**UNITED STATES DISTRICT COURT**

**SOUTHERN DISTRICT OF CALIFORNIA**

ALI HADIAN, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

FATE THERAPEUTICS, INC. et al.,

Defendants.

Case No.: 3:23-cv-00111-RBM-AHG

**ORDER GRANTING DEFENDANTS' MOTION TO DISMISS THE FIRST AMENDED CONSOLIDATED COMPLAINT**

**[Doc. 47]**

Pending before the Court is Defendants Fate Therapeutics, Inc., J. Scott Wolchko, Edward J. Dulac III, and Bahram Valamehr's (collectively, "Defendants") Motion to Dismiss the First Amended Consolidated Complaint ("Motion"). (Doc. 47-1.) Lead Plaintiff Heating, Piping, and Refrigeration Pension Fund, and United Food & Commercial Workers' Union Local 919 and Contributing Employers' Food Pension Fund ("Plaintiff") filed an Opposition to the Motion ("Opposition").[1] (Doc. 48.) Defendants filed a Reply. (Doc. 49.)

The Court finds the matter suitable for determination on the papers and without oral argument pursuant to Civil Local Rule 7.1(d)(1). For the reasons discussed below, Defendants' Motion is **GRANTED**.

[1] On May 4, 2023, the Court appointed Plaintiff as Lead Plaintiff. (Doc. 28.)

## I. FACTUAL BACKGROUND[2]

Plaintiff brings this action on behalf of itself and all persons or entities who purchased or otherwise acquired Fate common stock between August 5, 2020 and January 5, 2023 (the "Class Period"). (Doc. 44 ["FACC"] at 3.)[3] Plaintiff asserts two causes of action against all Defendants for: (1) violations of Section 10(b) of the Securities Exchange Act (the "Exchange Act") and Rule 10b-5 promulgated thereunder; and (2) violations of Section 20(a) of the Exchange Act. (*Id.* ¶¶ 103–116.) In the First Amended Consolidated Complaint ("FACC"), Plaintiff alleges that Defendants made materially false and misleading statements during the Class Period "that artificially inflated (or maintained the artificial inflation of) the price of Fate common stock" by failing to disclose: (i) known efficacy and manufacturing difficulties affecting Fate's product candidate cells (*id.* ¶¶ 5, 79); (ii) the increased risks such difficulties posed to Fate's performance under its collaboration with Janssen (*id.* ¶¶ 71, 81, 101, 108–109); and (iii) the risks such difficulties posed to Fate's future operational results and strategic direction (*id.* ¶¶ 110).

Defendants previously filed a Motion to Dismiss the Consolidated Class Action Complaint ("CCAC"). (Doc. 38.) On September 16, 2024, this Court granted Defendants' Motion to Dismiss the CCAC and granted Plaintiff leave to amend (the "MTD Order"). (Doc. 43.) On October 18, 2024, Plaintiff filed the FACC. (*See generally FACC*.) The Court summarizes the relevant facts and discusses new allegations in the FACC to the extent they bear on the Court's analysis.

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[2] The factual summary in this section reflects Plaintiffs' allegations, not conclusions of fact or law by this Court. Well-pleaded factual allegations are accepted as true for purposes of this Motion. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

[3] The Court cites the paragraph numbers of the Complaint and the CM/ECF electronic pagination for other citations unless otherwise noted.

**A. The Parties**

Fate is a clinical-stage biopharmaceutical company formed in 2007, with a focus on the development of programmed cellular immunotherapies for patients with cancer. (*Id.* ¶ 1.) Fate used iPSC—human "induced pluripotent stem cells"—technology to direct stem cells to become "programmed" cellular therapies to treat disease. (*Id.* ¶¶ 2, 20.) Its iPSC technology allowed Fate to rely on healthy donor-sourced cells and clonal master iPSC lines to manufacture, develop, and commercialize cellular immunotherapies. (*Id.* ¶ 22.) Specifically, Fate relied on human-donor cells to create their "natural killer" ("NK") cells and T-cells from a master iPSC line of cells. (*Id.*) An NK cell is a "type of immune cell that has granules (small particles) with enzymes that can kill tumor cells or cells infected with a virus." (*Id.* ¶ 23.) T-cells "play a vital role in both components of active immunity, including cell-mediated and to some extent humoral immunity." (*Id.* ¶ 24.)

Defendant J. Scott Wolchko ("Defendant Wolchko") has served as Fate's President and Chief Executive Officer ("CEO") at all relevant times. (*Id.* ¶ 14.) Prior to the the start of the Class Period until August 2020, Defendant Wolchko also served as Fate's Principal Financial Officer. (*Id.*) Defendant Edward J. Dulac III ("Defendant Dulac") has served as Fate's Chief Financial Officer ("CFO") since August 2020. (*Id.* ¶ 15.) Defendant Bahram Valamehr ("Defendant Valamehr") has served as Fate's Chief Research and Development ("R&D") Officer since March 2021. (*Id.* ¶ 16.)[4] Prior to March 2021, Defendant Valamehr served as the Company's Chief Development Officer and oversaw Fate's development activities regarding "off-the-shelf" product candidates derived from the Company's iPSC platform. (*Id.*)

**B. The Collaboration Agreement**

During the Class Period, Fate's primary focus was on strategic partnerships and collaboration agreements for the development and commercialization of its product

[4] Defendants Wolchko, Dulac, and Valamehr are collectively referred to herein as the "Individual Defendants."

candidates. (*Id.* ¶ 1.) On April 2, 2020, Fate entered into a collaboration agreement (the "Collaboration Agreement") with Janssen Pharmaceuticals ("Janssen") (the "Janssen Collaboration"). (*Id.* ¶ 2.) Under the terms of the Collaboration Agreement, Janssen provided Fate with proprietary antigen binding domains for up to four tumor-associated antigen targets, and Fate used "its 'iPSC product platform' to develop new iPSC-derived NK and T-cell product candidates." (*Id.*) Janssen was responsible for all clinical research costs and expenses to obtain approval for the drug from various regulatory bodies. (*Id.* ¶ 3.) In turn, Fate was responsible for acquiring investigational new drug ("IND") approvals from regulatory agencies charged with approving drugs, including the United States Food and Drug Administration ("FDA"), before Janssen conducted studies in humans. (*Id.*) An IND is an application made with the FDA when the sponsor, in this case Fate, requests the agency for permission to begin administering a drug to a human. (*Id.*)[5] Janssen also required Fate to demonstrate product candidate efficacy. (*Id.*) Additionally, the Collaboration Agreement provided that Fate "could potentially earn double-digit percentage royalty payments for Fate product candidates that Janssen selected for clinical development, presuming regulatory bodies across the globe approved a product candidate for use in humans." (*Id.* ¶ 25.)

On April 2, 2020, Fate issued a press release announcing the Collaboration Agreement. (*Id.*) Fate disclosed that, under the Collaboration Agreement, Fate was eligible to receive $1.8 billion for achieving development and regulatory milestones, and an additional $1.2 billion for certain commercial milestones. (*Id.*) In its announcement, Fate also stated that its "iPSC platform is uniquely capable of overcoming numerous limitations associated with the production of cell therapies . . . including batch-to-batch

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[5] "An IND contains information from three general areas: (i) preclinical data from which the agency can determine safety; (ii) information supporting whether the sponsor can adequately and consistently produce a supply of the drug; and (iii) detailed clinical protocols for proposed clinical studies." (FACC ¶ 2.)

and cell-to-cell variability that can affect clinical safety and efficacy." (*Id.* (cleaned up).) Defendant Wolchko discussed the scope of the Collaboration Agreement, stating that:

> [T]he collaboration is antigen targeted-based and includes both CAR NK and CAR [T-cell] candidates directed to up to 4 tumor-associated antigens. The binding domains directed to the 4 antigen targets are proprietary to and are being contributed by Janssen for construction of the CAR constructs. The cancers we are seeking to treat include both hematologic malignancies and solid tumors. Note that this is a deep collaboration in that it is not limited to a specific number of collaboration candidates. In fact, we can continue to innovate and develop next-generation collaboration candidates together against those 4 specific antigen targets. (*Id.* ¶ 30.)

**1. FT562**

During a conference call on February 24, 2021, Defendant Wolchko informed investors that Fate expected to submit an IND to the FDA for FT562, Fate's "first CAR NK cell program . . . under our collaboration with Janssen." (*Id.* ¶ 39.) On March 3, 2021, a Wells Fargo Securities, LLC ("Wells Fargo") analyst issued an analyst report and listed a 2021 IND filing for FT562 as a selected upcoming catalyst for Fate. (*Id.*) Moreover, on November 15, 2021, Plaintiff alleges that Fate held an investor call for the purpose of updating the market regarding the Company's "emerging cell-based cancer immunotherapy pipeline for solid tumors." (*Id.* ¶ 42.) During this investor call, Defendant Valamehr discussed information about FT562 and the Janssen Collaboration, stating:

> In addition to our wholly-owned solid tumor programs, we are collaborating with Janssen and Ono to develop multiplex engineered IPS-derived CAR NK and CAR [T-cell] product candidates for solid tumors. While I can't disclose how – much about these programs today, under our Janssen collaboration, we are incorporating novel Janssen binding domains into our multiplex ITC drug NK cell and [T-cell] backbones. On the left-hand side, the potency and specificity of our first Janssen collaboration product candidate [i.e., FT562] is highlighted in a solid tumor steroid assay, where steroids of antigen-bearing cancer cells are effectively eliminated at lower effective target ratio."

(*Id.* ¶ 42.) By the fourth quarter of 2021 ("4Q21"), Fate was allegedly experiencing difficulties replicating product candidate cells for use in the Janssen Collaboration which

"manifested themselves when Janssen rejected the first product candidate—designated FT562—because Fate was unable to demonstrate its efficacy." (*Id.* ¶ 5.)

Plaintiff provides statements from a confidential source, CS4, in which CS4 attests that Janssen declined to proceed with the FT562 program during 4Q21 because it did not demonstrate efficacy against solid tumors. (*Id.* ¶¶ 48, 90.) Plaintiff alleges that "[t]his initial failure was critical as Fate could not proceed with an IND application for the product FT562, and Janssen ultimately pulled the plug on the program." (*Id.* ¶¶ 5, 48.) Plaintiff further alleges that "FT562's failure also called into question Fate's ability to deliver under the Collaboration Agreement (demonstrate efficacy of Collaboration Agreement product candidates pursuant to Janssen's higher standards for preclinical data and research) and highlighted limitations with Fate's iPSC platform." (*Id.*)

**C. Materially Misleading Statements and Omissions**

Following the execution of the Collaboration Agreement, Defendants made several allegedly materially misleading statements.[6] Plaintiff alleges that the allegedly misleading statements "had the intended effect and caused Fate's common stock to trade at artificially inflated levels during the Class Period." (*Id.* ¶ 72.)

**1. Statements From 2020–2021**

Following the execution of the Collaboration Agreement, Defendant Wolchko made the following allegedly materially misleading statements:

> August 5, 2020: "We are also leveraging our unique ability to build multiplexed engineered cell products of increasing complexity using already established clonal master engineered iPSC lines with our collaboration partners, including under our newly formed collaboration with Janssen, which brings together Janssen's deep domain expertise in oncology and our industry-leading iPS cell product platform. We have successfully launched this collaboration with strong momentum." (*Id.* ¶ 33 (emphasis omitted).)

[6] Plaintiff notes that the Court previously dismissed several of the alleged statements but it "re-pleads the statements to maintain its appellate rights." (FACC at 12 n.3.)

> February 24, 2021: "We also continue to innovate and optimize our manufacturing process, including under our collaboration with . . . Janssen." (*Id.* ¶ 35 (emphasis omitted).)
>
> "And our collaborations, including . . . our Janssen collaboration, do involve the development of iPS-derived CAR [T-cell] candidates. So I would say that, while, for instance, our NK cell pipeline is more mature, I would not take that as an indication that we were—we are significantly betting on an NK cell approach over a [T-cell] approach. We are absolutely developing both cell types aggressively." (*Id.* ¶ 37 (emphasis omitted).)
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> November 4, 2021: "[T]he Janssen collaboration has continued to go very well. And obviously, as you can tell from the revenue that continues to increase, we continue to increase the resources under the collaboration. I think we've disclosed in the past that the collaboration started with 2 antigen targets, 1 in hematologic malignancies, 1 in solid tumors. A third antigen target has now been added to the collaboration, and Janssen reserves the right to add a fourth target to the collaboration. So collaboration is moving forward, we're really pleased with it. I think we'll be able to get a – give a little bit of visibility on the first product candidate at the solid tumor day, although we may not be able to disclose the target quite yet." (*Id.* ¶ 40 (emphasis omitted).)

Additionally, Defendant Valamehr made the following allegedly materially misleading statements:

> November 15, 2021: "[W]e are collaborating with Janssen and Ono to develop multiplex engineered IPS-derived CAR NK and CAR [T-cell] product candidates for solid tumors. While I can't disclose how—much about these programs today, under our Janssen collaboration, we are incorporating novel Janssen binding domains into our multiplex ITC drug NK cell and [T-cell] backbones. On the left-hand side, the potency and specificity of our first Janssen collaboration product candidate [ ] is highlighted in a solid tumor steroid assay, where steroids of antigen-bearing cancer cells are effectively eliminated at lower effective target ratio." (*Id.* ¶ 42 (emphasis omitted).)
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> November 15, 2021: Valamehr assured investors that the Collaboration Agreement was "proceeding well through preclinical development with the aim of IND submissions over the course of the next 18 months." (*Id.* ¶ 44 (emphasis omitted).)

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Plaintiff alleges that these statements were materially misleading because Fate was having difficulty replicating iPSCs and was unable to demonstrate to Janssen that it could create enough cells for use in a clinical setting. (*Id.* ¶¶ 36, 38, 41, 43, 45.)

**2. Statements After 2022**

In February 2022, Defendant Wolchko made the following allegedly materially misleading statements:

> February 9, 2022: Wolchko stated that the Collaboration Agreement was "good" and that "[he] expect[ed] that in the next couple months, [Fate] [would] nominate [their] second and third IND candidates under the J&J collaboration." (*Id.* ¶ 47 (emphasis omitted).)
>
> February 28, 2022: "[W]e are also developing multiplexed-engineered CAR NK and CAR T-cell product candidates for solid tumors, alongside our 2 partners, Janssen and Ono." (*Id.* ¶ 49 (emphasis omitted).)

On February 28, 2022, Fate filed its 2021 Form 10-K with the SEC, signed by Defendants Wolchko and Dulac, containing the following allegedly misleading statements:

> Cell-based cancer immunotherapies undergoing clinical investigation today most often rely on the use of autologous, or a patient's own, cells. The requirement to source, engineer, expand and deliver cells patient-by-patient is logistically complex, resource intensive and expensive, and can result in significant batch-to-batch variability in product identity, purity and potency as well as in manufacturing failures. Significant hurdles remain to ensure that cell-based cancer immunotherapies can be consistently manufactured and reliably delivered, in a cost-effective manner and at the scale necessary, to support broad patient access and wide-spread commercialization. Rather than rely on the use of a patient's own cells, we seek to use clonal master iPSC lines to manufacture, develop and commercialize first-in-class cellular immunotherapies. We believe our approach has the potential to improve cell product consistency and potency, reduce manufacturing costs, shorten time to treatment and reach more patients.
>
> Because we expect to continue to rely on our current corporate collaborators and to enter into new collaborations in the future, the development and commercialization of any of our product candidates could be substantially delayed, and our ability to receive future funding could be substantially impaired if one or more of our current or future collaborators . . . fails to select

> a product candidate for advancement into preclinical development, clinical development, or subsequent clinical development into a marketed product. (*Id*. ¶¶ 52, 54 (emphasis omitted).)

On March 16, 2022, Fate presented at the Barclays Global Healthcare Conference at which Defendant Dulac stated:

> We do benefit from 2 collaborations. . . . [A]nd then Janssen, just to remind everyone, it's a pretty big collaboration for us. We have 4 different targets, solid and liquid tumors, can be NK or [T-cells]. Those programs are going very, very well. J&J has already selected the first 3 targets. We have—we're not able to disclose those yet, and they're working on the fourth target, and we've been accelerating that work. So that collaboration is 2 years in. It's going really, really well. And we expect to file at least the first IND for the [first] program for J&J by the end of the year. It's important from an innovation perspective. We really value our partners. We could choose to do more such collaborations, but I also think what's on the table are potentially larger strategic collaborations. We're at that point where at the end of the Phase I study, where we have a derisked profile for lymphoma and then to myeloma that aligns really well with what larger biopharma companies look more on what they do well, right? We can take it through Phase I. They can be a great partner to help broaden the development program move very, very quickly and then commercializing the footprint that a very small up-and-coming company like ours cannot do. So I think there's multiple levers to consider around that. The collaborations are on the forefront of our minds, and we're constantly talking to existing parties and trying to see what might be possible (*Id*. ¶ 56 (emphasis omitted).)

On May 4, 2022, Fate held a conference call in which Defendant Wolchko made the following statements:

> Turning to our collaborations with Janssen and Ono. We continue to show strong momentum in bringing multiplexed-engineered iPS-derived CAR NK and CAR [T-cell] product candidates to patients for the treatment of hematologic malignancies and solid tumors. Under our collaboration with Janssen, we have now initiated IND-enabling activities for 2 iPS-derived CAR NK cell collaboration candidates. And we are actively working together with Janssen to prepare and submit IND applications for both of these candidates. For each of these collaboration candidates, Janssen maintains the option subject to its payment of an option fee prior to IND submission to initiate worldwide clinical development.

> We maintain the right in the U.S. alongside Janssen to co-commercialize and share equally in profits and losses of each collaboration candidate. As a reminder, under our collaboration, Janssen has the right to designate and contribute novel binding domains targeting up to 4 tumor-associated antigens. Janssen has now designated and contributed novel binding domains targeting 3 antigens. And we have now successfully achieved preclinical milestones for collaboration candidates targeting all 3 antigens. (*Id.* ¶ 58 (emphasis omitted).)

On August 3, 2022, Fate held a conference call in which Defendant Wolchko made the following statements:

> We maintain an opt-in right to co-commercialize and share equally in profits and losses of collaboration products in the U.S. under each antigen program. In May, Janssen exercised its option on a first antigen program, triggering a $10 million payment to fee, and we have now advanced a second antigen program to the stage of option exercise decision. We are currently working with Janssen to prepare and submit 2 IND applications: one for each of these 2 antigen programs for off-the-shelf iPS-derived CAR NK cell collaboration products. (*Id.* ¶ 60 (emphasis omitted).)

At the Morgan Stanley Global Healthcare Conference on September 12, 2022, Defendant Wolchko stated:

> Obviously, the third channel of conversation is around the clinical data that we're generating. And then importantly, we have a collaboration with J&J and in that collaboration with J&J, we have 4 targets that are under that collaboration. 2 are in hematologic malignancies, 2 are in solid tumors. With the J&J, the 2 hematologic malignancy candidates, we expect to file an IND this year on the first one and early next year on the second one. (*Id.* ¶ 62 (emphasis omitted).)

On November 3, 2022, Fate held a conference call where Defendant Wolchko also stated:

> The second CAR T-cell product candidate, FT862, is partnered with Janssen and targets KLK2, an antigen with prostate-restricted expression that is maintained during prostate cancer progression. Preclinical data generated under our collaboration with Janssen demonstrated that multiplexed-engineered iPS-derived CAR T-cells targeting KLK2 have the potential to

> effectively infiltrate tumor mass and eliminate tumor cells in a highly selective manner and to prolong survival in xenograft models of prostate cancer. As a reminder, Janssen funds all preclinical development of the FT862 program, and has the right to exercise an exclusive option to conduct worldwide clinical development and commercialization, and we maintain the right to co-commercialize and share equally in profits and losses of FT862 in the US. (*Id.*¶ 64 (emphasis omitted).)

Plaintiff alleges that these statements were materially misleading as Fate was having difficulty replicating iPSCs, was unable to demonstrate to Janssen that it could create enough cells for use in a clinical setting, and Janssen had already declined to proceed with FT562 "because that product candidate did not demonstrate efficacy against solid tumors." (*Id.* ¶¶ 36, 48, 51, 53, 55, 57, 59, 61, 63, 65.)

**D. Scienter**

Plaintiff alleges that Fate personnel knew about the efficacy, replication, and manufacturing difficulties affecting Fate's product candidates, including those associated with the Collaboration Agreement. (*Id.* ¶ 79.) "Rather than disclose material facts to shareholders, Defendants concealed them deliberately, and deprived investors of the ability to consider facts relevant to a Fate investment decision during the Class Period." (*Id.*)

**1. Direct Knowledge and Core Operations**

Plaintiff alleges that Defendants' public disclosures, such as Fate's 2021 Form 10-K, "indicate they had direct knowledge that information about significant problems relating to the Collaboration Agreement, or problems regarding the continued relationship between Janssen and Fate, would have been material to investors." (*Id.* ¶ 81.)

Plaintiff also alleges that the alleged misrepresentations and omissions concerned the Collaboration Agreement and Fate's ability to manufacture sufficient quantities of cells derived from its iPSC product platform, which both constitute central and "core" components to Fate's operations. (*Id.* ¶¶ 91–94.) "Fate's relationship with Janssen was important to the Company, and constituted a central component of the Company's operations." (*Id.* ¶ 92.) Defendants made several statements acknowledging the importance of the Janssen Collaboration and Fate's manufacturing abilities to the

Company. (*See id*. ¶¶ 92–93.) Defendant Dulac, for example, stated that potential collaborations "*are on the forefront of our minds*." (*Id.* ¶ 93 (emphasis in original).) Fate's 2021 Form 10-K further stated:

> *We depend on strategic partnerships and collaboration arrangements, such as our collaboration arrangements with Janssen and Ono*, for the development and commercialization of certain of our product candidates in certain indications or geographic territories, and if these arrangements are unsuccessful, this could result in delays and other obstacles in the development, manufacture or commercialization of any of our product candidates and *materially harm our results of operations*. (*Id.* ¶¶ 80, 92 (emphasis in the FACC).)
>
> Our strategy for fully developing and commercializing our product candidates *is dependent upon maintaining our current arrangements* and establishing new arrangements with research collaborators, corporate collaborators and other third parties. (*Id.* ¶ 92 (emphasis in the FACC).)
>
> Our *inability to manufacture sufficient quantities of our product candidates*, or the loss of our third-party contract manufacturers, or our or their *failure to supply* sufficient quantities of our product candidates at acceptable quality levels or prices, or at all, would materially and adversely affect our business. (*Id.* ¶ 94 (emphasis in the FACC).)

**2. Confidential Witnesses**

Plaintiff re-alleges statements from four confidential sources which remain largely unchanged and are as follows.

Confidential Source No. 1 ("CS1") was a Fate scientist from the fourth quarter of 2020 to 2022. (*Id*. ¶ 83.) CS1 worked with T-cells in support of the Collaboration Agreement which included determining why such T-cells lacked efficacy in the treatment of hematological malignancies. (*Id*.) CS1's work at Fate included CS1's work preceded the work done by the process developers who were responsible for replicating T-cells for the purpose of ramping up their production for use in a clinical setting. (*Id*.) "[H]owever, CS1's nature of work was purely pre-clinical and he left Fate before the products that he was working on could move into the IND-filing phase." (*Id*.) "CS1 had concerns that the

lack of efficacy in the [T-cells] would result in them not working as intended in a clinical application." (*Id.* ¶ 84.) CS1 expressed this concern to senior management, including Defendant Valamehr, in late 2021 or early 2022. (*Id.*) Defendant Valamehr acknowledged the concern but shut down the communication and failed to follow up. (*Id.*)

Confidential Source No. 2 ("CS2") was a Process Development Scientist who started working at Fate in April 2020 and resigned in October 2021. (*Id.* ¶ 85.) CS2 worked on developing processes to enable the manufacturing of large batches of T and NK cells for use in clinical trials. (*Id.*) CS2's work was also related to and in support of the Collaboration Agreement. (*Id.*) CS2's role was to replicate the results generated from iPSCs that had been produced in small quantities by Fate's R&D group and to replicate experiments involving iPSCs produced for clinical testing. (*Id.*) According to CS2, replicating the R&D results was an ongoing struggle and a significant problem in process development. (*Id.* ¶¶ 85–86.) CS2 added that the inability to replicate the previous experiments was a significant problem in process development, where it was important to have consistent results. (*Id.* ¶¶ 86.) CS2 stated that he or she communicated the data replication issues to another Fate employee who had observed similar problems. (*Id.*)

Confidential Source No. 3 ("CS3") was a Senior Research Associate in Fate's process development group from December 2021 to January 2023. (*Id.* ¶ 87.) Plaintiff adds that CS3's work included a project for Janssen related to the Collaboration Agreement. (*Id.*) CS3's team was responsible for upscaling production of the cell development process from R&D. (*Id.*) CS3 described this cell development process as inherently flawed, not properly designed, and requiring further research development. (*Id.* ¶¶ 87–88.) CS3 stated that upscaling production experienced numerous "hiccups" during his or her employment. (*Id.* ¶ 87.) In particular, CS3 attested the process team could neither replicate the R&D team's results nor achieve the development expectations as implemented by R&D and others. (*Id.* ¶ 88.) One reason the process development team could not replicate R&D's results was because the data was not robust enough to ensure smooth processing. (*Id.* ¶ 87) CS3 stated "the process development team attempted to do

what the R&D team should have done during late stages of the process development" but were unsuccessful. (*Id.* ¶ 88.) "[I]t became obvious to CS3 that repetition with different techs would be a solution," but issues regarding cell differentiation were noted and not resolved. (*Id.*) CS3 concluded the proper way to solve this issue was the leadership team's decision, which associates and scientists trusted to provide constructive feedback. (*Id.*) "In short, CS3 stated that Fate had a problem optimizing cell production, and Fate had not been meeting Janssen's requirements under the Collaboration Agreement." (*Id.* ¶ 87)

Confidential Source No. 4 ("CS4"), a former biopharmaceutical manager started working at Fate prior to the start of the Class Period and left Fate prior to the end of the Class Period. (*Id.* ¶ 89.) CS4 had regular involvement with the Collaboration Agreement. (*Id.*) CS4 regularly attended recurring weekly and monthly meetings with representatives from both Fate and Janssen to discuss the status of Fate's work under the Collaboration Agreement. (*Id.*) CS4 stated that Defendant Valamehr was a regular participant in these recurring meetings. (*Id.*) Individuals who also attended each meeting included about 10 to 20 Fate representatives and slightly fewer Janssen representatives. CS4 stated that Fate and Janssen's respective program managers would generate a summary of each meeting which was distributed to each person who attended that particular meeting. (*Id.*) CS4 expressed the opinion that Janssen was not happy with Fate's performance under the Collaboration Agreement and was skeptical about Fate's transparency. (*Id.*) CS4 stated that Fate had difficulty increasing the production of iPSCs for use in a clinical setting. (*Id.* ¶ 90.) According to CS4, Fate experienced difficulties replicating efficacy results for product candidates intended for use in the Janssen Collaboration. (*Id.*) CS4 attested that "Janssen killed the product candidate named FT562 during 4Q2021 including potentially applying for authorization from the FDA to administer the compound to humans, because Janssen concluded that FT562 was not effective." (*Id.*) "CS4 added that Janssen's decision to scrap FT562 was perceived as a negative blow to [Defendant] Valamehr because an IND application represented a significant milestone under the Collaboration Agreement." (*Id.*)

In the FACC, Plaintiff provides additional statements from CS4. After Janssen terminated FT562, CS4 stated that "Janssen became more diligent in regards to the programs they would move forward with under the Collaboration Agreement." (*Id.*) "CS4 added that Fate's standards did not align or meet Janssen's threshold for preclinical data and efficacy." (*Id.*) "In short, CS4 stated that demonstrating efficacy was a challenge Fate had in regards to executing under the Collaboration Agreement." (*Id.*)

**E. Termination and Economic Loss**

On January 3, 2023, Janssen terminated the Collaboration Agreement. (*Id.* ¶ 66.) After the market closed on January 5, 2023, Fate issued a press release announcing the termination and stating:

> On January 3, 2023, Fate Therapeutics, Inc. (the "Company") received notice of termination from Janssen Biotech. Inc. ("Janssen") of the Collaboration and Option Agreement dated April 2, 2020 by and between the Company and Janssen (the "Collaboration Agreement"), pursuant to which Janssen and the Company had agreed to collaborate to develop iPSC derived CAR NK – and CAR T-cell product candidates for the treatment of cancer. Janssen provided notice of termination after the Company declined a proposal from Janssen for continuation of the Collaboration Agreement on revised terms. The termination will take effect on April 3, 2023.

(*Id.* ¶ 66 (emphasis omitted).) On January 6, 2023, Fate's stock price fell 61.45% from $11.00 per share to $4.24 per share. (*Id.* ¶¶ 7, 70, 71.)

Plaintiff alleges that "[o]n January 5, 2023, the relevant truth and foreseeable risks concealed by Defendants' misconduct and their false and misleading misrepresentations and omissions during the Class Period were revealed when Janssen exercised its right to terminate the Collaboration Agreement after the Company declined a proposal from Janssen for continuation of the Collaboration Agreement on revised terms." (*Id.* ¶ 71.) "As a direct result of the disclosures on the evening of January 5, 2023, . . . Fate's stock price suffered a significant decline." (*Id.* ¶ 77.) Plaintiff and other Class Members who purchased Fate common stock during the Class Period therefore suffered economic loss. (*Id.* ¶ 71.)

### F. Loss Causation

Plaintiff alleges that "[t]he decline in Fate's common stock price on January 5, 2023 (post-market close) and sustained on January 6, 2023, was a direct result of the disclosure of truthful information relating to Defendants' misrepresentations and omissions regarding the risks to the Collaboration Agreement." (*Id.* ¶ 78.) Plaintiff adds that the January 5, 2023 disclosure was "a foreseeable consequence of Defendants' misrepresentations and omissions concerning risks to the Collaboration Agreement, including the capabilities of the Company's iPSC platform and the development and IND submission status of product candidates under the Collaboration Agreement." (*Id.* ¶ 75 (internal citations omitted).) Specifically, Defendants' misrepresentations and omissions allegedly caused the Class Members' loss because Fate's known difficulties with replicating efficacy signals in product candidates "manifested in Janssen's rejection of FT562 for lack of efficacy," which was "critical as Fate could not proceed with an IND application for the product candidate" (*Id.* (internal citations omitted).) The cancellation of FT562 "further called into question Fate's ability to deliver under the Collaboration Agreement, highlighted limitations with Fate's iPSC platform, and led to increased scrutiny by Janssen in regards to the projects with which they would move forward." (*Id.*)

## II. LEGAL STANDARD

### A. Federal Rule of Civil Procedure 12(b)(6)

A motion to dismiss under Federal Rule of Civil Procedure ("Rule") 12(b)(6) should be granted only where a plaintiff's complaint lacks a "cognizable legal theory" or sufficient facts to support a legal claim. *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988). For purposes of ruling on a Rule 12(b)(6) motion, the Court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). Dismissal is appropriate only where "the complaint fails to 'state a claim to relief that is plausible on its face." *Curry v. Yelp Inc.*, 875 F.3d 1219, 1224–25 (9th Cir. 2017) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

### B. Federal Rule of Civil Procedure 9(b)

In addition to Rule 12(b)(6), "[a] securities fraud complaint under § 10(b) and Rule 10b-5 must satisfy the dual pleading requisites" of Rule 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). *In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 701 (9th Cir. 2012). "[W]here a complaint includes allegations of fraud, [Rule] 9(b) requires more specificity including an account of the 'time, place, and specific content of the false representations.'" *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007) (quoting *Edwards v. Marin Park, Inc.*, 356 F.3d 1058, 1066 (9th Cir. 2004)). In "alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *see also In re Cutera Sec. Litig.*, 610 F.3d 1103, 1108 (9th Cir. 2010) ("To surmount a motion to dismiss, the investors must thus plead facts sufficient to plausibly articulate with particularity the circumstances constituting fraud." (cleaned up)).

Additionally, the PSLRA imposes "more exacting pleading requirements" on private securities fraud complaints. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009), *as amended* (Feb. 10, 2009). Under the PSLRA, a plaintiff in a securities fraud action must "plead with particularity both falsity and scienter." *Id*. (cleaned up); *see* 15 U.S.C. § 78u-4(b)(1)–(2)(A) ("[T]he complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading . . . [and] state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.").

## III. DISCUSSION

Plaintiff alleges two causes of action for: (1) violations of Section 10(b) and Rule 10b-5 of the Exchange Act and (2) violations of Section 20(a) of the Exchange Act against all Defendants. (FACC ¶¶ 103–116.) Defendants move to dismiss the FACC in its entirety with prejudice on the grounds that Plaintiff fails to allege loss causation and scienter to remedy the deficiencies identified in the Court's MTD Order. (Doc. 47-1 at 6.) The Court addresses each argument in turn.

**A. Exchange Act Section 10(b) and Rule 10b-5**

Section 10(b) of the Exchange Act forbids: (1) the use or employment of any deceptive device; (2) in connection with the purchase or sale of any security; and (3) in contravention of Securities and Exchange Commission rules and regulations. 15 U.S.C. § 78j(b); *see Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341 (2005). Additionally, Rule 10b–5 makes it unlawful to make any "untrue statement of a material fact" or to omit any material fact "necessary in order to make the statements made not misleading." 17 C.F.R. § 240.10b-5; *see Dura*, 544 U.S. at 341.

To state a claim under Section 10(b) and Rule 10b-5(b), Plaintiff must establish "(1) a material misrepresentation (or omission); (2) scienter, i.e., a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance . . . ; (5) economic loss; and (6) loss causation, i.e., a causal connection between the material misrepresentation and the loss." *Dura*, 544 U.S. at 341–42. For the reasons discussed below, the Court finds that Plaintiff sufficiently pleads the falsity and scienter requirements as to four alleged misstatements made after 2022 but fails to satisfy the loss causation requirement.

**1. Misrepresentations or Omissions of Material Facts (Falsity)**

To meet the first element of their § 10(b) claim, Plaintiff "must show that [Defendants] made a statement [or omission] that was '*misleading* as to a *material* fact.'" *Matrixx Initiatives*, 563 U.S. at 38 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988)) (emphasis original). When analyzing whether a plaintiff has satisfied this element, courts in the Ninth Circuit apply "the objective standard of a 'reasonable investor.'" *Glazer Cap. Mgmt., L.P. v. Forescout Techs., Inc.*, 63 F.4th 747, 764 (9th Cir. 2023) (internal citation omitted). Under this standard, a statement or omission is material "when 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.'" *Id*. (quoting *Basic*, 485 U.S. at 231–32).

Under the PSLRA's heightened pleading standard, a plaintiff must also "specify 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). A statement or omission is misleading when it "affirmatively create[s] an impression of a state of affairs that differs in a material way from the one that actually exists." *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). "Even if a statement is not false, it may be misleading if it omits material information." *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1008–09 (9th Cir. 2018) (citing *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1054 (9th Cir. 2014)).

In its prior MTD Order, the Court dismissed all alleged statements made before 2022 as inactionable and reasoned that Fate's alleged manufacturing issues did not render such statements misleading because Defendants had disclosed the risk of such issues. (Doc. 43 at 27−31.) By contrast, the Court held that Plaintiff sufficiently plead that four of the alleged misstatements made after Janssen decided to terminate FT562 in 2022 were misleading because Defendants did not disclose FT562's termination. (*Id*. at 47−49.) As to Defendants' statements made on February 9, 2022, March 16, 2022, and September 12, 2022, the Court found such statements "wrongly implied that Defendants were progressing seamlessly toward IND submissions when Defendants knew that its first IND candidate had been terminated." (*Id*.) The Court also found that Fate's 2021 Form 10-K contained misleading statements because the "risk" that Janssen could "fail to select a product candidate for advancement" had already come to pass when it declined FT562. (*Id*. at 33.)

Moreover, the Court determined that any alleged statements of corporate optimism made after Janssen terminated FT562 were not mere puffery. (*Id*. at 37.) Specifically, the Court held that statements about Fate's IND submission progress were not mere puffery because Defendants knew Fate was "performing poorly" in certain aspects of its work under the Collaboration Agreement. (Doc. 43 at 37 (citing *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d at 1143).) The Court relied on the facts that "Defendants knew, *at a minimum*, that Janssen had terminated its first IND candidate" when making the Challenged Statements in 2022. (*Id*.) Indeed, as the Court explained, "whether a statement constitutes puffery hinges in large part on what Defendants knew at the time the statement

was made." (*Id*. at 35.)[7]

In the FACC, Plaintiff re-asserts both sets of statements "only for appellate purposes." (FACC at 1 n.1.) As Plaintiff has not added or removed any allegations supporting falsity in the FACC, and Defendants do not argue otherwise (*see* Doc. 47-1 at 7, 20), the Court adopts its prior ruling (*see* Doc. 43 at 24–49) and finds Plaintiff has sufficiently alleged that the following four challenged statements are misleading and potentially actionable (collectively, the "Challenged Statements"):

> Wolchko's statement that the Collaboration Agreement was "good" and that "[he] expect[ed] that in the next couple months, [Fate] [would] nominate [their] second and third IND candidates under the J&J collaboration." (FACC ¶ 47 (emphasis removed).)
>
> "Because we expect to continue to rely on our current corporate collaborators and to enter into new collaborations in the future, the development and commercialization of any of our product candidates could be substantially delayed, and our ability to receive future funding could be substantially impaired if one or more of our current or future collaborators . . . fails to select a product candidate for advancement into preclinical development, clinical development, or subsequent clinical development into a marketed product." (*Id*. ¶ 54 (emphasis removed).)
>
> "We do benefit from 2 collaborations. . . . [A]nd then Janssen, just to remind everyone, it's a pretty big collaboration for us. We have 4 different targets, solid and liquid tumors, can be NK or [T-cells]. Those programs are going very, very well. J&J has already selected the first 3 targets. We have – we're not able to disclose those yet, and they're working on the fourth target, and we've been accelerating that work. So that collaboration is 2 years in. It's going really, really well. And we expect to file at least the first IND for the [first] program for J&J by the end of the year. It's important from an innovation perspective. We really value our partners. We could choose to do

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[7] While Defendants do not assert any arguments concerning puffery in the instant Motion, they rely on the Court's prior holding on this issue in support of their arguments on scienter. (*See* Doc. 47-1 at 21.) Defendants assert that the Court previously "concluded [the February 9, 2022 statement] could be materially misleading if, in reality, the undisclosed decision to stop work on FT562 (the first candidate) was 'a fatal blow' to management." (*Id*.) For the reasons explained *supra*, Defendants misconstrue the Court's prior holding.

> more such collaborations, but I also think what's on the table are potentially larger strategic collaborations. We're at that point where at the end of the Phase I study, where we have a derisked profile for lymphoma and then to myeloma that aligns really well with what larger biopharma companies look more on what they do well, right? We can take it through Phase I. They can be a great partner to help broaden the development program move very, very quickly and then commercializing the footprint that a very small up-and-coming company like ours cannot do. So I think there's multiple levers to consider around that. The collaborations are on the forefront of our minds, and we're constantly talking to existing parties and trying to see what might be possible." (*Id.* ¶ 56 (emphasis removed).)

> "And then importantly, we have a collaboration with J&J and in that collaboration with J&J, we have 4 targets that are under that collaboration. 2 are in hematologic malignancies, 2 are in solid tumors. With the J&J, the 2 hematologic malignancy candidates, we expect to file an IND this year on the first one and early next year on the second one." (*Id.* ¶ 62 (emphasis removed).)

**2. Scienter**

Scienter is a mental state that "not only covers intent to deceive, manipulate, or defraud, but also deliberate recklessness." *Schueneman v. Arena Pharm., Inc.*, 840 F.3d 698, 705 (9th Cir. 2016) (internal citations omitted). To plead scienter, the complaint must " state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). Scienter is adequately pleaded when "*all* of the facts alleged, taken collectively, give rise to a strong inference of scienter." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323 (2007). "[T]o raise an inference of scienter, the ultimate question is whether the defendant knew his or her statements were false, or was consciously reckless as to their truth or falsity." *In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 702 (9th Cir. 2012) (quoting *Gebhart v. SEC*, 595 F.3d 1034, 1042 (9th Cir. 2010)). A strong "inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 324.

In a securities fraud case alleging non-disclosure of potentially material facts, Plaintiff must plead "a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009), *as amended* (Feb. 10, 2009) (citations omitted). To do so, Plaintiff must allege that: "(1) the defendant knew of the potentially material fact, and (2) the defendant knew that failure to reveal the potentially material fact would likely mislead investors." *In re Peregrine Sys., Inc. Sec. Litig.*, No. 02CV870-BEN (RBB), 2005 WL 8158825, at *41 (S.D. Cal. Mar. 30, 2005); *In re Splunk Inc. Sec. Litig.*, 592 F. Supp. 3d 919, 948 (N.D. Cal. 2022) ("Plaintiff need only allege facts that raise the strong inference that [I]ndividual Defendants *were aware of the adverse facts* that cut against positive information conveyed in the challenged statements *and knew that the challenged statements would be misleading* to investors if they failed to disclose such adverse facts.").

In the FACC, Plaintiff alleges that Defendants knew and deliberately concealed Fate's efficacy, replication, and manufacturing difficulties affecting Fate's product candidates, including those associated with the Collaboration Agreement. (FACC ¶¶ 5, 79.) Plaintiff relies on four confidential witness statements, a core operations theory, and Defendants' public disclosures to establish the requisite mental state. (*See id.* ¶¶ 89–94.) Defendants set forth the same arguments regarding scienter as in their first motion to dismiss, contending the FACC supports a "compelling innocent inference" that Individual Defendants did not disclose Janssen's decision to terminate FT562 because they honestly believed it did not have a negative impact on the Janssen Collaboration. (Doc. 47-1 at 22.)

For the reasons discussed below, the Court finds that Plaintiff pleads sufficient facts to raise a strong inference of Individual Defendants' scienter because the allegations strongly suggest that: (1) Individual Defendants knew of adverse facts concerning FT562's termination; (2) Individual Defendants must have been aware that their failure to disclose

such facts when making the Challenged Statements would be misleading to investors because Fate's progress under the Collaboration Agreement was of obvious importance to investors based on Individual Defendants' own public disclosures about the efficacy and projected IND applications for Fate's product candidates, including FT562. Read as a whole, Plaintiff's allegations therefore create a strong inference that Defendants, at least with deliberate recklessness, misled investors by omitting adverse facts relating to Fate's first product candidate, FT562. *See Schueneman*, 840 F.3d at 708 (holding the company's failure to inform the market about certain risks to receiving FDA approval for a weight loss drug constituted "an extreme departure from the standards of ordinary care . . . which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.") (cleaned up).

The Court will first address Plaintiff's individual allegations before turning to consider whether Plaintiff's allegations collectively raise a strong inference of scienter.

**a. Confidential Sources**

Plaintiff relies on the accounts of four confidential witnesses as support for its theory of scienter. For a complaint to rely on confidential witnesses, the witnesses must first "be described with sufficient particularity to establish their reliability and personal knowledge." *Zucco*, 552 F.3d at 995. Plaintiff must provide "sufficient detail about a confidential witness' position within the defendant company to provide a basis for attributing the facts reported by that witness to the witness' personal knowledge." *Id*. Courts "look to the level of detail provided by the confidential sources, the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia." *Id*. (cleaned up). If the confidential sources are found to be reliable, the Court then assesses whether the witness' statements are "indicative of scienter." *Id*.

With the exception of statements from CS4, Plaintiff's allegations concerning the confidential witness statements remain largely unchanged. (*See* Sec.I.D.2.) As such, the Court incorporates its prior findings concerning the confidential sources and only discusses

the statements relevant to the Court's analysis. (*See* Doc. 43 at 60–63.)

**i. CS1**

CS1, a former scientist at Fate from 2020 to late 2022, performed work which included determining why T-cells developed for the Janssen Collaboration lacked efficacy. (FACC ¶ 83.) The Court again finds Plaintiff's allegations sufficiently establish that CS1 had firsthand knowledge of the efficacy of T-cells and that CS1 communicated such efficacy concerns to Defendant Valamehr. (*See* Doc. 43 at 61.) As before, however, Plaintiff does not allege that Defendant Valamehr shared CS1's concern about the product candidates' efficacy or believed these concerns meant the Janssen Collaboration was not going well, rendered Fate's goals under the Collaboration Agreement impossible, or would lead to its termination. (*See id*. (citing *Wochos v. Tesla*, Inc., 985 F.3d 1180, 1194 (9th Cir. 2021)).) CS1's statements alone are therefore insufficient to raise an inference of scienter.

While CS1's statements do not raise a strong inference of scienter, such statements are reliable based on CS1's position and corroborate Defendant Valamehr's knowledge of various R&D problems affecting Fate's product candidates around the time FT562 was terminated. CS1's statements will therefore be considered in the Court's holistic review of the FACC in its entirety. *See Tellabs*, 551 U.S. at 326 ("[T]he court's job is not to scrutinize each allegation in isolation but to assess all the allegations holistically.").

**ii. CS2 and CS3**

CS2, a former Process Development Scientist at Fate from April 2020 to October 2021, performed work related to and in support of the Collaboration Agreement. (FACC ¶ 85.) CS2's role was partially to replicate iPSCs that had been produced in small quantities by Fate's R&D group and manufacture large batches of T and NK cells for use in clinical trials. (*Id*.) CS2 stated that replicating the R&D results was an ongoing struggle and a significant problem in process development. (*Id.* ¶¶ 85–86.) CS2 communicated the data replication issues to another Fate employee who observed similar problems. (*Id.*) As Plaintiff's allegations concerning CS2 remain unchanged, the Court again finds that CS2 does not strengthen an inference of scienter because CS2 resigned from Fate before the

Challenged Statements were made and CS2 had no insight as to Individual Defendants' knowledge during this specific time frame. (*See* Doc. 43 at 62–63.)

CS3, a former Senior Research Associate at Fate from December 2021 to January 2023, stated that Fate experienced numerous challenges optimizing and upscaling cell production during CS3's employment. (FACC ¶¶ 87–88.) The Court previously found that CS3's statements did not support an inference of scienter because Plaintiff did not allege that CS3's work was related to the Collaboration Agreement and CS3 did not communicate the alleged concerns to any of the Individual Defendants or upper management. (Doc. 43 at 63.) In the FACC, Plaintiff newly alleges that CS3's work included a project for Janssen related to the Collaboration Agreement. (FACC ¶ 87.)

The Court finds that CS3's statements alone are still insufficient to raise an inference of scienter because, as before, CS3 did not communicate such concerns to any Individual Defendant. (Doc. 43 at 63 (citing *In re Accuray, Inc. Sec. Litig.*, 757 F. Supp. 2d at 949; and *Kovtun*, 2012 WL 4477647, at *18; *Jun Shi*, 2020 WL 5092910, at *6).) However, as Plaintiff now alleges that CS3 worked on a project related to the Janssen Collaboration, it may be plausibly inferred CS3 had first-hand knowledge that "Fate had not been meeting Janssen's requirements under the Collaboration Agreement." (*See* FACC ¶ 87.)

While CS2 and CS3's statements are insufficient to support a strong inference of scienter on their own, they are reliable statements based on the confidential witnesses' positions and will be considered in the Court's holistic review of the FACC in its entirety. *See S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 784 (9th Cir. 2008) ("Vague or ambiguous allegations are . . . properly considered as a part of a holistic review when considering whether the complaint raises a strong inference of scienter").

**iii. CS4**

CS4, a former biopharmaceutical manager at Fate, performed work that included regular involvement with the Collaboration Agreement and had first-hand knowledge of Janssen's decision to scrap FT562 in late 2021. (FACC ¶¶ 89–90.) CS4 attended recurring monthly and weekly meetings with Fate and Jannsen representatives about the status of

Fate's work under the Collaboration Agreement, which Defendant Valamehr also regularly attended. (*Id.*) "CS4 expressed an opinion that it was apparent from those meetings" Janssen was unhappy with Fate's performance and appeared skeptical about Fate's transparency. (*Id.* ¶ 89.) Moreover, CS4 attests that Janssen terminated FT562 "during 4Q2021 including potentially applying for authorization from the FDA to administer the compound to humans, because Janssen concluded that FT562 was not effective." (*Id.* ¶ 90.) According to CS4, "Janssen's decision to scrap FT562 was perceived as a negative blow to Valamehr because an IND application represented a significant milestone pursuant to the terms of the Collaboration Agreement." (*Id.*)

Although CS4 did not provide details about CS4's job title and dates of employment, the Court again finds CS4 to be a reliable witness based on CS4's active involvement with the Janssen Collaboration and CS4's presence at recurring meetings with Janssen (*see* Doc. 43 at 64–65). *See In re InfoSonics Corp. Sec. Litig.*, No. 06cv1231 BTM(WMc), 2007 WL 2301757, at *7 (S.D. Cal. Aug. 7, 2007) ("Plaintiffs have alleged enough to conclude that CW1 occupied a position that provided him with access to information regarding the problems . . . ."). CS4's statements therefore support that Defendant Valamehr knew Janssen concluded FT562 was not effective and subsequently decided to not proceed with the product candidate.

Defendants argue that CS4's statements cannot support an inference of scienter because CS4 is silent about how Individual Defendants interpreted FT562's termination. (Doc. 47-1 at 23.) Defendants further argue that CS4 "cannot allege that Valamehr himself, or any other Individual Defendant, shared this belief" and instead "appears to be sharing gossip by low-level employees." (*Id.*) The Court disagrees. Deliberative recklessness is sufficient to find scienter and "Plaintiff need not allege that [I]ndividual Defendants knew that the challenged statements were false to raise the inference of scienter." *In re Splunk Inc. Sec. Litig.*, 592 F. Supp. 3d at 948.

When considered alongside Plaintiff's other allegations, such as Defendants' appreciation of the importance of Fate's ability to manufacture sufficient product

candidates (*see* Sec.III.A.2.b) and that FT562 was Fate's first product candidate for the Janssen Collaboration, CS4's statements support a strong inference that Defendants were aware that FT562's termination for lack of efficacy and Fate's subsequent inability to file an IND application for FT562 were negative developments.[8] Indeed, the four confidential witness statements combine to corroborate that Defendant Valamehr, and the remaining Individual Defendants by virtue of their executive positions (*see* Sec.III.A.2.b), were aware of various issues with Fate's product candidates for the Janssen Collaboration around the time of FT562's termination.[9] *See In re Extreme Networks, Inc. Sec. Litig.*, No. 15-CV-04883-BLF, 2018 WL 1411129, at *27 (N.D. Cal. Mar. 21, 2018) ("The Court credits that the CWs corroborate each other with respect to what was going on internally at [the company], which further supports the reliability of their statements.").

Accordingly, the Court finds that CS4's statements strengthen an inference of scienter for the Challenged Statements made after Janssen's decision to terminate FT562.

**b. Core Operations**

Plaintiff alleges that Individual Defendants knew about material risks to the Collaboration Agreement under the core operations theory. Specifically, Plaintiff alleges that Defendants knew about Fate's efficacy and replication/manufacturing problems affecting its product candidates under the Janssen Collaboration because the Collaboration

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[8] In their Reply, Defendants indicate that the prior MTD Order contained an error because the Court relied on allegations about "*Valamehr's* negative reaction to Janssen's decision to scrap FT562," but both the initial complaint and the FACC only allege that "this decision '*was perceived* as a negative blow to Valamehr.'" (Doc. 49 at 5 (first quoting Doc. 43 at 64; then quoting FACC ¶ 90).) The Court recognizes such and notes that it does not rely on this characterization for purposes of resolving the instant Motion.

[9] While the Court finds that CS4's statements support scienter, for the reasons discussed *infra*, such statements do not support loss causation because CS4 left Fate before the end of the Class Period and thus had no reason to know the reasons behind Janssen's termination of the Collaboration Agreement.

Agreement and Fate's ability to manufacture sufficient quantities of product candidates were both central components of Fate's operations. (FACC ¶¶ 91–94.)

"The core operations theory of scienter relies on the principle that 'corporate officers have knowledge of the critical core operation of their companies.'" *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1062 (9th Cir. 2014) (cleaned up). Generally, "corporate management's general awareness of the day-to-day workings of the company's business does not establish scienter—at least absent some additional allegation of specific information conveyed to management and related to the fraud' or other allegations supporting scienter." *S. Ferry LP*, 542 F.3d at 784–85 (quoting *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1087 (9th Cir. 2008)). "A plaintiff must produce either specific admissions by one or more corporate executives of detailed involvement in the minutia of a company's operations, . . . or witness accounts demonstrating that executives had actual involvement . . . ." *Police Ret. Sys. of St. Louis*, 759 F.3d at 1062.

Here, Plaintiff sufficiently alleges the centrality of the Collaboration Agreement to Fate's operations. Plaintiff also sufficiently alleges that Fate's ability to manufacture sufficient quantities of its product candidates is a core process to Fate. Defendant Wolcko told investors that the Janssen Collaboration was "transformative" to Fate and that he "believed it significantly increase[d] [Fate's] ability to invest in innovation, build commercial-scale iPSC manufacturing operations, . . . and deliver value to shareholders." (FACC ¶¶ 2, 28–29.) In its 2021 Form 10-K, Fate highlighted its dependence on "strategic partnerships and collaboration arrangements," like the Janssen Collaboration, to develop and commercialize its product candidates. (*Id.* ¶ 80.) Fate also stated that "if these [collaboration] arrangements are unsuccessful," it could "materially harm [Fate's] results operations." (*Id.* ¶¶ 80, 92, 94.) In the same 2021 Form 10-K, Fate represented that its "inability to manufacture sufficient quantities of our product candidates" and "failure to supply sufficient quantities of [its] product candidates at acceptable quality levels or prices, or at all, would materially and adversely affect [Fate's] business." (*Id.* ¶ 94.) Thus, the

nature of Fate's problems affecting its product candidates under the Janssen Collaboration were "of such prominence that it would be absurd to suggest that management was without knowledge of the matter." *S. Ferry LP*, 542 F.3d at 785–86 (cleaned up).

Moreover, Plaintiff has pled sufficient facts to support that Defendant Valamehr was actually involved with the Janssen Collaboration and with Fate's development of product candidates for use in the Janssen Collaboration, including FT562. As Fate's Chief R&D Officer, Defendant Valamehr oversaw Fate's R&D activities. (FACC ¶ 16.) Plaintiff alleges that, based on CS4's statements, Defendant Valamehr regularly participated in weekly and monthly meetings with Janssen representatives about the status of Fate's work and that Janssen terminated FT562 at the end of 2021 "because [it] concluded that FT562 was not effective." (*Id*. ¶¶ 89–90.) Another confidential witness, CS1, also attested that he informed Defendant Valamehr of the T-cells' lack of efficacy in late 2021 or early 2022. (*Id*. ¶ 84.) Defendant Valamehr was therefore involved in Fate's core operations. Defendant Valamehr, and the remaining Individual Defendants as top executives in the Company, also knew that Janssen terminated FT562 for lack of efficacy and were aware of various issues around the time FT562 was terminated. *See In re Cadence Design Sys., Inc. Sec. Litig.*, 692 F. Supp. 2d 1181, 1192–93 (N.D. Cal. 2010) ("[H]aving penetrated the Defendants' executive circle, so to speak, Plaintiffs may support an inference that the other executive officers were aware of certain key facts about certain key deals.").

Given the importance of the Janssen Collaboration, and Fate's product candidates, Plaintiff's allegations strengthen an inference that Defendants knew or should have known their failure to reveal a potentially material fact concerning Fate's product candidates under the Collaboration Agreement would likely mislead investors.

**c. Holistic Review**

Having evaluated the strength of Plaintiff's scienter allegations individually, the Court must now determine "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter" and consider "plausible, nonculpable explanations for the

defendant's conduct, as well as inferences favoring the plaintiff." *Tellabs*, 551 U.S. at 323–24.

To plead scienter based on non-disclosure of potentially material facts, Plaintiff must first "allege facts that raise the strong inference that [I]ndividual Defendants were aware of the adverse facts that cut against positive information conveyed in the challenged statements." *In re Splunk*, 592 F. Supp. 3d at 948. In this case, Defendants failed to disclose FT562's termination when making the Challenged Statements. Based on Plaintiff's core operations theory and the confidential witness statements, particularly from CS4 (*see* Sec.III.A.2.a.i–iii), Individual Defendants knew that Janssen terminated FT562 for lack of efficacy against solid tumors and that such declination prevented Fate from submitting an IND application for FT562. Individual Defendants also knew that, under the Collaboration Agreement's terms, an IND application was a "significant milestone" from which Fate stood to potentially earn milestone payments. (*See* FACC ¶¶ 3, 25.) Plaintiff's allegations therefore satisfy the first element of scienter based on an alleged omission.

To satisfy the second element of scienter, Plaintiff must also "plead a highly unreasonable omission . . . which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Zucco*, 552 F.3d at 991. "The danger of misleading buyers must be actually known or so obvious that any reasonable man would be legally bound as knowing, and the omission must derive from something more egregious than even 'white heart/empty head' good faith." *Platforms Wireless Int'l Corp.*, 617 F.3d at 1095 (quoting *Hollinger v. Titan Capital Corp.*, 914 F.2d 1564, 1569 (9th Cir. 1990) (en banc)).

In the FACC, Plaintiff alleges that Defendants' public disclosures "indicate they had direct knowledge that information about significant problems relating to the Collaboration Agreement, or problems regarding the continued relationship between Janssen and Fate, would have been material to investors." (FACC ¶ 81.) Indeed, Defendants publicly acknowledged the importance of the Collaboration Agreement to Fate on several

occasions. (*See id*. ¶¶ 2, 28–29, 80, 92, 94.) Fate also publicly disclosed the importance of receiving regulatory approval for its product candidates and stated:

> If we fail to complete preclinical or clinical development of, or *obtain regulatory approval for, our product candidates*, we will not be able to generate any revenues from product sales *and our ability to receive milestone or other payments under any collaboration agreements may be impaired*, which will harm our business, prospects, financial condition and results of operations.

(*Id*. ¶ 77 (emphasis in the FACC).)

Under the Collaboration Agreement, Fate was responsible for acquiring regulatory approval to conduct studies in humans which required the submission of an IND application with the FDA. (*Id*. ¶ 3.) Per Defendants' own statements, investors were informed that Fate stood to potentially earn additional revenue from the achievement of development and regulatory milestones (*id*. ¶¶ 2, 25) and that Fate expected to file an IND application for FT562 (*id*. ¶ 39). Notably, Defendants discussed the status of its CAR NK and CAR T-cell product candidates and specifically shared details about FT562 with investors on several occasions. (*See id*. ¶¶ 37, 42, 60, 64.) For example, Defendant Wolchko informed investors during a February 24, 2021 conference call that Fate "expected to submit an IND to the FDA for FT562, '[their] CAR NK cell program'" for the Janssen Collaboration. (*Id*.) On November 15, 2021, Defendant Valamehr told investors that FT562's "potency and specificity [was] highlighted in a solid tumor steroid assay, where steroids of antigen-bearing cancer cells are effectively eliminated at lower effective target ratio." (*Id*. ¶ 42 (emphasis omitted).)

In light of such disclosures, and Defendants' knowledge of the facts surrounding FT562's termination, Plaintiff's allegations support a strong inference that Defendants understood the market would attach significance to FT562's termination. Because the Challenged Statements concerned Fate's progress on IND submissions, such an omission from the Challenged Statements presented an "obvious" risk that investors would be misled about Fate's filing an IND for FT562, Fate's progress towards IND submissions, and its

overall performance under the Collaboration Agreement. *See Zucco*, 552 F.3d at 991.

Plaintiff's allegations likewise support a strong inference that Defendants were aware FT562's termination concerned a potential risk to the Jannsen Collaboration when making the Challenged Statements. Defendants knew that Fate's performance under the Collaboration Agreement depended on Fate's ability to demonstrate its product candidates' efficacy and to submit IND applications for regulatory approval of testing such candidates on humans. (*See* Sec.III.A.2; FACC ¶ 3.) Defendants thereby knew that an IND was a "significant milestone" under the Collaboration Agreement from which Fate could earn additional revenue. As Janssen determined that FT562 was not effective against solid tumors, and Fate could no longer file an IND for this product candidate, FT562's termination shows that there were certain dangers known to Defendants which could affect Fate's performance under the Collaboration Agreement. Thus, it may be strongly inferred that Defendants appreciated the gravity of the risk of misleading investors and consciously disregarded that risk when making the Challenged Statements. *See In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 390 (9th Cir. 2010) ("[A]n actor is reckless if he had reasonable grounds to believe material facts existed that were misstated or omitted, but nonetheless failed to obtain and disclose such facts although he could have done so without extraordinary effort."). Plaintiff has therefore sufficiently alleged that Defendants were, at the very least, deliberatively reckless in failing to disclose FT562's termination and acted with the requisite scienter.[10]

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[10] Because Plaintiff has sufficiently alleged Individual Defendants' scienter, and the Parties do not dispute that Individual Defendants acted within their apparent authority, their scienter may also be attributed to Fate. *See In re ChinaCast Educ. Corp. Sec. Litig.*, 809 F.3d 471, 476 (9th Cir. 2015) ("The scienter of the senior controlling officers of a corporation may be attributed to the corporation itself to establish liability as a primary violator of § 10(b) and Rule 10b-5 when those senior officials were acting within the scope of their apparent authority.").

Defendants argue that "[f]or purposes of scienter, the question is [whether] Individual Defendants believe[d] that Janssen's decision about FT562 was a 'fatal blow' that should be disclosed to investors, or alternatively an unremarkable development in a productive commercial relationship[.]" (Doc. 47-1 at 22.) The Court disagrees. Deliberate recklessness is sufficient to find scienter when "an actor . . . had reasonable grounds to believe material facts existed that were misstated or omitted, but nonetheless failed to obtain and disclose such facts although he could have done so without extraordinary effort." *In re Oracle*, 627 F.3d at 390 (quoting *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1064 (9th Cir. 2000)).

Here, Defendants knew of information concerning FT562's termination that would cause their optimistic representations in the Challenged Statements to be consciously misleading. Specifically, Defendants knew that: (1) Janssen terminated FT562—Fate's first product candidate—for lack of efficacy; (2) Janssen's declination prevented Fate from submitting an IND application for FT562; (3) IND submissions were a "significant milestone" under the Janssen Collaboration; and (4) Fate was experiencing various R&D difficulties around the time FT562 was terminated. Despite this knowledge, and having provided investors with positive information about FT562, Defendants made the Challenged Statements about its progress towards IND submissions without disclosing that the first IND candidate, FT562, had been terminated. *See Platforms Wireless Int'l Corp.*, 617 F.3d at 1094 ("When the defendant is aware of the facts that made the statement misleading, he cannot ignore the facts and plead ignorance of the risk.") (cleaned up). Because Defendants "[chose] to tout positive information to the market" concerning Fate's progress on product candidates and IND applications, they were "bound to do so in a manner that wouldn't mislead investors, including disclosing adverse information that cuts against the positive information." *Schueneman*, 840 F.3d at 705–06 (quoting *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 987 (9th Cir. 2008) (analyzing the falsity requirement) (cleaned up). By failing to disclose FT562's termination, Defendants thereby exhibited "an extreme departure from the standards of ordinary care intended to fairly

inform reasonable investors." *Zucco*, 552 F.3d at 991.

Defendants also argue that the facts alleged raise a more compelling, innocent inference that Individual Defendants "honestly believed . . . the decision had no negative impact on Fate's relationship with Janssen." (Doc. 47-1 at 22.) In support of their contention, Defendants point to several allegations including: that FT562 was one of several product candidates being developed under the Janssen Collaboration, that Janssen continued to invest in other product candidates, that Janssen triggered millions of dollars in milestone payments, and that the Parties attempted to renegotiate the commercial terms of the Collaboration Agreement prior to its termination. (*Id.*; Doc. 49 at 13.) The Court agrees that the statements relied on by Defendants show FT562's termination did not immediately cause the Collaboration Agreement to end. However, in context, such statements do not change that Defendants knew *at the time the Challenged Statements were made* the significance of FT562's termination but concealed such risks. Indeed, it appears that Fate did not submit an IND application until the fourth quarter of 2022, after the Challenged Statements were made. (*See* FACC ¶ 67.)

Taken together, Plaintiff's allegations raise a strong inference of scienter, that is "at least as compelling" as any competing inferences, which support that Individual Defendants knew or must have been aware the Challenged Statements would be misleading to investors. *See Tellabs*, 551 U.S. at 324.

**3. Loss Causation**

"Even when deceptive conduct is properly pleaded, a securities fraud complaint must also adequately plead loss causation." *Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1209 (9th Cir. 2016) (cleaned up). Loss causation is essentially proximate cause in the securities fraud context. *In re Genius Brands Int'l, Inc. Sec. Litig.*, 97 F.4th 1171, 1183 (9th Cir. 2024). To demonstrate loss causation, a plaintiff must allege "a causal connection between the material misrepresentation and the loss." *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 342 (2005); *see* 15 U.S.C. § 78u-4(b)(4). A plaintiff is not required to show that a misrepresentation was the sole reason for the investment's decline. *Nuveen Mun. High*

*Income Opportunity Fund v. City of Alameda*, 730 F.3d 1111, 1119 (9th Cir. 2013) (cleaned up). Instead, "the ultimate issue is whether the defendant's misstatement, as opposed to some other fact, foreseeably caused the plaintiff's loss." *Lloyd*, 811 F.3d at 1210.

The Ninth Circuit has taken a flexible approach to loss causation that recognizes there are an "infinite variety of ways for a tort to cause a loss." *Mineworkers' Pension Scheme v. First Solar Inc.*, 881 F.3d 750, 753 (9th Cir. 2018). Although Rule 9(b)'s heightened pleading standard applies to allegations of loss causation, "[t]hat effort 'should not prove burdensome,' for even under Rule 9(b) the plaintiff's allegations will suffice so long as they give the defendant 'notice of plaintiffs' loss causation theory' and provide the court 'some assurance that the theory has a basis in fact.'" *In re BofI Holding, Inc. Sec. Litig.*, 977 F.3d 781, 791 (9th Cir. 2020) (quoting *Dura Pharms.*, 544 U.S. at 347; *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 989–90 (9th Cir. 2008)).

Defendants argue that "the FACC fails to draw a causal connection between Janssen's decision to focus on other product candidates instead of FT562 (the lone remaining alleged omission) and Janssen's termination of the Collaboration Agreement (the lone alleged corrective disclosure)." (Doc. 47-1 at 14.) Plaintiff responds that additional allegations in the FACC "including specific facts from CS4 [and] Company admissions" sufficiently plead loss causation under a corrective disclosure theory, a general proximate cause theory, and a materialization of the risk theory. (Doc. 48 at 10, 16–25.)[11] The Court addresses each theory of loss causation in turn.

**a. Corrective Disclosure Theory**

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[11] Plaintiff seemingly advances only two theories of loss causation based on corrective disclosures and materialization of the risk. (Doc. 48 at 25.) However, for the reasons detailed below (*see* Sec.III.A.3.a), the Court addresses Plaintiff's arguments concerning the proximate cause test as a different theory of loss causation, separate from its corrective disclosure theory. *See In re Splunk Inc. Sec. Litig.*, 592 F. Supp. 3d 919, 952 (N.D. Cal. 2022) ("Plaintiff need not allege facts consistent with a revelation-of-the-fraud theory to plausibly allege loss causation, where . . . it has plausibly alleged loss causation under a cognizable alternative theory.").

Defendants argue that "the FACC fails to draw a causal connection between Janssen's decision to focus on other product candidates instead of FT562 (the lone remaining alleged omission) and Janssen's termination of the Collaboration Agreement (the lone alleged corrective disclosure)." (Doc. 47-1 at 14.) Plaintiff responds, that the FACC "sufficiently alleges loss causation as the termination revealed the financial impacts of the fraud." (Doc. 48 at 19 (citing *First Solar*, 881 F.3d at 754).) The Court finds that Plaintiff does not plead that a corrective disclosure revealed the allegedly misleading statements and therefore fails to allege loss causation under a corrective disclosure theory. *See First Solar*, 881 F.3d at 754 ("When plaintiffs plead a causation theory based on market revelation of the fraud, this court naturally evaluates whether plaintiffs have pleaded or proved the facts relevant to their theory.").

"A plaintiff can satisfy the loss-causation pleading burden by alleging that a 'corrective disclosure' revealed the truth of a defendant's misrepresentation and thereby 'caused the company's stock price to drop and investors to lose money.'" *Grigsby v. BofI Holding, Inc.*, 979 F.3d 1198, 1205 (9th Cir. 2020) (quoting *Lloyd*, 811 F.3d at 1209). "Courts refer to this theory as 'fraud-on-the market.'" *Irving Firemen's Relief & Ret. Fund v. Uber Techs., Inc.*, 998 F.3d 397, 407 (9th Cir. 2021) (citation omitted). To adequately plead loss causation by relying on one or more corrective disclosures, a plaintiff must "plausibly allege that the *defendant's fraud was revealed to the market* and caused the resulting losses." *Loos v. Immersion Corp.*, 762 F.3d 880, 887 (9th Cir. 2014) (quoting *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1062 (9th Cir. 2008) (emphasis added)).

As Plaintiff correctly notes, a disclosure need not "mirror" the alleged fraud. (Doc. 48 at 17 (quoting *Lloyd*, 811 F.3d at 1210).) Nonetheless, corrective disclosures "must at least relate back to the misrepresentation and not to some other negative information about the company." *Grigsby v. BofI Holding, Inc.*, 979 F.3d 1198, 1207-08 (9th Cir. 2020) (quoting *Lloyd*, 811 F.3d at 1210). A corrective disclosure must reveal "new facts" that, taken as true, "render some aspect of the defendant's prior statements false or misleading."

*In re BofI Holding, Inc. Sec. Litig.*, 977 F.3d at 790. Indeed, Plaintiff must "plead that the truth became known." *First Solar*, 881 F.3d at 754.

Plaintiff re-alleges that its loss occurred when "[t]he January 5, 2023 disclosure" revealed "the relevant truth . . . concealed" by Defendants' misrepresentations and omissions "concerning risks to the Collaboration Agreement, including the capabilities of [Fate's] iPSC platform and the development and IND submission status of product candidates under the Collaboration Agreement." (FACC ¶¶ 73, 75 (internal citations omitted).) In the FACC, Plaintiff now adds that the press release issued on January 5, 2023 (the "Termination Announcement") contained the following language:

> On January 3, 2023, Fate Therapeutics, Inc. (the "Company") received notice of termination from Janssen Biotech. Inc. ("Janssen") of the Collaboration and Option Agreement dated April 2, 2020 by and between the Company and Janssen (the "Collaboration Agreement"), pursuant to which Janssen and the Company had agreed to collaborate to develop iPSC derived CAR NK—and CAR T-cell product candidates for the treatment of cancer. *Janssen provided notice of termination after the Company declined a proposal from Janssen for continuation of the Collaboration Agreement on revised terms.* The termination will take effect on April 3, 2023.

(FACC ¶ 66 (emphasis added).)

However, the Termination Announcement does not include information about Fate's financial performance, issues with its iPSC platform, or Janssen's rejection of FT562. Instead, it solely attributes Janssen's termination of the Collaboration Agreement to Fate's rejection of "revised terms." (*See id.*) Plaintiff claims that Defendant Wolchko's statement on February 28, 2023 supports its loss causation theory because he "highlighted that the revised terms included 'significantly reduce[d]' spending by Janssen under the Collaboration Agreement." (Doc. 48 at 14 (quoting FACC ¶ 74).) But Plaintiff does not explain how the "revised terms" concerning reduced spending relate back to the alleged misstatements. The Termination Announcement therefore "d[id] not reveal any information from which [the alleged fraud] might reasonably be inferred." *See Loos*, 762 F.3d at 887–90; *Or. Pub. Emps. Ret. Fund*, 774 F.3d at 608 (affirming loss causation was

not alleged where it was "unclear what claims made by the Defendants were invalidated" by the alleged corrective disclosure). "It stands to reason then that [a] disclosure that does not reveal anything new to the market is, by definition, not corrective." *In re Novatel Wireless Sec. Litig.*, 830 F. Supp. 2d 996, 1019 (S.D. Cal. 2011) (cleaned up).

Further, Plaintiff relies on the district court's decision in *First Solar* and argues that loss causation may be predicated on the Termination Announcement because it allegedly revealed the financial impacts of the fraud which were recognized by market analysts. (Doc. 48 at 16, 19 (citing FACC ¶¶ 68–69, 90).) But "[s]imply pleading 'that the market reacted to the purported 'impact' of the alleged fraud . . . rather than to the fraudulent acts themselves' is not sufficient." *In re Facebook, Inc. Sec. Litig.*, 87 F.4th 934, 955 (9th Cir. 2023) (quoting *Oracle*, 627 F.3d at 392). In *First Solar*, the district court held a causal connection was sufficiently established to avoid summary judgment as to several earnings releases but not as to a stock decline that followed a press release announcing the departure of the company's CEO. *Smilovits v. First Solar Inc.*, 119 F. Supp. 3d 978, 997 (D. Ariz. 2015), *aff'd sub nom. First Solar*, 881 F.3d 750.[12] As to the earnings releases and an earnings guidance, the plaintiff presented sufficient evidence to show that "the very facts [the defendants] allegedly fraudulently concealed—the scope of the [manufacturing] defect and its resulting financial impact—were substantial factors in causing [the plaintiffs'] loss." *Id*. at 994–996, 998–1001. However, unlike the earnings releases, the court noted that when the CEO's departure was announced, "[n]o financial statements were released that revealed additional financial impacts from the alleged fraud." *Id*. at 997. The court determined an inference connecting the CEO's departure to the alleged fraud was therefore unsupported and based on pure speculation. *Id*.

[12] Contrary to Plaintiff's assertion (*see* Doc. 48 at 18), the Court notes that the Ninth Circuit affirmed the loss causation standard used by the district court and did not decide on the merits on the underlying case. *See First Solar*, 881 F.3d at 754.

Like the announcement of the CEO's departure in *First Solar*, the Termination Announcement does not provide information from which the alleged misrepresentations "might be reasonably inferred." *See Loos*, 762 F.3d at 887–90. In support of its contention, Plaintiff points to an article published by FierceBiotech on January 6, 2023, which reported that "Fate Therapeutics has begun 2023 with a big reset of its business" (FACC ¶ 67), and a company update predicting "increased risks for the iPSC platform" following the termination of the Janssen Collaboration (*id*. ¶ 68). While analysts opined on the implications of the Collaboration Agreement's termination on Fate's future, these reports "do not reveal any information from which [the alleged misrepresentations] might reasonably be inferred" and do not support an inference that the market understood the Termination Announcement as a revelation of Fate's allegedly fraudulent conduct. *See Loos*, 762 F.3d at 887–90 (holding a corporation's disappointing financial results and internal investigation announcement did not establish loss causation as neither "partial disclosure" revealed information from which fraud "might be reasonably inferred."). Plaintiff also does not allege that "the truth" concerning the alleged fraud "became known" to the market at any point following the Termination Announcement. For example, Plaintiff does not allege that the market learned about FT562's termination, a previously omitted fact. Thus, any decline in the stock price can only be plausibly attributed to market speculation about whether fraud occurred which "cannot form the basis of a viable loss causation theory." *Loos*, 762 F.3d at 890. The Court finds the Termination Announcement, without more, is insufficient to allege loss causation under a corrective disclosure theory.

**b. Proximate Cause Theory**

Defendants argue that Plaintiff fails to plead loss causation because the "FACC is devoid of any new, particularized allegations linking Janssen's termination decision to FT562" and instead provides "ample reason to conclude that intervening events caused the termination decision." (Doc. 47-1 at 15, 17.) Plaintiff contends that additional allegations in the FACC plausibly allege that "Janssen's sudden termination of the Collaboration Agreement . . . was a foreseeable consequence of the Company's failure to produce a

product candidate that would satisfy the basic requirements of an IND to be filed with the FDA." (Doc. 48 at 9–10 (citing FACC ¶¶ 5, 48, 71–76, 90).)

Although it is common to show loss causation by alleging that the defendant's fraud was revealed to the market, "[r]evelation of fraud in the marketplace is simply one of the 'infinite variety' of causation theories a plaintiff might allege to satisfy proximate cause." *First Solar*, 881 F.3d at 754 (quoting *Lloyd*, 811 F.3d at 1210). "A plaintiff can satisfy loss causation by showing that 'the defendant misrepresented or omitted the *very facts* that were a substantial factor in causing the plaintiff's economic loss.'" *Nuveen*, 730 F.3d at 1120 (emphasis in original) (quoting *McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 425 (3d Cir. 2007)). "The 'ultimate issue' . . . 'is whether the defendant's misstatement, as opposed to some other fact, foreseeably caused the plaintiff's loss.'" *First Solar*, 881 F.3d at 754 (quoting *Lloyd*, 811 F.3d at 1210).

In its MTD Order, the Court instructed Plaintiff to "connect the allegedly material omissions to the termination of the Collaboration Agreement." (Doc. 43 at 73.) In response, Plaintiff provides additional Company admissions and statements from CS4 which it claims "plausibly allege a causal connection between the misstatements and omissions (the iPSC replication problems that led to the termination of FT562) and the disclosure (Janssen's decision to terminate the Collaboration Agreement)." (Doc. 48 at 9.)

In the FACC, CS4 adds that "demonstrating efficacy was a challenge Fate had in regard[ ] to executing under the Collaboration Agreement." (FACC ¶ 90.) CS4 also states that "after Janssen pulled the plug on FT562, Janssen became more diligent in regard[ ] to the programs they would move forward with under the Collaboration Agreement" and "Fate's standards did not align or meet Janssen's threshold for preclinical data and efficacy." (*Id.*) Plaintiff claims these statements establish that Janssen's termination of FT562: (1) meant that Fate could not proceed with an IND application for FT562; (2) highlighted limitations with Fate's iPSC platform; and (3) called into question Fate's ability to demonstrate the product candidates' efficacy, and thus its ability to perform under the Collaboration Agreement, in accordance with Janssen's "higher standards" for

preclinical data and research. (Doc. 48 at 9, 19; *see* FACC ¶ 5.) According to Plaintiff, the consequences that followed FT562's termination "marked a significant change in the collaboration," that led to Janssen's increased scrutiny over projects to move forward, which, in turn, resulted in Janssen exercising its right to terminate the Collaboration Agreement and caused a drop in Fate's stock. (Doc. 48 at 9–10; FACC ¶¶ 5, 48.)

Defendants argue that CS4's statements cannot support loss causation because CS4 was not employed at the Company when Janssen terminated the Collaboration Agreement. The Court agrees. As CS4 "left the Company prior to the end of the Class Period" (FACC ¶ 89), CS4 would not have reason to know Janssen's reasons for terminating the Janssen Collaboration. The Court also finds CS4's statements concerning Janssen's increased diligence and Fate's inability to meet Janssen's standards are unsupported and insufficient to infer a causal connection between FT562's cancellation and the termination of the Collaboration Agreement. CS4's statements therefore do not support a plausible inference that the "change" resulting from FT562's termination *substantially caused* Janssen to terminate the Collaboration Agreement. *See Nuveen*, 730 F.3d at 1120.

Plaintiff correctly asserts that "a plaintiff is not required to show 'that a misrepresentation was the *sole* reason for the investment's decline in value' in order to establish loss causation." (Doc. 48 at 20 (quoting *In re Daou Sys., Inc.*, 411 F.3d 1006, 1025 (9th Cir. 2005)).) Instead, "a plaintiff must plead . . . the 'misrepresentation is one *substantial cause* of the investment's decline in value.'" (*Id.* (quoting *In re Daou Sys., Inc.*, 411 F.3d at 1025).) However, Plaintiff's contention that FT562's cancellation was a "substantial factor" in Fate's stock decline is further undermined by Janssen's alleged conduct in furtherance of the Collaboration Agreement between its decision to cancel FT562 in late 2021 and its termination of the Janssen Collaboration in 2023. *See In re BofI Holding, Inc. Sec. Litig.*, 977 F.3d at 790 (reasoning that while not dispositive, "[t]he determination of whether there is a causal link includes a temporal component."). During this time frame, Fate filed an IND application in 2022 and Janssen continued to work on other product candidates. (*See* FACC ¶ 67 ("The partnership looked to be on track in the

fourth quarter of 2022, when an IND application and exercising of a second commercial option triggered $13 million in milestone payments to Fate.").)

Moreover, the Termination Announcement itself points to a more plausible explanation for Janssen's decision to terminate the Collaboration Agreement—Fate rejected its proposed terms. *See Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1065 (9th Cir. 2008) (holding the plaintiff failed to allege loss causation where one of the disclosures contained a "far more plausible reason" for the company's stock decline and made it "even further unwarranted to infer" the market understood it as revelation of fraud). While discussing the Janssen Collaboration's termination, Defendant Wolchko explained that "Janssen desired to significantly reduce its 2023 spending under the collaboration, as well as modify certain key financial and intellectual property terms of" the Collaboration Agreement. (FACC ¶ 74.) The FACC, however, does not contain facts to support that the "revised" terms relate back to the omitted facts about FT562.

The Court therefore finds that Plaintiff's allegations do not support the chain of inferences necessary to plausibly connect the concealed facts at issue to Janssen's termination of the Collaboration Agreement, and ultimately the decline in Fate's stock value. *See In re Syntex Corp. Sec. Litig.*, 95 F.3d 922, 926 (9th Cir. 1996) (affirming dismissal of securities fraud complaint because "conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss for failure to state a claim."). Because Plaintiff's new allegations do not connect the causal deficiencies the Court identified in its prior MTD Order, Plaintiff again fails to plead loss causation under the proximate cause standard.

**c. Materialization of the Risk**

Plaintiff also relies on a "materialization of the risk" theory to argue loss causation. Defendant argues that Plaintiff fails to plead loss causation under a materialization of the risk theory because Fate had already disclosed the risks associated with the Collaboration Agreement and Plaintiff does not explain how these risks were caused by FT562's termination. (Doc. 47 at 17.)

As a preliminary matter, the Ninth Circuit has neither adopted nor rejected the "materialization of the risk" theory. *See Nuveen*, 730 F.3d at 1120 n.5 (noting that while district courts in the circuit have applied the materialization of the risk theory, the Ninth Circuit has not "decide[d] whether to endorse" the approach). The materialization of the risk approach recognizes that "a misstatement or omission is the proximate cause of an investment loss if the risk that caused the loss was within the zone of risk concealed by the misrepresentations and omissions alleged by a disappointed investor." *Nuveen*, 730 F.3d at 1120 (cleaned up). "Under this theory, the plaintiff must show that 'it was the very facts about which the defendant lied which caused its injuries.'" *Id*. (quoting *McCabe*, 494 F.3d at 431). Indeed, the Ninth Circuit has "continued to require securities fraud plaintiffs to allege that the defendant lied about 'the very facts' causing the plaintiffs' losses, and it is unclear in any event that courts employing the 'zone of risk' theory require any lesser showing." *In re Nektar Therapeutics Sec. Litig.*, 34 F.4th 828, 838 n.6 (9th Cir. 2022) (quoting *Nuveen*, 730 F.3d at 1120); *see also First Solar Inc.*, 881 F.3d at 754 ("The 'ultimate issue' . . . 'is whether the defendant's misstatement, as opposed to some other fact, foreseeably caused the plaintiff's loss.'") (quoting *Lloyd*, 811 F.3d at 1210).

For the reasons previously discussed (*see* Sec.III.A.3.b), the Court finds it need not determine the applicability of this approach because Plaintiff has failed to plausibly establish that the "the very facts about which [Defendants] lied" were a substantial cause of its alleged loss. *See Nuveen*, 730 F.3d at 1120 (citation omitted); *Eng v. Edison Int'l*, Case No.: 3:15-cv-01478-BEN-KSC, 2018 WL 1367419, at *3 (S.D. Cal. Mar. 16, 2018), *aff'd sub nom. City of Fort Lauderdale Gen. Employees' Ret. Sys. v. Edison Int'l*, 786 F. App'x 685 (9th Cir. 2019).

**4. Conclusion**

Based on the foregoing, Plaintiff has alleged sufficient facts to satisfy the falsity and scienter requirements for a Section 10(b) and Rule 10b-5 violation as to the four Challenged Statements. However, the Court finds that Plaintiff does not sufficiently allege that Plaintiff's losses were caused by Defendants' alleged misstatements. Defendants' Motion

is therefore **GRANTED** as to the First Cause of Action.

**B. Exchange Act Section 20(a)**

Plaintiff also brings a claim for violations of Section 20(a) of the Exchange Act. This claim, however, depends on a primary violation of Section 10(b) or Rule 10b-5. *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1035 n.15 (9th Cir. 2002) ("[T]o prevail on their claims for violations of § 20(a) and § 20A, plaintiffs must first allege a violation of § 10(b) or Rule 10b 5."). Because the Court determined that Plaintiff's Section 10(b) and Rule 10b-5 claim fails, Defendants' Motion as to the Section 20(a) claim is also **GRANTED**. *See Zucco*, 552 F.3d at 990 ("Section 20(a) claims may be dismissed summarily . . . if a plaintiff fails to adequately plead a primary violation of section 10(b).").

**C. Leave to Amend**

"If a complaint is dismissed for failure to state a claim, leave to amend should be granted 'unless the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency.'" *DeSoto v. Yellow Freight Sys., Inc.*, 957 F.2d 655, 658 (9th Cir. 1992) (quoting *Schreiber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986)). "Dismissal with prejudice and without leave to amend is not appropriate unless it is clear . . . that the complaint could not be saved by amendment." *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir.2003). "Adherence to these principles is especially important in the context of the PSLRA," which "requires a plaintiff to plead a complaint of securities fraud with an unprecedented degree of specificity and detail." *Id*.

Although the deficiencies in Plaintiff's loss causation theories are significant, the Court allows Plaintiff one last opportunity to amend the FACC and rectify the identified loss causation issues. The FACC is therefore **DISMISSED with leave to amend**. While the Court grants leave to amend, it may dismiss Plaintiff's claims with prejudice if the second amended complaint fails to plausibly state a claim. *See Zucco*, 552 F.3d at 1007 (holding that failure to correct pleading deficiencies after dismissal is a "strong indication" that further amendment would be futile).

## IV. CONCLUSION

Based on the foregoing, Defendants' Motion is **GRANTED** with leave to amend. Plaintiff may file an amended complaint addressing the identified deficiencies on or before **October 17, 2025**.

**IT IS SO ORDERED.**

DATE: September 22, 2025

HON. RUTH BERMUDEZ MONTENEGRO
UNITED STATES DISTRICT JUDGE