UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ZACHARY SALZMAN, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

IMMUNITYBIO, INC., RICHARD ADCOCK, DAVID C. SACHS, and PATRICK SOON-SHIONG,

Defendant.

Case No.: 23-cv-01216-GPC-VET

ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS

[ECF Nos. 50, 56]

ImmunityBio is a pharmaceutical company that develops cancer treatments. Its portfolio includes at least seventeen product candidates, but this dispute concerns just one: the company's flagship product candidate, an antibody called N-803, known internally as Anktiva. Plaintiff alleges that Defendants,[1] in the course of seeking FDA approval for Anktiva, misled investors to believe that Anktiva was manufactured in

[1] The Individual Defendants are ImmunityBio's CEO, CFO, and Chief Scientific and Medical Officer, respectively. ECF No. 37 ("Amended Complaint" or "AC") at ¶¶ 21–23.

compliance with industry standards. In fact, Plaintiff alleges, Defendants knew that Anktiva's manufacturing process was noncompliant and that it suffered from serious and persistent issues relating to recordkeeping, quality control, basic sanitation standards, and deviation management.

Pending before the Court is Defendants' Motion to Dismiss Plaintiff's Amended Complaint ("AC"). Defendants argue that Plaintiff has failed to allege either a materially misleading statement or a strong inference of scienter. For the reasons stated below, the motion is **GRANTED IN PART AND DENIED IN PART**.

BACKGROUND

The Court recites the relevant facts as provided in the complaint and corroborated by a number of confidential witnesses, taking them to be true and viewing them in the light most favorable to the Plaintiff.

Anktiva is a biologic drug, which means that it is produced from living organisms. Because the process can involve microorganisms, plant cells, or even animal cells, manufacturing biologic products is an especially sensitive process, and producing biologic products "at scale requires a series of highly-technical steps . . . to ensure a consistent end product free from impurities." AC at ¶ 5. Due to the sensitivity of this process, "even minor deviations from normal manufacturing processes can result in significant changes in product composition." *Id.* at ¶ 69. Any deviation must "be recorded and justified." *See id.* (citing 21 C.F.R. § 211.100).

The FDA will not approve a biologic product if its production fails to comply with the FDA's minimum standards for drug manufacturing, otherwise known as current good manufacturing practices ("cGMP"). Thus, in order to introduce a biologic drug to the market, a company must file a Biologics License Application ("BLA"). A BLA is composed of "data and supporting materials collected in clinical trials, along with other . . . information on the manner in which the product is manufactured." This includes

"proposed process and protocols for manufacturing at scale, [and] also must include data generated in connection with previously-produced process performance qualification ('PPQ') batches using the stated manufacturing processes and equipment." *Id.* at ¶ 43. These qualification studies serve "to validate that the proposed manufacturing process is capable of reproducing results within predetermined specifications at commercial scale." *Id.*

These studies are further corroborated by an FDA inspector's pre-approval visit to the manufacturing facility. The inspector "observ[es] the site in operation but also [reviews] appropriate records at the facility reflecting past activities." *Id.* at ¶ 46. At the conclusion of an inspection, the inspector may issue a "Form 483," which "memorialize[s] significant deficiencies observed during the inspection that, in the judgment of the inspector[], constitute violations of FDA regulations, including cGMP." *Id.* ¶ 64. "After completing its review, the FDA will either approve the BLA or send the sponsor a complete response letter ('CRL'). A CRL outlines any issues identified by the FDA during the review that prevent approval of the BLA in its current form and, where possible, recommend actions that a sponsor may take to remedy the issues or otherwise position the application for approval." *Id.* at ¶ 48 (citing 21 C.F.R. § 601.3(a)).

ImmunityBio "was formed in connection with a merger between two clinical-stage biopharmaceutical companies controlled by Defendant Soon-Shiong on March 9, 2021," *id.* at ¶ 2, and submitted its BLA for Anktiva to the FDA on May 23, 2022, *id.* at ¶ 7. On May 11, 2023, the FDA rejected the BLA. *Id.* at ¶ 14. Which came as a surprise to most of the company's shareholders. Anktiva's Phase 3 clinical trials had been "impressive," and in the year leading up to the rejection, ImmunityBio had repeatedly touted its manufacturing capabilities. For instance, ImmunityBio had asserted numerous times in press releases and SEC-mandated disclosures that "[t]he company ha[d] established GMP manufacturing capacity at scale." *See, e.g.*, *id.* at ¶ 108. It asserted that for its "Anktiva

product candidate, [it had] contracted with a multi-national biologics manufacturer with multiple cGMP-compliant facilities." *See, e.g.*, *id.* at ¶ 102. And it asserted that those "facilities ha[d] robust process development and validation and quality oversight." *Id.* But shareholders learned on May 11, 2023, that the FDA had rejected Anktiva's BLA because of deficient manufacturing practices. To shareholders, the news was shocking. But to company executives, the rejection was nothing more than "business disappointment." ECF No. 50 at 39. For the signs of manufacturing woe had appeared to leadership more than two years prior, as early as March of 2021.

ImmunityBio learned of these deficiencies from its contract manufacturing organization ("CMO"), AGC Biologics, Inc., which manufactured the active ingredient in Anktiva. AGC had originated the technique for producing the active ingredient, and ImmunityBio had continued to entrust the process to AGC, as "it would [have] be[en] exceedingly expensive and risky to transfer th[e] technology in-house, particularly with Phase 3 clinical trials . . . ." AC at ¶ 60. Despite its use of a CMO, ImmunityBio remained "ultimately responsible for the manufacture" of Anktiva, a fact it reminded investors of in its SEC disclosures. ECF No. 50-10 at 6. ImmunityBio maintained a "Quality Agreement" with AGC, whereby AGC notified the company of the "findings of any inspection by a government agency," including any deviations. AC at ¶ 168.

Three times, in the two years preceding the BLA's rejection, ImmunityBio learned that FDA inspectors had observed conditions at the Anktiva facility that violated federal law. ECF No. 50-3 at 2. AGC was first cited for manufacturing deficiencies in March of 2021 during a non-routine FDA inspection. The inspection resulted in a sixteen-item Form 483 that identified numerous deficiencies in Anktiva's production, including failures "on the part of AGC's quality unit to adequately investigate deviations, inadequate oversight of manufacturing procedures on the part of the quality unit, lack of adequate documentation for quality control testing, poorly qualified and validated

manufacturing processes, and gaps in record keeping such that inspectors could not determine whether manufacturing was operating in a state of control." *Id.* at ¶ 65. In response, AGC "committed to implement a CAPA," a corrective and preventative action, to address the concerns raised in the Form 483. *Id.*

AGC was cited again for manufacturing deficiencies four months later, in July of 2021. The inspection, which was routine, resulted in a three-item Form 483. *Id.* at ¶ 66. The inspector observed that "the firm either had deficient procedures or failed to follow existing procedures for sanitation, cleaning, and maintenance." *Id.* Additionally, the FDA inspector again "condemned AGC's failure to document conclusions or follow up actions in response to deviations." *Id.*

Following the receipt of the two Forms 483, ImmunityBio bolstered its Quality Agreement with AGC, requiring that AGC notify ImmunityBio as to any deviation, "even those classified as minor." *Id.* at ¶ 169. Through the modified Quality Agreement, ImmunityBio learned that "AGC suffered from myriad cGMP problems, including a recurring inability to timely release batch records, close deviations, [or] conduct stability testing, and [a history of] running out of critical reference material needed for testing." *Id.* at ¶ 171. ImmunityBio "began to 'remind' AGC at each test window to perform the testing because of the known buildup of misses before the Anktiva BLA," but "AGC was consistently unable to provide batch records, deviation reports, and stability tests on schedule throughout the Class Period." *Id.* at ¶¶ 171–72. These records were "especially 'important' to ImmunityBio leadership in 2021 because the results were needed for the Anktiva BLA," so Defendant Richard Adcock, the CEO of ImmunityBio, began meeting monthly with AGC executives to discuss the delays and other manufacturing deficiencies. *Id.* at ¶¶ 171–73. Despite leadership's attention, the issues continued. Even with the addition of costly contract workers, hired and placed by ImmunityBio, AGC "regularly failed" to document departures from written procedures and "regularly failed" to conduct

quality control tests. *Id.* at ¶¶ 67–71, 175. These issues resulted in frequent supply delays for the company's flagship product that lasted for months. *Id.* at ¶ 72.

ImmunityBio nonetheless forged ahead with its plan to submit the Anktiva BLA, which included AGC's quality control documentation. The FDA notified AGC on November 1, 2022, that in February 2023, it planned to hold a pre-license inspection at the facility used to manufacture Anktiva. The inspection would last "two weeks and involve six inspectors," which was far more intense than the typical inspection "conducted by one or two inspectors over several days." *Id.* at ¶ 178. ImmunityBio leadership became nervous "upon learning about the scope of the inspection." *Id.*

Accordingly, they planned a mock inspection for AGC, with extensive involvement from Defendant Adcock. The results were poor. ImmunityBio's representatives identified several deficiencies in cGMP compliance, including persistent concerns about AGC's repeated testing delays. These results were presented directly to Defendant Adcock, and ImmunityBio's leadership was soon "engaged 'on a very technical level' with prep for the FDA inspection." *Id.* at ¶ 181.

The FDA's pre-license inspection took place from February 2, 2023, to February 10, 2023. ImmunityBio sent at least six representatives to attend the inspection and settled on a plan to update leadership as to the inspection's progress. *Id.* at ¶ 182. That plan changed, however, when the FDA observed a number of deficiencies on the very first day of the inspection. *Id.* at ¶ 183. Overnight, Defendant Adcock flew up to Washington to be present for the next several days of the inspection. *Id.* Defendant Soon-Shiong demanded a personal call at the end of each day to debrief. *Id.* He further demanded that ImmunityBio employees be allowed in the room with the inspectors, and AGC eventually agreed to have an employee feed information back to ImmunityBio's leadership in real time. *Id.* at ¶ 184.

On February 10, 2023, the FDA issued a five-item Form 483. The FDA again cited multiple instances of inadequate deviation management, beginning as early as January 2021. *Id.* at ¶ 80. Specifically, the FDA observed that AGC failed to promptly address deviations and that most deviations were closed without documenting any conclusions or the implementations of any CAPA. *Id.* "[L]ess than forty percent of all deviations since July 2021 were closed on schedule, and eighty investigations remained open at the time of the inspection, including several that were open for two years." *Id.*

FDA inspectors further identified "deficiencies in data integrity, missing validation for computer systems, and lack of reliability of audit trails." *Id.* at ¶ 81. They concluded that the site "failed in critical sanitation and contamination-management practices," finding "violations in pest control in the warehouse area, deficient filtration in a clean corridor, and a pool of standing liquid on the solution prep room floor." *Id.* at ¶ 82. And they found that AGC did not follow its own standard operating procedures and that its quality unit failed to adequately oversee manufacturing operations, observing that "for 'such a critical deviation to occur, quality oversight failed at multiple steps in the process.'" *Id.* at ¶ 84.

On May 11, 2023, the FDA issued a CRL rejecting the Anktiva BLA based on "deficiencies relat[ing] to the FDA's pre-license inspection of the Company's third-party contract manufacturing organizations," and ImmunityBio common stock fell $3.43 per share, or 55.14%. *Id.* at ¶ 158–59 (emphasis removed).

STATEMENTS

On June 30, 2023, Plaintiff filed the instant suit under Section 10(b) and Section 20(a) of the Securities Exchange Act, alleging that Defendants misled investors as to ImmunityBio's compliance with cGMP in its production of Anktiva. Plaintiff challenges two categories of highly repetitive statements, consisting of sixty-two statements in total, issued at regular intervals between March 10, 2021, and May 10, 2023.

The first category involves non-risk-factor statements about GMP manufacturing capacity. Plaintiff argues that these statements were misleading because they suggested that Anktiva was not experiencing GMP difficulties, even though Defendants knew from FDA inspectional observations and Quality Agreements that it was. Those statements, with some variation, are as follows:

> We have established Good Manufacturing Practice (GMP) manufacturing capacity at scale with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned research and development (R&D), clinical trial, and regulatory operations and development teams.
>
> . . . .
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> For our Anktiva product candidate, we have contracted with a multinational biologics manufacturer with multiple cGMP-compliant facilities in the United States, Europe and Asia for our current clinical trials and future commercial sales, if approved. The facilities have robust process development and validation and quality oversight with high-capacity production suites operating multiple 2,000-20,000L production bioreactors.
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> . . . .
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> "We are pleased the FDA has begun its review, and ImmunityBio is prepared to move rapidly to manufacturing and marketing should the Agency approve our therapeutic for this indication," said Richard Adcock, President and CEO of ImmunityBio.

See, e.g., AC at ¶¶ 120, 122, 133.

The second category involves risk-factor statements. Plaintiff argues that these statements were misleading because they portrayed the risk of production difficulties as merely hypothetical, when in fact that risk had already materialized. Those statements, with some variation, are as follows:

> The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling up of our manufacturing capabilities. If we or our related parties, or any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

> . . . .
>
> If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize such products.
>
> . . . .
>
> Our or our CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, and with other FDA, state, and foreign regulatory requirements, and there is no guarantee that we or our CMOs will be able to successfully pass all aspects of a pre-approval inspection by the FDA or other foreign regulatory authorities.
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> . . . .
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> As the Company remains focused on preparing for the potential approval of the BLA by the FDA as described above, it intends to continue to explore opportunities to engage in incremental financing transactions to raise the working capital needed to fund the Company's ongoing operations through the anticipated May 23, 2023 PDUFA date and execute the Company's business strategy and initiatives.
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> . . . .
>
> It is unclear when the FDA will approve our BLA, if at all.

See, e.g., AC at ¶¶ 106, 114, 133, 144.

STANDARD OF REVIEW

On Defendants' motion to dismiss, the Court asks whether the facts viewed in the light most favorable to the Plaintiff plausibly plead a claim. To state a claim under Section 10(b) and SEC Rule 10b-5(b), Plaintiff must plead six elements, including "a material misrepresentation or omission" and "scienter." *Stoneridge Inv. Partners, LLC v. Sci.-Atlanta, Inc.*, 552 U.S. 148, 157 (2008). Plaintiff "must state with particularity the circumstances constituting fraud or mistake," Fed. R. Civ. Pro. 9(b), and meet the heightened pleading requirements of the PSLRA, *see* 15 U.S.C. § 78u-4(b)(1)–(2).

Rule 10b-5(b) prohibits "half-truths, not pure omissions." *Macquarie Infrastructure Corp. v. Moab Partners, L. P.*, 144 S. Ct. 885, 891 (2024). Disclosure is required only where necessary to render statements made—whether via press release or SEC-mandated disclosure—not misleading. *In re Facebook Inc.*, 87 F.4th 934, 948 (9th

Cir. 2023). Material information may be withheld, if in its absence "statements already made are clear and complete." *Id.* Accordingly, a company may limit what it must disclose by limiting what it says in public. *See Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 706 (9th Cir. 2016). A company that chooses to tout positive information to the market must do so without "directly contradicting what the defendant knew at the time, or creating an impression of a state of affairs that differs in a material way from the one that actually exists." *Facebook*, 87 F.4th at 948 (cleaned up).

A plaintiff pleads scienter under the PSLRA where the complaint states "with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* at 952 (cleaned up) (quoting 15 U.S.C. § 78u-4(b)(2)(A)). A strong inference exists "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007).

ANALYSIS

I. Materially Misleading Statements

1. Non-risk-factor Statements

Plaintiff argues that Defendants materially misled investors by representing in press releases and SEC disclosures that "[t]he company ha[d] established GMP manufacturing capacity at scale." *See, e.g.*, AC at ¶ 99. Plaintiff alleges that these statements were misleading because they created the impression that Anktiva's manufacturing process was not experiencing cGMP difficulties, when in fact "(i) [ImmunityBio] relied on a CMO to manufacture Anktiva at a facility that suffered from a collection of serious and recurring cGMP failings; and (ii) the aforementioned cGMP failings were not remediated and, thus, allowed to continue." *Id.* Plaintiff argues that Defendants had a duty to correct this misunderstanding through the disclosure of AGC's Forms 483 or the other cGMP deficiencies made known to Defendants through their Quality Agreements. Defendants argue that the statements are not actionable for a

variety of reasons: They argue that no reasonable investor would read the statements as Plaintiff does, and that even if some investors did, the statements were not made misleading by the nondisclosure of the company's cGMP difficulties. The Court addresses those arguments in turn.

i. **Anktiva's GMP Compliance**

"Whether a public statement is misleading, or whether adverse facts were adequately disclosed is a mixed question to be decided by the trier of fact." *Fecht v. Price Co.*, 70 F.3d 1078, 1081 (9th Cir. 1995) (quoting *Durning v. First Boston Corp.*, 815 F.2d 1265, 1268 (9th Cir. 1987). Dismissal at this stage is warranted only if the adequacy of the disclosure "is so obvious that reasonable minds [could] not differ." *Id.* (internal quotations omitted). This is a high threshold, and Defendants do not meet it.

Defendants begin by arguing that the assertion that they had "established GMP manufacturing capacity at scale" did not specifically mention Anktiva, and that in any event a reasonable investor would have read the statements as a discussion of ImmunityBio's manufacturing capacity, not the manufacturing capacity of its CMO, AGC. But Anktiva was the company's lead product candidate. During the class period, ImmunityBio "did not generate any meaningful revenues from the commercial sale of any other products, and did not expect to generate any meaningful revenue from the commercial sale of any products unless Anktiva received marketing approval." AC at ¶ 3. The Court doubts that a reasonable investor would have read the statements to pertain to every drug but the company's lead product candidate.

Context further undermines Defendants' argument. Statements about GMP compliance were often immediately preceded by discussions of Anktiva's clinical results and approval status:

> Based on the reported results of our Phase 2/3 trial (QUILT 3.032), we have initiated discussions with the FDA to file a BLA for N-803 plus BCG for BCG-unresponsive NMIBC CIS. We held a pre-BLA meeting with the

> FDA in May and reached agreement with the agency with regard to the content and plan to submit our BLA for N-803 plus BCG for BCG-unresponsive NMIBC CIS. We anticipate that the final internal quality review of the BLA will be completed within the next ten days upon which we will submit our BLA.
>
> *We have established GMP manufacturing capacity at scale* with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations, and development teams.
>
> . . . .
>
> We believe that our innovative approach to orchestrate and combine therapies for optimal immune system response will become a therapeutic foundation across multiple clinical indications. Additionally, we believe that data from multiple clinical trials indicates N-803 has broad potential to enhance the activity of therapeutic monoclonal antibodies (mAbs), including checkpoint inhibitors (e.g., Keytruda), across a wide range of tumor types. N-803 is currently being studied in 21 clinical trials (both ImmunityBio and investigator-sponsored) across 13 indications. Although such designations may not lead to a faster development process or regulatory review and may not increase the likelihood that a product candidate will receive approval, N-803, ImmunityBio's novel antibody cytokine fusion protein, has received Breakthrough Therapy and Fast Track designations from the FDA in combination with BCG for the treatment of patients with BCG-unresponsive NMIBC with CIS with or without Ta or T1 disease. In May 2022, we announced the submission of a BLA to the FDA for our product candidate, N-803 in combination with BCG for the treatment of patients with BCG-unresponsive NMIBC with CIS with or without Ta or T1 disease. In July 2022, we announced the FDA has accepted our BLA for review and set a PDUFA target action date of May 23, 2023. It is unclear when the FDA will approve our BLA, if at all.
>
> *We have established GMP manufacturing capacity at scale* with cutting-edge cell manufacturing expertise and ready-to-scale facilities, as well as extensive and seasoned R&D, clinical trial, and regulatory operations, and development teams.

See, e.g., ECF Nos. 51-3 at 5 (emphasis added); 51-4 at 5 (emphasis added). Moreover, ImmunityBio consistently claimed responsibility of its CMOs and did not meaningfully

distinguish between its own manufacturing and that of AGC's. *See, e.g.*, ECF No. 51-2 at 9 (emphasis added) (discussing AGC under the heading "*Our* Large-Scale GMP Biologic Manufacturing Capabilities" and the subheading "Overview of *our* Manufacturing Model"); *see also* AC at ¶ 133 ("ImmunityBio is prepared to move rapidly to manufacturing . . . should the Agency approve our therapeutic for this indication."). Accordingly, the Court concludes that a reasonable investor could have read the statements about compliance to pertain to Anktiva's production.

Next, Defendants argue that even if the statements could be read to concern Anktiva, the statements do not suggest that the company had established GMP manufacturing compliance. Defendants argue that the statements merely recited the standard under which the company operated. The argument requires the Court to ignore the plain meaning of the language, and is not persuasive at this stage of the litigation.[2] *See, e.g.*, AC at ¶ 110 (emphasis removed) ("The company has established GMP manufacturing capacity at scale . . . ."). Further, Defendants' reliance on *In re Ocular Therapeutix, Inc. Sec. Litig.*, is misplaced. No. CV 17-12146-GAO, 2019 WL 1950399, at *6 (D. Mass. Apr. 30, 2019), *aff'd sub nom. Mehta v. Ocular Therapeutix, Inc.*, 955 F.3d 194 (1st Cir. 2020). There, the court dealt with statements about "using current good manufacturing practices," and bolstered its holding with the fact "that the Company promptly disclosed its receipt of the two Forms 483." *Id.* Here, where the company's statement is stronger and disclosure much weaker, *Ocular* has little persuasive value.

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[2] Defendants make an identical argument as to statements about AGC being a Multinational Biologics Manufacturer with multiple cGMP-Compliant facilities, that the Court rejects for the same reason. At this stage of the litigation, the Court declines to conclude that no reasonable investor could have interpreted the statement to suggest that the AGC facility that produced Anktiva was cGMP compliant.

Finally, Defendants argue that the statements are too broad to be assigned any meaning. But the fact that ImmunityBio stated that it had established GMP manufacturing capacity "at scale," does not demonstrate the statement's ambiguity; it demonstrates breadth. And a company's decision to boast sweepingly does not operate to truncate its duty to disclose. Rather, it extends it.

Defendants' argument, however, is meritorious as to some variations of the "established" language challenged by Plaintiff. Specifically, statements about the company "adopt[ing] the strategy of establishing GMP manufacturing capacity at scale" or "optimizing investments in manufacturing capabilities for our next generation targeted antibody cytokine fusion proteins" are different. *See, e.g.*, AC at ¶¶ 95–96. Indeed, these statements were often made in the context of ImmunityBio's plans to vertically integrate and develop its own, in-house Anktiva manufacturing process. They do not suggest that AGC's manufacture of Anktiva was cGMP compliant, and the motion to dismiss is **GRANTED** as to those statements. (Statements 1–2, 26, 37, 54).[3]

The Court concludes that the other statements about established compliance are at the very least susceptible to Plaintiff's interpretation. To the extent that an investor read the statements to mean that AGC's production of Anktiva was cGMP compliant, the Court further concludes that the statements plausibly create the impression that AGC was not experiencing cGMP difficulties.

ii. Puffery

Defendants next argue that statements about AGC's "robust process development . . . and quality oversight" amount to nothing more than inactionable puffery and that no investor would have relied upon the statements to any detriment. But "[w]hat might be

[3] The numbering of the statements refers to the numbering provided in Exhibit A of Defendants' Motion to Dismiss. ECF No. 50-2.

innocuous 'puffery' or mere statement of opinion standing alone may be actionable as an integral part of a representation of material fact when used to emphasize and induce reliance upon such a representation." *Rihn v. Acadia Pharms. Inc.*, No. 15-CV-00575-BTM-DHB, 2016 WL 5076147, at *7 (S.D. Cal. Sept. 19, 2016) (quoting *Casella v. Webb*, 883 F.2d 805, 808 (9th Cir. 1989)). Here, statements about the CMO responsible for manufacturing the active ingredient in the company's lead product candidate were "coupled with, and served to emphasize" Defendants' other representations about the strength of their manufacturing capacity, including their claim that GMP manufacturing capacity had been established at scale and that Defendants had contracted with a multi-national biologics manufacturer with multiple cGMP-compliant facilities. *See Casella*, 883 F.2d at 808. The Court concludes that these statements, when read in context, are more than mere puffery and that a reasonable investor certainly could have read these statements together to suggest that AGC was not experiencing cGMP difficulties in its manufacture of Anktiva. *See In re Emergent BioSolutions Inc. Sec. Litig.*, 2023 WL 5671608, at *28 (D. Md. Sept. 1, 2023) (holding that statements describing manufacturer's quality checks for cGMP as "rigorous" were not puffery).

iii. **Duty to Disclose**

Defendants next argue that even if the non-risk-factor statements could be read to concern Anktiva's GMP compliance, they were not made misleading by the failure to disclose either the Forms 483 or the persistent issues observed and made known to ImmunityBio's leadership through the quality agreement.

Plaintiff's response is straightforward. ImmunityBio's statements that it "ha[d] established GMP Manufacturing Capacity at scale," that it had "contracted with a multinational biologics manufacturer with multiple cGMP-compliant facilities" and "robust process development and validation and quality oversight," and that it was "prepared to move rapidly to manufacturing" created the impression that AGC was not

experiencing cGMP difficulties with Anktiva. But in fact, in the two years preceding the BLA rejection, "there were legion cGMP failures at the [AGC] facility where Anktiva was made," including persistent issues in deviation processes and quality oversight, and the company was not prepared to move rapidly to manufacturing. Company leadership became familiar with these failures through their Quality Agreement with AGC, their review of materials for the BLA, and three separate Forms 483 from the FDA. Furthermore, leadership, including Defendants Adcock and Soon-Shiong, found these issues to be sufficiently serious such that they were intricately involved in attempts to remedy these failures and received frequent updates from AGC leadership. Accordingly, Plaintiff concludes, it is at least plausible that AGC was noncompliant with industry standards and that Defendants' statements about compliance directly contradicted what Defendants knew at the time, or created for investors an impression of a state of affairs that differed in a material way from the one that actually existed.

Defendants first argue that even if their statements were read to be about compliance, those statements did not create a duty to disclose "every known problem with cGMP compliance at every manufacturing facility." ECF No. 50 at 22. Plaintiff does not ask for such broad disclosures. Plaintiff's complaint is merely that Defendants did not disclose *any* of the known and serious manufacturing problems it was actively working to fix, while simultaneously boasting about its manufacturing capabilities. As alleged in the complaint, these problems were severe and persistent, repeatedly identified by FDA inspectors, and peculiarly resistant to Defendants' years-long attempts to fix them. Their nondisclosure made statements about established compliance and robust quality oversight, misleading.

Defendants next cite to three cases, but the cases do nothing more than establish that a defendant's decision to disclose something negative does not entitle a plaintiff to every detail. *In re Rigel Pharm. Inc., Sec. Litig.*, 697 F.3d 869, 880 (9th Cir. 2012)

(disclosure of severe side effects did not entitle plaintiffs to disclosure of mild ones); *Richman v. Goldman Sachs Grp., Inc.*, 868 F. Supp. 2d 261, 274 (S.D.N.Y. 2012) (disclosure of government investigation into financial misconduct did not entitle plaintiffs to every update); *Anderson v. Abbott Labs.*, 140 F. Supp. 2d 894, 903 (N.D. Ill. 2001) (disclosure of FDA noncompliance did not entitle plaintiffs to every tangentially related fact); *see also In re Discovery Labs. Sec. Litig.*, 2007 WL 789432, at *4 (E.D. Pa. Mar. 15, 2007), *aff'd*, 276 F. App'x 154 (3d Cir. 2008) (disclosure of Form 483 did not entitle plaintiffs to every detail). These cases stand for the premise that an initial negative disclosure is not rendered misleading by attempts to downplay the issue's severity or the absence of some details. As the court in *Discovery* observed, "[i]t is not the role of the courts to split hairs over *how* positively corporate executives are allowed to describe a negative event. It is sufficient that the markets were aware that the Form 483 was a serious setback for Discovery." 2007 WL 789432, at *3. That does not help Defendants, here, where they did not disclose any of their GMP issues, much less the receipt of several Forms 483.

Defendants next argue that Plaintiff's claim fails because the Complaint fails to allege that the cGMP issues were not correctable. They fashion this correctability requirement from *Discovery*, where the court mentioned correctability in response to plaintiff's argument that Discovery had downplayed the concerns raised in the Form 483. *Discovery's* application to these facts is unclear. The *Discovery* court reasoned that Discovery's characterization of the issues as "not fundamentally fatal" was not misleading because the problems "[we]re eminently correctable." *Id.* at *4. Correctability supported Discovery's statements because correctability suggested that the issues were not fundamentally fatal. Here, Plaintiff's complaint is not that Defendants downplayed or mischaracterized certain negative news, but that Defendants never disclosed *any* negative news relating to their manufacturing capacity. Under these

circumstances, the Court concludes that the potential correctability of severe and persistent manufacturing deficiencies did not make statements which boasted of *present* manufacturing compliance any less misleading. The fact that an issue had been *corrected* might have made some difference, but the fact that an issue was *correctable* does not. Defendants repeatedly stated that they had established GMP compliance, not that they were several correctable issues away from achieving it. Thus, at this stage, the Court rejects Defendants' correctability argument.

Finally, Defendants argue that nondisclosure did not render statements about GMP compliance misleading because the observations made in the Forms 483 were preliminary and did not represent the final view of the FDA. As an initial matter, this argument ignores the allegation that Defendants were well aware of manufacturing deficiencies through other means, including their quality agreements, and "neither a Form 483 nor a Warning Letter is necessary to impute knowledge of [cGMP] violations" at a manufacturing facility. *Todd v. STAAR Surgical Co. (STAAR II)*, No. CV-14-05263-MWF-RZ, 2016 WL 6699284, at *12 (C.D. Cal. Apr. 12, 2016).[4] Moreover, the cases that Defendants cite make clear that disclosure of a Form 483's observations may be necessary depending upon "the number, severity, and pervasiveness of objectionable conditions noted, as well as whether a company has failed to address or correct the deficiencies noted by the FDA." *Pub. Pension Fund Grp. v. KV Pharm. Co.*, 679 F.3d 972, 983 (8th Cir. 2012); *see also Deka Int'l S.A. v. Genzyme Corp. (In re Genzyme Corp. Sec. Litig.)*, 754 F.3d 31, 42 n.4 (1st Cir. 2014). Here, Plaintiff has alleged a number of serious and pervasive deficiencies relating to quality control, deviation

[4] Defendants argue that *STAAR II* is distinguishable because "the challenged statements here were not specific representations of Company-wide regulatory compliance." ECF No. 52 at 9. The Court has rejected this argument.

management, and basic sanitation protocols. These issues persisted despite Defendants' attempts to ameliorate them, and were repeatedly observed by inspectors trained by the FDA to only report "significant deficiencies." AC at ¶ 64. The inspectors further noted that certain remedial measures had been promised but not taken, and that issues beginning in early 2021 had persisted until the 2023 pre-inspection approval. *Id.* at ¶ 84. Under these circumstances, the Court finds that a reasonable investor would have been misled by Defendants' nondisclosure of any cGMP deficiencies.

Defendants argue that "[t]he circumstances do not suggest that disclosure of *another company's* Form 483 was required here." But AGC, as alleged, was not simply "another company." It was the Defendant's CMO: the one that produced the active ingredient in their lead product candidate, the one explicitly mentioned in their disclosures, and the one Defendants had touted as having multiple cGMP-compliant facilities and robust process development and quality oversight, despite Defendants' knowledge to the contrary. Most importantly, as Defendants stated in their SEC disclosures, they remained ultimately responsible for AGC's compliance with cGMP. Here, the circumstances, viewed in the light most favorable to the Plaintiff, required disclosure of AGC's shortcomings. Accordingly, the Court concludes that Plaintiff has plausibly alleged that Defendants' statements about GMP compliance were misleading.

2. Risk-Factor Statements

Plaintiff next challenges statements made in Defendants' SEC disclosures, which advise of potential production risks associated with the complexities of drug manufacturing. Falsity allegations "survive a motion to dismiss when the complaint plausibly allege[s] that a company's SEC filings warned that risks 'could' occur when, in fact, those risks had already materialized." *Facebook*, 87 F.4th at 948–49 (quoting *Alphabet Sec. Litig., R.I. v. Alphabet, Inc.*, 1 F.4th 687, 702 (9th Cir. 2021)). Defendants' risk statements warned of potential "difficulties in production," including an inability to

"comply with . . . cGMP" or "reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements." *See, e.g.*, AC at ¶¶ 97, 106. Plaintiff argues that these statements were misleading because "the risks posed by a failure to comply with cGMP . . . were not merely hypothetical." AC at ¶ 115.

Defendants argue that none of these risk-factor statements are actionable because none of the disclosed consequences of cGMP failures came to fruition. For example, Defendants argue that the statements warning of "production difficulties" are not actionable because "[t]he Complaint does not allege that ImmunityBio has been unable to maintain a commercially viable cost structure, or that the supply of its product candidates for clinical trials was ever delayed or stopped due to production difficulties." ECF No. 50 at 30.

> The manufacture of our product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, or scaling up of our manufacturing capabilities. If we or our related parties, or any of our third party manufacturers encounter such difficulties*, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure*.

See, e.g., AC at ¶ 97 (emphasis added). But, as Plaintiff argues, Defendants' argument fails because it confuses the risk for its consequence. This approach was rejected in *Facebook*. There, Facebook had stated that "[a]ny failure to prevent or mitigate . . . improper access to or disclosure of our data or user data . . . could result in the loss or misuse of such data, which could harm Facebook's business and reputation and diminish our competitive positions." *Id.* at 944 (alteration in original). The dissent focused on the latter portion of this risk statement—*i.e.*, the consequence—observing that the statements "advise that improper access to data *could* harm Facebook's reputation and business." *Id.* at 959 (Bumatay, J., *dissenting*). The dissent reasoned that the risk-factor statement was

inactionable because the plaintiff-shareholders had "not sufficiently alleged that Facebook knew its reputation and business were *already* harmed at the time of the filing of the 10-K." *Id.* The majority rejected this position, holding that case law does not require the consequence of a risk "to have materialized for a statement to be materially misleading." *Id.* at 949. Instead, the majority concluded that Facebook's risk-factor statement was plausibly materially misleading because Facebook had presented the risk of improper access to user data "as purely hypothetical when it had already occurred." *Id.* at 950. Here, the Court concludes that Defendants' risk-factor statements are plausibly materially misleading because Defendants presented the prospect of "production difficulties" and cGMP deficiencies as purely hypothetical when they had already occurred. The fact that the consequences had not yet materialized makes no difference.[5]

But the statements "it is unclear when the FDA will approve our BLA, if at all" and "the Company remains focused on preparing for the potential approval of the BLA by the FDA," fare differently. These statements do not advise of GMP difficulties but rather are premised entirely on the potential approval of the BLA. Plaintiff argues that these statements are misleading, insisting that the complaint plausibly alleges that the BLA was non-viable following the FDA's pre-inspection report. But as Defendants explain, a Form 483 does not represent the FDA's final observations, and a company "can receive inspectional observations in a Form 483 and still receive an agency determination of compliance." ECF No. 50 at 13. Plaintiff turns to the testimony of his expert, Todd Clark, and suggests that the Court should consider his testimony in the fashion of the Ninth Circuit in *E. Ohman J:or Fonder AB v. NVIDIA Corp.*, 81 F.4th 918,

[5] Defendants take a similar tact as to the other risk statements warning of GMP failures, and those arguments are rejected for the same reason. *See* ECF No. 50 at 31–32.

930–31 (9th Cir. 2023). But Mr. Clark's opinion, that the observed violations "would, at a minimum, lead to a recommendation to withhold rather than approve the Anktiva BLA by the FDA," AC at ¶ 89, is entirely conclusory and bereft of the "carefully disclosed and . . . consistently conservative" analytical assumptions that accompanied the expert opinion in *Fonder*. Accordingly, the Court declines to rely upon those conclusions as pled. *See In re Nektar Therapeutics Sec. Litig.*, 34 F.4th 828, 837 (9th Cir. 2022).[6] Plaintiff argues, in the alternative, that much like in *Yanek v. Staar Surgical Co. (STAAR I)*, 388 F. Supp. 2d 1110, 1129–30 (C.D. Cal. 2005), a reasonable investor would have read these statements to "necessarily imply[] that there would be no serious impediments to timely approval," but in *STAAR I* the defendant had stated that they "look[ed] forward to the commercialization of the ICL," which provides much stronger grounds for inferring anticipation. Here, where Defendants were cautious to only speak of approval in the hypothetical, the Court is not inclined to draw a similar inference. Accordingly, the motion to dismiss is **GRANTED** as to these statements premised solely on FDA approval. (Statements 4, 11, 50, 60–62). To the extent that Plaintiff wishes to amend the complaint and further supplement his claims of non-viability, he will have thirty days from the filing of this order.

II. Scienter

In order to survive a motion to dismiss, Plaintiff must also "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *STAAR II*, 2016 WL 6699284, at *12 (quoting 15 U.S.C. § 78u–4(b)(2)(A)). "To

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[6] Defendants' Notice of Supplemental Authority, filed June 18, 2024, observes that the U.S. Supreme Court has granted certiorari in *Fonder* and invites the Court to defer its decision on the instant motion. ECF No. 62. But the Court finds Plaintiff's citation to *Fonder* unpersuasive and thus declines to defer its decision.

satisfy the requisite state of mind element, "a complaint must allege that the defendant[ ] made false or misleading statements either intentionally or with deliberate recklessness." *Id.* (alteration in original) (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009), *as amended* (Feb. 10, 2009)). Here, a holistic analysis supports a strong inference of scienter. *See Zucco*, 552 F.3d at 992.

Plaintiff has alleged that, during the relevant time period, Defendants were well-informed as to AGC's manufacturing deficiencies but consistently declined to inform investors. Defendants had learned as early as March of 2021, through their quality agreement with AGC, that FDA inspectors had observed numerous cGMP failures relating to process development, basic sanitation, and quality oversight. Defendants actively worked to fix those issues, meeting regularly with AGC leadership and even hiring costly contract workers to supplement AGC's existing workforce. Prior to the pre-inspection approval, Defendants commissioned a mock inspection, where their own representatives identified numerous issues, including a host of unresolved issues previously identified in the Forms 483. The results of the mock inspection, and the preliminary results of the 2023 FDA inspection, incentivized Defendants' direct involvement in a last-ditch, hands-on effort to prevent a rejection of the BLA, which involved the CEO flying overnight to the Anktiva site and the Chief Scientific and Medical Officer's requests for a daily debrief of the inspection. Taken together, these allegations create a strong inference that ImmunityBio and its leadership—the Individual Defendants—were well aware of the persistent manufacturing issues afflicting AGC. They considered them to be serious, as evidenced by their attempts to resolve the issues, but nevertheless declined to disclose any information to investors.

This "inference of scienter is further bolstered by the importance" of Anktiva to Defendants, as their lead product candidate. *STAAR II*, 2016 WL 6699284, at *13. As alleged in the complaint, ImmunityBio "did not generate any meaningful revenues from

the commercial sale of any other products, and did not expect to generate any meaningful revenue from the commercial sale of any products unless Anktiva received marketing approval." AC at ¶ 3. Just as in *STAAR II*, the Court finds that under these circumstances it is reasonable to infer that ImmunityBio's leadership "would be involved closely in ensuring compliance with FDA regulations, especially where any violations could postpone the approval of [Anktiva]." 2016 WL 6699284, at *13 (citing *Reese v. Malone*, 747 F.3d 557, 576 (9th Cir. 2014).

"Defendants' failure to timely disclose [any of] the Form[s] 483" further supports an inference of intentional deceit. *Id.* at *14. Defendants were repeatedly informed by FDA inspectors of severe deficiencies in Anktiva's manufacturing process and confirmed this for themselves through the Quality Agreement, their own inspection of the facilities, and their review of AGC's compliance documentation in preparation for the BLA. The company actively labored to fix these issues, but continued to convey to the public that it was not experiencing GMP difficulties, that it had in fact established GMP manufacturing capacity at scale. All this supports an inference of intentional deceit.

Defendants respond that Plaintiff has failed to demonstrate "that anyone knew the problems at AGC could not be corrected in time and were destined to preclude the approval of the Anktiva BLA," but as previously discussed the actionable statements are those relating to GMP compliance, not approval of the BLA, and Defendants' correctability argument does not move the needle as to statements about established compliance.[7] Defendants next argue that the absence of stock sales undermines an

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[7] Defendants attack the credibility of the confidential witnesses, but these attacks are premature. ECF No. 50 at 33. At the motion to dismiss stage, the Court is "satisfied that Plaintiffs have described the confidential witnesses with sufficient detail . . . identif[ying] each confidential witness by title and job description, and in quite a few instances includ[ing] the name of the individual to whom they reported." *In re: Bofi Holding, Inc.*

inference of scienter, *but see No. 84 Employer-Teamster v. America W. Holding*, 320 F.3d 920, 944 (9th Cir. 2003), and highlight Defendant Soon-Shiong's personal investment of an additional $300 million into ImmunityBio in December of 2021. This investment certainly suggests some level of faith in the company's ultimate success—indeed, Defendants have requested this Court's notice of the FDA's April 22, 2024, approval of Anktiva—but neither fact resolves Defendants' attempts to mislead investors as to the state of their manufacturing compliance between March 10, 2021, and May 10, 2023.[8] As alleged in the complaint, Anktiva's manufacturing was deficient and never corrected. While Soon-Shiong's investment is potentially consistent with a belief that manufacturing deficiencies had in fact been corrected, it is also consistent with the attempts of a majority owner, AC at ¶ 30, to provide his company additional runway as it attempts to fix critical production deficiencies. In other words, the investment is wholly consistent with the competing inference of scienter: Defendants continued to mislead investors so that Soon-Shiong could protect his $300 million investment and the company could solicit other investments as it "continue[d] to explore opportunities to engage in incremental financing transactions to raise the working capital needed to fund the Company's ongoing operations through the anticipated May 23, 2023 PDUFA date." AC at ¶ 155. Accordingly, the Court concludes that Plaintiff has sufficiently pled a strong inference scienter.

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Sec. Litig., No. 3:15-CV-02324-GPC-KSC, 2016 WL 5390533, at *10 (S.D. Cal. Sept. 27, 2016); AC at ¶¶ 25–28.

[8] Because the Court does not rely upon it, finding it irrelevant, Defendants' Request for Judicial Notice is **DENIED AS MOOT**. ECF No. 56.

CONCLUSION

Defendants argue that the complaint alleges nothing more than ordinary corporate optimism and is really nothing more than an attempt to impose liability with the benefit of hindsight. Defendants argue that denial of their motion requires that "every Company intending to operate under cGMP in pursuit of highly technical, biopharmaceutical innovation must achieve manufacturing perfection at all times, or relay the inherent, day-to-day ups and downs of doing so to avoid misleading investors." ECF No. 50 at 25. Not so. The Court holds only that a company suffering from severe and persistent manufacturing deficiencies must provide investors with some idea of the full picture if it chooses to boast of its manufacturing prowess. Defendants were entitled to their optimism; but they were not entitled to peddle that optimism to investors in a manner that materially misrepresented the facts. Accordingly, the Motion to Dismiss is **GRANTED** as to those statements enumerated as inactionable in the order, and **DENIED** as to the rest. Plaintiff is provided leave to file a Second Amended Complaint to cure the deficiencies identified herein within thirty days from the filing of this order.

IT IS SO ORDERED.

Dated: June 20, 2024

Hon. Gonzalo P. Curiel
United States District Judge