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 7, 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 7.01. Regulation FD Disclosure.

On June 7, 2021, Aziyo Biologics, Inc. (the "Company" or "Aziyo") issued a press release announcing its voluntary recall pertaining to a single donor lot of its FiberCel Fiber Viable Bone Matrix, a bone repair product made from human tissue that is used in various orthopedic and spinal procedures and that, out of an abundance of caution, sales of FiberCel will be suspended by its distributor until further notice. Given the uncertainty regarding any potential impact to Aziyo's business resulting from the recall and the pause in FiberCel sales, Aziyo is suspending its revenue guidance for full year 2021, previously announced on May 4, 2021.

A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K ("Form 8-K") and is incorporated into this Item 7.01 by reference.

The information contained in this Item 7.01 (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On June 7, 2021, the Company announced that notice of the voluntary recall was issued on June 2, 2021 to hospitals that received product from a single donor lot of its FiberCel Fiber Viable Bone Matrix following the Company's learning of post-surgical infections in patients treated with FiberCel, including some patients that tested positive for tuberculosis. The lot consists of 154 units of FiberCel, all derived from a single donor, that were shipped to facilities in 20 states. Aziyo is investigating the source of the infections in coordination with its distributor, the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention. The Company is in the process of recovering the unused units from this lot. At present, the Company has no reason to believe any other units of FiberCel are affected by this situation.

According to the CDC, tuberculosis is caused by a bacterium called *Mycobacterium tuberculosis*. Because tuberculosis is a communicable disease, infection needs to be reported to the local or state health department tuberculosis program, and is treated with a combination of antibiotics.

Forward-Looking Statements

This 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 suspension of sales of FiberCel and any impact of the recall and suspension of sales of FiberCel on the Company's business. 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; the misuse of the Company's 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 to the extent required by law, the Company undertakes no obligation to update or review any estimate, projection, or forward-looking statement.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Aziyo Biologics, Inc., dated June 7, 2021

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 7, 2021

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

Exhibit 99.1

Aziyo Biologics Comments on June 2nd Voluntary Recall of One Lot of its FiberCel Fiber Viable Bone Matrix

SILVER SPRING, Md. – June 7, 2021 – Aziyo Biologics, Inc. (Nasdaq: AZYO) on June 2, 2021 issued a voluntary recall pertaining to a single donor lot of its FiberCel Fiber Viable Bone Matrix, a bone repair product made from human tissue that is used in various orthopedic and spinal procedures.

Notice of the voluntary recall was issued to hospitals that received product from this specific lot following the Company's learning of post-surgical infections in patients treated with FiberCel, including some patients that tested positive for tuberculosis. The lot consists of 154 units of FiberCel, all derived from a single donor, that were shipped to facilities in 20 states. Aziyo is investigating the source of the infections in coordination with its distributor, the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention. The Company is in the process of recovering the unused units from this lot. At present, the Company has no reason to believe any other units of FiberCel are affected by this situation.

According to the CDC, tuberculosis is caused by a bacterium called *Mycobacterium tuberculosis*. Because tuberculosis is a communicable disease, infection needs to be reported to the local or state health department tuberculosis program, and is treated with a combination of antibiotics.

"Patient health and safety are our highest priority. Accordingly, we have implemented this voluntary recall and instructed hospitals that received FiberCel product from this specific donor lot to immediately quarantine and return any remaining product to us," said Ron Lloyd, Aziyo's president and chief executive officer. "We are committed to a thorough, timely and transparent investigation into the root cause of these infections."

Out of an abundance of caution, sales of FiberCel will be suspended by its distributor until further notice. Given the uncertainty regarding any potential impact to Aziyo's business resulting from the recall and the pause in FiberCel sales, Aziyo is suspending its revenue guidance for full year 2021, previously announced on May 4, 2021.

About FiberCel Fiber Viable Bone Matrix

FiberCel is a fiber-based bone repair product made from human tissue and engineered to maintain characteristics of natural tissue. It is marketed for use in orthopedic or reconstructive bone grafting procedures in combination with autologous bone or other forms of allograft bone or alone as a bone graft. FiberCel provides handling properties that are critical for use as a bone void filler in various orthopedic and spinal procedures. FiberCel contains cancellous bone particles with preserved living cells and demineralized cortical bone fibers to facilitate bone repair and healing.

About Aziyo Biologics

Aziyo Biologics is a commercial-stage regenerative medicine company focused on creating the next generation of differentiated products and improving outcomes in patients undergoing surgery, concentrating on patients receiving implantable medical devices. Since its founding in 2015, the Company has created a portfolio of commercial-stage products used in cardiovascular, orthopedic, and reconstructive specialties. For more information, visit www.Aziyo.com.

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