LAW360®

Portfolio Media. Inc. | 230 Park Avenue, 7th Floor | New York, NY 10169 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Biotech Co.'s Facility Failures Lost Investors Money, Suit Says

By **Sydney Price**

Law360 (January 8, 2025, 7:40 PM EST) -- The executives and directors of biotechnology company Humacyte Inc. have been hit with a shareholder derivative suit in North Carolina federal court alleging the company concealed that its manufacturing facility failed to comply with certain quality assurance practices, leading to delayed regulatory review for its product candidate.

According to the **complaint** shareholder Nathan Silva filed Tuesday, Humacyte and its executives and directors failed to disclose for several months there were issues at its Durham, North Carolina, manufacturing facilities, such as the absence of microbial testing. These deficiencies were not revealed publicly until the U.S. Food and Drug Administration announced in October 2024 that Humacyte's facilities were noncompliant.

Humacyte manufactures acellular tissue engineered vessels, or lab-grown blood vessel implants, that can serve as replacements for damaged blood vessels, according to the complaint. In addition to naming the company as a nominal defendant, its CEO Laura E. Niklason and several company directors are named defendants in the suit.

The suit's relevant period begins April 29, 2024, the day Humacyte filed an allegedly false and misleading annual proxy statement with the U.S. Securities and Exchange Commission.

"The 2024 proxy failed to disclose that the Company was beset with compliance problems that posed significant risks of harm, and that the board lacked a system to oversee mission-critical compliance risks," Silva said.

In other statements throughout the relevant period, Humacyte continued to conceal problems at its manufacturing facilities, the shareholder alleged. For example, on May 10, the defendants touted the company's "strong progress" on its application for its blood vessel implant and told investors Humacyte had a "very successful interaction" with the FDA regarding the application's approval.

A couple of months later, on Aug. 9, Humacyte announced the FDA will require additional time to complete its review of Humacyte's application.

On this news, Humacyte shares fell $1.29, or about 16%, to close at $6.62 per share on Aug. 12, according to the complaint.

Despite the disclosure, investors would not learn of Humacyte's compliance failures until Oct. 17, when the FDA released a statement confirming it had observed quality oversight issues at Humacyte's North Carolina manufacturing facilities.

On this news, Humacyte shares fell 95 cents, or about 16%, to close at $4.86 per share on Oct. 17, according to the complaint.

Additionally, Silva alleged Humacyte agreed to sell approximately $30 million worth of common stock to an institutional investor in a deal that was expected to close Oct. 7, several days before the FDA's announcement, according to the suit.

The suit accuses the defendants of wasting corporate assets, insider trading, abuse of control, gross mismanagement and violating the Exchange Act.

The complaint also notes Humacyte is facing a **securities class action** in North Carolina federal court alleging the company misstated and omitted information regarding its facilities.

Representatives of the parties did not immediately respond to requests for comment Wednesday.

Silva is represented by Emily J. Beeson of Ward Black Law, Seth D. Rigrodsky, Timothy J. MacFall and Vincent A. Licata of Rigrodsky Law PA, and Joshua H. Grabar of Grabar Law Office.

Counsel information for Humacyte and the individual defendants was not available Wednesday.

The case is Silva v. Sebelius et al., case number 1:25-cv-00005, in the U.S. District Court for the Middle District of North Carolina.

--Editing by Lakshna Mehta.
