

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

JAMES A. CUTSHALL,)
individually and on behalf)
of all others similarly)
situated, et al.,)
)
Plaintiffs,)
)
v.) 1:24CV954
)
HUMACYTE, INC., et al.,)
)
Defendants.)

MEMORANDUM OPINION AND ORDER

THOMAS D. SCHROEDER, District Judge.

This is a putative federal securities class action on behalf of all persons who owned common stock or warrants, sold put options, or bought call options of the biopharmaceutical company Humacyte, Inc. ("Humacyte"), between August 14, 2023, and March 25, 2025 (the "class period").¹ In their corrected first amended complaint (the "complaint"), Plaintiffs seek recovery for stock losses pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), as amended by the Private Securities Litigation Reform Act of 1995 ("PSLRA") and Rule 10-b5 promulgated thereunder, 17 C.F.R. § 240.10b-5. (Doc. 37.) The Defendants are: Humacyte; Laura E. Niklason, M.D., Ph.D.,

¹ The lead Plaintiffs are Frederick Foote, Mathew Cognetti, and Damion Hopwood. (Doc. 37.) However, the entire putative Plaintiff class (including the lead Plaintiffs) will be referred to simply as "Plaintiffs."

Humacyte's co-founder, president, chief executive officer ("CEO") during the class period, and member of the board of directors since 2004 (id. ¶ 17); Dale A. Sander, Humacyte's chief financial officer ("CFO") during the class period and member of the board of directors since 2015 (id. ¶ 18); and Heather Prichard, Humacyte's chief operating officer ("COO") during the class period (id. ¶ 19) (together, "Defendants"). Before the court is Defendants' motion to dismiss the complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). (Docs. 40, 41.) Plaintiffs filed a response in opposition (Doc. 42), and Defendants replied (Doc. 43). The court heard argument on the motion on March 17, 2026. For the reasons set forth below, Defendants' motion to dismiss will be granted in part and denied in part.

I. BACKGROUND

The facts alleged in the complaint, which are accepted as true and viewed in the light most favorable to Plaintiffs for purposes of the present motion, and the contents of other documents which the court may consider in deciding the motion to dismiss, show the following:

Humacyte is a biopharmaceutical company that develops and manufactures off-the-shelf, implantable, and bioengineered human tissues. (Doc. 37 ¶ 3.) Humacyte's lead product, a human acellular vessel ("HAV") known as either the Acellular Tissue Engineered Vessel ("ATEV") or Symvess, is a lab-grown blood vessel

implant that can act as a replacement for an injured or damaged blood vessel. (Id.) During the class period, Humacyte had one facility in Durham, North Carolina, that housed its corporate headquarters, manufacturing capability, and research and development, along with approximately 180 to 220 employees. (Id. ¶ 35.)

On December 12, 2023, Humacyte submitted its Biologics License Application (“BLA”) for Symvess to the Food and Drug Administration (“FDA”). (Id. ¶ 32.) That same day, Dr. Niklason noted in a press release that the BLA sought approval for Symvess “in urgent arterial repair following extremity vascular trauma when a synthetic graft is not indicated and when autologous vein use is not feasible.” (Id. ¶ 33(a) (emphasis omitted).) The FDA accepted the BLA on February 9, 2024, and provided Humacyte with a Prescription Drug User Fee Act (“PDUFA”) date of August 10, 2024. (Id. ¶ 32.) This PDUFA date was the date by which the FDA had to respond to Humacyte’s BLA. (Id.) Immediately after the FDA’s acceptance of its BLA, Humacyte issued another press release where Dr. Niklason announced the PDUFA date of August 10, 2024. (Id. ¶ 34.)

On August 9, 2024, Humacyte issued a press release announcing that the FDA would require additional time to complete its review of the BLA. (Id. ¶ 7.) On the next trading day, August 12, Humacyte’s stock price dropped from \$7.91 to \$6.62 per share, a

decline of 16.37%, on high trading volume. (Id. ¶¶ 7, 149.)

Ultimately, the FDA issued a BLA approval letter to Humacyte for Symvess on December 19, 2024. (Id. ¶ 47.) This approval, however, was limited to “use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible.” (Id.; see Doc. 41-1 at 21.) Moreover, the BLA approval letter noted the FDA’s imposition of a black-box warning to highlight Symvess’s risk of rupture, stating, “Given the serious risk of arterial bleeding from mid-graft rupture or anastomotic failure (9.9%) following implantation of SYMVESS in this small cohort, the clinical team included this information as a boxed warning in SYMVESS prescribing information.”² (Doc. 37 ¶ 125(a); see Doc. 41-1 at 19.)

A. Material Misrepresentations and Omissions

During the class period, Defendants made public statements regarding the safety and efficacy of Symvess, the state of Humacyte’s manufacturing facility, and the adequacy of Humacyte’s cash and cash equivalents. In their complaint, Plaintiffs challenge several of these statements, as set forth below, as material misrepresentations and omissions.

² According to the FDA’s Clinical Review Memorandum for Symvess, “[t]he term rupture is used to include instances of mid-graft loss of ATEV integrity as well as anastomotic failure consistent with the term used in [Humacyte’s] case summaries.” (Doc. 41-1 at 147.) Thus, an “[a]nastomotic failure is a type of rupture.” (Doc. 43 at 10.)

1. Product safety fraud

Humacyte's BLA relied on results from two trials. (Doc. 37 ¶ 33(a).) The first trial, known as the V005 trial, evaluated Symvess for vascular replacement or reconstruction in 71 patients with life- or limb-threatening vascular trauma. (Doc. 41-1 at 7.) Thus, the patients in the V005 trial received Symvess for either an extremity or a torso/iatrogenic indication. (Id. at 7-8.) The V005 trial measured primary efficacy via the rate of primary vascular graft patency (i.e., blood flow without intervention) and secondary vascular graft patency (blood flow with intervention) 30 days after treatment. (Id. at 8.) To determine Symvess's primary efficacy, however, the V005 trial evaluated only the 54 patients who received Symvess for an extremity indication. (Id.) The 30-day rates of infection and amputation comprised the trial's secondary endpoints. (Id. at 195.)

The second trial, known as the V017 trial, reviewed results from 16 wartime Ukrainian patients treated with Symvess through Humacyte's Humanitarian Aid Program. (Id. at 8.) Like the V005 trial, the V017 trial focused on an endpoint of Symvess's primary efficacy after 30 days. (Id. at 161.) Plaintiffs allege that several of Defendants' statements and filings related to the results of the V005 and V017 trials constitute material misrepresentations or omissions. (Doc. 37 ¶ 103.)

On August 14, 2023, Humacyte issued a press release announcing

the results of the V017 trial, stating:

Clinicians reported that the rate of success in treating patients with the HAV was high, with an observed 30-day HAV patency (presence of blood flow) of 95%, 30-day limb salvage of 100%, 30-day survival of 100%, and zero cases of infection of the HAV.

(Id. ¶ 104(a) (emphasis omitted).) The same day, Humacyte held an earnings call where Dr. Niklason touted these results while noting Symvess's "very high success rate." (Id. ¶ 104(b) (emphasis omitted).) She also favorably compared the V017 trial to the V005 trial, stating that "[t]he patency results in Ukraine have been outstanding. They're actually not that different from some of the early patency results that we've talked about for V005." (Id. (emphasis omitted).) Moreover, in response to a question about the control benchmark used by Humacyte for its V005 trial, she stated:

[T]he historical control benchmark for the V005 trial is based on a comprehensive literature review. And the structure of the literature review and the meta-analysis was actually something that we agreed upon with the FDA before undertaking this. So, this is really a comprehensive review of the world's literature over the last 20 years using any type of synthetic graft. . . . But this is also high-quality studies [sic]. So . . . the surgical literature is sometimes messy, and there's a lot of single-arm studies that are of low quality. Those studies were excluded with agreement from the FDA. So, we're focusing on high-quality studies. And because of that, the benchmark that we've obtained, we feel is robust and we feel will provide excellent support for eventual approval of the HAV and trauma.

(Id. (second alteration in original).)

On September 12, 2023, Humacyte issued a press release announcing positive top line results from the V005 trial. Specifically, Humacyte claimed, "The single arm clinical trial was a success and showed that the HAV in this study had higher rates of patency, and lower rates of amputation and infection, compared to historic synthetic graft benchmarks." (Id. ¶ 105 (emphasis omitted).) The press release then described the V005 trial's methodology, noting:

[T]he comparators for the HAV results were benchmark outcomes for treatment with synthetic grafts based on a systematic literature search. The principal means of evaluation was comparability of secondary patency (blood flow) at 30 days, with primary patency (blood flow without intervention) also evaluated. Secondary comparisons comprised of improvement in rates of amputation and rates of infection at 30 days.

(Id. (emphasis omitted).) Further, the press release provided a detailed statistical breakdown of the results from the V005 trial compared to the benchmark literature review of synthetic grafts:

The V005 trial was a success, and the principal comparison of 30-day secondary patency for the HAV in the clinical trial was 90.2% for the extremity patients (89.9% for total patients) compared to 81.1% historically reported for synthetic grafts. Primary patency for total HAV patients and for extremity patients was 81.2% and 84.3%, respectively For the secondary comparison of amputation rates, the HAV demonstrated an improvement with a rate of 9.8% for extremity patients (10.1% for total patients) compared to 20.6% historically reported for synthetic grafts. For the secondary comparison of infection rate, the HAV demonstrated an improvement, with a rate of 2.0% for the extremity patients (2.9% for the total patients) compared to 8.9% historically reported for synthetic grafts. There were no unexpected safety signals for the

HAV in this study.

(Id. (emphasis omitted).) Finally, the press release also provided a favorable comparative breakdown for the V017 trial:

For this population, 30-day secondary patency for the HAV was 93.8% compared to 81.1% historically reported for synthetic grafts. The rate of amputation for the HAV was 0.0% compared to 20.6% historically reported for synthetic grafts. The rate of infection for the HAV was 0.0% compared to 8.9% historically reported for synthetic grafts.

(Id. (emphasis omitted).)

On September 12, 2023, Humacyte held a key opinion leader webinar with analysts where Humacyte's chief medical officer repeated the favorable results of the V005 trial in comparison to benchmark literature for synthetic grafts, while noting that the study's "primary endpoint [was] 30-day patency in patients with extremity injuries." (Id. ¶ 106(a) (emphasis omitted).) The chief medical officer then repeated the detailed, favorable statistical breakdown of the results of both trials in comparison to the literature review benchmark. (Id. ¶ 106(b).)

In response to a question about the data comparison, Dr. Niklason reiterated that Humacyte "actually worked out the protocol for doing the meta analysis with the [FDA] before [Humacyte] performed it. . . . So we have a high degree of confidence, that the [FDA] will accept this benchmark, given that it was developed in collaboration with folks of the FDA." (Id. ¶ 106(c) (emphasis omitted).) Further, Dr. Niklason added that

because “[t]he primary factor is saving life and limb at the time of the acute crisis[,] . . . this is why the FDA has acknowledged that 30-day patency is actually a salient endpoint.” (Id. ¶ 106(d) (emphasis omitted).) Finally, in response to a question about the V017 trial composition, Dr. Niklason asserted that “even though this was not a clinical trial per se, but the inclusion criteria for the humanitarian effort, actually mirrored the inclusion criteria for the V005 trial.” (Id. ¶ 106(e).)

Dr. Niklason repeated the positive results of both the V005 and V017 trials in a live key opinion leader event on September 20, 2023, in an earnings press release and earnings call on November 9, 2023, and again in a press release on November 17, 2023. (Id. ¶¶ 107-10(d).) Moreover, in the November 17 press release, Humacyte touted the safety of Symvess:

There were no unexpected safety signals for the HAV in the V005 and V017 studies. . . . There were four deaths among the extremity patients in the V005 trial, and zero deaths in the V017 trial. There were no deaths among extremity patients in the V005 trial attributed to the HAV. A meta-analysis combing the V005 and V017 trials showed a rate of death for extremity patients comparable to that historically reported for synthetic grafts, with a 30-day rate for the HAV for 3.5%, and a 30-day rate of deaths attributed to the HAV of 0.0%. A 30-day rate of death of 3.4% is reported historically for synthetic grafts, although deaths attributed to the synthetic grafts were not reported.

(Id. ¶ 110(e) (emphasis omitted); see Doc. 43-1 at 4.)

Humacyte continued to report these favorable results from both the V005 and V017 trials in a December 2023 press release, a

February 2024 press release, a March 2024 press release, and a March 2024 earnings call. (Doc. 37 ¶¶ 111-13.) Then, on March 28, 2024, Humacyte filed a Form 10-K with the Securities and Exchange Commission ("SEC") for the 2023 fiscal year. (Id. ¶ 114.) Most significantly, the 2023 Form 10-K reported only one HAV rupture among the V005 extremity group.³ (Id. ¶ 114(f); see Doc. 41-1 at 197.) Then, on May 10, 2024, Humacyte issued a press release and held an earnings call. (Doc. 37 ¶¶ 115-16.) Both during the earnings call and in the press release, Dr. Niklason noted that Humacyte "remain[ed] on track with our BLA review and commercial launch preparations, and we remain confident in the approvability of the HAV in vascular trauma." (Id. (emphasis omitted); see Doc. 43-1 at 10.)

Humacyte met with the FDA at the Late Cycle Meeting on May 20, 2024, after which Dr. Niklason continued to express her optimism about the results of the trials and the progress toward FDA approval. (Doc. 37 ¶¶ 99, 117.) But on August 9, 2024, Humacyte issued the press release announcing the delayed FDA approval. (Id. ¶ 118.) In this press release, Dr. Niklason asserted:

FDA leadership noted that Humacyte's ATEV is a first-in-class product, and that Priority Review had been granted, which allows only a six-month review cycle, as

³ Notably, the 2023 Form 10-K included only 51 patients in the V005 extremity group, while the FDA's BLA approval letter noted 54 patients in the same group. (Contrast Doc. 41-1 at 8, with id. at 195.) The parties have not offered any explanation for this discrepancy.

compared to the standard ten-month review cycle for most products. During the course of the BLA review, the FDA has conducted inspections of our manufacturing facilities and clinical sites and has actively engaged with us in multiple discussions regarding our BLA filing, including post-marketing and labeling discussions. Based on these interactions, we are confident in the approvability of the ATEV in treating vascular trauma. The FDA leadership expressed an apology for their inability to complete the review by the PDUFA date, and currently we do not yet have a revised action date.

(Id. ¶ 118(a).) The press release again touted the favorable results obtained by Symvess in the V005 and V017 trials in comparison to historical synthetic grafts. (Id. ¶ 118(b).)

A few days later, in an August 13, 2024 earnings press release, Dr. Niklason stated, "We were surprised to be notified by the FDA that they will require additional time to complete their review of the BLA for our ATEV (acellular tissue engineered vessel) in vascular trauma." (Id. ¶ 119(a).) Moreover, she noted, "During the course of the BLA review, the FDA has conducted inspections of our manufacturing facilities and clinical sites and has actively engaged with us in multiple discussions regarding our BLA filing, including post-marketing and labeling discussions." (Id.) And in an earnings call the same day, in response to an analyst's question about a new approval date, Dr. Niklason stated that she could not provide further clarity and asserted that the FDA "said simply that they need more time and they did not give us insight into a new date or how we would be informed." (Id. ¶ 120.) CFO Sander

reiterated, “[W]e don’t know what the delay will be at this instance.” (Id. (emphasis omitted).)

Humacyte issued another press release and held an earnings call on November 8, 2024, where Dr. Niklason reiterated that the FDA “actively engaged with us in multiple discussions regarding our BLA filing, including agreement on post-marketing commitments, as well as labeling discussions.” (Id. ¶ 121-22 (emphasis omitted).) In response to a question about the delay in approval, Dr. Niklason answered:

So since the PDUFA date, and when the FDA told us they needed more time, we’ve since had occasional, what I’m calling, ping-pong. We reach out to the CBER leadership every few weeks and offer them material that may help in the review, ask them if they have timelines or questions for us. And we have offered additional material, for example, some of the webinars that we’ve shown that they’ve accepted. But they have not given us a new date, and they have not really engaged in much question asking. I will say that we’ve gotten a couple requests for sort of standard documentation on the CMC side just in the last couple of weeks that our quality team and our CMC team are responding to timely. But it would be too far to say that we’re having substantive discussions with them. That’s . . . we are offering them that material, and they’ve asked us a couple of paperwork questions.

(Id. ¶ 122.) On November 21, 2024, Humacyte issued another press release where it repeated the favorable results from the V005 and V017 trials in comparison to synthetic graft benchmarks and announced the publishing of Humacyte’s clinical results in the journal JAMA Surgery. (Id. ¶ 123.) This press release described longer-term follow-up results, noting:

The ATEV was observed to be mechanically durable and does not appear to dilate or become stenotic over time. . . . The average follow-up duration for patients receiving the ATEV for extremity trauma is 334.4 days, with a total patient exposure of 61.3 years. These results showcased the potential of the ATEV to retain patency over the longer duration of follow up. No ATEV infections or patient deaths were reported after month three.

[. . .]

Evaluation of the safety of the ATEV indicated no safety signals attributable to ATEV mechanical weakness, contamination, or immune rejection. Overall, Adverse Events (AEs) and Serious Adverse Events (SAEs) were consistent with patients suffering from acute injuries. Adverse Events of Special Interest (AESIs) including thrombosis, rupture, aneurysm, and pseudoaneurysm, occurred at rates that were consistent with reports of other vascular conduits, including autologous vein and synthetic grafts. The meta-analysis combining the V005 and V017 trials showed a 30-day rate of death in ATEV patients of 3.5%, comparable to the 3.4% rate historically reported for synthetic grafts. There were no deaths attributable to the ATEV.

(Id. ¶ 123(c)-(d).)

Finally, on December 19, 2024, Humacyte issued a press release announcing the BLA's approval. (Id. ¶ 124(a)-(b).) The press release quoted Dr. Niklason in touting the FDA's "full approval of SYMVESS." (Id. (emphasis omitted); see Doc. 41-1 at 393.) Concerning Symvess's safety and efficacy, the press release stated:

SYMVESS . . . is a first-in-class bioengineered human tissue that is designed to be a universally implantable vascular conduit for use in arterial replacement and repair. While harvesting [a] vein from a trauma patient takes valuable surgical time, SYMVESS is available off-the-shelf, and does not require further injuring the

patient to obtain vascular repair material. Humacyte's BLA included positive results from the V005 pivotal Phase 2/3 clinical study, as well as real-world evidence from the treatment of wartime injuries in Ukraine under a humanitarian aid program. SYMVESS was used to repair many types of traumatic injuries including car accidents, gunshot wounds, blast wounds, and industrial accidents. It was utilized by vascular and trauma surgeons in Level 1 Trauma centers throughout the U.S. and Israel to repair severe limb-threatening and life-threatening injuries, and in front-line hospitals in Ukraine to treat wartime injuries. Results from these studies were published in JAMA Surgery on November 20, 2024. In the civil and military clinical studies, SYMVESS was observed to have high rates of patency, or blood flow, and low rates of amputation and infection.

(Doc. 37 ¶ 124(c) (emphasis omitted); see Doc. 41-1 at 393.)

2. Facility fraud

The FDA inspected Humacyte's Durham facility from April 1 to 5, 2024. (Doc. 37 ¶ 45.) On April 5, 2024, the FDA issued a Form 483 to Humacyte, which identified two "inspectional observations": (1) a lack of "microbial quality assurance"; and (2) inadequate quality oversight for four distinct issues. (Id. (emphasis omitted).) Defendants did not disclose their receipt of the Form 483, but the FDA ultimately released the Form 483 on October 17, 2024. (Id. ¶ 44.) Plaintiffs allege that several of Defendants' statements and filings related to Humacyte's readiness to safely manufacture Symvess, the sufficiency of the quality assurance and oversight, and the results of the FDA's inspection constitute material misrepresentations or omissions. (Id. ¶ 126.)

Before the FDA's inspection of Humacyte's facility, at the

key opinion leader webinar in September 2023, Dr. Niklason responded to a question about Humacyte's quick work in preparing the BLA:

[O]ur manufacturing system, called the Luna200 system, which allows us to make HAVs at commercial scale, has already been in use. We've been using this system to produce vessels for our ongoing clinical trials since the middle of 2021.

As part of transitioning to that commercial scale system, we did a very detailed filing to our IND with the FDA back in 2020. And they reviewed that filing and have given us a sign-off to use our current commercial system in our clinical studies.

(Id. ¶ 127 (alteration in original).) In her closing remarks, she added, "[W]e're currently using systems that allow us to perform commercial scale manufacturing. And the total capacity in the building in which we now occupy, will allow us to produce approximately \$1 billion worth of product, when we're fully built out." (Id. (alteration in original).) Later, Humacyte's November 2023 press release asserted that "[t]he HAV can be produced at commercial scale in Humacyte's existing manufacturing facilities, which are expected to have the capacity to provide thousands of vessels for treating patients in need." (Id. ¶ 128 (emphasis omitted).) Dr. Niklason reiterated this ability to manufacture at commercial scale in Humacyte's February 2024 press release. (Id. ¶ 129.)

During the March 2024 earnings call, in response to a question about Humacyte's manufacturing readiness, Dr. Niklason stated:

So, yes, certainly, after the BLA file was accepted and we got our PDUFA date in August, the FDA moved rapidly to begin scheduling interim meetings and also our inspection, which is upcoming in the near future. As far as what we've been doing to prepare for this, we've actually run two mock inspections, one last summer and one just last month in February, where we brought consultants in to Humacyte who were all ex-FDA inspectors. And they really did a deep dive on two separate occasions, really helping us be as prepared as possible for this upcoming inspection. I would say that since we began preparing for this last summer, we've really been able to execute on all of the remediations that were picked out, certainly from 2023. And we're feeling very confident about how this inspection is going to go. We believe that the facility is in great shape. Our manufacturing processes are well characterized and well understood. Obviously, with the Center for Biologics, you're right, a big focus is always on manufacturing and the facility and the robustness of the process. But we believe we're in good shape.

(Id. ¶ 130.) In response to a question about Humacyte's work on additional HAV platforms, Dr. Niklason answered, "One of the beauties of the platform, and this was designed with intention, is that our LUNA manufacturing machines, each of which right now can make up to about 1,000 40-centimeter HAV[']s per year." (Id.) And in response to a question about potential margin improvements, Dr. Niklason stated, "Right now, we have built out only a fraction of our manufacturing floor because we have eight LUNA[']s installed, although we have room for 40." (Id.)

Next, in the 2023 Form 10-K, Humacyte discussed the ability to manufacture Symvess at commercial scale at the Durham facility, noting, "We believe our established, controlled manufacturing process demonstrates a significant competitive advantage in the

regenerative medicine market.” (Id. ¶ 131(a) (emphasis omitted).) Moreover, the 2023 Form 10-K described Humacyte’s modular approach to the manufacturing process, which allowed it “to produce HAVs in smaller batches for clinical trials and scale out to larger batches for commercial manufacturing.” (Id. ¶ 131(b) (emphasis omitted).) The 2023 Form 10-K touted the Durham facility’s then-current manufacturing capacity, stating, “We currently have eight LUNA200 systems installed, commissioned and qualified in our manufacturing facility, creating an annual gross HAV capacity of approximately 7,200 HAVs.” (Id. ¶ 131(d) (emphasis omitted).) According to Humacyte, “[u]sing our existing LUNA manufacturing equipment, we can generate 400 13cm HAVs per batch. Our modular manufacturing platform can be scaled without impacting the operating parameters that support the HAV growth process.” (Id. ¶ 131(f) (emphasis omitted).)

After the FDA’s inspection of the Durham facility and as previously noted, Humacyte issued its May 2024 earnings report, in which Dr. Niklason asserted, “[T]he FDA completed its Pre-Licensing Inspection of our manufacturing facilities in Durham, North Carolina as part of the BLA review process. We remain on track with our BLA review and commercial launch preparations and remain confident in the approvability of the HAV in vascular trauma.” (Id. ¶ 132 (emphasis omitted).) Dr. Niklason repeated this assurance during an earnings call the same day. (Id.

¶ 133(a).) During the earnings call, an analyst asked Dr. Niklason, “[C]an you talk about the facility inspection with FDA? Any observations? Anything that you guys had to correct? How clean was that? And just help us know that we’re kind of checking those boxes before PDUFA.” (Id. ¶ 133(b) (alteration in original).) She responded,

[W]e completed our pre-license inspection of our manufacturing facility and had a very successful outcome. And based on the outcome of inspection and all of the other FDA interactions as a whole, we remain very confident in approval of the HAV in vascular trauma. And we won’t necessarily comment on any single interaction or the details, but we do feel very confident. And it was a very successful interaction that we have with the FDA, and we feel like it concluded very successfully.

(Id. (alteration in original).) And in response to a question about manufacturing capacity and steps required to reach commercial scale, COO Prichard said,

[A]s our manufacturing capacity stands now, as you know, at about 8,000 HAVs growth per year. And as far as scaling that out with the LUNA system that we have that manufactures our product, that is just a case of putting in more LUNA lines. Our facility is already ready in a shelled out space that’s already plumbed for electrical and gases and utilities for us to add additional units LUNAs up to about 40,000 HAVs per year annual gross yield.

So we’re prepared, and we’re prepared for a launch to be able to produce enough vessels in the first few years. And then we’re also prepared and have begun planning for that expansion within the space. So as demand grows, we can produce enough HAVs for the market.

(Id. ¶ 133(c) (alteration in original).) Finally, in response to

a question about FDA interactions, Dr. Niklason said,

[A]s we mentioned, we've already completed the inspection of our facility. So things are tracking along exactly as we would have expected, given the timelines for a Priority Review. So again, we see no reason that the PDUFA date will shift. Of course, what - exactly what the FDA does is always out of our control, but we have no indication that we're not on track. Everything just seems to be progressing along as we would have expected.

(Id. ¶ 133(d) (alteration in original).)

On June 17, 2024, Humacyte issued a press release stating, "The company's manufacturing facilities are capable of producing ATEVs at commercial scale to meet the potential needs of thousands of patients." (Id. ¶ 134 (emphasis omitted).) Then, in the press release announcing the delayed BLA approval on August 9, 2024, Dr. Niklason stated,

During the course of the BLA review, the FDA has conducted inspections of our manufacturing facilities and clinical sites and has actively engaged with us in multiple discussions regarding our BLA filing, including post-marketing and labeling discussions. Based on these interactions, we are confident in the approvability of the ATEV in treating vascular trauma.

(Id. ¶ 135.) She essentially repeated this same statement in both the August 13, 2024 earnings release and earnings call. (Id. ¶ 136(a)-(b).) Moreover, in response to a question about the FDA's inspection and follow-ups, Dr. Niklason stated,

So we had a total of five inspections. I would say all of those inspections went very well. In terms of follow-up items, there are - there's a small number of standard follow-up items on assays and CMC having to do with validation of certain methods. But these are sort of

standard things that we've worked out with the [FDA].

Some of those were completed pre-PDUFA. Some of those were slated for post-PDUFA. For example, one study is shipping the product during winter, and we couldn't do that until winter, so we agreed to do that in winter. So but these are sort of standard, I don't want to say cookie cutter, but these are standard validation and test procedures that we do not believe are impacting the timing of the file.

(Id. ¶ 136(b).)

3. Liquidity fraud

According to Plaintiffs, Humacyte's liquidity posed a serious concern to investors and analysts. (Id. ¶ 138.) These investors and analysts therefore closely tracked Humacyte's cash and cash equivalents. (Id.) Humacyte's Form 10-Ks defined cash equivalents as "all short-term, highly liquid investments, including certificates of deposit ('CDs') purchased with an original maturity of three months or less at the date of purchase." (Id.) Humacyte also received funding through an agreement with Oberland Capital Management LLC, which provided discrete tranches of funding "dependent on the satisfaction of the conditions and receipt of funds from the previous tranche." (See Doc. 41-1 at 320.) Plaintiffs allege that several of Defendants' statements and filings related to whether Humacyte had sufficient cash and cash equivalents to fund its operations constitute material misrepresentations or omissions. (Doc. 37 ¶ 138.)

In both the August 2023 earnings release and earnings call,

Humacyte and CFO Sander stated, "We believe our cash and cash equivalents and planned funding from the Oberland funding agreement are adequate to fund operations past the anticipated timelines for approval and commercialization of the HAV in vascular trauma." (Id. ¶ 139(a)-(b) (emphasis omitted).) And in response to a question about Humacyte's cash burn, CFO Sander noted,

I would not expect more than \$40 million burn for the remainder of the year. And we've given a sense that the Oberland transaction, combined with how we expect to operate, and also the cash on hand we expect takes us well past the approval and commercialization in vascular trauma. But from a calendar point of view, that means going to the end of 2025 at a minimum in terms of how we expect to operate.

(Id. ¶ 139(b).) Humacyte also filed a Form 10-Q with the SEC in August 2023, which stated multiple times with slight variation:

As of June 30, 2023, the Company had cash and cash equivalents of \$114.6 million. The Company believes its cash and cash equivalents will be sufficient to fund operations, including clinical trial expenses and capital expenditure requirements, for at least 12 months from the issuance date of these interim financial statements.

(Id. ¶ 139(c) (emphasis omitted).)

In November 2023, Humacyte again referenced the Oberland funding agreement in its earnings release and earnings call, stating a belief that its "cash and cash equivalents and expected funding from the Oberland arrangement are adequate to finance operations past the currently anticipated timelines for potential FDA approval and commercialization of the HAV in the vascular

trauma indication.” (Id. ¶ 140(a)-(b) (emphasis omitted).) In the 12-month projection contained within its November 2023 Form 10-Q, however, Humacyte omitted reference to the Oberland funding agreement and expressed a belief that “its cash and cash equivalents on hand will be sufficient to fund operations, including clinical trial expenses and capital expenditure, for at least 12 months.” (Id. ¶ 140(c) (emphasis omitted).)

In March 2024, Humacyte issued an earnings release that stated:

Humacyte believes that its cash and cash equivalents, including net proceeds from the March offering and additional draw under the Oberland funding arrangement, will be adequate to finance operations for at least 12 months from the date of this financial report, well past the currently anticipated timelines for FDA approval of commercialization of the HAV in the vascular trauma indication.

(Id. ¶ 141(a) (emphasis omitted).) The same day, on an earnings call, CFO Sander said, “We believe that our cash and cash equivalents are adequate to finance operations past the currently anticipated timelines for FDA approval and commercialization of the HAV in the vascular trauma indication.” (Id. ¶ 141(b) (emphasis omitted).) And in response to a question about Humacyte’s cash burn, CFO Sander answered,

The way we look at it is we ended December 31 with a little more than - well, right around \$81 million in cash. And when we add on the \$63-plus million that we achieved through the equity financing as well as the additional draw into our Oberland facility. That means we’re entering the year with about \$144 million in cash,

which leaves us very well positioned. Our net cash burn for 2023 rounded to about \$69 million. But if you back out the effect of some net financing transactions from an operating cash point of view and from a capital expenditure point of view, we've burned about \$73.5 million in 2023 in those activities. So suggesting we're very well positioned with the cash that we have on hand right now.

In terms of how we'll proceed in the upcoming year, we haven't given super specific guidance, but I'll share what we've guided in the past is that certainly, we expect to expand our commercialization activities during the year, including near the time of launch, bringing on a relatively small sales force to address this very concentrated market. So we will have, obviously, higher commercialization expenses during this year. But we do also have a wind down of certain clinical costs during the year with the V005 study just in long-term follow-up and not as intensive activities as we had during 2023 as we prepared for the close out of that study and for filing of the BLA. And then also our dialysis trial [V017] will be winding down in the second half of the year, too. So we expect somewhat of an increase in overall cash burn for the upcoming year, but not to a great extent on a net basis. And we believe that the cash on hand is certainly adequate to take us well past the commercial launches in trauma and AV access and well pas[t] or certainly through 2026. So we certainly don't have any cash concerns at this point in time.

(Id. ¶ 141(b).) And finally, in the 2023 Form 10-K filed on March 28, 2024, Humacyte noted its belief that the "cash and cash equivalents will be sufficient to fund [Humacyte's] operations, including clinical trial expenses and capital expenditure requirements, for at least 12 months from the date of this Annual Report on Form 10-K." (Id. ¶ 141(c) (emphasis omitted).) Thus, in March 2024, Humacyte never mentioned any reliance on the Oberland funding agreement.

In May 2024, Humacyte's earnings release and earnings call again omitted reference to the Oberland funding agreement in asserting Humacyte's belief that its cash and cash equivalents would adequately finance the next 12 months of operations, "well past the currently anticipated timelines for FDA approval of commercialization of the HAV in the vascular trauma indication." (Id. ¶ 142(a)-(b) (emphasis omitted).) Similarly, the May 2024 Form 10-Q made no mention of Humacyte's reliance on the Oberland funding agreement to fund the next 12 months of operations. (Id. ¶ 142(c).)

B. Humacyte's Public Offerings and the Post-Approval Articles

After the markets closed on February 29, 2024, Humacyte published two press releases announcing an underwritten public offering for 13.4 million shares of Humacyte common stock at the price of \$3.00 per share. (Id. ¶ 145(a)-(b).) This price represented a 31 percent discount from the February 29 closing market price of \$4.35 per share. (Id. ¶ 145(b).) On this news, Humacyte's stock price dropped from \$4.35 to \$3.24 per share, a decline of 25.52%, on high trading volume. (Id. ¶ 146.)

Next, four days after announcing the delay in BLA approval, on August 13, 2024, Humacyte filed a Form 10-Q with the SEC revealing a believed inability to fund operations for the next 12 months:

As of June 30, 2024, we had cash and cash equivalents of \$93.6 million. The extension of time required by the FDA to review our vascular trauma BLA, and the delay in potential approval, has delayed, among other items, our ability to draw an additional \$40.0 million in [Oberland funding agreement] proceeds. Accordingly, we do not believe our available cash and cash equivalents on hand will be sufficient to fund operations, including clinical trial expenses and capital expenditure requirements, for at least one year from the date of this Quarterly Report without achieving approval of the ATEV for vascular trauma and generating sufficient cash flows from commercial sales on a timely basis and/or obtaining additional capital.

(Id. ¶ 150; see Doc. 43-1 at 62.) For the first time, this Form 10-Q also included a going concern warning: "These factors raise substantial doubt about the Company's ability to continue as a going concern. Accordingly, the Company will, over the course of the next year, require additional financing to continue its operations." (Doc. 37 ¶ 150 (emphasis omitted); see Doc. 43-1 at 62.) Humacyte's stock price dropped from \$6.65 to \$6.01 per share, a decline of 9.62%, on high trading volume. (Doc. 37 ¶ 151.)

On September 24, 2024, after the markets closed, Humacyte announced two new agreements with Lincoln Park Capital Fund, LLC, granting Humacyte the right "to sell to Lincoln Park shares of the Company's common stock . . . having an aggregate value of up to \$50,000,000" at a discount. (Id. ¶ 152 (emphasis omitted).) Once again, Humacyte's stock price dropped - this time from \$6.12 to \$5.46 per share, a decline of 10.87%, on high trading volume. (Id. ¶ 153.)

During market hours on October 17, 2024, the FDA released the Form 483 from its April 2024 inspection of the Durham facility. As previously noted, the Form 483 included two observations: (1) a lack of “microbial quality assurance”; and (2) insufficient quality oversight for four distinct issues. (Id. ¶ 154 (emphasis omitted).) On this news, Humacyte’s stock price dropped from \$5.81 to \$4.86 per share, a decline of 16.35%, on high trading volume. (Id. ¶ 155.)

Before the markets opened on November 14, 2024, Humacyte disclosed another offering of stock via a securities purchase agreement. (Id. ¶ 156.) The press release indicated a \$15 million registered direct offering of Humacyte stock via an agreement to sell 2,808,988 shares of common stock in addition to warrants to purchase up to 2,808,988 shares of common stock. (Id.) Humacyte also filed a prospectus supplement, which stated that Humacyte “intend[ed] to use the net proceeds from this offering to fund the development of the product candidates in our pipeline, the planned commercial launch of the ATEV in the vascular trauma indication, if approved, and for working capital and general corporate purposes.” (Id. (alteration in original).) The same day, Humacyte’s stock price dropped from \$5.34 to \$4.84 per share, a decline of 9.36%, on high trading volume. (Id. ¶ 157.)

After the markets closed on March 24, 2025, the New York Times published an article describing disagreements between Humacyte and

the FDA regarding trial participants who did not reach the 30-day endpoint, either because of death, limb amputation, or simple failure to follow up. (Id. ¶ 158(a).) These disagreements, according to the article, ultimately resulted in a significant overcount of successes in Humacyte's public disclosures. (Id.) Moreover, one FDA reviewer pointed out that 37 of the 54 extremity patients were not assessed in a safety check four months after treatment, with many either dead or lost to follow-up. (Id.) The New York Times article also noted the strong opposition to Symvess approval registered by another FDA reviewer, Dr. Robert E. Lee. (Id. ¶ 158(b).) Dr. Lee, a vascular surgeon, apparently resigned from his FDA position in protest over the FDA's decision to approve Humacyte's BLA. (Id.) And in his review of the BLA, Dr. Lee made note of Symvess's "unacceptable risk for whatever slim benefit, if any, th[e] product provide[d] above the current standard treatments," given the risk of "unpredictable, catastrophic, and life-threatening" rupture. (Id. (emphasis omitted).)

The New York Times article further discussed the FDA's conclusion that the V005 study demonstrated a 67 percent success rate, rather than Humacyte's reported 84 percent rate - and significantly lower than the 82 percent success rate of existing synthetic grafts. (Id. ¶ 158(d).) Moreover, the article quoted the FDA's Statistical Review Memorandum to note that, according to the memorandum's preparer, neither the V005 nor the V017 trial

“met the usual criteria for an adequate and well-controlled trial.” (Id. ¶ 158(e) (emphasis omitted).) Finally, the article quoted the director of the Amy J. Reed Medical Device Safety Collaborative at Northwestern School of Law, who noted, “If the graft falls apart, . . . it is basically akin to the patient getting shot.” (Id. ¶ 158(f) (emphasis omitted).)

One day later, during the market hours on March 25, 2025, Bloomberg published an article online in which Dr. Lee described “pressure [on the FDA reviewers] to get the device approved ‘one way or another,’” presumably in part because Symvess “was highly sought after by military officials.” (Id. ¶ 159(a) (emphasis omitted).) The Bloomberg article further quoted Dr. Lee, who said, “This thing [the HAV] has grave safety concerns and they buried it.” (Id. ¶ 159(b) (alteration in original) (emphasis omitted).) He expressed concern over Symvess’s “potential to kill soldiers and citizens.” (Id. (emphasis omitted).) Moreover, the Bloomberg article detailed a three-year back-and-forth between the FDA and Humacyte, during which “Humacyte repeatedly asked to change aspects of the study, varying from the type and number of patients it was studying to how success was measured, all while the trial was ongoing.” (Id. ¶ 159(c) (emphasis omitted).) Finally, the Bloomberg article reported additional concerns from one FDA reviewer who claimed that the V005 and V017 trial results could not be combined because the V017 patients had less severe injuries,

while Dr. Lee continued to warn of unacceptable risks and three outside experts noted that Symvess “did not demonstrate superiority to existing treatment options.” (Id. ¶ 159(d)-(e) (emphasis omitted).) From March 24 to March 25, 2025, Humacyte’s stock price dropped from \$3.32 to \$2.88 per share, a decline of 13.40%, on high trading volume. (Id. ¶ 160.)

After the markets closed on March 25, 2025, Humacyte published a press release announcing an underwritten public offering of common stock, with an option for a 30-day period to purchase up to an additional 15 percent of the number of shares sold in the offering. (Id. ¶ 161(a).) And later that night, Humacyte published a second press release announcing that this underwritten public offering would be for 25 million shares at a price of \$2.00 per share - a discount of more than 30 percent from the March 25, 2025 closing market price of \$2.88 per share. (Id. ¶ 161(b).) On this news, Humacyte’s stock price dropped from \$2.88 to \$2.00 per share, a decline of 30.43%, on extremely high trading volume. (Id. ¶ 162.)

C. Additional Facts Related to Scienter

Plaintiffs allege additional facts to demonstrate that Defendants knew, or at least recklessly disregarded, that their public statements and omissions were materially false or misleading.

First, in a March 27, 2025 press release issued in response

to the New York Times article, Dr. Niklason stated that the FDA had informed Humacyte before the PDUFA date that it was considering “convening an Advisory Committee of outside experts.” (Id. ¶ 165.) Humacyte “did not object to this.” (Id. (emphasis omitted).) Plaintiffs allege that this admission establishes Humacyte’s advance knowledge of the reason for the FDA’s delay. (Id.) The press release also described discussions between the FDA and Humacyte in the period between the PDUFA date and the eventual BLA approval:

It took time to complete the internal discussions at the FDA regarding Dr. Lee’s objections, and to compile responses from outside experts. Although our original PDUFA date was August 10, 2024, the FDA took an additional 19 weeks to complete its review of the risks and benefits of Symvess. After taking all views into account, the FDA agreed that our product was safe and effective for use in repair of vascular trauma of the extremities in situations where there is an urgent need for revascularization and where autologous vein grafting is not feasible. The agency issued its approval of Symvess on December 19, 2024.

The FDA’s review process was conservative and time consuming, but that’s how it should work. We all want federal agencies to take their responsibilities seriously, and I appreciate that the FDA took the time it needed to evaluate our product. Furthermore, as part of the FDA’s review of Symvess, we are committed to conducting a post-approval study to continue to assess the rate and severity of adverse events in trauma patients treated with Symvess.

(Id. ¶ 166.)

Next, Plaintiffs allege that the FDA made Defendants aware of several issues that could delay BLA approval or lead to a

substantially narrower indication no later than the Late Cycle Meeting on May 20, 2024. (Id. ¶¶ 167-70.) According to Plaintiffs, now-released FDA documents demonstrate that the FDA expressed concerns and made recommendations for Humacyte's clinical trials, and the two sides engaged in repeated discussions regarding Symvess's development. (Id. ¶¶ 173-74.) Moreover, via confidential witnesses who worked as Humacyte employees during the class period, Plaintiffs allege that COO Prichard and Dr. Niklason had personal knowledge of ongoing manufacturing and quality issues, critical equipment failures, and Humacyte's non-compliance with current good manufacturing practices. (Id. ¶¶ 179-84.)

To provide evidence of motive and opportunity, Plaintiffs also point to the individual Defendants' insider transactions during the class period. (Id. ¶ 185.) Dr. Niklason transferred almost all her directly held Humacyte stock to the Niklason Living Trust, a non-reporting entity, in April 2024. (Id. ¶ 186.) She also sold most of the shares held by the LLC co-owned by her and her husband during the class period, netting \$38,804,277.82 - 29.81% more than her net proceeds during the preceding 17.5 months. (Id. ¶ 187(a).) These proceeds were 33.5 times greater than her total 2023 and 2024 compensation. (Id.)

COO Prichard, meanwhile, "completely sold out of her Humacyte position" on May 31, 2024, less than two weeks after the Late Cycle Meeting. (Id. ¶ 186.) She netted \$1,212,061.31, whereas her

transactions during the 17.5 months preceding the class period resulted in a net loss. (Id. ¶ 187(b).) These proceeds were more than 2.5 times her salary and almost double her total compensation in 2023 and 2024. (Id.) CFO Sander also netted \$162,282.68 through a single transaction on Humacyte stock during the class period, in comparison to his purchasing 2,000 shares at a cost of \$9,060 during the preceding 17.5 months. (Id. ¶ 187(c).)

Finally, Plaintiffs allege scienter through Humacyte's repeated raising of funds at artificially inflated prices during the class period. (Id. ¶¶ 188-89.) They point to the fact that the alleged fraud implicated Humacyte's core operations, suggesting knowledge on the part of the individual Defendants and other Humacyte executives. (Id. ¶¶ 190-92.) Plaintiffs also allege the individual Defendants' roles in preparing the false and misleading SOX-certified SEC filings, the individual Defendants' violations of Humacyte's internal Code of Conduct regarding insider trading, and the departure of high-level Humacyte directors as well as the chief quality officer. (Id. ¶¶ 193-200.)

D. Procedural History

Plaintiff Foote filed a motion seeking appointment as lead plaintiff pursuant to the PSLRA by members of the putative class. (Doc. 11.) Plaintiffs Cognetti and Hopwood then filed a motion seeking appointment as co-lead plaintiffs. (Doc. 14.) They all later stipulated to serve as co-lead plaintiffs (Doc. 17 at 4-5),

and the court granted their joint stipulation and thereby appointed Plaintiffs as co-lead plaintiffs (Doc. 21 at 7). Plaintiffs then filed a complaint alleging violations of Section 10(b) of the Exchange Act against all Defendants and violations of Section 20(a) of the Exchange Act against the individual Defendants. (Doc. 37.)

In their complaint, Plaintiffs allege Defendants made false and misleading statements regarding three general areas of Humacyte's operations: the safety and efficacy of Symvess; the manufacturing capabilities of the Durham facility; and the liquidity of Humacyte based on cash and cash equivalents. Defendants moved to dismiss the complaint, contending that Plaintiffs have failed to allege material false or misleading statements or allege sufficient facts to give rise to a strong inference of scienter under the PSLRA's heightened pleading standards. (Docs. 40, 41.) Plaintiffs responded in opposition (Doc. 42), and Defendants replied (Doc. 43). The court held a hearing on March 17, 2026, and the motion is now ready for decision.⁴

II. ANALYSIS

A. Standard of Review

Pursuant to Rule 8 of the Federal Rules of Civil Procedure,

⁴ Two related and consolidated cases, Silva v. Sebelius, Civil Docket No. 1:25-cv-00005, and Misko v. Niklason, Civil Docket No. 1:25-cv-00028, have been stayed pending the court's issuance of a final decision and order on Humacyte's motion to dismiss.

a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The purpose of a 12(b)(6) motion to dismiss is to "test[] the sufficiency of a complaint" and not to "resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." Republican Party of N.C. v. Martin, 980 F.2d 943, 952 (4th Cir. 1992). In considering a Rule 12(b)(6) motion, a court "must accept as true all of the factual allegations contained in the complaint," Erickson v. Pardus, 551 U.S. 89, 94 (2007) (per curiam), and all reasonable inferences must be drawn in the non-movant's favor, Ibarra v. United States, 120 F.3d 472, 474 (4th Cir. 1997). To be facially plausible, a claim must "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable" and must demonstrate "more than a sheer possibility that a defendant has acted unlawfully." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556-57 (2007)).

While these standards govern the consideration of a Rule 12(b)(6) motion generally, claims of securities fraud are subject to "strict pleading standards" pursuant to Federal Rule of Civil Procedure 9(b) and the PSLRA. Singer v. Reali, 883 F.3d 425, 439 (4th Cir. 2018). In addition to the requirement that "a party must state with particularity the circumstances constituting fraud" under Rule 9(b), the PSLRA "imposes additional pleading

requirements to prevent Securities Exchange Act claims from being 'employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law.'" Id. (first quoting Fed. R. Civ. P. 9(b); and then quoting Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 313 (2007)). In particular, the PSLRA establishes heightened pleading standards with respect to allegations of falsity and scienter. Zak v. Chelsea Therapeutics Int'l, Ltd., 780 F.3d 597, 606 (4th Cir. 2015). If a plaintiff alleges that a defendant made false or misleading statements, the PSLRA requires that the plaintiff "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, . . . state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). In addition, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." Id. § 78u-4(b)(2)(A). "If those exacting pleading requirements are not satisfied, the complaint must be dismissed." Singer, 883 F.3d at 439.

The court notes at the outset that Plaintiffs do not challenge the exhibits attached to either Defendants' brief in support of the motion to dismiss or Defendants' reply brief. (See Docs. 41-1, 43-1.) These unchallenged exhibits include documents expressly

relied on or referenced in the complaint. Accordingly, the court finds that the consideration of the documents is appropriate in this instance, where neither party challenges their authenticity and their content is incorporated by reference or otherwise integral to the complaint. See Plymouth Cnty. Ret. Ass'n v. Primo Water Corp., 966 F. Supp. 2d 525, 536-37 (M.D.N.C. 2013) (“[I]n a securities fraud case, the court may consider ‘public documents quoted by, relied upon, incorporated by reference or otherwise integral to the complaint.’” (quoting In re Royal Ahold N.V. Sec. & ERISA Litig., 351 F. Supp. 2d 334, 349 (D. Md. 2004))).

B. Section 10(b) Claims

In their complaint, Plaintiffs allege that Defendants made false and misleading statements about the safety profile and efficacy of Symvess, Humacyte’s manufacturing readiness, and Humacyte’s ability to fund its operations. Plaintiffs identify challenged statements that generally fall into three categories: (1) product safety fraud; (2) facility fraud; and (3) liquidity fraud. (Doc. 37 ¶¶ 4, 103-43.) Defendants contend that the complaint fails to allege falsity or establish a strong inference of scienter as required under the PSLRA’s heightened pleading standards. (Doc. 41 at 10-11.) Defendants further assert that several of the challenged statements are non-actionable opinions or forward-looking statements. (Id. at 11.)

Pursuant to Section 10(b) of the Exchange Act and Rule 10b-

5, it is unlawful for a company to make a false or misleading statement or omission in connection with the sale of a security. See 17 C.F.R. § 240.10b-5(b); 15 U.S.C. § 78j(b). A plaintiff bringing a claim under Section 10(b) must establish: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." City of Southfield Gen. Emps.' Ret. Sys. v. Advance Auto Parts, Inc., 167 F.4th 637, 646 (4th Cir. 2026) (quoting Stoneridge Inv. Partners, LLC v. Sci.-Atlanta, Inc., 552 U.S. 148, 157 (2008)). As noted above, claims of securities fraud are subject to heightened pleading standards with respect to falsity and scienter pursuant to Rule 9(b) and the PSLRA.

To establish an actionable false or misleading statement or omission, "the challenged statement or omission must be factual, i.e., one that is demonstrable as being true or false; it must be false, or the omission must render public statements misleading; and any statement or omission of fact must be material." Lerner v. Nw. Biotherapeutics, 273 F. Supp. 3d 573, 586 (D. Md. 2017) (citation modified); Longman v. Food Lion, Inc., 197 F.3d 675, 682 (4th Cir. 1999). As for materiality:

[T]here must be a "substantial likelihood that a reasonable purchaser or seller of a security (1) would consider the fact important in deciding whether to buy

or sell the security or (2) would have viewed the total mix of information made available to be significantly altered by disclosure of the fact.”

Emps.’ Ret. Sys. v. MacroGenics, Inc., 61 F.4th 369, 382 (4th Cir. 2023) (quoting U.S. SEC v. Pirate Inv. LLC, 580 F.3d 233, 240 (4th Cir. 2009)). “Although Rule 10b-5 ‘prohibit[s] any misrepresentation of a fact deemed material’ it does not ‘prohibit any misrepresentation - no matter how willful, objectionable, or flatly false - of immaterial facts, even if it induces reactions from investors that, in hindsight or otherwise, might make the misrepresentation appear material.’” Id. (alteration in original) (quoting Greenhouse v. MCG Cap. Corp., 392 F.3d 650, 656 (4th Cir. 2004)).

Though “section 10(b) and SEC Rule 10b-5 ‘do not create an affirmative duty to disclose any and all material information,’” the “disclosure of material information is required ‘when necessary to make statements made, in the light of the circumstances under which they were made, not misleading.’” Singer, 883 F.3d at 440 (quoting Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011)). Courts have recognized that “where the duty to disclose arises from a need to avoid false or misleading statements ‘the inquiries as to duty and materiality coalesce.’” In re Sanofi-Aventis Sec. Litig., 774 F. Supp. 2d 549, 564 (S.D.N.Y. 2011) (quoting In re Time Warner Inc. Sec. Litig., 9 F.3d 259, 267 (2d Cir. 1993)). “Ultimately, the inquiry

is whether, read as a whole, the statements or omissions would have misled a reasonable investor about the nature of the securities.” Emps.’ Ret. Sys., 61 F.4th at 382-83 (quoting Lerner, 273 F. Supp. 3d at 586-87).

“For scienter, the plaintiff must show that the defendant acted with ‘a mental state embracing intent to deceive, manipulate, or defraud.’” City of Southfield Gen. Emps.’ Ret. Sys., 167 F.4th at 646 (quoting Tellabs, 551 U.S. at 319). The Fourth Circuit has emphasized that “raising a ‘strong inference’ of scienter is no small burden.” Cozzarelli v. Inspire Pharms. Inc., 549 F.3d 618, 624 (4th Cir. 2008). If the plaintiff relies on reckless conduct to establish a strong inference of scienter, such conduct must either be “severe” or “so highly unreasonable and such an extreme departure from the standard of ordinary care as to present a danger of misleading the plaintiff to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it.” Lerner, 273 F. Supp. 3d at 594 (first quoting Ottmann v. Hanger Orthopedic Grp., Inc., 353 F.3d 338, 344 (4th Cir. 2003); and then quoting Matrix Cap. Mgmt. Fund, LP v. BearingPoint, Inc., 576 F.3d 172, 181 (4th Cir. 2009)).

Standing alone, allegations of motive and opportunity to raise capital to support ongoing business operations are generally insufficient to support a strong inference of scienter. Cozzarelli, 549 F.3d at 627 (“All investments carry risk,

particularly in a field like biopharmaceuticals. If we inferred scienter from every bullish statement by a pharmaceutical company that was trying to raise funds, we would choke off the lifeblood of innovation in medicine by fueling frivolous litigation - exactly what Congress sought to avoid by enacting the PSLRA.”). However, the deliberate misreporting of material information may give rise to a strong inference of scienter in certain cases. See U.S. SEC, 580 F.3d at 243 (holding that district court did not clearly err in finding plaintiffs established strong inference of scienter, where the court found individual defendant had actual knowledge that his statement was false at the time he made it as well as the “clear financial motive for the misrepresentations”); Medina v. Clovis Oncology, Inc., 215 F. Supp. 3d 1094, 1127 (D. Colo. 2017) (finding plaintiffs adequately alleged scienter where plaintiffs alleged that defendants had actual knowledge of the confirmed response rates of the ongoing clinical trials but continued to report the more favorable unconfirmed response rates to investors).

“In securities litigation cases premised upon a drug company’s partial non-disclosure of drug trials to the investing public, the key inquiry is whether the non-disclosure at issue results in a suspiciously incomplete data set that yields a strong inference of scienter.” In re Hum. Genome Scis. Inc. Sec. Litig., 933 F. Supp. 2d 751, 760 (D. Md. 2013) (collecting cases). As one

district court noted:

The key, of course, is the honest belief of the management in the truth of the information issued to the public. If the management knows that certain facts will necessarily prevent the regulatory approval or the marketing of the drug and conceals these facts from the investing public, then there is scienter. There is also scienter if the management is reckless in dealing with such adverse facts.

In re AstraZeneca Sec. Litig., 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008), judgment aff'd sub nom., State Univs. Ret. Sys. v. AstraZeneca PLC, 334 F. App'x 404 (2d Cir. 2009).

The court must undertake a comparative analysis of the scienter allegations and any opposing inferences that may be drawn from the facts. Zak, 780 F.3d at 606. "When weighing inferences, 'the court's job is not to scrutinize each allegation in isolation but to assess all the allegations holistically.'" City of Southfield Gen. Emps.' Ret. Sys., 167 F.4th at 646 (quoting Tellabs, 551 U.S. at 326). Ultimately, "a complaint will not be dismissed so long as 'the malicious inference is at least as compelling as any opposing innocent inference.'" Zak, 780 F.3d at 606 (quoting Yates v. Mun. Mortg. & Equity, LLC, 744 F.3d 874, 885 (4th Cir. 2014)).

1. Product safety fraud

a. Material false or misleading statements

Plaintiffs challenge Defendants' statements regarding Symvess's safety in six ways. (Doc. 37 ¶ 103.) According to

Plaintiffs, (1) Defendants “downplayed the risk of HAV rupture and anastomotic failure”; (2) Defendants “touted” Symvess’s positive 30-day results in part by counting even deceased patients without 30-day follow-ups as successes; (3) Defendants similarly “touted” the 30-day results “while downplaying the need for long-term data”; (4) Defendants falsely and misleadingly claimed that the literature review benchmarks were agreed to by the FDA, even though the benchmark data was “inapplicable”; (5) Defendants positively presented data from the V017 trial without disclosing the trial as retrospective and observational, which permitted researchers to “cherry-pick positive results”; and (6) Defendants “misled the market about” the reasons for the FDA’s delayed approval of the BLA. (Id.)

i. Symvess’s safety risks

Defendants contend that Plaintiffs fail to allege “any facts establishing that Defendants actually concealed any safety risks.” (Doc. 41 at 23.) Rather, Defendants assert, Humacyte reported the adverse events and risks from the V005 and V017 trials in the 2023 Form 10-K. (Id.) Further, Defendants argue that Humacyte disclosed the black-box warning “within hours of receiving FDA approval.” (Id.) Ultimately, Defendants contend that any challenged statement amounts to only a non-actionable disagreement over data interpretation. (Id. at 23-24.)

In the 2023 Form 10-K, Humacyte disclosed that only one

patient among the V005 trial's extremity group suffered an HAV rupture.⁵ (Doc. 41-1 at 197.) Based on this data, Humacyte maintained that only 2.0% of extremity group patients suffered a rupture. (Id.) But in the Clinical Review Memorandum, the FDA reviewer noted that four, or 7.4%, of V005 trial extremity group patients suffered an HAV rupture - either via mid-graft rupture or anastomotic failure. (Id. at 142; see Doc. 37 ¶ 83.) The reviewer also noted three ruptures among the trial's 17 torso/iatrogenic group patients. (Doc. 41-1 at 142.) The FDA therefore concluded that seven, or 9.9%, of V005 trial patients suffered a "loss of SYMVESS integrity" due to rupture. (Id. at 19, 142; see Doc. 37 ¶ 83.)

In addressing this discrepancy, Defendants characterize the differences between Humacyte's analysis and the FDA's analysis as "a reasonable difference in interpretation" of data. (Doc. 43 at 8.) Accordingly, Defendants rely heavily on Employees' Retirement System, where the Fourth Circuit held that the defendants had no duty to disclose a graph where they "accurately interpreted" and "orally communicated" the graph's data. Emps.' Ret. Sys., 61 F.4th at 385. The court further reasoned, "It would be a stretch for us to find the existence of false or misleading statements where 'a defendant's competing analysis or interpretation of data is itself

⁵ The 2023 Form 10-K does not appear to report adverse events for the V005 trial's torso/iatrogenic group. (See Doc. 41-1 at 197.)

reasonable.'" Id. (quoting Kleinman v. Elan Corp., plc, 706 F.3d 145, 154 (2d Cir. 2013)).

Here, as Plaintiffs correctly assert and unlike the challenged data interpretation in Employees' Retirement System, Defendants' challenged statements involve the reported V005 trial data itself.⁶ Specifically, in the 2023 Form 10-K, Humacyte reported only one rupture among the extremity group (Doc. 41-1 at 197), whereas the FDA reviewer concluded in the Clinical Review Memorandum that four patients from the extremity group lost "SYMVESS integrity" because of rupture, along with three patients in the torso/iatrogenic group (id. at 19, 142). The FDA reviewer did note that Humacyte had classified one rupture in the V005 trial's extremity group as a "vascular graft complication," but the two additional ruptures among the extremity group remain unexplained by Defendants. (Id. at 142; see Doc. 41 at 23-24.) Moreover, the FDA reviewer described Symvess's observed rate of rupture as "worrisome" and noted that benchmark literature "suggests" an incidence of rupture from zero to six percent "when using autologous vein or synthetic grafts." (Doc. 41-1 at 147,

⁶ Even if Defendants' challenged statements constituted an interpretation of data, the court would be disinclined to find Defendants' interpretation non-actionable at the pleading stage given the FDA's previous recommendations that uncertain or missing data from the while-on-treatment approach "should be handled conservatively." (Doc. 41-1 at 121.) As noted, "disclosure of material information is required 'when necessary to make statements made, in the light of the circumstances under which they were made, not misleading.'" Singer, 883 F.3d at 440 (quoting Matrixx Initiatives, 563 U.S. at 44).

161; see Doc. 37 ¶ 83.) Thus, given the FDA's revised data, Symvess did not represent a safer alternative to existing treatment methods, and the "serious risk of arterial bleeding from mid-graft rupture or anastomotic failure" warranted a black-box warning. (Doc. 41-1 at 19; see Doc. 37 ¶¶ 83(a), 125.)

ii. Clinical trials

Next, as to the clinical trials, Defendants contend that Plaintiffs' allegations "boil down to disagreements with how Humacyte designed and conducted clinical trials." (Doc. 41 at 24-25.) Further, Defendants argue that the 2023 Form 10-K disclosed the existence of clinical trial limitations that could result in a failure to establish the safety and efficacy of Symvess. (Id. at 25.) Defendants also point to the fact that the FDA ultimately approved Symvess based on the V005 and V017 trials while noting that the data "support the conclusion that ATEV can provide meaningful clinical benefit" with "substantial evidence of effectiveness." (Id. at 26; see Doc. 41-1 at 21, 161.)

In support, Defendants again rely on Employees' Retirement System, where the court noted that "[s]ecurities law is simply not a vehicle through which courts will police . . . the parameters of clinical trials." Emps.' Ret. Sys., 61 F.4th at 388 (quoting Zagami v. Cellceutix Corp., No. 15 Civ. 7194, 2016 WL 3199531, at *13 (S.D.N.Y. June 8, 2016)). Indeed, "[w]here a company accurately reports the results of a scientific study, it is under

no obligation to second-guess the methodology of that study.” Id. at 385 (quoting Lerner, 273 F. Supp. 3d at 587-88). Defendants also cite In re Novan, Inc., No. 17CR999, 2018 WL 6732990, at *10 (M.D.N.C. Nov. 30, 2018), where the court found that the defendant had no duty to disclose unfavorable FDA recommendations on its clinical trial design after the defendant affirmatively represented that its trial design was based on FDA feedback.

Plaintiffs, on the other hand, contend that Defendants had a duty to disclose details of the while-on-treatment approach to make the V005 and V017 trial data “not misleading.” (Doc. 42 at 29.) According to Plaintiffs, this duty was compounded by Dr. Niklason’s misleading assertion that the FDA had agreed to “the structure of the literature review and the meta-analysis” before the trials. (Id. at 29-30; Doc. 37 ¶ 104(b).) And finally, Plaintiffs argue that Defendants released incomplete information to conceal known weaknesses in Symvess’s safety and efficacy. (Doc. 42 at 30.)

Here, Defendants repeatedly disclosed data obtained via the while-on-treatment approach to favorably compare Symvess to synthetic grafts. (Doc. 37 ¶ 125(b) (collecting every instance of comparison).) Using this while-on-treatment approach, Defendants sometimes counted patients who died or had their limbs amputated as successes, so long as the independent adjudication committee determined Symvess did not cause the death or limb loss. (Doc. 41

at 14.) To be sure, the FDA did broadly agree to this while-on-treatment strategy. (Doc. 41-1 at 121.) But the FDA also recommended that when causality of the patient's death or amputation could not be determined, or when patency status was missing post-implant, such patients should be included as patency failures. (Id.) And as Plaintiffs rightly contend, the FDA ultimately conducted its own adjudication and concluded that Symvess's primary patency rate, secondary patency rate, and infection rate were all worse than the rates observed with synthetic grafts in the benchmark literature.⁷ (Id. at 44.) Given the fact that the real trial results were arguably contrary to Humacyte's disclosures, it is difficult at this stage to conclude that Humacyte "accurately reported the results of [the] scientific study." Cf. Emps.' Ret. Sys., 61 F.4th at 385 (quoting Lerner, 273 F. Supp. 3d at 587-88).

Further, the complaint and referenced FDA documents support the claim that Defendants received notice of the likelihood of the FDA's disagreement while misleadingly suggesting that the FDA had agreed to the clinical trials' parameters. For example, the BLA

⁷ After FDA adjudication, the primary patency rate for Symvess at Day 30 was 66.7%, while the primary patency rate for synthetic grafts was 82.4%. (Doc. 41-1 at 84.) The secondary patency rate for Symvess at Day 30 was 72.2%, while the secondary patency rate for synthetic grafts was 78.9%. (Id.) The limb salvage rate for Symvess at Day 30 was 75.9%. (Id.) The infection rate for Symvess at Day 30 was 3.7%, while the infection rate for synthetic grafts in civilian trauma was 2.5%. (Id. at 84-85.)

Clinical Review Memorandum indicates that the FDA had recommended to Humacyte that uncertain or missing data from the while-on-treatment approach “should be handled conservatively.” (Doc. 41-1 at 121; see Doc. 37 ¶¶ 95, 125(b).) Dr. Niklason, meanwhile, attested that the FDA had agreed to “the structure of the literature review and meta-analysis” before the V005 trial. (Doc. 37 ¶ 104(b).)

But unlike the defendant in Novan, Defendants here failed to disclose that the feedback received from the FDA in advance of the V005 and V017 trials “did not constitute an agreement that the FDA” had accepted the trials’ design. Cf. Novan, 2018 WL 6732990, at *11. Humacyte’s generic warnings in its 2023 Form 10-K that “the FDA may still determine that [the] trials do not adequately establish the safety and effectiveness of our products” and that “[d]ata obtained from preclinical and clinical studies are subject to varying interpretations, which may delay, limit, or prevent marketing approval” lack context and do not mitigate the otherwise misleading data reported. (Doc. 41-1 at 256); see Singer, 883 F.3d at 442 (holding general warnings in a Form 10-K insufficient to shield an otherwise misleading omission).

* * *

At bottom, as to the product safety fraud, Plaintiffs sufficiently allege that Defendants inaccurately reported the ruptures in the V005 trial. Moreover, because Defendants favorably

presented the results of the V005 and V017 trials in comparison to the benchmark literature review of synthetic grafts, Plaintiffs sufficiently allege a duty on the part of Defendants to disclose the limitations of the while-on-treatment approach. See Schueneman v. Arena Pharms., Inc., 840 F.3d 698, 705-06 (9th Cir. 2016) (“But ‘once defendants cho[ose] to tout’ positive information to the market, ‘they [are] bound to do so in a manner that wouldn’t mislead investors,’ including disclosing adverse information that cuts against the positive information.” (alterations in original) (quoting Berson v. Applied Signal Tech., Inc., 527 F.3d 982, 987 (9th Cir. 2008))).

These two allegations are enough to sustain Plaintiffs’ Section 10(b) claims, based on product safety fraud, that Defendants’ misstatements and omissions misled investors that Symvess represented a more effective and safer alternative to synthetic grafts. And because a reasonable investor would have considered these facts important in deciding whether to buy or sell Humacyte stock or would have found the total mix of information significantly altered by these facts, Defendants’ statements and omissions were material. Thus, the material misrepresentation element is satisfied.

b. Scierter

Plaintiffs must also satisfy the scierter element. And here, Defendants contend that Plaintiffs have failed to allege facts

establishing that concerns over Symvess's safety caused the delay in FDA approval. (Doc. 41 at 37.) Rather, Defendants assert that Plaintiffs seek to establish scienter through an impermissible chain of inferences. (Id.) Moreover, Defendants argue that Humacyte's repeated correspondence with both the FDA and the public during the class period regarding the trial limitations and safety risks "strengthens the competing inference of innocence." (Id. at 38 (quoting In re Triangle Cap. Corp. Sec. Litig., 988 F.3d 743, 755 (4th Cir. 2021)).)

Plaintiffs counter that Defendants focus narrowly on the role of product safety concerns in the delayed BLA approval but ignore the continual presentation of misleading trial data. (Doc. 42 at 45.) According to Plaintiffs, the complaint sufficiently alleges that the FDA expressed concerns over trial design, long-term follow up, trial benchmarks, trial modifications, and the black-box warning throughout the class period. (Id.) At minimum, Plaintiffs point to the Late Cycle Meeting on May 20, 2024, at which time Plaintiffs allege that the FDA made Defendants aware of serious concerns related to Symvess. (Id. at 45-46; see Doc. 37 ¶¶ 168-72.)

The complaint alleges that Humacyte had almost real-time awareness of adverse events - like ruptures - because the V005 trial protocol required investigators to notify the contract research organization within 24 hours, which then had to inform

Humacyte within one business day thereafter. (Doc. 37 ¶ 97.) It also alleges that the FDA raised concerns over the BLA throughout the class period. (Id. ¶¶ 98, 168, 170.) In fact, as previously noted, the Clinical Review Memorandum clearly indicates that the FDA recommended to Humacyte that uncertain or missing data from the while-on-treatment approach “should be handled conservatively.” (Doc. 41-1 at 121.) Humacyte, therefore, plausibly knew of the likelihood that the FDA would disagree with its data and reach a contrary conclusion regarding Symvess’s safety compared to synthetic grafts. And while the inference that Defendants may have known their reported data was inaccurate “does not alone satisfy the scienter requirement,” Maguire Fin., LP v. PowerSecure Int’l, Inc., 876 F.3d 541, 547 (4th Cir. 2017), the court must “assess all the allegations holistically,” City of Southfield Gen. Emps.’ Ret. Sys., 167 F.4th at 646 (quoting Tellabs, 551 U.S. at 326).

Plaintiffs also allege more generalized theories of scienter, focusing largely on Defendants’ trading activity. “Insider trading allegations will only support an inference of scienter ‘if the timing and amount of a defendant’s trading were unusual or suspicious.’” Yates, 744 F.3d at 890 (quoting Tchrs.’ Ret. Sys. v. Hunter, 477 F.3d 162, 184 (4th Cir. 2007)). “To determine whether an insider’s sales were ‘unusual in scope,’” the court considers “factors such as ‘the amount of profit made, the amount

of stock traded, the portion of stockholdings sold, or the number of insiders involved.’” Id. (quoting In re Suprema Specialties, Inc. Sec. Litig., 438 F.3d 256, 277 (3d Cir. 2006)). “When the sale of stock during the class period is not substantially out of line with the sale of stock during the control period, the inference of scienter is lessened.” KBC Asset Mgmt. NV v. DXC Tech. Co., 19 F.4th 601, 611 (4th Cir. 2021).

Here, Plaintiffs allege that Dr. Niklason netted around \$38.8 million from stock sales during the class period, and she transferred almost all her direct holdings to a non-reporting trust in the weeks before the May 2024 Late Cycle Meeting. (Doc. 37 ¶¶ 185-86.) In comparison to the preceding 17.5-month control period, these proceeds represented a 29.81% increase; they were also 33.5 times her total compensation in 2023 and 2024. (Id. ¶ 187(a).) And contrary to Defendants’ assertions, the inference created by Dr. Niklason’s \$38.8 million gain is only partially mitigated by her exercise of options worth \$182,000, the fact that her sales occurred through an LLC co-owned by her and her husband (who, Plaintiffs allege, serves as Chairman of Humacyte), and the fact that the transfer to a trust did not independently realize any income.⁸ Thus, Dr. Niklason’s stock transactions, in both

⁸ Defendants cite City of North Miami Beach Police Officers’ & Firefighters’ Retirement Plan v. National General Holdings Corp., 19-CV-10825, 2021 WL 212337, at *7 (S.D.N.Y. Jan. 21, 2021), for the proposition that the LLC’s sales do not establish Dr. Niklason’s scienter because her husband “solely controls the LLC.” (Doc. 41 at 41.) But

timing and amount, lend support to an inference of scienter.

As for COO Prichard, Plaintiffs allege that she netted approximately \$1.2 million from a single stock sale during the class period, where she fully sold her Humacyte position less than two weeks after the Late Cycle Meeting. (Id. ¶ 187(b).) On the other hand, in the 17.5 months preceding the class period, COO Prichard's stock transactions netted a loss of \$7,391.36. (Id.) Moreover, according to Plaintiffs, her net gains during the class period were 2.5 times her salary and almost double her total compensation from 2023 and 2024. (Id.) COO Prichard may have retained stock options in Humacyte despite her sell-off, as Defendants contend, but these retained stock options only partially mitigate the alleged insider transaction. Both the timing and amount of COO Prichard's sale therefore lend support to an inference of scienter.

while Plaintiffs here allege significant individual sales by COO Prichard and CFO Sander, the plaintiffs in City of North Miami Beach did not allege any individual defendant sold shares during the class period. City of N. Miami Beach, 2021 WL 212337, at *7. Moreover, Plaintiffs allege that Dr. Niklason and her husband co-own the LLC at issue here, whereas a defendant's "extended" family owned the relevant entity in City of North Miami Beach. Id.

Defendants also cite In re DraftKings, Inc. Securities Litigation, 650 F. Supp. 3d 120, 176 n.31 (S.D.N.Y. 2023), for the proposition that a transfer, unaccompanied by a sale, does not support an inference of scienter. But the court in DraftKings noted that the complaint did not allege any additional facts "to support the claim that an intra-family transfer, unaccompanied by a sale, would be indicative of scienter." DraftKings, 650 F. Supp. 3d at 176 n.31. Here, on the other hand, Dr. Niklason's transfer is only one of several suspicious insider transactions alleged by Plaintiffs. (See Doc. 37 ¶ 186.)

And as for CFO Sander, Plaintiffs allege that he made \$162,282.68 in net proceeds from a single stock transaction during the class period. (Id. ¶ 137(c).) During the prior 17.5 months, however, CFO Sander purchased 2,000 shares for a net cost of \$9,060. (Id.) Moreover, Plaintiffs allege that CFO Sander's proceeds from stock transactions during the class period were 32.2% of his salary and 23.5% of his total compensation in 2023 and 2024. (Id.) As Defendants persuasively point out, however, CFO Sander's one sale came after Humacyte's stock dropped because of the announced delay in BLA approval. (Doc. 43 at 24.) Nevertheless, the sale did occur shortly before Humacyte announced additional capital raises in late 2024, which substantially affected its share price. Accordingly, CFO Sander's insider transaction lends slight support to an inference of scienter.

Plaintiffs further allege an additional series of facts to support additional generalized inferences of scienter. Specifically, Plaintiffs allege that Humacyte's fundraising during the class period, the alleged fraud's implication of core operations, the quotations or SOX-certifications from the individual Defendants in various SEC filings, the purported violations of Humacyte's insider trading policy, and the departures of high-level Humacyte employees all combine to support Defendants' scienter. And while Defendants are correct that any one of these facts, by itself, would not suffice, a holistic

assessment of the complaint creates an inference of wrongdoing that is at least as likely as any opposing, innocent explanation. See Matrix Cap. Mgmt. Fund, 576 F.3d at 187-88 (“[A]llegations of scienter that would not independently create a strong inference of scienter might compl[e]ment each other to create an inference of sufficient strength to satisfy the PSLRA.”); cf. Yates, 744 F.3d at 89 (holding that the plaintiffs failed to meet their burden of pleading scienter under the PSLRA, where the facts indicated that the “more compelling . . . inference [was] that the [defendants] were, at most, negligent”). Accordingly, Defendants’ motion to dismiss Plaintiffs’ Section 10(b) claims based on alleged product safety fraud will be denied.

2. Facility fraud

a. Material false or misleading statements

Plaintiffs challenge Defendants’ statements regarding the Durham facility in three main ways, largely related to the FDA’s April 2024 facility inspection and resulting Form 483: (1) Defendants misled about the facility’s readiness to safely manufacture Symvess at commercial scale; (2) Defendants misled about the sufficiency of the facility’s quality assurance and oversight; and (3) Defendants misled about the outcome of the FDA’s inspection. (Doc. 37 ¶ 126.)

Defendants argue that their pre-inspection statements constitute non-actionable opinions and that fraud cannot be

established by hindsight due to a later-issued Form 483. (Doc. 41 at 28.) Moreover, Defendants contend that they had no independent obligation to disclose the Form 483, nor do the observations noted in the Form 483 contradict any of Defendants' statements. (Id. at 29-30.) Finally, Defendants assert that several of the challenged statements were forward-looking and protected by the PSLRA's safe harbor. (Id. at 31.)

Plaintiffs counter that Defendants' opinion statements are actionable because Defendants either lacked a reasonable basis for the opinions or omitted material facts necessary to prevent the opinions from misleading investors. (Doc. 42 at 34-35.) They argue that Defendants' post-inspection statements were, at minimum, misleading because Defendants had at least some indication after the Form 483 that they were not on track for BLA approval by the August 10, 2024 PDUFA date. (Id. at 34.) According to Plaintiffs, once Defendants chose to speak positively of the results of the FDA inspection, they had to disclose the Form 483's findings. (Id.) Moreover, Plaintiffs contend, the PSLRA's safe harbor does not apply because Defendants had actual knowledge of the statements' falsity and many of the challenged statements lacked meaningful cautionary language. (Id. at 35-36.) Finally, Plaintiffs point to several allegations in the complaint to argue they have sufficiently pled falsity on statements regarding Humacyte's ability to manufacture Symvess at commercial scale.

(Id. at 36.)

“Unlike statements of fact, statements of opinion do not ‘express[] certainty about a thing.’” Emps.’ Ret. Sys., 61 F.4th at 387 (alteration in original) (quoting Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 575 U.S. 175, 183 (2015)). “Opinions are only actionable under the securities laws if they are not honestly believed and lack a reasonable basis.” Id. (quoting City of Edinburgh Council v. Pfizer, Inc., 754 F.3d 159, 170 (3d Cir. 2014)).

First, Plaintiffs fault Defendants for several public statements related to their future ability to manufacture Symvess at commercial scale. (See Doc. 37 ¶ 137.) According to Plaintiffs, Humacyte’s lack of quality oversight and other known manufacturing issues made these statements false and misleading. (Id.) But Plaintiffs allege no facts to indicate that these issues would have prevented Humacyte from appropriately scaling its Symvess production, or that they delayed approval of the BLA. (See id. ¶¶ 127-31, 137.) At most, the facts alleged demonstrate that Defendants knew of manufacturing or oversight issues present in the months prior to the August 2024 PDUFA date while they continued to express confidence in a future ability to manufacture Symvess at scale.⁹ Indeed, Plaintiffs never contest the reality that

⁹ Several of Defendants’ statements regarding their future ability to produce Symvess at scale also constitute opinions, forward-looking

Humacyte seemingly does now produce Symvess at commercial scale from the same Durham facility.

Next, Plaintiffs challenge several of Defendants' pre-inspection statements. For example, Dr. Niklason stated that Humacyte "fe[lt] very confident about how this inspection [was] going to go" and "believe[d] the facility [was] in great shape." (Id. ¶ 130.) Yet, through confidential witnesses, Plaintiffs allege that Defendants knew of insufficient microbial quality assurance prior to the FDA inspection. (E.g., id. ¶ 41(c).) According to Plaintiffs, the employee responsible for microbial quality assurance left Humacyte before the April 2024 inspection, and Humacyte had not replaced her by the time of the inspection. (Id.) The Form 483 ultimately noted this lack of microbial quality assurance. (Id. ¶ 45.)

Even if Defendants knew of the issues described prior to the inspection, however, Plaintiffs have not specifically alleged that Defendants believed their readiness for inspection was false. In fact, the results of the FDA inspection militate against a finding that Defendants lacked a reasonable basis for their pre-inspection optimism, because the relevant FDA document suggests that the FDA

statements, or both. (See, e.g., Doc. 37 ¶ 129 (noting that Humacyte's existing facilities "are expected to have the capacity to provide thousands of vessels"); id. ¶ 131(e) ("[W]e believe [it] will enable us to manufacture our HAVs, if approved, in commercial quantities in compliance with [current good manufacturing practices]." (first and second alterations in original)).)

considered its Form 483 observations remediable without further FDA action. Specifically, the BLA approval letter indicated that the FDA classified the April 2024 inspection of the Durham facility as “Voluntary Action Indicated” (Doc. 41-1 at 14), which means that the FDA “determined that the facility can voluntarily correct its deficiencies and will not recommend any action” (Doc. 41 at 17 (quoting Inspection Classification Database, U.S. Food & Drug Admin. (Sep. 13, 2024), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-classification-database>)).

Plaintiffs also challenge several of Defendants’ post-inspection statements. For example, Dr. Niklason asserted, “We remain on track with our BLA review and commercial launch preparations,” while COO Prichard stated, “[W]e completed our pre-license inspection of our manufacturing facility and had a very successful outcome.” (Doc. 37 ¶ 133(a)-(b) (alteration in original).) Dr. Niklason also stated that the FDA “already completed the inspection of [Humacyte’s] facility,” that Humacyte saw “no reason that the PDUFA date will shift,” and that Humacyte “ha[d] no indication that [the BLA was] not on track.” (Id. ¶ 133(d).)

In defending the post-inspection statements, Defendants rely heavily on In re Genzyme Corp. Securities Litigation, 754 F.3d 31, 41 (1st Cir. 2014), where the court held that the defendants did

not fraudulently conceal a Form 483, even where the PDUFA date was ultimately delayed, in part because the Form 483 did not postpone the PDUFA date or "otherwise state that the . . . BLA had been compromised." The court further reasoned that the relevance of the Form 483 was not made clear until four months after its issuance, "given the advisory language that accompanies all Forms 483, to the effect that the circumstances noted therein are merely observational in nature, and do not represent the FDA's final word." Genzyme, 754 F.3d at 42.

Here, Plaintiffs have again failed to sufficiently allege that Defendants lacked a reasonable basis for the statements of opinion on the inspection or the BLA approval process. Moreover, the court is not persuaded that the failure to mention the Form 483 constitutes an actionable omission. As the court in Genzyme explained, a Form 483 contains advisory language and does not represent the FDA's final word. Plaintiffs also never allege that the Form 483 postponed the PDUFA date or otherwise indicated that Humacyte's BLA for Symvess had been compromised. In fact, the relevant FDA documents here directly contradict the notion that the delay in BLA approval related to observations in the Form 483 or to any other facility shortfall.

The FDA's BLA approval letter described the Durham facility as "sufficient and acceptable." (Doc. 41-1 at 13.) The BLA approval letter then noted that Humacyte had "adequately responded

to the [Form 483] observations” and “[a]ll inspectional issues were resolved.” (Id. at 14.) And even though the BLA approval letter provided no indication as to when Humacyte resolved the inspectional issues, the FDA’s BLA Review Addendum disclosed that the lack of a decision “on the PDUFA action date [was] due to further clarification needed for the clinical benefit/risk assessment.” (Id. at 28 (emphasis added).) Given this undisputed evidence, in addition to the FDA’s determination that Humacyte could voluntarily correct its deficiencies without further action, Defendants’ statements were not false or misleading even by their failure to mention the Form 483.

Moreover, Plaintiffs do not ever allege that Humacyte’s inability to resolve the specific “inspectional observations” noted in the Form 483 led to the delay in BLA approval. Rather, to connect the delay to the alleged facility fraud, Plaintiffs point to several facility-related allegations stemming from confidential witnesses who observed challenges at the Durham facility pertaining to quality control, manufacturing, and sterility testing in addition to poor maintenance tracking. But even assuming that the individual Defendants were personally aware of such challenges, it does not follow that they doubted Humacyte’s ability to produce Symvess at scale in accordance with FDA requirements by the PDUFA date. Again, the FDA’s April 2024 inspection resulted only in a “Voluntary Action Indicated”

classification, and the FDA's own BLA approval addendum attributed the delay to the need to further clarify "the clinical benefit/risk assessment." (Id. at 14, 28.) And while the complaint alleges Humacyte's "slow response" to the FDA's sterilization validation concerns, it contains no facts suggesting Humacyte's response to these concerns served as a prerequisite for BLA approval.¹⁰ (See Doc. 37 ¶¶ 64, 66(d), 169, 172.)

Finally, Defendants are correct that several of the challenged facility fraud statements are protected by the PSLRA's safe harbor as forward-looking statements. See 15 U.S.C. § 78u-5(c). A defendant cannot be liable for any forward-looking statement if:

- (1) the forward-looking statement is "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement";
- (2) the forward-looking statement is "immaterial"; or
- (3) the plaintiff fails to prove that the forward-looking statement was made by a person - or if the statement [is] a business entity's, was made or approved by an officer - "with actual knowledge by that person [or officer] that the statement was false or misleading."

TransEnterix Inv. Grp. v. TransEnterix, Inc., 272 F. Supp. 3d 740,

¹⁰ Plaintiffs also allege that Humacyte "wanted to address" apparently unrelated problems with sterility assurance identified in the Form 483 by November 13, 2024. (Doc. 37 ¶ 66(e).) But again, Plaintiffs never directly allege that Humacyte's problem with sterility assurance would have prevented BLA approval - especially where the Form 483 did not appear to mention any sterility issues, and the FDA classified the inspection as "Voluntary Action Indicated." (See Doc. 37 ¶ 45.)

757 (E.D.N.C. 2017) (second alteration in original) (quoting 15 U.S.C. § 78u-5(c)(1)). And as already noted, Plaintiffs have not sufficiently alleged that Defendants made forward-looking statements about Humacyte's manufacturing capabilities, the Durham facility's inspection readiness, or the BLA approval timeline with actual knowledge that these statements were false or misleading.

b. Scierter

However, even if Plaintiffs sufficiently alleged false or misleading statements regarding facility fraud, the allegations do not support the necessary "strong inference" of scierter. Confidential witnesses may have identified challenges related to Defendants' manufacture of Symvess, but presumably every biopharmaceutical company developing and scaling a new product faces some manufacturing difficulties. Allegations of deferred maintenance, low yield rates before the PDUFA date, and even the closeout of incomplete work orders do not provide sufficient evidence of Defendants' reckless disregard of the likelihood of misleading investors, especially where the alleged facts otherwise suggest that the FDA permitted Humacyte to voluntarily resolve the inspectional issues and the delay in FDA approval was unrelated. The same is true for the alleged sterilization concerns, which the court is asked to infer caused, at least in part, the delay of the BLA's approval. Seemingly, the court "should then 'infer from that inference that [defendants] acted with scierter.'" City of

Southfield Gen. Emps.' Ret. Sys., 167 F.4th at 648 (alteration in original) (quoting Maguire Fin., 876 F.3d at 547). But “[a] plaintiff may not stack inference upon inference to satisfy the PSLRA’s pleading standard,” and the “strong inference of scienter” must “be supported by facts, not other inferences.” Maguire Fin., 876 F.3d at 547. Plaintiffs’ generalized theories of scienter also do not sufficiently move the needle as to the facility fraud claims.

Ultimately, the more likely inference is that Defendants reasonably and correctly believed they could resolve any manufacturing challenges - including those identified in the Form 483 - prior to the PDUFA date, or that the identified issues would not prevent BLA approval. Indeed, after the announcement of the BLA approval delay, Dr. Niklason said as much when she explained that certain post-inspection follow-ups had always been “slated for post-PDUFA” and were not believed to have impacted the timing of approval. (Doc. 37 ¶ 136(b).) Thus, as to facility fraud, the court finds that Plaintiffs’ allegations are not as cogent or compelling as the competing, innocent inference. Defendants’ motion to dismiss Plaintiffs’ Section 10(b) claims related to facility fraud will therefore be granted.

3. Liquidity fraud

a. Material false or misleading statements

Plaintiffs challenge several of Defendants’ statements about

whether Humacyte had sufficient cash and cash equivalents to fund its operations. (Doc. 37 ¶ 138.) Defendants argue that they adequately disclosed Humacyte's reliance on the Oberland funding agreement and that the act of raising funds at various points throughout 2024 and 2025 does not mean that any liquidity projections were false. (Doc. 41 at 34-35.) Further, Defendants contend that the liquidity statements are non-actionable both as opinions and forward-looking statements. (Id. at 35.)

Plaintiffs counter that the challenged liquidity projections generally failed to disclose any reliance on the Oberland funding agreement. (Doc. 42 at 36-37.) Further, Plaintiffs assert that the statements were at least misleading and lacked a reasonable basis when made by Defendants, especially considering how quickly and frequently Humacyte raised capital at discounted prices after the announced delay of BLA approval. (Id. at 37-38.) Finally, Plaintiffs contend that confidential witness statements regarding Humacyte's "cost-cutting measures" support an inference that Humacyte raised capital not because of "prudent" fiscal management but rather because of realized funding shortfalls. (Id. at 38.)

As both parties acknowledge, the relevant liquidity statements fall largely into one of two buckets: either (1) Humacyte had enough money to fund operations past the anticipated timeline for FDA approval and commercialization of Symvess based on cash, cash equivalents, and the Oberland funding agreement; or

(2) Humacyte had enough money to fund operations for the next relevant 12-month period based solely on cash and cash equivalents. (Doc. 42 at 37; Doc. 43 at 17-18.) Defendants correctly point out that these two timelines are distinct, and it is plainly logical that the Oberland funding agreement would be necessary to support the longer timeline of Symvess's anticipated commercialization but not necessary for any individual 12-month period identified in a quarterly financial statement. (Doc. 43 at 17-18.) Moreover, Defendants are correct that the liquidity statements, as statements of opinion, are not actionable unless the statements were not honestly believed or lacked a reasonable basis when made. See In re Lehman Bros. Sec. & ERISA Litig., 799 F. Supp. 2d 258, 298 (S.D.N.Y. 2011) ("[T]he statements that [the defendant's] liquidity pool was sufficient to meet its expected needs over the next twelve months . . . were statements of opinion.").

Plaintiffs have failed to sufficiently allege facts supporting the argument that the challenged liquidity statements are actionable. True, Defendants represented a belief in May 2024 that their cash and cash equivalents would adequately fund operations for the next 12 months (that is, until May 2025) - "well past the currently anticipated timelines for FDA approval [and] commercialization of the HAV in the vascular trauma indication." (Doc. 37 ¶ 141(a) (emphasis added).) But the anticipated timelines for FDA approval and commercialization shifted when the FDA

indicated it would not provide a decision by the PDUFA date. (Id. ¶ 7.)

The fact that Humacyte's August 2024 Form 10-Q - issued after the announced delay - included a going concern warning does not contradict Humacyte's previous statement that it believed its cash and cash equivalents would last until May 2025, let alone demonstrate that Humacyte lacked a reasonable basis for its positive liquidity projection at the time it was shared. Indeed, Humacyte's August 2024 admission that it "d[id] not believe [its] available cash and cash equivalents on hand w[ould] be sufficient to fund operations . . . for at least one year from the date of this Quarterly Report," unless Humacyte obtained timely FDA approval and/or additional capital, represented a new 12-month period three months beyond Humacyte's May 2024 projection. (See Doc. 43-1 at 62.) As Defendants persuasively argue, Humacyte presumably based this sudden pessimism on new facts and a delayed ability to generate revenue, given that Humacyte would be forced to operate at a net loss for longer than anticipated.

Plaintiffs further contend that the temporal proximity between the announced delay of BLA approval and Humacyte's three subsequent capital raises supports an inference that Defendants lacked a reasonable basis to believe that cash and cash equivalents would fund operations until May 2025. (Doc. 42 at 37; see Doc. 37 ¶ 143(c)-(d).) Similarly, Plaintiffs point to allegations from

confidential witnesses that cash shortfalls prevented the resolution of various maintenance issues while Humacyte leadership emphasized a need to cut back on spending during a company-wide meeting in late 2023. (Id. at 38; see Doc. 37 ¶ 143(e).) But as Defendants rightly contend, “it is only prudent for companies to curb spending or raise capital well before they run out of cash.” (Doc. 43 at 17.) In fact, it would seem to impose an untenable burden on medical innovation to find evidence of securities fraud where a company shared positive 12-month liquidity projections but then raised capital or cutback spending within that 12-month window.¹¹

b. Scierter

Even assuming Plaintiffs sufficiently alleged that the challenged liquidity statements were false or misleading because of Humacyte’s decision to raise capital during the subsequent 12-month periods, Plaintiffs have not provided a strong inference of scierter. In fact, Humacyte’s almost immediate disclosure following the BLA approval delay that it “d[id] not believe [its] available cash and cash equivalents on hand w[ould] be sufficient to fund operations . . . for at least one year from the date” of the August 2024 Form 10-Q more strongly supports Defendants’

¹¹ This reality likewise forecloses the finding of actionable misstatements based on Humacyte’s August and November 2023 Form 10-Qs, which expressed a belief that Humacyte’s cash and cash equivalents would fund operations for the next 12-month periods, where Humacyte then offered discounted shares in February 2024. (See Doc. 37 ¶ 143(a).)

transparency rather than a fraudulent attempt to mislead. And similar to the facility fraud claims, Plaintiffs' generalized scienter allegations do not sufficiently alter the balance of inferences as to the liquidity fraud claims. Accordingly, the facts, when evaluated holistically and viewed in the light most favorable to Plaintiffs, are more consistent with Defendants having a good faith belief in their 12-month liquidity projections - before reacting to indefinitely delayed BLA approval by raising capital - rather than acting with dishonest or reckless behavior to mislead investors.

Ultimately, the complaint does not allege sufficient facts to demonstrate that Humacyte became illiquid during the 12-month period after its quarterly projections, let alone that Humacyte lacked a reasonable belief in its 12-month liquidity projections at the time these projections were made or acted with scienter. Again, "[a] plaintiff may not stack inference upon inference to satisfy the PSLRA's pleading standard." Maguire Fin., 876 F.3d at 548. Defendants' motion to dismiss Plaintiffs' Section 10(b) claims based on Defendants' alleged liquidity fraud will therefore be granted.

C. Section 20(a) Claims

Plaintiffs also allege the individual Defendants violated Section 20(a) of the Exchange Act. (Doc. 37 ¶¶ 229-32.) Section 20(a) imposes liability on any person who "directly or indirectly,

controls any person liable" for violations of the Exchange Act, "unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action." 15 U.S.C. § 78t(a). Plaintiffs have alleged that each of the individual Defendants had authority over the content and dissemination of the challenged statements and qualifies as a control person within the meaning of Section 20(a) of the Exchange Act. (Doc. 37 ¶¶ 229-32.)

Defendants' argument for dismissal of the Section 20(a) claims turns on the dismissal of the Section 10(b) claims. (Doc. 41 at 46.) Thus, Plaintiffs' Section 20(a) claims will be dismissed to the extent they are based on the alleged facility fraud or liquidity fraud. Because the court will decline to dismiss the Section 10(b) claims based on the alleged product safety fraud, however, these Section 20(a) claims also survive. See Singer, 883 F.3d at 438 ("The liability of a control person under section 20(a) is derivative of - and dependent upon - liability of a controlled person under section 10(b).").

III. CONCLUSION

For the reasons stated,

IT IS THEREFORE ORDERED that Defendants' motion to dismiss (Doc. 40) is GRANTED IN PART and DENIED IN PART, and that Plaintiffs' claims pursuant to Sections 10(b) and 20(a) related to alleged facility fraud and liquidity fraud are DISMISSED WITHOUT

PREJUDICE,¹² leaving the claims to go forward to the extent they are based on Defendants' alleged product safety fraud.

/s/ Thomas D. Schroeder
United States District Judge

March 31, 2026

¹² The court dismisses Plaintiffs' claims without prejudice because, in their response in opposition to Defendants' motion to dismiss, Plaintiffs ask for leave to amend "to address the Court's concerns" if the court declines to deny Defendants' motion. (Doc. 42 at 51 n.25.) However, no motion to amend has been filed. In such circumstances, the Fourth Circuit has declined to "find that requests made in opposition memoranda constitute a proper motion to amend." ACA Fin. Guar. Corp. v. City of Buena Vista, 917 F.3d 206, 218 (4th Cir. 2019).