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): October 25, 2021

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:

	Trading	Name of each exchange on which
Title of each class	Symbols	registered
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 \boxtimes

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 2.02. Results of Operations and Financial Condition.

Preliminary Third Quarter Revenue Results

On October 25, 2021, Aziyo Biologics, Inc. (the "Company" or "Aziyo") announced preliminary revenue of approximately \$11.5 million for the three months ended September 30, 2021, compared to \$11.8 million for the three months ended September 30, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The preliminary information set forth above does not represent a comprehensive statement of the Company's results of operations or financial condition as of or for the quarterly period ended September 30, 2021. The final comprehensive statements of our results of operations and financial condition as of and for the quarterly period ended September 30, 2021 may vary from the Company's current expectations and may be different from the information described above as the Company's quarterly financial statement close process is not yet complete and additional developments and adjustments may arise between now and the time the financial information for this period is finalized. In addition, these preliminary estimates are not necessarily indicative of the results to be achieved for the remainder of 2021 or in any future period. There can be no assurance that these estimates will be realized, and estimates are subject to risks and uncertainties, many of which are not within the Company's control which are highly uncertain and cannot be predicted.

Conference Call

Aziyo expects to issue full financial results for the third quarter 2021 on Tuesday, November 9, 2021, to be followed by its quarterly conference call at 1:30 PM Pacific Time / 4:30 PM Eastern Time that day. To listen to the conference call, please dial (833) 665-0667 (US/Canada) or (914) 987-7319 (International) and use the conference ID number 1677709 approximately ten minutes prior to the start time. A webcast of the conference call can be accessed at <u>www.aziyo.com</u> under the investor relations section and will be archived for future reference.

The information in this Current Report on Form 8-K (including Exhibit 99.1) 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 9.01	Financial Statements and Exhibits.
(d) Exhibits	
<u>Exhibit No.</u>	Description
<u>99.1</u>	Press Release of Aziyo Biologics, Inc., dated October 25, 2021
104	Cover Page Interactive Data File (embedded within the 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.

Date: October 25, 2021

AZIYO BIOLOGICS, INC.

By: /s/ Matthew Ferguson

Matthew Ferguson Chief Financial Officer



Aziyo Biologics Provides Business Update and Preliminary Third Quarter 2021 Revenue Results and Announces Timing for Third Quarter 2021 Financial Results

SILVER SPRING, Md. – October 25, 2021 – Aziyo Biologics, Inc. (Nasdaq: AZYO), a commercial-stage regenerative medicine company focused on creating the next generation of differentiated products and improving outcomes in patients undergoing surgery, today announced that it was informed by Medtronic that, after conducting a thorough review of customer and patient needs, Medtronic has made the decision to cease distribution of Cellular Bone Matrix (CBM) products. As a result of this decision, the two companies are working toward a mutual termination of their FiberCel distribution agreement.

"While we are disappointed that Medtronic made the decision to cease distribution of Cellular Bone Matrix products, including Aziyo's FiberCel Fiber Viable Bone Matrix, we will continue to collaborate and mutually support patients that were impacted by the previously announced recall of a single donor lot of this product," said Ron Lloyd, Aziyo's president and chief executive officer. "Over the past several months, Aziyo has developed and implemented measures to further enhance the safety of future production lots. These measures include implementing additional donor screening procedures and developing methodologies to test tissue products for *m.tuberculosis*. We believe these safeguards exceed applicable FDA and industry standards for donor screening and testing. We remain committed to providing high-quality, safe and effective CBM products."

Preliminary Third Quarter Revenue Results

Aziyo announced preliminary revenue of approximately \$11.5 million for the three months ended September 30, 2021, compared to \$11.8 million for the three months ended September 30, 2020. These preliminary results are based on management's initial analysis of operations for the quarter ended September 30, 2021.

"Despite some persistent COVID-related headwinds, as well as the impact of the suspension of sales by our FiberCel distribution partner, we saw strength throughout our product portfolio and growing market support of our regenerative medicine products," added Lloyd. "We are very excited about our near-term growth drivers, especially progress on our next generation CanGaroo envelope. I'm confident that our diversified product portfolio will continue to allow us to address multiple end markets for patients receiving regenerative medicine."

Conference Call

Aziyo expects to issue full financial results for the third quarter 2021 on Tuesday, November 9, 2021, to be followed by its quarterly conference call at 1:30 PM Pacific Time / 4:30 PM Eastern Time that day. To listen to the conference call, please dial (833) 665-0667 (US/Canada) or (914) 987-7319 (International) and use the conference ID number 1677709 approximately ten minutes prior to the start time. A webcast of the conference call can be accessed at <u>www.aziyo.com</u> under the investor relations section and will be archived for future reference.



About Aziyo's Fiber Viable Bone Matrix

Aziyo's Fiber Viable Bone Matrix, which is marketed and separately branded by multiple distributors, is a fiber-based bone repair product made from human tissue and engineered to maintain characteristics of natural tissue. It is marketed for use in orthopedic or reconstructive bone grafting procedures in combination with autologous bone or other forms of allograft bone or alone as a bone graft. Aziyo's Fiber Viable Bone Matrix provides handling properties that are critical for use as a bone void filler in various orthopedic and spinal procedures. This product contains cancellous bone particles with preserved living cells and demineralized cortical bone fibers to facilitate bone repair and healing.

About Aziyo Biologics

Aziyo Biologics is a commercial-stage regenerative medicine company focused on creating the next generation of differentiated products and improving outcomes in patients undergoing surgery, concentrating on patients receiving implantable medical devices. Since its founding in 2015, the Company has created a portfolio of commercial-stage products used in cardiovascular, orthopedic, and reconstructive specialties. 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. 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 ability of the Company's portfolio to address patients receiving regenerative medicine. 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, the important factors discussed under the caption "Risk Factors" in Aziyo's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021, as such risk factors may be updated from time to time in Aziyo's other filings with the SEC, which are accessible on the SEC's website at www.sec.gov and the Investor Relations page of Aziyo's website at www.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. Except to the extent required by law, the Company undertakes no obligation to update or review any estimate, projection, or forward-looking statement.



Investors:

Leigh Salvo Gilmartin Group <u>investors@aziyo.com</u>

Media:

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