UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): June 22, 2021

AZIYO BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39577**	**47-4790334**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

12510 Prosperity Drive, Suite 370
Silver Spring, MD 20904
(Address of principal executive offices) (Zip Code)

(240) 247-1170
(Registrant's telephone number, include area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbols**	**Name of each exchange on which registered**
Class A Common Stock, $0.001 par value per share	AZYO	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

FiberCel Recall Update

As previously announced on June 7, 2021, Aziyo Biologics, Inc. (the "Company" or "Aziyo") issued a voluntary recall on June 2, 2021 pertaining to a single donor lot of its FiberCel Fiber Viable Bone Matrix after learning of post-surgical infections in several patients treated with the product, including some patients that tested positive for tuberculosis.

Since issuing the recall, the Company has been working diligently with the U.S. Food and Drug Administration ("FDA") and the U.S. Centers for Disease Control and Prevention ("CDC") to secure all identified unused product, ascertain the medical status of patients treated with the single donor lot, understand whether there is any relationship between the post-surgical infections and the FiberCel single donor lot used and determine the medical cause of these infections.

At this time, the Company believes that it has identified the 154 units comprising the product lot in question. Based on information from the CDC, 136 units within this product lot were implanted into 113 patients and 18 units have either been returned to Aziyo or the CDC. Of the 113 patients, CDC has identified at least 72 patients who have exhibited clinical or diagnostic findings consistent with tuberculosis infection.

Working with state health agencies, the CDC has advised the Company that it has contacted all patients treated with this lot of FiberCel to help ensure they are directed to appropriate medical treatment. Through its communications with the CDC, the Company has learned that eight patients who received the product from this lot have died, however, the cause of death is still being determined.

Samples of the recalled product have now undergone PCR analysis by a lab contracted by the CDC and tested positive for *Mycobacterium tuberculosis*. Cell culture testing of the recalled product is being conducted by the same lab to corroborate the PCR testing results.

As part of its continuing cooperation with the FDA and CDC and its efforts to conduct a prompt and fulsome investigation into this matter, the Company has reviewed its processes for screening donors and producing FiberCel and has not identified any deviations from its established protocols, which are based on industry standards and government requirements. Based on currently known information, the Company has no reason to believe that other units of FiberCel are affected.

Aziyo remains committed to completing a full and thorough investigation into the root cause of the adverse events associated with the recalled single donor lot of FiberCel.

Legal and Regulatory Update

On June 16, 2021, a lawsuit was filed in the Superior Court of the State of Delaware, County of New Castle, captioned Richard Williams v. Aziyo, Inc., et al., C.A. No. N21C-06-166 EMD, against the Company and certain Medtronic entities, alleging that the plaintiff contracted tuberculosis following the implantation of Fibercel during a spinal fusion operation and seeking unspecified compensatory and punitive damages and medical monitoring.

On June 17, 2021, the FDA initiated an inspection of the Company's Richmond, California facility where FiberCel is produced, and that inspection is ongoing.

Forward-Looking Statements

This Current Report on Form 8-K)"Form 8-K") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including statements and information concerning: the impact of the recall and suspension of sales of FiberCel on the Company's business; the outcome of or impact from any pending, or initiation of new, legal and regulatory matters; and the potential for the identification of additional Fibercel units that result in post-surgical infections in patients treated with the product. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect the Company's business, strategy, operations or financial performance, and actual results may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, and other important factors that may cause actual results, performance or achievements to differ materially from those contemplated or implied in this Form 8-K, including, but not limited to: risks regarding the technical complexity and requisite high levels of quality control and precision in processing of tissue needed for the Company's products, including FiberCel; defects, failures or quality issues associated with the Company's products that lead to product recalls or safety alerts, adverse regulatory actions, litigation, including product liability claims, and negative publicity; sufficient insurance coverage and reimbursement for procedures incorporating the Company's products; product liability claims, including those that have resulted from the recall of FiberCel, for which the Company may not receive adequate, if any, product liability coverage; the Company's risk exposure from warranty claims on its products; and other important factors discussed under the caption "Risk Factors" in Aziyo's Annual Report on Form 10-K for the annual period ended December 31, 2020 filed with the Securities and Exchange Commission ("SEC"), as such risk factors may be updated from time to time in Aziyo's other filings with the SEC, which are accessible on the SEC's website at www.sec.gov and the Investor Relations page of Aziyo's website at www.Aziyo.com. Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. Except as required by law, the Company undertakes no obligation to update or review any estimate, projection, or forward-looking statement.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AZIYO BIOLOGICS, INC.

Date: June 22, 2021

By: /s/ Ronald Lloyd
Ronald Lloyd
President and Chief Executive Officer