
**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): April 21, 2023 (April 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:

| <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 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 1.01 Entry into a Material Definitive Agreement.

On April 20, 2023, Aziyo Biologics, Inc. (the “Company” or “Aziyo”) entered into a Distribution Agreement (the “Agreement”) with LeMaitre Vascular, Inc., a Delaware corporation (“LeMaitre”). Under the Agreement, Aziyo appointed LeMaitre as its exclusive distributor for its ProxiCor® PC, ProxiCor® CTR, Tyke® and VasCure® product lines (the “Products”) in the United States (the “Territory”) for a three-year period, subject to certain terms and conditions.

The Agreement provides for an initial purchase of Products by LeMaitre, and subsequent purchases of Products by LeMaitre from time to time thereafter, subject to certain minimum purchase volumes beginning October 1, 2023. Under the Agreement, Product prices are subject to annual adjustment by Aziyo, subject to certain limitations, upon prior written notice to LeMaitre.

The three-year term of the Agreement may be extended by mutual agreement of Aziyo and LeMaitre, and either party may terminate the Agreement upon written notice to the other if the other party experiences certain bankruptcy or insolvency-related events, or materially breaches certain provisions of the Agreement. In addition, LeMaitre may terminate the Agreement upon written notice to Aziyo at any time following the first anniversary of the Agreement’s effective date, and Aziyo may terminate the Agreement upon written notice to LeMaitre if, among other things, LeMaitre does not meet certain minimum volume purchase requirements regarding the Products.

The Agreement also provides LeMaitre with an exclusive option, exercisable upon written notice during the final two years of the Agreement’s initial term or under certain other specified circumstances, to acquire all rights to the Products and related assets from Aziyo for a purchase price based on a multiple of trailing twelve-month worldwide sales of the Products, subject to a specified minimum. The purchase would be subject to an acquisition agreement, to be negotiated by LeMaitre and Aziyo in good faith, which would include, among other things, customary representations and warranties, indemnities, confidentiality provisions and closing conditions.

The Agreement also contains customary representations and warranties of each party, including representations and warranties with respect to the Products, and customary covenants of each party, including covenants with respect to orders and deliveries of Products, the use of trademarks and other intellectual property of Aziyo, sales reports and audit rights, insurance, confidentiality and indemnification.

The foregoing description of the Agreement does not purport to be a complete description of the rights and obligations of the parties thereunder and is qualified in its entirety by reference to the full text of the Agreement that will be filed as an exhibit to the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2023.

Item 7.01 Regulation FD Disclosure.

On April 20, 2023, Aziyo issued a press release announcing the Agreement, a copy of which is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 (including Exhibit 99.1) of this Current Report on 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.

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 future actions or activities of the Company and LeMaitre Vascular, Inc. under or pursuant to the Distribution Agreement. 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 ability to successfully execute or realize the anticipated benefits under its distribution arrangement with LeMaitre Vascular; the Company's inability to generate sufficient revenue to achieve or sustain profitability; adverse changes in economic conditions and instability and disruption of credit markets; the Company's ability to continue as a going concern; the Company's products and its ability to enhance, expand, develop and commercialize its product offerings; 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 the Company's distribution partner; the Company's dependence on its commercial partners; 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; the Company's intellectual property rights; and other important factors which can be found in the "Risk Factors" section of the Company's public filings with the Securities and Exchange Commission ("SEC"), including the Company'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 the Company's other filings with the SEC, including without limitation, the Company's Quarterly Reports on Form 10-Q, accessible on the SEC's website at www.sec.gov and the Investor Relations page of the Company'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 the Company's 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, the Company's 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 April 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: April 21, 2023

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

Aziyo Biologics and LeMaitre Vascular Partner for the Distribution of Aziyo's Cardiovascular Portfolio

SILVER SPRING, Md., April 20, 2023 — 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 it has entered into a distribution agreement with LeMaitre Vascular, Inc. (Nasdaq: LMAT) (“LeMaitre”), a provider of vascular devices, implants and services. Under the agreement terms, Aziyo will grant LeMaitre exclusive U.S. distribution rights for the products within its cardiovascular segment: ProxiCor® PC, ProxiCor® CTR, Tyke® and VasCure®.

“We are thrilled to collaborate with LeMaitre, an established leader in the vascular space, to distribute our cardiovascular surgery products,” said Dr. Randy Mills, President and Chief Executive Officer of Aziyo. “Our products are designed to be highly efficacious across a wide range of applications, and we look forward to expanding their availability by leveraging LeMaitre’s much larger commercial organization. This partnership should increase our operational efficiency as we focus our commercial resources behind our CanGaroo Envelope, which is utilized to help reduce complications associated with implantable electronic devices such as pacemakers, defibrillators and neuromodulation devices.”

Aziyo’s cardiovascular products are based on an extracellular matrix derived from porcine small intestine submucosa, which has been shown to modulate biologic healing response and reduce inflammation in a range of surgical applications. The products include: ProxiCor® PC, used for pericardial closure; ProxiCor® CTR, used for cardiac tissue repair; Tyke®, the only extracellular matrix cleared for neonatal and infant patch, pledget and intracardiac repair; and VasCure® for vascular repair. The term of the collaboration is three years, and LeMaitre will have the exclusive option to acquire the product line following the first year or under certain other circumstances.

David Roberts, LeMaitre’s President, commented, “We are pleased to be partnering with Aziyo to add these next-generation products to our U.S. product offering and to provide our vascular and cardiac surgeons an extracellular option in addition to our existing range of biologic patches.”

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 effectiveness of our products, the ability to expand availability of our products or increase our operational efficiency as a result of our distribution arrangement with LeMaitre, and the potential success of our distribution arrangement with LeMaitre. 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 arrangement with LeMaitre; 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 its 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; 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; 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 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.

Investors:

Matt Steinberg
FINN Partners
matt.steinberg@finnpartners.com

Media:

Courtney Guyer
Aziyo Biologics, Inc.
PR@aziyo.com
