

**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): July 13, 2023

AZIYO BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-39577
(Commission
File Number)

47-4790334
(IRS 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, including 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Class A Common Stock, \$0.001 par value per share	AZYO	The Nasdaq Capital 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 July 13, 2023, Aziyo Biologics, Inc. (the “Company” or “Aziyo”) issued a press release announcing the events described in Item 8.01 of this Current Report on Form 8-K (“Form 8-K”). A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K and is incorporated herein 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 July 13, 2023, the Company announced the voluntary recall of its viable bone matrix products, which are bone repair products made from human tissue that are used primarily in orthopedic and spinal procedures.

Notice of the voluntary recall was issued to centers after the Company learned of post-surgical Mycobacterium tuberculosis (“MTB”) infections in two patients treated with viable bone matrix product from a single donor lot. Prior to release, samples from this specific lot had tested negative for MTB by an independent laboratory using a nucleic acid test that is designed to specifically detect the MTB organism. Aziyo is investigating the source of the infections in coordination with the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention (“CDC”).

Out of an abundance of caution, the Company has suspended shipments of all viable bone matrix products from all donor lots. The Company is also working closely with CDC staff to notify physicians of the patients who received the particular donor lot at issue to initiate post-exposure prophylaxis.

Forward-Looking Statements

This current report on 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. Forward-looking statements can be identified by words such as “projects,” “may,” “will,” “could,” “would,” “should,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” “potential,” “promise” or similar references to future periods. All statements contained in this press release 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 the Company’s viable bone matrix products, and any impact of the recall and suspension of sales of these products 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 our 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: the technical complexity and requisite high levels of quality control and precision in processing of tissue needed for the Company’s products, including its viable bone matrix; 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 may arise from the recall of its viable bone matrix, for which the Company may not receive adequate, if any, product liability coverage; the Company’s risk exposure from warranty claims on its products; our inability to generate sufficient revenue to achieve or sustain profitability; adverse changes in economic conditions and instability and disruption of credit markets; our ability to continue as a going concern; our products and our ability to enhance, expand, develop and commercialize our product offerings; our dependence on our commercial partners; physician awareness of the distinctive characteristics, and acceptance by the medical community, of our products; the ability to obtain regulatory approval or other marketing authorizations; our intellectual property rights; and other important factors which can be found in the “Risk Factors” section of Aziyo’s public filings with the Securities and Exchange Commission (“SEC”), including Aziyo’s Annual Report on Form 10-K for the year ended December 31, 2022, as such factors may be updated from time to time in Aziyo’s other filings with the SEC, including, Aziyo’s Quarterly Reports on Form 10-Q, accessible on the SEC’s website at www.sec.gov and the Investor Relations page of Aziyo’s website at <https://investors.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. Any forward-looking statement made by Aziyo in this press release is based only on information currently available and speaks only as of the date on which it is made. Except as required by applicable law, Aziyo expressly disclaims any obligations to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Aziyo Biologics, Inc., dated July 13, 2023
104	Cover Page Interactive Data File (formatted as Inline XBRL document)

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.
(Registrant)

Date: July 13, 2023

By: /s/ Matthew Ferguson
Matthew Ferguson
Chief Financial Officer

Aziyo Biologics Announces Voluntary Recall of Viable Bone Matrix Products

SILVER SPRING, Md., July 13, 2023 — Aziyo Biologics, Inc. (Nasdaq: AZYO), a company that develops and commercializes biologic products to improve compatibility between medical devices and the patients who need them, today announced a voluntary recall of its viable bone matrix products, which are bone repair products made from human tissue that are used primarily in orthopedic and spinal procedures.

Notice of the voluntary recall was issued to centers after the Company learned of post-surgical *Mycobacterium tuberculosis* (MTB) infections in two patients treated with viable bone matrix product from a single donor lot. Prior to release, samples from this specific lot had tested negative for MTB by an independent laboratory using a nucleic acid test that is designed to specifically detect the MTB organism. Aziyo is fully cooperating and investigating the events in coordination with the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention (CDC).

Out of an abundance of caution, the Company has suspended shipments of all viable bone matrix products from all donor lots. The Company is also working closely with CDC staff to notify physicians of the patients who received the particular donor lot at issue to initiate post-exposure prophylaxis.

“We are taking immediate action to safeguard patients by implementing a full product recall as we work with the CDC to investigate this event,” said Dr. Randy Mills, President and Chief Executive Officer of Aziyo Biologics. “The people of Aziyo care deeply about the patients we serve and will continue to work with the medical community, patients, and regulatory authorities as we gather additional information.”

About Aziyo Biologics

Aziyo develops and commercializes biologic products to improve compatibility between medical devices and the patients who need them. With a growing population in need of implantable technologies, Aziyo’s mission is to humanize medical devices to improve patient outcomes. For more information, visit www.Aziyo.com.

Forward-Looking Statements

This press release 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. Forward-looking statements can be identified by words such as “projects,” “may,” “will,” “could,” “would,” “should,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” “potential,” “promise” or similar references to future periods. All statements contained in this press release 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 the Company’s viable bone matrix products, and any impact of the recall and suspension of sales of these products 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 our 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 press release, 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 viable bone matrix; 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 may arise from the recall of viable bone matrix, for which the Company may not receive adequate, if any, product liability coverage; the Company’s risk exposure from warranty claims on its products; our inability to generate sufficient revenue to achieve or sustain profitability; adverse changes in economic conditions and instability and disruption of credit markets; our ability to continue as a going concern; our products and our ability to enhance, expand, develop and commercialize our product offerings; our dependence on our commercial partners; physician awareness of the distinctive characteristics, and acceptance by the medical community, of our products; the ability to obtain regulatory approval or other marketing authorizations; our intellectual property rights; and other important factors which can be found in the “Risk Factors” section of Aziyo’s public filings with the Securities and Exchange Commission (“SEC”), including Aziyo’s Annual Report on Form 10-K for the year ended December 31, 2022, as such factors may be updated from time to time in Aziyo’s other filings with the SEC, including, Aziyo’s Quarterly Reports on Form 10-Q, accessible on the SEC’s website at www.sec.gov and the Investor Relations page of Aziyo’s website at <https://investors.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. Any forward-looking statement made by Aziyo in this press release is based only on information currently available and speaks only as of the date on which it is made. Except as required by applicable law, Aziyo expressly disclaims any obligations to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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