



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

March 20, 2023

SILVER SPRING, Md., March 20, 2023 (GLOBE NEWSWIRE) -- 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.

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 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 press release, 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 impact on the Company's business of the recall of a single lot of its FiberCel product 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 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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