (Am. Compl. ¶ 23.)

[3] Defendants have noted the "seasonality" of Inspire's business. (*E.g.*, Am. Compl. ¶ 83.) Historically, in the first half of the year, a disproportionate share of procedures are paid for by government payors, with commercial insurance more heavily weighted to the second half of the year. (*See generally* ECF No. 41-3 (2022 10-K) at 33 (native pagination).)

Inspire cannot recognize the sale of a device (*i.e.*, revenue) until a patient's authorization is approved by the insurer and the implant procedure had been scheduled. (*Id.* ¶ 31.) To receive insurance approval, patients must complete a "rigorous 'prior authorization' process" through their medical providers. (*Id.* ¶ 26.) Before an implant procedure can be scheduled, medical providers must provide evidence of the patient's difficulty with CPAP therapy and the patient must undergo medical testing, including an observed "sleep study" and drug-induced sleep endoscopy. (*Id.* ¶¶ 26–27, 50.) Medical providers must also submit extensive documentation of a patient's eligibility. (*Id.* ¶¶ 26–27.) Insurance approval could be delayed or denied if an error occurs in completing the authorization process, which in turn delays or prevents Inspire from recognizing revenue. (*Id.* ¶ 31.)

To facilitate the insurers' prior authorization, Inspire developed a Prior Authorization Approval Process ("PAAP"). (*Id.* ¶ 28.) The PAAP developed advertising campaigns to bring patients to Inspire's website and telephone hotline, which connected patients with medical providers to schedule an evaluation for the device. (*Id.* ¶ 29.) Once a patient began the process, the PAAP teams of employees oversaw and managed the steps of the patient's prior authorization. (*Id.* ¶ 30.) These employees oversaw and advised the medical provider's testing for each patient, completed prior authorization applications, and handled appeals if authorizations were denied. (*Id.*)

The PAAP was allegedly "the key to Inspire's success," and "the key to the PAAP was the fact that Inspire was directly involved in assisting patients and medical providers to complete the prior authorization approval process." (*Id.* ¶ 32.) In essence, the PAAP meant that Inspire employees were completely in charge of documents for the medical providers to move the prior authorization process along.

B. Changes to the PAAP

Beginning in January 2023, Inspire (1) adopted a pilot program that ceased offering medical providers assistance with prior authorizations and (2) restructured its incentive compensation so that sales representatives were no longer motivated to ensure that medical providers completed each step of the prior authorization process quickly and correctly. (*Id.* ¶ 37, 62–63.) Medical providers were to handle the prior authorization process on their own. (*Id.* ¶ 36.)

Inspire disclosed that it was changing the compensation aspect of its prior authorization program during a fourth quarter 2024 earnings call on February 7, 2023.[4] (ECF No. 41-2.) Herbert stated that Inspire had "modified" its incentive compensation to

[4] When considering motions to dismiss securities fraud claims, courts consider analyst reports "to determine what may or may not have been disclosed to the public." *SEC v. Ustian*, 229 F. Supp. 3d 739, 761–62 (N.D. Ill. 2017) (citing *Reinschmidt v. Zillow, Inc.*, No. C12-2084 RSM, 2014 WL 5343668, at *3 (W.D. Wash. Oct. 20, 2014)). The Court considers the February 7 earnings call to determine what Defendants disclosed to the public about the prior authorization process.

focus on utilization at existing centers. (*Id.* at 6.) When asked to elaborate, Herbert explained:

> [I]n the past years, [compensation has] been based on what we call patients expecting therapy are more around patients in the prior authorization process.
> But as we continue to mature, *it's important that we shift that from individual patient count to more utilization at site*. So, we've kind of *switched over the parameter starting this year to really focus more on the utilization site*. So I think, we just presented it at the national sales meeting just a week ago, and team is very excited about the progress that they made last year, as well as the prospects moving forward.

(*Id.* at 19 (emphasis added).)

Some former employees of Inspire contend that the changes to the PAAP had a "disastrous" effect on Inspire's business. (Am. Compl. ¶¶ 40, 46.) FE 1, a former Senior Territory Manager from the greater Chicago area, explained that prior to 2023, "Inspire did these [prior authorizations] every day" and was highly skilled at them, but "now the clinics were doing them weekly and [they] were not very good at it." (*Id.* ¶ 40; *see id.* ¶ 39 n.1 (alleging FE 1 worked from the beginning of 2019 to the beginning of 2024 and reported to a Regional Sales Manager).) FE 1 noted that Inspire changed its compensation structure such that "they took the incentive away from us to help with the prior authorizations." (*Id.* ¶ 39.)

According to FE 1, these changes "definitely affected [Inspire's] accuracy of forecasting revenue because we lost the visibility of patient surgeries in the funnel." (*Id.* ¶ 40.) And insurers issued "more denials with forgetting documentation. The approval

percentage definitely went down dramatically by outsourcing the prior authorizations to the clinics. It was not a good setup for success." (*Id.*)

FE 1 maintains that her manager and Area Vice President were aware of the prior authorization problems and "were all referencing this up to the CEO. This started pretty early in the process." (*Id.* ¶ 55.) She recalled being on an Inspire conference call "no later than the second quarter of 2023" in which Herbert "discussed the slowdown in prior authorizations." (*Id.*)

FE 2, another former Territory Manager, explained that Inspire's withdrawal of prior authorization support "slow[ed] down the time that it takes from patient to get submitted to patient on table." (*Id.* ¶ 44; *see id.* ¶ 41 n.2 (alleging FE 2 worked from March 2022 to April 2023 in two geographic territories and reported to a Regional Manager).) FE 2 claimed that the PAAP changes resulted in "absolutely a massive slowdown." (*Id.* ¶ 44.)

FE 3, a former Territory Manager, corroborated that Inspire previously offered extensive prior authorization assistance. (*Id.* ¶ 46 & n.3 (FE 3 worked in Iowa from June 2021 through October 2023 and reported to a Regional Manager).) According to FE 3, Inspire stopped offering this assistance at the end of 2022. (*Id.* ¶ 46.) As a result, providers stopped prioritizing the processing of prior authorization applications for Inspire devices, and sales dropped off. (*Id.*) According to FE 3, "prior to these changes, the time from submission of a prior authorization had typically been less than 30 days, but after

the changes, the timeline typically got pushed out to at least 60 to 90 days." (*Id.* ¶ 48.) She stated that "[Inspire] lost patients that were waiting too long and decided to opt out of having the procedure done," as "patients quickly lost interest" when their procedures were delayed. (*Id.*)

Finally, FE 4, another Territory Manager, allegedly warned her immediate supervisor of her concern with these changes in January 2023. (*Id.* ¶ 51; *see id.* ¶ 50 n.4 (FE 4 worked in Wisconsin from mid-2020 through June 2023).) FE 4 reports that management carefully tracked the prior authorization process for patients using Microsoft Dynamics software, and so "Herbert and Buchholz had real-time access to detailed metrics demonstrating this slowdown." (*Id.* ¶ 54.)

C. Inspire's 2022 Form 10-K

In its 2022 Form 10-K, Inspire characterized the PAAP as one of two "pillar[s] of [its] reimbursement strategy" and a "competitive strength[]." (*Id.* ¶¶ 32–33; *see* ECF No. 41-1 at 6, 21[5].) The 2022 Form 10-K represented that Inspire "will continue to benefit from this efficient prior authorization process." (Am. Compl. ¶ 33.) The 2022 Form 10-K also stated the Inspire maintained a "[d]edicated team focused on providing market access for patients and providers," and that the team "helps patients and providers work with payors to secure prior authorization approvals in advance of initial treatment." (*Id.* ¶ 32.) Inspire characterized the PAAP as "highly effective" and "successful in helping to

[5] Page citations reference ECF page numbers unless otherwise noted.

secure reimbursement from hundreds of commercial payors to date." (*Id.* ¶¶ 32–33.) The 2022 Form 10-K did not disclose the pilot program or changes that Inspire had made to the PAAP.

D. The Alleged Misstatements

Plaintiff alleges that on two earnings calls and at two healthcare conferences in May, August, and September 2023, Defendants made materially false and misleading statements and omissions in a scheme to deceive the market. (*Id.* ¶¶ 17–18, 99.)

1. May 2, 2023 1Q 2023 Earnings Call (day before Class Period)

On May 2, 2023, Inspire reported its financial results for the first quarter of 2023 ("1Q 2023"). (*Id.* ¶ 69.) During the earnings call that day, Herbert stated that Inspire had "steadfastly improved our conversion of contact to patients receiving therapy . . . ." (*Id.*) Herbert relayed that Inspire was seeing "signs of improvement in the patient pathway and specifically by reducing the time from patient contact to implant." (*Id.*)

Herbert also stated that Inspire's "digital scheduling pilot continues to make strides and we are currently experiencing a 30% improvement in physician appointments in the pilot centers compared to traditional phone and e-mail scheduling through our Advisor Care Program and are adding technology to support the next wave of participating centers." (*Id.* ¶ 72.)

2. May 16, 2023 - RBC Capital Markets Global Healthcare Conference

On May 16, 2023, Inspire presented at the RBC Capital Markets Global Healthcare Conference. (*Id.* ¶ 74.) Herbert stated that Inspire sales representatives used to be compensated based on patients expecting therapy, which once "could take 4 to 6 months to get an insurance approval. Now we get approved in just 2 to 5 days. So we really are in the phase of teaching center[s] that—to help them just kind of submit their own prior authorizations." (*Id.*) Herbert continued:

> So now we need to do a transition of sales team a little bit and we incent them more on having high utilized centers, high utilization centers. As we talked about, primary purpose, center with the highest utilization has the best patient outcomes. . . . Started January 1 and *it's been well received so far*. The sales force really is able to understand the need to have an incentive like that and they know how to really get behind it and be able to drive the utilization. *So it's been very well received.*

(*Id.*)

3. August 1, 2023 - 2Q 2023 Earnings Call

On August 1, 2023, Inspire reported its financial results for the second quarter of 2023 ("2Q 2023"). (*Id.* ¶ 78.) During the earnings call that day, Herbert stated:

> In the second quarter, the number of visitors to our website surpassed 2.9 million. From these visits, we had over 12,000 physician contacts. *And even with the typical summer slowdown in contact, we steadfastly improved our conversion of patients receiving therapy.*

(*Id.*) In response to an analyst's question about whether there was a "backlog or pentup demand that's continuing to come in and support strong results," Herbert responded "[y]es." (*Id.* ¶ 81.) He explained that Inspire was "seeing continued growth across all of

our centers," that "same-store sales drove the growth in Q2, as it did in Q1, and I think will continue to do so as we move forward." (*Id.*) He noted that "efficiency and conversions of patients through implant continues to be strong." (*Id.*)

4. September 6, 2023 - Wells Fargo Securities Healthcare Conference

On September 6, 2023, Inspire presented at the Wells Fargo Securities Healthcare Conference. (*Id.* ¶ 83.) During the conference, an analyst noted Inspire's historically "seasonal business," and asked whether there was "[a]nything different about this year." (*Id.*) Buchholz responded that in the second quarter Inspire "had a little bit higher mix of Medicare versus commercial," and that they "expect[ed] that to revert back to a heavier commercial mix in the second half of the year." (*Id.*) When asked about "pent-up demand, some bolus of patients that came through in the second quarter," and whether the mix was "a headwind," Buchholz responded that Inspire had "a robust pipeline of patients awaiting therapy. So I don't expect that to be a headwind." (*Id.*)

E. November 7 Disclosure

On November 7, 2023, Inspire issued a press release reporting its financial results for the third quarter of 2023. (*Id.* ¶ 62.) The press release attributed the results to a "decline in prior authorization submissions" based on a "pilot program regarding prior authorization submissions by our customers" that had been implemented at the beginning of 2023. (*Id.*) In the press release, Herbert stated:

> Early in the year, we implemented a pilot program regarding prior authorization submissions by our customers, and in tracking the results of

> the program, *we observed a decline in prior authorization submissions for patients seeking Inspire therapy. . . . After recognizing this trend, we reinvigorated our efforts to facilitate patient access to Inspire therapy by more closely engaging with our customers with the prior authorization submission process,* including involving our corporate prior authorization team to assure consistency and accuracy of submissions. These challenges had a short-term impact on the number of implant procedures early in the third quarter, but the increase in patient prior authorizations at the end of the quarter reinforces our confidence in the fourth quarter and beyond.

(ECF No. 41-13 at 2–3 (emphasis added); *see* Am. Compl. ¶ 62.)

During the November 7 earnings call, Herbert stated that "in early 2023," Defendants had made the decision to "minimize our involvement with [our customers'] prior authorization process." (Am. Compl. ¶¶ 63, 91; ECF No. 41-14 at 6.) Herbert described the pilot study as involving "a significant number of centers . . . that have higher utilization to be able to leverage the learnings at those centers." (ECF No. 41-14 at 9.) He explained that, because of the pilot program's changes, "a significant number of our customer[s] experienced challenges with their prior authorization submission process," which led to a "decrease in the number of submissions by our customers seeking prior authorization" and an "impact on the number of implant procedures." (Am. Compl. ¶ 63.) Herbert represented that Inspire's leadership team was "comfortable that we're able to work with those centers and reenergize the field team and reenergize the prior authorization team to support these centers to get the prior authorization submissions back online, and we're seeing continued growth there and confidence moving forward." (ECF No. 41-14 at 9.)

An analyst remarked, "you started to learn about this early in the third quarter [and] I imagine it probably overlapped with the second quarter call," and asked when Herbert "knew about it and why not mention on 2Q?" (Am. Compl. ¶ 91; *see id.* ¶ 64.) Herbert responded that the problems had "started to become evident maybe a little bit in the second quarter" (the quarter beginning April 1, 2023), and that, by the beginning of the third quarter (the quarter beginning July 1, 2023), Defendants "realized we needed to take some corrective action." (*Id.* ¶¶ 7, 64, 92.) Herbert explained that Inspire had "tracked the decrease in the number of submissions by our customers seeking prior authorization to the Inspire procedure, resulting in a short-term impact on the number of Implant procedures during the early part of the third quarter." (*Id.* ¶ 92.)

Relying on an analyst's estimate, Plaintiff alleges that the problems with the pilot program caused a loss of around "400 procedures," resulting in a $7–10 million shortfall in revenue in Q3 2023.[6] (*Id.* ¶¶ 6, 62, 67, 102; *see id.* ¶ 23 (alleging that Inspire receives an average price of $25,000 per device).)

After the November 7 press release and call, Inspire's stock price dropped $31.79 per share, from a closing price of $161.74 per share on November 7, 2023, to a closing

[6] Defendants challenge this calculation, arguing that it is unreliable because it is based on an analyst's Q3 2023 expectation. (ECF No. 40 at 18 n.4; *see* Am. Compl. ¶ 67; ECF No. 41-17 (JPMorgan article).) Plaintiff responds that Herbert blamed Inspire's "disappointing results on the PAAP changes and said that those changes had impacted a '*significant* number of our customers'" which is enough to quantify the effect of the slowdown. (ECF No. 46 at 34 n.5 (emphasis added).) At this stage of this litigation, the Court accepts as true the assertion that the effect of the slowdown was significant.

price of $129.95 per share on November 8, 2023, on unusually high volume. (*Id.* ¶ 65; ECF No. 41-21 at 6.)

After the Class Period, Inspire beat its annual guidance for 2023, and by the close of business on February 9, 2024, its stock price was $194.87. (ECF No. 41-21 at 8.)

II. This Litigation

Plaintiff represents a putative class of all persons or entities who purchased or otherwise acquired Inspire's common stock between May 3, 2023, and November 7, 2023, inclusive ("Class Period"). (Am. Compl. ¶ 108.) They allege that Defendants falsely assured investors throughout the Class Period that the PAAP was growing even more effective and continuing to fuel Inspire's growth. (*Id.* ¶ 5.) Defendants allegedly knew, or were reckless in not knowing, that their statements were false and misleading when made. (*Id.* ¶¶ 20, 90–98.) Count I alleges violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 against all Defendants, and Count II alleges violations of Section 20(a) of the Exchange Act against Herbert and Buchholz. (*Id.* ¶¶ 114–29.) Defendants move to dismiss these claims.

ANALYSIS

I. Count I: Section 10(b) and Rule 10b-5 Claim

Count I alleges that Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(b). Section 10(b) makes it unlawful "[t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance

in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b). Rule 10b–5(b) forbids any person from making "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." 17 C.F.R. § 240.10b–5(b). Congress imposed heightened pleading requirements on Section 10(b) plaintiffs by enacting the Private Securities Litigation Reform Act ("PSLRA"). *Podraza v. Whiting*, 790 F.3d 828, 836 (8th Cir. 2015); *see In re 2007 Novastar Fin. Inc., Sec. Litig.*, 579 F.3d 878, 882 (8th Cir. 2009) ("The PSLRA goes beyond the ordinary pleading requirements described in Rules 8(a)(2) and 9(b) of the Federal Rules of Civil Procedure."). The PSLRA requires that a complaint: (1) "specify each false statement or misleading omission and explain why the omission was misleading," and (2) "state 'with particularity' facts giving rise to a 'strong inference' that the defendant acted with the scienter required for the cause of action." *In re Navarre Corp. Sec. Litig.*, 299 F.3d 735, 742 (8th Cir. 2002) (citations omitted).

To survive a motion to dismiss, Plaintiff must plausibly plead a claim for relief under Section 10(b) and Rule 10b–5 when accepting all alleged facts as true. *Tellabs*, 551 U.S. at 322. The Court considers the amended complaint as a whole, documents incorporated into the amended complaint by reference, and matters of which a court may take judicial notice. *Id.*

A. Misleading Statements and Omissions

The Court first considers whether the amended complaint contains sufficient allegations of falsity. The PSLRA's heightened pleading standard requires Plaintiff to "plead the 'who, what, when, where and how' of the misleading statements or omissions." *Novastar*, 579 F.3d at 882 (citation omitted). The amended complaint must "indicate why the alleged misstatements would have been false or misleading at the several points in time in which it is alleged they were made." *In re Hutchinson Tech., Inc. Sec. Litig.*, 536 F.3d 952, 958–59 (8th Cir. 2008) (citation omitted).

1. 1Q 2023 Earnings Call (May 2) and RBC Capital Markets Global Healthcare Conference (May 16)

a. Fraud by Hindsight

Defendants argue that several of Herbert's "admissions" in May were nothing more than fraud by hindsight. A material misstatement must be "false when made, not just in hindsight." *In re Stratasys Ltd. S'holder Sec. Litig.*, 864 F.3d 879, 883 (8th Cir. 2017). "[M]anagement's failure to accurately forecast evolving business conditions does not equate to fraudulent conduct." *City of Sterling Heights Police & Fire Ret. Sys. v. Vodafone Grp. Pub. Ltd.*, 655 F. Supp. 2d 262, 269 (S.D.N.Y. 2009).

During the November 7 earnings call, Herbert admitted that problems with the pilot program "*started* to become evident *maybe a little bit* in the second quarter." (Am. Compl. ¶¶ 64, 92 (emphasis added).) Because the second quarter runs from April 1 to June 30, Plaintiff contends that Herbert knew about the pilot-program problems when he

made allegedly misleading statements on May 2 and May 16. But the second quarter did not end until a month and a half after Herbert made the allegedly misleading statements. Plaintiff does not allege facts plausibly inferring that Herbert learned of problems with the pilot program in May. Moreover, Herbert's acknowledgment that problems "started to become evidence a little bit" is too vague to infer that he knew his statements were materially misleading when he made them in May. *See In re Apogee Enters., Inc. Sec. Litig.*, No. 18-CV-3097 (NEB/BRT), 2020 WL 1445856, at *10 (D. Minn. Mar. 25, 2020) (concluding that plaintiffs failed to allege with particularity facts suggesting that defendants knew the significance of the problems with certain projects on a particular day, despite an officer's later acknowledgment of the problems "in hindsight"); *Navarre*, 299 F.3d at 743 ("Simply alleging that defendants made a particular statement at a given time . . . and then showing in hindsight that the statement is false misses the PSLRA pleading requirement.").

Similarly, FE 1's vague representation that Herbert "discussed the slowdown in prior authorizations" during a company conference call "no later than the second quarter of 2023," (Am. Compl. ¶ 55), is not sufficiently particular to show that Herbert's statements in May were false or misleading. She does not allege that Herbert understood that the pilot program caused the slowdown or that the slowdown was impacting Inspire's revenue when he made the May statements.[7] (*See id.* ¶ 40 (FE 1 noting that the

[7] Herbert's comments differ significantly from those in *Sanchez v. Centene Corporation*, 407 F. Supp. 3d 831 (E.D. Mo. 2019), relied upon by Plaintiff. There, an officer told analysts that changes were not required to get the company's balance sheet "up to snuff," when

changes to the prior authorization process "lost the visibility of patient surgeries in the funnel"); *id.* ¶ 43 (FE 2 noting that leaving medical providers to do their own prior authorizations "takes away, from a rep perspective, your visibility into what's going on").)

b. Puffery

Some of Herbert's May statements also fall in the category of inactionable puffery. If a statement is "so vague and such obvious hyperbole that no reasonable investor would rely upon it," the statement is puffery and is not material. *Stratasys*, 864 F.3d at 882 (citation omitted). Puffery encompasses "optimistic rhetoric" and "promotional phrases used to champion the company" but are "devoid of any substantive information." *Id.* (citation omitted).

On May 16, Herbert stated that Inspire was "in the phase of teaching center[s] . . . to help them just kind of submit their own prior authorizations" and "it's been well received so far." (Am. Compl. ¶ 74.) Plaintiff argues that this statement materially misled investors because it suggested that "Inspire remained heavily involved in the prior authorization process and was actively engaged in assisting medical providers to submit their own prior authorization documentation." (ECF No. 46 at 47–48.)

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the defendants knew of issues at the time and had been working on a redesign for "several months." *Id.* at 842.

Herbert's statement that Inspire was in a phase of teaching centers how to help them submit their own prior authorizations is not sufficiently concrete that it would induce the reliance of a reasonable investor. *See generally Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 606 (9th Cir. 2014) (holding that defendant's statements were "inherently subjective 'puffing'," including defendant's "use of general terms like 'educational content' and 'teaching resources'"). Plaintiff contends that this statement fails to convey that Inspire had minimized its involvement with the prior authorization process, or that the PAAP changes were "profound[ly] and obvious[ly]" impacting Inspire's business. (ECF No. 46 at 47.) But as discussed above, the factual allegations do not suggest that Defendants knew that changes to the PAAP had caused a profound or obvious effect on Inspire's business on or before May 16.

Moreover, the statement that the teaching phase had been "well received so far" is so vague that no reasonable investor would rely on it. *See In re Target Corp. Sec. Litig.*, 955 F.3d 738, 743 n.2 (8th Cir. 2020) (statements like, "we're right where we want to be right now," and "we feel really good about where we are today," were "inactionable puffery"); *Hutchinson Tech.*, 536 F.3d at 960 (statement that the company was "well-positioned" on some new programs was too vague); *Norfolk Cnty. Ret. Sys. v. Tempur-Pedic Int'l, Inc.*, 22 F. Supp. 3d 669, 687 (E.D. Ky. 2014) (statement that the company's "collection continues to be well-received by retailers" was "non-material, vague puffery"), *aff'd*, 614 F. App'x 237 (6th Cir. 2015).

c. Unrelated to the Pilot Program

Finally, some of the May statements fail because they do not relate to the pilot program.

First, Herbert allegedly misled investors on May 2 when he stated that "*digital* scheduling pilot continues to make strides and we are currently experiencing a 30% improvement in physician appointments in the pilot centers compared to traditional phone and e-mail scheduling through our Advisor Care Program and are adding technology to support the next wave of participating centers." (Am. Compl. ¶ 72 (emphasis added).) Defendants contend that the "digital scheduling pilot" has nothing to do with the pilot program that caused Inspire's problems. Plaintiff asserts that the "digital scheduling pilot" was "a key aspect of the PAAP," but offers no facts explaining how it is related to the PAAP. (ECF No. 46 at 31 n.4.) The amended complaint does not sufficiently support this statement as false or misleading.

Second, Plaintiff challenges Herbert's May 2 statement that Inspire had "steadfastly improved our conversion of contact to patients receiving therapy." (Am. Compl. ¶ 69.) Plaintiff asserts that the opposite was true: Inspire had minimized its involvement with patients' prior authorization process, which worsened the process and timing of conversion of contact to patients receiving therapy. (*Id.* ¶ 70.)

Defendants contend that "conversion" did not address the prior authorization process, rather, it addressed the percentage of people who visited the website, contacted

physicians, and became Inspire patients. (ECF No. 40 at 35.) The statement, read in context, supports Defendants' position:

> In the first quarter, the number of visitors to our website surpassed 3.4 million, which is significant. The website is the introduction for patients and the source of the growth in therapy adoption. In January of 2022, we initiated our first national media campaign, which resulted in a onetime spike in website visitors surpassing the 3.4 million in the first quarter, but the current volume has us in a very strong position entering 2023. *From these visits, we had over 19,000 physician contacts and have steadfastly improved our conversion of contact to patients receiving therapy.*

(ECF No. 41-7 at 6 (emphasis added)); *see In re InvenSense, Inc. Sec. Litig.*, No. 15-CV-00084-JD, 2017 WL 11673462, at *3 (N.D. Cal. Apr. 12, 2017) (finding that the plaintiff failed to plead falsity because there was "a mismatch between the statement identified as false and misleading on the one hand, and the reasons why plaintiff says the statement was false or misleading on the other," and noting that "reading the statement in its full context makes it even more clear" that the speaker was discussing a different topic).

Even if the statement is construed as referring to the prior authorization process, Plaintiff provides no "particularized basis" for challenging the veracity of the statement, aside from an analyst's estimate in November 2023 that hundreds of sales were lost. Moreover, during the November 7 earnings call, Herbert repeated that Inspire's conversion rate "continued to improve." (*See* ECF No. 41-14 at 6 ("[W]e continued to improve our conversion of patients receiving Inspire therapy.").) His continued assertion—after the corrective disclosure—suggests that either the conversion rate was unrelated to the prior-authorization or pilot-program problems, or that the statement was

not false or misleading when made. *See In re Allergan PLC Sec. Litig.*, No. 18 Civ. 12089 (CM)(GWG), 2022 WL 17584155, at *16 (S.D.N.Y. Dec. 12, 2022) ("[I]if a statement is revealed to be true—even following the Class Period—Plaintiff cannot prove that it was 'objectively false.'"), *aff'd sub nom. DeKalb Cnty. Pension Fund v. Allergan PLC*, No. 23-117, 2024 WL 677081 (2d Cir. Feb. 20, 2024).[8]

Third, also on May 2, Herbert stated that Inspire "see[s] signs of improvement in the patient pathway and specifically by reducing the time from patient contact to implant, which continues to be approximately 6 months." (ECF No. 41-7 at 6; *see* Am. Compl. ¶ 69.) This statement was allegedly misleading because Herbert omitted that the pilot program had led to a massive slowdown in prior authorizations and lost patients who waited too long and gave up on the procedure (which led lost revenue). (Am. Compl. ¶¶ 70–71.) Defendants argue that Herbert's statement did not address the prior authorizations or the pilot program. The Court is unconvinced. Inspire's 2022 Form 10-K represented that the PAAP—one of its two competitive strengths—"helps patients and providers work with payors to secure prior authorization approvals in advance of initial treatment." (ECF No. 41-1 at 7; Am. Compl. ¶ 32.) A reasonable investor could consider Herbert's

[8] The Court notes that on *Allergan*'s appeal, the Second Circuit considered whether "literally true statements were actionable half-truths that, by virtue of 'their context and manner of presentation,' were misleading because they were 'susceptible to quite another interpretation by the reasonable investor.'" *DeKalb Cnty. Pension Fund*, 2024 WL 677081, at *2 (citation omitted) (concluding that the statements at issue were not actionable half-truths).

"reducing the time from patient contact to implant" statement as addressing the prior authorizations because "the time from patient contact to implant" necessarily includes the prior-authorization process. (ECF No. 41-7 at 6; *see, e.g.*, ECF No. 41-15 at 31 (Nov. 7, 2023 8-K: graphic of patients' path to Inspire)). But, as explained below, even if this statement were misleading, it fails for lack of scienter.

Plaintiff's allegations about Defendants' knowledge of the pilot-program problems "do not provide particular details about *when* [Defendants] knew of these issues." *Stratasys*, 864 F.3d at 883. Plaintiff cites no specific facts suggesting that Defendants were aware of pilot-program problems causing "the time from patient contact to implant" to increase, or the "conversion" rate to significantly deteriorate, such that these statements were false or misleading.

Fourth, at the healthcare conference on May 16, Herbert stated that while it had once taken "4 to 6 months to get an insurance approval . . . [n]ow we get approved in just 2 to 5 days." (Am. Compl. ¶ 74.) Plaintiff contends that the PAAP had not sped up to as little as "2 to 5 days" but had slowed down due to Inspire's changes to its prior authorization process.[9] (*Id.* ¶ 75.) This assumption is based on the former employees'

[9] According to Plaintiff, Defendants ask the Court to interpret Herbert's "2 to 5 days" statement in their favor as referring only to the time it took submitted prior authorization forms to be approved. The Court disagrees. Herbert's statement refers to the time for "insurance approval." And Defendants presented a six-month estimate for the contact-to-implant process before and after the November 7 disclosure. (*See* ECF No. 41-7 at 6 (May 2, 2023 earnings call: Herbert noting that the time from patient contact to implant "continues to be approximately 6 months"); ECF No. 41-15 at 31 (Nov. 7, 2023 8-K

assertion that the pilot program caused a "massive slowdown" in the approval process resulting in lost sales. But FE 2's anecdotal claim of a "massive slowdown" does not indicate whether the problems with the pilot program had materially affected Inspire's sales at the time Herbert made this statement.

2. 2Q 2023 Earnings Call (August 1) and Wells Fargo Securities Healthcare Conference (September 6)

Plaintiff also alleges that three statements made during the 2Q 2023 earnings call in August and during the Wells Fargo Securities Healthcare Conference in September were false or misleading.

First, Plaintiff alleges that Herbert misled investors on August 1, 2023, when he stated during the Q3 2023 earnings call that "even with the typical summer slowdown in contact, [Inspire] had steadfastly improved our conversion of contact to patients receiving therapy." (Am. Compl. ¶ 78.) According to Plaintiff, this statement was misleading because Herbert admitted that by "the beginning of the third quarter"—early July—the pilot-program problems had become so significant that Defendants were forced to "take some corrective action" and reverse the changes they had made to the process. (*Id.*)

Presentation: "Time from ACP contact to implant can be as much as 6 months"); ECF No. 41-20 at 35 (Feb. 6, 2024 8-K Presentation: same).) Given Defendants' consistent six-month estimate, a reasonable investor would not believe that the entire prior approval process took only 2 to 5 days.

This statement is similar to one Herbert made on May 2. As with the May 2 statement, Defendants assert that this statement is unrelated to the prior authorization process. Herbert explained:

> In the second quarter, the number of visitors to our website surpassed 2.9 million. From these visits, we had over 12,000 physician contacts. *And even with the typical summer slowdown in contact, we steadfastly improved our conversion of patients receiving therapy*. We continue to make numerous changes to our website to enhance how patients engage with our Advisor Care Program, and we have a new website design in the works for later this year. . . .

(ECF No. 41-10 at 6 (emphasis added).) Like the May 2 statement, when read in context, this statement appears related to the conversion of website hits to Inspire patients, rather than the prior authorization process.

Even if the statement encompassed the prior authorization process, Plaintiff does not show how the alleged improvement of conversion is untrue or that the pilot-program problems had materially worsened "conversion"; indeed, Defendants continued to make this statement after the corrective disclosure. (*See* ECF No. 41-14 at 6 (Nov. 7, 2023 earnings call: "[W]e continued to improve our conversion of patients receiving Inspire therapy.").) And so the amended complaint fails to sufficiently allege that this statement is false or misleading.

Second, when Herbert was asked about the outlook for the back half of 2023 on August 1, he stated, "I think we're seeing continued growth across all of our centers." (Am. Compl. ¶ 81.) Plaintiff contends that this statement was misleading at that time

because Defendants knew that Inspire was not achieving growth across all centers, but was instead experiencing severe delays, denials, and lost sales because of the pilot-program problems. (*Id.* ¶ 82.) Inspire's record for the second half of 2023 suggests that Herbert's statement was truthful:

- Inspire beat the 2023 annual revenue guidance it issued in Q3 2023 by $12 million, (*compare* ECF No. 41-15 at 20 (Nov. 7, 2023 8-K: "FY2023 revenue range of $608M – $612M") *with* ECF No. 41-19 at 95 (2023 10-K: revenue of $624,799 million);
- Inspire grew 40% year-over-year from Q3 2022 to Q3 2023, (ECF No. 41-13 at 1); and
- Inspire earned more revenue in Q3 2023 than Q2 2023, (*compare* ECF No. 41-9 at 7 (Q2 2023 10-Q: $151 million) *with* ECF No. 41-12 at 7 (Q3 2023 10-Q: $153 million)).

Inspire's positive revenue results suggest that the company continued to see growth during the second half of 2023. *See generally In re Stratasys Ltd.*, No. 15-CV-0455 (PJS/FLN), 2016 WL 3636992, at *11 (D. Minn. June 30, 2016) ("Compounding plaintiffs' problem is the fact that, in contrast to many securities-fraud actions, defendants' financial predictions were actually fairly accurate."), *aff'd*, 864 F.3d 879 (8th Cir. 2017).

Finally, at a healthcare conference on September 6, an analyst asked CFO Buchholz whether there was pent-up demand or a headwind. Buchholz responded that Inspire has "a robust pipeline of patients awaiting therapy. So [I] don't expect a headwind." (Am. Compl. ¶ 83.) Plaintiff argues that this statement was misleading because Defendants knew by this time that the loss of prior authorizations was a "headwind," as Inspire was losing millions of dollars in sales because of the changes to the PAAP. (*Id.* ¶ 84.)

Defendants contend that Buchholz's statement was puffery and was not false. As explained above, statements found to be puffery are inactionable. And, as noted above, Inspire arguably experienced "robust" growth in 2023, beating its annual revenue guidance by $12 million. And so the amended complaint does not plausibly allege that this statement was false.

B. Scienter

While the amended complaint fails to plead material misstatements and omissions with the requisite particularity, it also fails to plead a strong inference of scienter, and so fails on that ground as well. To survive a motion to dismiss, Plaintiff must allege particular facts supporting a "strong inference" that Defendants made misstatements with the requisite scienter. *Navarre*, 299 F.3d at 745 (citing 15 U.S.C. § 78u-4(b)(2)). Scienter is "the intent to deceive, manipulate, or defraud," *id.* at 741, and "requires a showing of 'reckless or intentional wrongdoing.'" *Podraza*, 790 F.3d at 836 (citation omitted). Recklessness requires "an extreme departure from the standards of ordinary care" that present a danger of misleading investors which is "either known to the defendant or is so obvious that the defendant must have been aware of it." *Fla. State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 645, 654 (8th Cir. 2001) (citation omitted). The complaint allegations must "raise a strong inference of scienter for each defendant and with respect

to each alleged misrepresentation."[10] *Horizon Asset Mgmt. Inc. v. H & R Block, Inc.*, 580 F.3d 755, 761 (8th Cir. 2009). An 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.

Plaintiff alleges scienter based on Defendants' knowledge of information suggesting that their public statements were not accurate.[11] A "'classic' fact pattern giving rise to a strong inference of scienter is that defendants made statements when they knew or had access to information suggesting these public statements to be materially inaccurate." *Navarre*, 299 F.3d at 746 (citing *Green Tree*, 270 F.3d at 665). But conclusory allegations that contrary information "must have existed and must have been known" by Defendants do not support an inference of scienter. *Elam v. Neidorff*, 544 F.3d 921, 930 (8th Cir. 2008); *see Detroit Gen. Ret. Sys. v. Medtronic, Inc.*, 621 F.3d 800, 808 (8th Cir. 2010) (affirming a dismissal where plaintiff had not alleged facts to support the inference that any individual defendant was aware of the information that allegedly should have been disclosed).

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[10] *See In re St. Jude Med., Inc. Sec. Litig.*, 836 F. Supp. 2d 878, 896 (D. Minn. 2011) ("The knowledge and scienter of a corporate officer such as its CEO or CFO may of course be imputed to the corporate entity.").

[11] Because Plaintiff does not allege scienter based on motive or opportunity, its allegations tending to show Defendants' scienter must be "particularly strong in order to meet the [PSLRA] standard." *In re K-tel Int'l, Inc. Sec. Litig.*, 300 F.3d 881, 894 (8th Cir. 2002) (citation omitted).

In determining whether alleged facts support a strong inference of scienter, the Court takes the factual allegations as true, and, assessing them collectively, determines whether a reasonable person would find "the inference of scienter at least as strong as any opposing inference." *Tellabs*, 551 U.S. at 326. The Court considers inferences favoring Plaintiff as well as "plausible, nonculpable explanations" for Defendants' conduct. *Podraza*, 790 F.3d at 837 (citing *Tellabs*, 551 U.S. at 324).

Plaintiff allege Defendants' scienter based on (1) Herbert's November 7 "admissions" of knowledge, (2) the analysts' reactions to the disclosures, (3) the former employees' allegations, and (4) the core operations allegations. The Court addresses these allegations in turn before considering them holistically in deciding whether the amended complaint alleges a strong inference of scienter. *See Cornelia I. Crowell GST Tr. v. Possis Med., Inc.*, 519 F.3d 778, 782 (8th Cir. 2008) (holding that a court must consider "whether *all* the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any allegation, scrutinized in isolation meets that standard" (citing *Tellabs*, 551 U.S. at 323)).

1. Herbert's November 7 "Admissions" of Knowledge

To adequately plead scienter, a plaintiff "must demonstrate that a defendant knew a statement was false at the moment it was made." *Stratasys*, 864 F.3d at 883. Plaintiff contends that it has pled Defendants' scienter based on Herbert's November 7 "admissions" to knowing about problems with the pilot program as early as the second

quarter of 2023. Plaintiff points to Herbert's statement that prior-authorization problems had "started to become evident *maybe a little bit* in the second quarter," and that Inspire had "tracked the decrease in the number of submissions by our customers seeking prior authorization to the Inspire procedure." (Am. Compl. ¶¶ 92–93 (emphasis added).) According to Plaintiff, these "admissions" show that Defendants knew or had access to information suggesting that their earlier statements were materially inaccurate. *See In re Apple Inc. Sec. Litig.*, No. 19-CV-02033-YGR, 2020 WL 6482014, at *10 (N.D. Cal. Nov. 4, 2020) (finding a strong inference that the company had information contradicting prior statements where its CEO later admitted that the company "'saw' . . . troubling signs . . . 'as the quarter went on'").

Herbert's so-called admission must be read in context. Responding to an analyst's question about when Defendants started to learn about this issue, suggesting that "it probably overlapped with the second quarter call" and asking "why not mention on 2Q?" ECF No. 41-14 (Nov. 7, 2023 earnings call) at 9.) Herbert responded,

> Well, we're going to start out by looking at, certainly, *we needed data as we continue to move through the first and second quarter.* I mean, we talked about the first quarter is really focused on Medicare cases as we come out of the fourth quarter. *And we also are in the process of implementing the pilot program. Further into the second quarter was being educated with new centers, and that's when we were able to start to track that a little closer*.
>
> *It wasn't until the beginning of the third quarter that we realized we needed to take some corrective action*. And that *we implemented that change, but we also want to watch for the data on those changes, which, of course, we don't see until later into the third quarter*. And at that point with our capacity, it's challenging to be able to add those additional implant procedures within the third quarter.

> *But it started to become evident maybe a little bit in the second quarter, but with tracking of the data, we really didn't take the action until early in the third quarter when we had a strong confirmation on that*.

(*Id.* (emphasis added).) Herbert's response does not suggest that Defendants knew or should have known of extent of the pilot-program problems in May 2023, when most of the statements at issue were made. *See Stratasys*, 864 F.3d at 883–84 ("Without tying the timing of the knowledge to the allegedly misleading statements, the shareholders do not plead facts sufficient to support a strong inference of scienter.").

As for the statements made in August and September, Defendants argue that those statements do not address the pilot program and thus they were not required to disclose any problems with them. As explained above, the Court has found that some statements do not appear to relate to the prior authorization process or pilot program. To the extent that statements could be construed as addressing the prior authorization process, "awareness of a problem on its own is not enough to demonstrate that a defendant acted with the requisite mental state." *Trustees of Welfare & Pension Funds of Loc. 464A - Pension Fund v. Medtronic PLC*, 726 F. Supp. 3d 938, 981 (D. Minn. 2024). Plaintiff must show that "Defendants made 'highly unreasonable omissions . . . that . . . present a danger of misleading buyers or sellers which is either known to the defendant, or is so obvious that the defendant must have been aware of it.'" *Id.* (citing *In re Ceridian Corp. Sec. Litig.*, 542 F.3d 240, 244 (8th Cir. 2008)). Defendants' failure to disclose issues with a pilot program

when answering analyst questions about business topics do not suggest an "extreme departure from the standards of ordinary care." *Green Tree*, 270 F.3d at 654.

2. Analysts' Reactions

Plaintiff next argues that the fact that some analysts "understood" Herbert's disclosures to be admissions of knowledge confirms that those disclosures were admissions.[12] It cites three cases in which courts concluded that analyst reports offered supporting evidence. *See Ind. Pub. Ret. Sys. v. Pluralsight, Inc.*, 45 F.4th 1236, 1262 (10th Cir. 2022) (reversing a finding of no inference of scienter where "the district court disregarded that 'multiple analysts contemporaneously reported that Defendants admitted that they knew of the capacity gap' and failed to disclose it"); *Baker v. SeaWorld Ent., Inc.*, 423 F. Supp. 3d 878, 927 (S.D. Cal. 2019) (considering analyst reports on summary judgment because they "demonstrate[d] how the market understood and interpreted SeaWorld's disclosure"); *In re Salix Pharms., Ltd.*, No. 14-CV-8925 (KMW), 2016 WL 1629341, at *11 (S.D.N.Y. Apr. 22, 2016) (addressing the actual-knowledge safe harbor: "The Court's reading of these statements is bolstered by Plaintiffs' allegations

[12] Plaintiff points to comments of three analysts. (ECF No. 46 at 57–58.) One analyst stated that "during Q2" Inspire management "began to realize there was a consistent slowdown in prior authorization submissions . . . moving through the year into the summer months." (Am. Compl. ¶¶ 66, 94, 102.) The second analyst reported that management had "noted a slowdown in P[rior] A[uthorizations] in early Q3" and that "the signs were probably there in Q2." (*Id.* ¶ 67.) A third analyst asked during Inspire's November 7 earnings call why they had not mentioned the slowdown during the Q2 2023 earnings call on August 1. (*Id.* ¶¶ 64, 92.)

regarding public comments made by analysts after the conference calls. . . . These comments reveal that analysts understood the Defendants' statements as representations of the *current* levels of wholesaler inventory, not just future projections.").

Having reviewed the November 7 earning call and analyst reports, the Court finds that Plaintiff distorts the analysts' reactions to Defendants' statements. For example, the amended complaint alleges that "Analysts were *incredulous* that Defendants did not disclose the material issues with the [PAAP] earlier, specifically highlighting the fact that Defendants had known of these problems at the time they made their false and misleading statements." (Am. Compl. ¶ 94 (emphasis added); *see also id.* ¶ 66 ("[A]nalysts *excoriated* Defendants for their failure to disclose this material adverse information earlier and for management's lack of transparency in discussing the issue." (emphasis added).) But the analysts' responses during and after the November 7 earnings call do not suggest such a negative response. (*See* ECF No. 41-14 at 9–18 (Nov. 1, 2023 earnings call transcript); ECF No. 41-17 at 2 (Nov. 8, 2023 JP Morgan article: "[W]e think [Inspire's management] team has a good handle on 4Q and can return to its prior beat and raise trajectory. This wasn't the quarter we were hoping for, but we're inclined to view it as a blip on a nearly perfect track record, and we'd support it."); ECF No. 41-18 at 2 (Nov. 8, 2023 Truist report: despite expecting a Q3 revenue shortfall, "there is no change to our Buy thesis and we continue to see INSP as well-positioned").) Indeed, analyst reports suggest that Defendants recognized the problems caused by the pilot program and began

correcting them in the third quarter. For example, Truist reported that "a pilot program implemented early in the year that ultimately put the burden of pre-authorization submissions more into customer hands and had the (*unanticipated*) result of slowing private insurance prior-auth submissions in the July timeframe." (ECF No. 41-18 at 2 (emphasis added).) The analyst noted that "[d]uring 2Q mgmt. had noticed a mix shift towards Medicare vs. private pay and *wasn't entirely sure of the cause* (this was called out on the Q2 call)," and that "[t]his was an *unintended consequence* of some sales force incentive changes made at the beginning of 2023, but very fixable and now corrected." (*Id*. at 2–3 (emphases added).) For these reasons, the analyst reports do not support a finding of scienter.

3. Confidential Former Employees' Testimony

"Unlike other factual allegations in a complaint, courts are not required to wholly accept as true statements from a confidential witness." *Shoemaker v. Cardiovascular Sys., Inc.*, 300 F. Supp. 3d 1046, 1055 (D. Minn. 2018) (citing *Minneapolis Firefighters' Relief Ass'n v. MEMC Elec. Materials, Inc.*, 641 F.3d 1023, 1030 (8th Cir. 2011)). Even accepting the allegations as true, the Court can only infer from the former employees' testimony that lower-level employees knew that prior authorizations had dropped off dramatically after Inspire started its pilot program. The former employees, all of whom are territory managers, were at least five levels removed from Herbert on Inspire's organizational chart. (*See* ECF No. 41-20 at 33, 39–40.) Plaintiff fails to explain how FE 2, FE 3, or FE 4,

had access to or contact with Defendants. *See generally City of Plantation Police Officers Pension Fund v. Meredith Corp.*, 16 F.4th 553, 557 (8th Cir. 2021) (discounting confidential former employee's allegations when nothing suggested that he or his sources "had any insight into what, if anything," the individual defendant knew); *Steamfitters Loc. 449 Pension & Ret. Sec. Funds v. Sleep No. Corp.*, No. 21-CV-2669 (PJS/DTS), 2023 WL 4421688, at *8 (D. Minn. July 10, 2023) ("expressions of concern" did not show scienter, "particularly when those expressions are filtered through a low-level retail employee many layers removed from top management").

The only former employee to have any contact with an individual Defendant was FE 1, who claims that Herbert was on a company call "no later than the second quarter of 2023" during which Herbert "discussed the slowdown in prior authorizations." (Am. Compl. ¶ 55.) But FE 1 does not specify when the call occurred, or suggest how many submissions were impacted, the duration of the slowdown, or the impact on Inspire's revenue. Without factual information to provide perspective, this allegation amounts to nothing more than "anecdotal evidence" from a former employee. *Stratasys*, 2016 WL 3636992, at *12. The allegation does not support the inference that Herbert understood the impact that the changes in the PAAP would have on Inspire's revenue.

FE 2's general assertion that an "absolutely a massive slowdown" occurred does not provide supporting facts, such as when or in which territories the slowdown occurred, how many accounts were affected, or whether or how the slowdown impacted

Inspire's revenue. (Am. Compl. ¶ 44.) "The PSLRA, however, requires more than rhetorical flourishes; it requires plaintiffs to 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Stratasys*, 2016 WL 3636992, at *11 (citing 15 U.S.C. § 78u–4(b)(2)(A)); *see, e.g.*, *Steamfitters*, 2023 WL 4421688, at *9 (allegations about supply-chain and logistics issues were "vague as to timing or content (or both)" and so failed to satisfy the PSLRA).

FE 3 asserts that the timeline in her territory of Iowa was pushed out to at least 60 to 90 days, but does not state that this was true as of Herbert's statements on May 16 or that Herbert was aware of them. *See In re Hutchinson Tech. Inc. Sec. Litig.*, 502 F. Supp. 2d 884, 895 (D. Minn. 2007) (discounting confidential witness's testimony because it "provide[d] little, if any, evidence that the return allowances were knowingly false"), *aff'd*, 536 F.3d 952 (8th Cir. 2008). Nor does the amended complaint allege that FE 3 had any knowledge of timelines in Inspire's other territories, or that FE 3 learned of such timelines from the individual Defendants or other upper-level management. *Id.* (discounting confidential witness testimony about customer-return rates for similar reasons). The FEs' general assertions fail to provide meaningful support to Plaintiff's scienter allegation. *See Cornelia I. Crowell GST Tr.*, 519 F.3d at 783 (holding that the level of detail provided by anonymous testimony failed to support scienter).

4. Core Operations

Finally, Plaintiff contends that Defendants knew that the changes to the PAAP negatively impacted Inspire based on its "core operations" allegations. The core operations doctrine presumes that "misstatements and omissions made on 'core matters of central importance' to the company and its high-level executives give[] rise to an inference of scienter when taken together with additional allegations connecting the executives' positions to their knowledge." *In re Urb. Outfitters, Inc. Sec. Litig.*, 103 F. Supp. 3d 635, 653–54 (E.D. Pa. 2015) (citation omitted). The Eighth Circuit has not yet decided whether a plaintiff can use core operations allegations to plead scienter. *See Elam*, 544 F.3d at 929. But it has held that, to attribute knowledge to company officers, a plaintiff must at least show that the relevant information "was known within the company at that time." *Id.*

Plaintiff argues that the core operations doctrine applies because: Inspire's implant was its sole product; prior insurer authorization was required for around 70% of its revenue; Inspire's 2022 Form 10-K represented that the PAAP was a "competitive strength" and a "pillar of [Inspire's] reimbursement strategy" that was highly effective in obtaining prior authorizations for Inspire devices; and Defendants knew that changes were made to the PAAP. From these allegations, Plaintiff maintains that Herbert and Buchholz "were clearly aware of the impact that these changes were having on Inspire's business." (ECF No. 46 at 54); *see In re CenturyLink Sales Pracs. & Sec. Litig.*, 403 F. Supp.

3d 712, 731 (D. Minn. 2019) ("[A]t the motion to dismiss stage, it is reasonable to assume that top management were 'aware of matters central to that business's operation.'" (citation omitted)).

Defendants read "core operations" more narrowly, arguing that "prior authorization support" was not a core operation, such that the Court can assume executives had "real-time" knowledge of the pilot-program issues. But even if the Court reads "core operations" broadly, the question is *when* Defendants learned of the impact that the changes to the PAAP were having on Inspire's operations.

As for timing, Plaintiff alleges that: (1) Inspire territory managers (the FEs) were experiencing slowdowns, increased denials, and lost procedures because of the PAAP changes in early 2023; (2) this information was being reported up the chain to management; and (3) Herbert discussed the issue at an internal meeting no later than the second quarter. (ECF No. 46 at 56 n.17.) But the allegations that Herbert discussed the slowdown in a meeting no later than the second quarter is a far cry from Herbert, or the company at large, understanding the *effect* of the slowdown in the second quarter of 2023.

The Court has considered the allegations of scienter as a whole and concludes that the amended complaint does not sufficiently allege that a strong and compelling inference of scienter against Defendants. The Court finds more compelling the plausible alternative inference that Defendants did not fully appreciate the extent of the pilot-program problems until the third quarter for two reasons. First, under the pilot program,

medical centers began submitting their own prior authorization paperwork that Defendants were unable to track. (Am. Compl. ¶¶ 38 ("Inspire lost visibility into its sales pipeline"), 40 ("the Company immediately lost all visibility into its revenue forecasting"), 43 (FE 2 explaining, "it takes away, from a rep perspective, your visibility into what's going on"), 49 (FE 3 confirming "the loss of visibility into the process").) Second, Inspire's commercial sales are lower during the first part of the year. (*Id.* ¶ 83 (analyst noting Inspire's historically "seasonal business"); ECF No. 41-3 (2022 10-K) at 34, 42; *id.* at 78 ("Our revenue has fluctuated, and may continue to fluctuate, from quarter to quarter due to a variety of factors. For example, we have historically experienced seasonality in our first and fourth quarters . . . .").)

For these reasons, the motion to dismiss Count I is granted.

II. Count II: Section 20(a) Claim

Count II alleges that Herbert and Buchholz violated Section 20(a) of the Exchange Act as control persons. Defendants assert that Count II should be dismissed for the same reasons Count I should be dismissed. Because Count I is dismissed, the motion to dismiss Count II is granted.

CONCLUSION

Based on the foregoing and on all the files, records, and proceedings herein, IT IS HEREBY ORDERED THAT:

1. Defendants' motion to dismiss (ECF No. 38) is GRANTED; and

2. The Amended Complaint is DISMISSED WITH PREJUDICE.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: March 24, 2025

BY THE COURT:

s/Nancy E. Brasel
Nancy E. Brasel
United States District Judge