

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): March 20, 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
(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 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 March 20, 2023, Aziyo Biologics, Inc. (the “Company”) issued a press release to provide an update on its submission to the U.S. Food and Drug Administration (“FDA”) for the CanGaroo® RM Antibacterial Envelope, the Company’s next-generation biomaterial envelope intended for use with implantable electronic devices.

The information in this Item 7.01 (including Exhibit 99.1) of this Form 8-K 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.

As previously reported, in April 2022, the Company submitted a 510(k) premarket notification to the FDA for the Company’s CanGaroo® RM Antibacterial Envelope, its next-generation biomaterial envelope for use with implantable electronic devices (IED) intended to securely hold a cardiac implantable electronic device or neurostimulator, creating a stable environment when implanted in the body. As a combination product containing device and drug components, the filing was reviewed by the Center for Devices and Radiological Health (CDRH) and the Center for Drug Evaluation and Research (CDER). On March 16, 2023, the Company received a Not Substantially Equivalent (“NSE”) determination from the FDA. The notice defined the outstanding items that need to be addressed in furtherance of potential market clearance. These items relate to drug testing, primarily a request by FDA to modify an *in vitro* drug release assay employed as a manufacturing control. As a result, the Company does not expect to appeal the FDA’s decision but intends to provide the FDA with additional data as requested.

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 Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding the potential regulatory clearance of CanGaroo RM. 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 Current Report on Form 8-K, including, but not limited to, risks regarding the Company’s products and its ability to enhance, expand, develop and commercialize its product offerings; the Company’s significant litigation related to the recall of a single lot of its FiberCel product and its impact on the Company’s business and the discontinuation of its sales by its distribution partner; the Company’s dependence on its commercial partners; the Company’s future capital needs and available sources of funding; the adverse changes in economic conditions and instability and disruption of credit markets; physician awareness of the distinctive characteristics, and acceptance by the medical community, of the Company’s products; the ability to obtain regulatory approval or other marketing authorizations; and the Company’s 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, 2021, as such factors may be updated from time to time in Aziyo’s other filings with the SEC, including without limitation, Aziyo’s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022, 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 Current Report on Form 8-K 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Aziyo Biologics, Inc., dated March 20, 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.

Date: March 20, 2023

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

Aziyo Biologics Provides Update on FDA Submission for CanGaroo® RM Antibacterial Envelope

SILVER SPRING, Md., March 20, 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, provides an update on its submission to the U.S. Food and Drug Administration (FDA) for the CanGaroo® RM Antibacterial Envelope, the Company's next-generation biomaterial envelope. The device is intended to securely hold a cardiac implantable electronic device or neurostimulator, creating a stable environment when implanted in the body. The CanGaroo RM Antibacterial Envelope contains the antibiotics rifampin and minocycline, which have been shown in preclinical testing to reduce bacterial colonization on the envelope.

As previously announced, the Company submitted a 510(k) premarket notification for the CanGaroo RM Antibacterial Envelope to the FDA in April 2022. As a combination product containing device and drug components, the filing was reviewed by the Center for Devices and Radiological Health (CDRH) and the Center for Drug Evaluation and Research (CDER). On March 16, 2023, the Company received a Not Substantially Equivalent determination from FDA. The notice defined the outstanding items that need to be addressed in order to obtain market clearance. The items relate to drug testing, primarily a request by FDA to modify an *in vitro* drug release assay employed as a manufacturing control. As a result, the Company does not expect to appeal the decision, as it believes the most expeditious path forward is to work with FDA to provide the additional data requested.

"While we are disappointed with the delay, we are gratified that the completed review did not raise any questions surrounding the appropriateness of the pathway or majority of the data submitted to support the filing," said Dr. Randy Mills, President and Chief Executive Officer of Aziyo Biologics. "We have our marching orders and are confident that we can address the FDA's questions promptly."

As a reminder, Aziyo Biologics' management team will be hosting its previously scheduled conference call and webcast to discuss its fourth quarter and full-year 2022 financial results on Wednesday, March 22, 2023 at 4:30 p.m. ET. The Company will provide additional information at that time.

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.

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