UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

_____, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. HUMACYTE, INC., LAURA E. NIKLASON, and DALE A. SANDER, Defendants.	Case No. **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **DEMAND FOR JURY TRIAL**

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Plaintiff _____ ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, his counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Humacyte, Inc. ("Humacyte" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Humacyte; and (c) review of other publicly available information concerning Humacyte.

NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Humacyte securities between May 10, 2024 and October 17, 2024, inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Humacyte and its consolidated subsidiaries (including Humacyte Global, Inc.) engage in the development and manufacture of off-the-shelf, implantable, and bioengineered human tissues. The Company is currently engaged in engineering and manufacturing Acellular Tissue Engineered Vessel ("ATEV"). ATEV, formerly referred to as "Human Acellular Vessel", is a lab-grown blood vessel implant that can act as a replacement for an injured or damaged blood vessel. In December 2023, the Company filed a Biologics License Application with the Food and Drug Administration for ATEV in a vascular trauma indication. In February 2024 the Food and Drug Administration accepted Humacyte's Biologics License Application and granted Priority Review with a Prescription Drug User Fee Act date of August 10, 2024.

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3. On August 9, 2024, after the market closed, Humacyte issued a press release announcing that the FDA "will require additional time to complete its review of its Biologic License Application (BLA) for the acellular tissue engineered vessel (ATEV) in the vascular trauma indication." The press release disclosed in part, that, "[***dJuring 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***[.]"

4. On this news, the Company's stock price declined $1.29, or 16.4%, to close at $6.62 per share on August 12, 2024, on unusually heavy volume.

5. On October 17, 2024, during market hours, the FDA released a Form 483 concerning Humacyte's Durham, North Carolina facility. An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic Act and related Acts. The Form 483 revealed that, during an inspection performed by the FDA on April 1, 2024 through April 5, 2024, of Humacyte's facility, the FDA identified a number of violations including, among other things, references to "***no microbial quality assurance***," "***no microbial testing***," and "***quality oversight is inadequate***" for a number of issues.

6. On this news, the Company's stock price declined $0.95, or 16.35%, to close at $4.86 per share on October 17, 2024, on unusually heavy volume.

7. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) the Company received a Form 483 concerning Humacyte's Durham, North Carolina facility citing violations including inadequate quality oversight; (2) as a result, the Company's FDA's BLA approval was

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substantially likely to be delayed past the PDUFA date; and (3) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

8. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

9. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

11. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company's principle executive offices are located in this District.

12. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

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PARTIES

13. Plaintiff ____, as set forth in the accompanying certification, incorporated by reference herein, purchased Humacyte securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

14. Defendant Humacyte is incorporated under the laws of Delaware with its principal executive offices located in Durham, North Carolina. Humacyte's common stock trades on the NASDAQ exchange under the symbol "HUMA."

15. Defendant Laura E. Niklason ("Niklason") was the Company's founder, President, and Chief Executive Officer ("CEO") at all relevant times.

16. Defendant Dale A. Sander ("Sander") was the Company's Chief Financial Officer ("CFO") at all relevant times.

17. Defendants Niklason, and Sander (together, the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

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SUBSTANTIVE ALLEGATIONS

Background

18. Humacyte and its consolidated subsidiaries (including Humacyte Global, Inc.) engage in the development and manufacture of off-the-shelf, implantable, and bioengineered human tissues. The Company is currently engaged in engineering and manufacturing Acellular Tissue Engineered Vessel ("ATEV"). ATEV, formerly referred to as "Human Acellular Vessel", ("HAV") is a lab-grown blood vessel implant that can act as a replacement for an injured or damaged blood vessel. In December 2023, the Company filed a Biologics License Application ("BLA") with the Food and Drug Administration ("FDA") for ATEV in a vascular trauma indication. In February 2024 the FDA accepted Humacyte's BLA for ATEV and granted Priority Review with a Prescription Drug User Fee Act ("PDUFA") date of August 10, 2024.

Materially False and Misleading

Statements Issued During the Class Period

19. The Class Period begins on May 10, 2024. On that date, Humacyte, issued a press release reporting its financial results for its fiscal first quarter ended March 31, 2024. The press release touted the Company's progress on its BLA application for the ATEV (herein referred to as HAV) and the Company's PDUFA date of August 10, 2024. Specifically, the press release stated, in relevant part: [1]

> **Humacyte First Quarter 2024 Financial Results and Business Update**
>
> ***-Biologics License Application (BLA) for HAV™ Accepted by FDA-***
>
> ***-BLA Granted Priority Review for Vascular Trauma Indication; PDUFA date set for August 10, 2024-***

[1] Unless otherwise stated, all emphasis in bold and italics hereinafter is added, and all footnotes are omitted.

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-Raised approximately $43 million in net proceeds from public offering of common stock-

* * *

"During the first quarter of 2024, we achieved a major milestone with the acceptance by the Food and Drug Administration (FDA) of our Biologics License Application (BLA) seeking approval of the HAV in the vascular trauma indication," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. ***"The FDA's decision to grant Priority Review sets a Prescription Drug User Fee Act (PDUFA) date of August 10, 2024, and the entire Humacyte team is working to support our planned U.S. market launch.*** Among our recent accomplishments is the completion of a Budget Impact Model illustrating the potential economic value of the HAV compared to current standard of care in vascular trauma. ***In addition, the 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."***

* * *

	Three Months Ended March 31,	
	2024	2023
Revenue	$ —	$ —
Operating expenses:		
Research and development	21,264	17,278
General and administrative	5,314	5,234
Total operating expenses	26,578	22,512
Loss from operations	**(26,578)**	**(22,512)**
Other income (expense), net:		
Change in fair value of contingent earnout liability	(4,593)	(14,191)
Other expense (net)	(725)	(266)
Total other expense, net	(5,318)	(14,457)
Net loss and comprehensive loss	**$ (31,896)**	**$ (36,969)**
Net loss per share, basic and diluted	$ (0.29)	$ (0.36)
Weighted-average shares outstanding, basic and diluted	108,246,008	103,263,528

20. On May 10, 2024, the Company held earnings call regarding its financial results for its fiscal first quarter ended March 31, 2024 (the "1Q24 Earnings Call"). During the 1Q24 Earnings Call, Defendant Niklason touted the Company's strong progress on the HAV BLA submission to the FDA, including that the "***FDA has completed its pre-licensing inspection of***

our manufacturing facilities in Durham, North Carolina as part of the BLA review process." Defendant Niklason further assured investors that the Company "***remain[s] on track with our BLA review and commercial launch preparations***." Specifically, during the 1Q24 Earnings Call, the following discussions occurred, in relevant part:

> <**Laura Niklason:>**
>
> I'll begin with our HAV program in vascular trauma. You'll recall that in December of 2023, we submitted our BLA to the FDA. During our last quarterly call, we discussed in detail the robust data package supporting our submission, which included positive results from our V005 Phase 2/3 clinical trial as well as real-world evidence from the treatment of wartime injuries in Ukraine under the humanitarian aid program that was supported by the FDA.
>
> ***In February of 2024. the FDA accepted our BLA in vascular trauma, granting Priority Review and establishing a PDUFA goal date for action of August 10th. The FDA has 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 we remain confident in the approvability of the HAV in vascular trauma.***
>
> * * *
>
> We are on the cusp of being able to provide an innovative regenerative medicine product for patients who are suffering from traumatic vascular injury. ***Based on the strength of our BLA data package, combined with our Priority Review and the RMAT designation from the FDA, we're looking forward to the PDUFA date***.

21. During the 1Q24 Earnings Call, the Company hosted a question and answer session, during which analyst Ryan Zimmerman of BTIG, directly asked: "***can you talk about the facility inspection with FDA? Any observations? Anything that you guys had to correct***?" In response, the Company's Chief Operating Officer, Heather Prichard, stated "***we completed our pre-license inspection of our manufacturing facility and had a very successful outcome***." Specifically, during the 1Q24 Earnings Call, the following discussions occurred, in relevant part:

> **<Q: Ryan Zimmerman - BTIG>**
>
> Well, congrats on all the progress, getting closer to PDUFA here. Laura, ***can you talk about the facility inspection with FDA? Any observations? Anything that you***

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guys had to correct? How clean was that? And just help us know that we're kind of checking those boxes before PDUFA.

<A: Laura Niklason>

So I'm going to ask our COO, Heather Prichard. She and our Head of Quality really oversaw that inspection. I'm going to ask her to take this question.

<A: Heather Prichard>

Hi, Ryan. Yes, as Laura stated, we 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 on the 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***.

22. During the 1Q24 Earnings Call, Defendant Niklason reiterated that the FDA had "***already completed the inspection of our facility***" and "***things are tracking along exactly as we would have expected***" and the Company sees ***"no reason that the PDUFA date will shift***." Defendant Niklason assured investors "***[e]verything just seems to be progressing along as we would have expected***" and the Company has "***no indication that we're not on track"*** Specifically, during the 1Q24 Earnings Call, the following discussions occurred, in relevant part:

<Q: Bruce Jackson - the Benchmark Company>

Hi, most of my questions have been answered. If maybe you could just give us a little bit of a ***flavor of the interaction with the FDA. What types of questions are they asking?*** And how close do you think you're getting to concluding the BLA?

<A: Laura Niklason>

Well, as with any BLA filing, part of the standard procedure is that after you file and after they accept the file, there is a lot of back and forth that they ask for clarifying. They ask clarifying questions. They ask for additional information. And that's been going on, frankly, since January. ***And those interactions have been going very smoothly***, and we've been able to address all of the questions that they've been asking. There are also specific meetings that are part of the normal process, there's what's called a mid-cycle meeting, which we've already completed.

So I think that -- and as we mentioned, we've already completed the inspection of our facility. So things are tracking along exactly as we would have expected,

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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.

23. On May 13, 2024, the Company submitted its quarterly report for the period ended March 31, 2024 on a Form 10-Q filed with the SEC (the "1Q24 10-Q"). The 1Q24 10-Q affirmed the previously reported financial results. The 1Q24 10-Q purported to warn of the risks facing the Company, including those related to the Company's "development of clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that it or its third-party manufacturers are able to successfully manufacture our product." Specifically, the 1Q24 10-Q stated the following, in relevant part:

> [N]umerous risks and uncertainties associated with the development of our product candidates, including:
>
> * * *
>
> • ***the timing, receipt and terms of any marketing approvals from applicable regulatory authorities including the FDA*** and non-U.S. regulators;
>
> * * *
>
> • development of clinical and commercial ***manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that it or its third-party manufacturers are able to successfully manufacture our product***;
>
> * * *
>
> ***A change in the outcome of any of these variables could lead to significant changes in the costs and timing associated with the development of our product candidates***. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate being required to conduct in order to complete the clinical development of any of our product candidates, or if we experience significant delays in the enrollment or the conduct of any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

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24. The 1Q24 10-Q purported to describe the relevant overview of the Company's operations and the progress of the Company's BLA for ATEV. Specifically, the 1Q24 10-Q stated in relevant part:

> In September 2023, we announced positive topline results from our V005 Phase 2/3 trial in vascular trauma, and in December 2023, we filed a BLA for urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated, and when autologous vein use is not feasible. ***In February 2024, the FDA accepted the BLA filing and granted priority review and set a Prescription Drug User Fee Act date of August 10, 2024***.

25. On July 31, 2024, Humacyte issued a press release announcing positive top-line results from its Phase 3 clinical trial of the ATEV in arteriovenous access for patients with end-stage renal disease. The press release touted the Company's progress on the ATEV BLA and the upcoming August 10, 2024 PDUFA date. Specifically, the press release stated, in relevant part:

> A Biologics License Application for the ATEV in the vascular trauma indication is ***currently under review by the FDA and was granted Priority Review with a PDUFA date of August 10, 2024***.

26. The above statements identified in ¶¶ 19-25 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) the Company received a Form 483 concerning Humacyte's Durham, North Carolina facility citing violations including inadequate quality oversight; (2) as a result, the Company's FDA's BLA approval was substantially likely to be delayed past the PDUFA date; and (3) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

27. The truth began to emerge on August 9, 2024, after the market closed, when Humacyte issued a press release announcing that the FDA "***will require additional time to complete its review of its Biologic License Application (BLA)*** for the acellular tissue engineered

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vessel (ATEV) in the vascular trauma indication." The press release disclosed in part, that, "[*d]uring 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*[.]" Specifically, the press release stated, in relevant part:

> **Humacyte Announces FDA Communication of Additional Time Required to Complete Review of acellular tissue engineered vessel (ATEVTM) BLA for the Treatment of Vascular Trauma**
>
> * * *
>
> Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced that the ***U.S. Food and Drug Administration (FDA) will require additional time to complete its review of its Biologic License Application (BLA) for the acellular tissue engineered vessel (ATEV) in the vascular trauma indication. The ATEV trauma program BLA was submitted to FDA in December 2023, and the FDA granted a Priority Review in February 2024 and assigned a PDUFA date of August 10, 2024. In a phone call from FDA CBER leadership today, the Company was informed that the FDA required additional time to complete its review.***
>
> "We received a call from FDA CBER leadership this afternoon apologizing to us and stating that additional time was required for review." said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "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 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.

28. On this news, the Company's stock price declined $1.29, or 16.4%, to close at $6.62 per share on August 12, 2024, on unusually heavy volume.

29. On August 13, 2024, Humacyte issued a press release reporting its financial results for its fiscal second quarter ended June 30, 2024. The press release also reported the Company was

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"***surprised***" to be notified that the FDA would require additional time to complete their review of the BLA for ATEV. The press release touted that 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" and these interactions lead the Company to be "***confident.***" Specifically, the press release stated, in relevant part:

> "***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," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "FDA leadership noted that Humacyte's ATEV is a first-in-class product, and that Priority Review had been granted, which involves only a six-month review cycle, as 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, although we currently do not yet have a revised action date."

* * *

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	23,753	20,540	45,017	37,818
General and administrative	5,746	6,191	11,060	11,425
Total operating expenses	29,499	26,731	56,077	49,243
Loss from operations	**(29,499)**	**(26,731)**	**(56,077)**	**(49,243)**
Other income (expense), net:				
Change in fair value of contingent earnout liability	(25,571)	3,627	(30,164)	(10,564)
Other income (expense) (net)	(1,593)	398	(2,318)	132
Total other income (expense), net	(27,164)	4,025	(32,482)	(10,432)
Net loss and comprehensive loss	**$ (56,663)**	**$ (22,706)**	**$ (88,559)**	**$ (59,675)**
Net loss per share, basic and diluted	$ (0.48)	$ (0.22)	$ (0.78)	$ (0.58)
Weighted-average shares outstanding, basic and diluted	119,174,681	103,361,501	113,710,344	103,312,785

30. On August 13, 2024, the Company submitted its quarterly report for the period ended June 30, 2024 on a Form 10-Q filed with the SEC (the "2Q24 10-Q"). The 2Q24 10-Q affirmed the previously reported financial results. The 2Q24 10-Q purported to warn of the risks

facing the Company, including the Company's "development of clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that it or its third-party manufacturers are able to successfully manufacture our product." Specifically, the 2Q24 10-Q stated the following, in relevant part:

> [N]umerous risks and uncertainties associated with the development of our product candidates, including:
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> * * *
>
> • ***the timing, receipt and terms of any marketing approvals from applicable regulatory authorities including the FDA*** and non-U.S. regulators;
>
> * * *
>
> • development of clinical and commercial ***manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that it or its third-party manufacturers are able to successfully manufacture our product***;
>
> * * *
>
> ***A change in the outcome of any of these variables could lead to significant changes in the costs and timing associated with the development of our product candidates***. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate being required to conduct in order to complete the clinical development of any of our product candidates, or if we experience significant delays in the enrollment or the conduct of any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

31. The 2Q24 10-Q purported to describe the relevant overview of the Company's operations and the progress of the Company's BLA for ATEV. Specifically, the 1Q24 10-Q stated in relevant part:

> We are initially using our proprietary, scientific technology platform to engineer and manufacture ATEVs. Our investigational ATEVs are designed to be easily implanted into any patient without inducing a foreign body response or leading to immune rejection. We are developing a portfolio, or "cabinet", of ATEVs with varying diameters and lengths.
>
> * * *

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> In September 2023, we announced positive topline results from our V005 Phase 2/3 trial in vascular trauma, and in December 2023, we filed a BLA for urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated, and when autologous vein use is not feasible. ***In February 2024, the FDA accepted the BLA filing and granted priority review and set a Prescription Drug User Fee Act date of August 10, 2024. On August 9, 2024, the FDA informed us that it required additional time to complete its review of the BLA for the vascular trauma indication***.

32. The above statements identified in ¶¶ 27, 29-31 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) the Company received a Form 483 concerning Humacyte's Durham, North Carolina facility citing violations including inadequate quality oversight; (2) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

Disclosures at the End of the Class Period

33. On October 17, 2024, during market hours, the FDA released a Form 483 concerning Humacyte's Durham, North Carolina facility. An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic Act and related Acts. The Form 483 revealed that, during an inspection performed by the FDA on April 1, 2024 through April 5, 2024, of Humacyte's facility, the FDA identified a number of violations including, among other things, references to "***no microbial quality assurance***," "***no microbial testing***," and "quality oversight is inadequate" for a number of issues. Specifically, the Form 483 stated, in relevant part:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp.: Alifiya H. Ghadiali Telephone: 301-796-2064 Industry Information: www.fda.gov/oc/industry	04/01/2024 - 04/05/2024
	FEI NUMBER 3014294024

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Heather Prichard, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Humacyte Global, Inc.	2525 E. Highway NC 54
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Durham, NC 27713	Drug product manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. There is no microbial quality assurance of the (b) (4) used for the (b) (4) Specifically, there is no microbial testing or (b) (4) formulated using (b) (4) steps.

2. Quality oversight is inadequate for the following issues observed:

a. Investigating Out of Specification Results, SOP-0313-04, does not contain procedures for requesting an extension or opening a deviation if the investigation is not completed within the recommended 60 days. There were 10 out of 31 out-of-specification investigations from (b) (4) that were open for more than 100 days, with the longest being open for 710 days.

b. The contract cleaning crew was not current with their (b) (4) cGMP Refresher Training as required by the Training Program, SOP-0315-04. Additionally, one member of the cleaning crew was not current on the GxP Cleaning Contractor Core Training "Facility Cleaning and Disinfection".

c. A complete record for the role-based training (b) (4) was not available for an operator observed participating in (b) (4) in (b) (4) Room (b) (4)

d. The quality review of the (b) (4) preventative maintenance of the air handling unit was approved without the required documentation in (b) (4) per Use of (b) (4) SOP-0127-01 and Preventative Maintenance, SOP-0169-04.

SEE REVERSE OF THIS PAGE	/S/	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Alifiya H. Ghadiali, Lead Consumer Safety Officer Zainab Mansaray-Storms, Consumer Safety Officer Laura Ricles, Division Director Jin Sung Hong, Biologist	04/05/2024

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS Page 1 of 1

34. On this news, the Company's stock price declined $0.95, or 16.35%, to close at $4.86 per share on October 17, 2024, on unusually heavy volume.

CLASS ACTION ALLEGATIONS

35. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired Humacyte securities between May 10, 2024 and October 17, 2024, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

36. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Humacyte's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Humacyte shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Humacyte or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

37. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

38. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

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39. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Humacyte; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

40. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

41. The market for Humacyte's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Humacyte's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Humacyte's securities relying upon the integrity of the market price of the Company's securities and market information relating to Humacyte, and have been damaged thereby.

42. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Humacyte's securities, by publicly issuing false and/or misleading statements

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and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about Humacyte's business, operations, and prospects as alleged herein.

43. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Humacyte's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

44. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

45. During the Class Period, Plaintiff and the Class purchased Humacyte's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

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SCIENTER ALLEGATIONS

46. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Humacyte, their control over, and/or receipt and/or modification of Humacyte's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Humacyte, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE
(FRAUD-ON-THE-MARKET DOCTRINE)

47. The market for Humacyte's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Humacyte's securities traded at artificially inflated prices during the Class Period. On July 31, 2024, the Company's stock price closed at a Class Period high of $9.46 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Humacyte's securities and market information relating to Humacyte, and have been damaged thereby.

48. During the Class Period, the artificial inflation of Humacyte's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading

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statements about Humacyte's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Humacyte and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

49. At all relevant times, the market for Humacyte's securities was an efficient market for the following reasons, among others:

(a) Humacyte shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Humacyte filed periodic public reports with the SEC and/or the NASDAQ;

(c) Humacyte regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Humacyte was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

50. As a result of the foregoing, the market for Humacyte's securities promptly digested current information regarding Humacyte from all publicly available sources and reflected such

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information in Humacyte's share price. Under these circumstances, all purchasers of Humacyte's securities during the Class Period suffered similar injury through their purchase of Humacyte's securities at artificially inflated prices and a presumption of reliance applies.

51. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

52. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker

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had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Humacyte who knew that the statement was false when made.

FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and

Rule 10b-5 Promulgated Thereunder

Against All Defendants

53. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

54. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Humacyte's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

55. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Humacyte's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

56. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a

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continuous course of conduct to conceal adverse material information about Humacyte's financial well-being and prospects, as specified herein.

57. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Humacyte's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Humacyte and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

58. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

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59. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Humacyte's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

60. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Humacyte's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Humacyte's securities during the Class Period at artificially high prices and were damaged thereby.

61. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems

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that Humacyte was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Humacyte securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

62. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

63. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM

Violation of Section 20(a) of The Exchange Act

Against the Individual Defendants

64. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

65. Individual Defendants acted as controlling persons of Humacyte within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were

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issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

66. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

67. As set forth above, Humacyte and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

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Dated: _____, 2024

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