



## Aziyo Biologics Announces Publication of a CanGaroo® Case Study Demonstrating Bioenvelope Benefits for Reoperative Procedures

August 30, 2023

Case provides first histologic evidence that CanGaroo can catalyze development of new healthy tissue layer within an existing cardiac implantable electronic device (CIED) pocket

SILVER SPRING, Md., Aug. 30, 2023 (GLOBE NEWSWIRE) -- Aziyo Biologics, Inc. (Nasdaq: AZYO) ("Aziyo"), a company that develops and commercializes biologic products to improve compatibility between medical devices and the patients who need them, today announced the publication of a case report highlighting results that demonstrate the potential benefits of using a biological device envelope during reoperative procedures for CIEDs.

The report, titled "[Rehabilitation of an Existing Device Implant Pocket Using a Biologic Extracellular Matrix Envelope](#)," was published in the peer-reviewed journal *Heart Rhythm Case Reports*. The results suggest a biological envelope may mitigate the risks and procedural difficulty associated with reusing fibrotic implant pockets, which could facilitate future reoperations and decrease post-operative complications. This case study builds upon interim results from the HEAL Study indicating that CanGaroo can significantly reduce fibrous lead entrapment and decrease procedural difficulty when used during initial device implantation. CanGaroo is the only biological envelope available for use with implantable electronic devices.

"This case study builds upon the interim HEAL Study data presented earlier this year at Heart Rhythm 2023," said Dr. Michelle LeRoux Williams, Chief Scientific Officer of Aziyo. "These results provide an opportunity to evaluate the use of CanGaroo within a reoperative pocket. CanGaroo has proven to show superior tissue remodeling properties and can provide a solution for patients and their physicians seeking to avoid complications associated with reoperations."

### Case Study Overview:

The patient was a 73-year-old man with normal immune and kidney function who underwent a replacement procedure for an Implantable Cardioverter Defibrillator (ICD). At the time of the reoperation, the existing pocket was highly fibrotic. The ICD was surgically removed and leads freed, but most of the fibrotic tissue remained. To rehabilitate the fibrotic pocket, the new ICD was placed into a CanGaroo envelope and implanted.

Five months later, an additional procedure was performed to resolve a lead complication. At that time, the entire pocket was observed to be lined with a soft vascularized capsule, and now the leads were free of fibrosis and calcification.

A biopsy of the pocket showed a new pocket wall containing thin, cellularized and vascularized tissue, consistent with a fully remodeled envelope. The implanted CanGaroo was fully resorbed.

The patient had an uneventful recovery and remains stable at three years post-operation. The findings in this case study are consistent with previously reported data published in [Circulation](#) demonstrating that CanGaroo prevents foreign body reactions within the host, reducing hypovascular fibrous capsule development.

### 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](http://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 any statements and information concerning the effectiveness of the CanGaroo RM Antibacterial Envelope. 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 ability to successfully execute or realize the anticipated benefits under our distribution arrangements with LeMaitre Vascular and Sientra; 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 ability to successfully execute or achieve expected benefits from a divestiture of our Orthopedics business; our products and our ability to enhance, expand, develop and commercialize our product offerings; the impact on our business of the recall of a single lot of our FiberCel product and the discontinuation of its sales by our distribution partner; consequences of our recall of a single lot of one of our viable bone matrix products and market withdrawal of all of our viable bone matrix products; our dependence on our commercial partners; the impact of the bankruptcy of Surgalign Holdings, Inc., a significant customer of the Company, on our future revenues; 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; and 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](http://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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