

**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): May 10, 2023 (May 4, 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**  
(IRS 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, including 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>
<b>Class A Common Stock, \$0.001 par value per share</b>	<b>AZYO</b>	<b>The Nasdaq Capital Market</b>

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 2.02 Results of Operations and Financial Condition.**

On May 10, 2023, Aziyo Biologics, Inc. (the “Company” or “Aziyo”) issued a press release announcing its results for the first quarter ended March 31, 2023. A copy of the Company’s press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02 of 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 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.**

On May 4, 2023, the Company received written notice (the “Notice”) from the Listing Qualifications Department (the “Staff”) of The Nasdaq Stock Market LLC (“Nasdaq”) notifying the Company that, for 30 consecutive business days, the Company’s Market Value of Listed Securities (“MVLS”) was below the minimum of \$35 million required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2) (the “Market Value Standard”). The Staff also noted that the Company does not meet the requirements under Nasdaq Listing Rules 5550(b)(1) (Equity Standard) and 5550(b)(3) (Net Income Standard).

The Notice provided that, in accordance with Nasdaq Listing Rule 5810(c)(3)(C) (the “Compliance Period Rule”), the Company has a period of 180 calendar days from the date of the Notice, or until October 31, 2023 (the “Compliance Date”), to regain compliance with the Market Value Standard. During this period, the Company’s common stock will continue to trade on the Nasdaq Capital Market. If at any time before the Compliance Date the Company’s MVLS closes at or above \$35 million for a minimum of 10 consecutive business days as required under the Compliance Period Rule, the Staff will provide written confirmation of compliance and will close the matter.

In the event the Company does not regain compliance with the Market Value Standard by the Compliance Date, the Staff will provide a written notification to the Company that its common stock will be subject to delisting. At that time, the Company may appeal the Staff’s delisting determination to a Hearings Panel. However, there can be no assurance that, if the Company receives a delisting notice and appeals the delisting determination by the Staff, such appeal would be successful.

The Company intends to monitor its MVLS between now and the Compliance Date, and may, if appropriate, evaluate available options to resolve the deficiency under the Market Value Standard and regain compliance with the Market Value Standard. The Company may also try to regain compliance with Nasdaq’s alternative continued listing requirements by having stockholders’ equity of at least \$2.5 million, or net income from continuing operations of \$500,000 in the most recently completed fiscal year or in two of the three most recently completed fiscal years. However, there can be no assurance that the Company will be able to regain or maintain compliance with the Nasdaq listing criteria.

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**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

<u>Number</u>	<u>Description</u>
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<a href="#">99.1</a>	<a href="#">Press Release of Aziyo Biologics, Inc., dated May 10, 2023</a>
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104	Cover Page Interactive Data File (formatted as an Inline XBRL document)
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**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.**  
*(Registrant)*

Date: May 10, 2023

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

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## **Aziyo Biologics Reports Highest Sales and Gross Profit in Company History**

*- All Four Business Segments Achieved Growth Led by Strong SimpliDerm and CanGaroo Sales -*

SILVER SPRING, Md., May 10, 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 provided a business update and reported financial results for the first quarter ended March 31, 2023.

### **Business Highlights:**

- Net sales rose 14% compared to the prior-year period, to a record \$13.1 million for first quarter 2023.
- Gross margin increased 11 percentage points year-over-year to 49%.
- Signed a partnership with LeMaitre Vascular to distribute Aziyo’s cardiovascular repair portfolio within the U.S., increasing sales representative coverage 5-fold.
- Launched a U.S. distribution partnership with Sientra to drive availability and utilization of SimpliDerm.
- Held a productive meeting with the U.S. Food and Drug Administration (FDA) confirming the path to resubmit CanGaroo® RM 510(k) for pre-market clearance.

“Aziyo’s record first quarter performance is a testament to our products, people and plan,” said Dr. Randy Mills, President and Chief Executive Officer of Aziyo Biologics. “The company charged forward with strong results on all fronts, highlighted by the highest quarterly net sales and gross profit in company history. We also made great progress in the strategic evolution of Aziyo, closing two key partnerships with LeMaitre Vascular and Sientra, thereby significantly boosting the sales coverage of our cardiovascular and SimpliDerm product lines. Lastly, we met with the FDA and are executing a plan to deliver the Agency the information it requested in connection with the clearance of CanGaroo RM. Thank you to the entire Aziyo team for your grit and determination in delivering a great performance.”

### **First Quarter 2023 Financial Results**

Net sales for the first quarter of 2023 were \$13.1 million, an increase of 14% compared to the first quarter of 2022. Growth was achieved in all four of the Company’s major product categories, led by SimpliDerm and CanGaroo, for which net sales grew 40% and 14%, respectively, versus the first quarter of 2022.

Gross profit for the first quarter of 2023 was \$6.3 million and gross margin was 49%, as compared to \$4.3 million and 37%, respectively, in the corresponding prior-year period. Gross margin, excluding intangible asset amortization (a measure not presented in accordance with U.S. generally accepted accounting principles (“GAAP”)) was 55% for the first quarter of 2023, as compared to 45% in the first quarter of 2022. The increase in gross margin was primarily due to efficiency and yield improvements in the Company’s Orthobiologics and Women’s Health business units.

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Total operating expenses were \$12.7 million for the first quarter of 2023, as compared to \$11.2 million in the corresponding prior-year period.

Net loss was \$8.0 million in the first quarter of 2023, as compared to \$8.1 million in the corresponding prior year period. Net loss per share in the first quarter of 2023 was \$0.49 per share, as compared to a loss of \$0.60 per share in the first quarter of 2022.

Aziyo's cash balance as of March 31, 2023, was \$11.8 million.

### **Conference Call**

Aziyo will host a conference call today at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time to discuss its first quarter 2023 financial results and performance.

Individuals interested in listening to the conference call are required to register online. Participants are recommended to register at least 15 minutes before the start of the call. A live and archived webcast of the event and the accompanying presentation materials will be available on the "Investors" section of the Aziyo website at <https://investors.aziyo.com/>.

### **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).

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## 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 as a result of our distribution arrangements with LeMaitre Vascular and Sientra, the potential success of our distribution arrangements with LeMaitre Vascular and Sientra, and our expectations relating to the FDA regulatory process for 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 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; 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](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.

### Investors:

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**AZIYO BIOLOGICS, INC.**  
**CONSOLIDATED BALANCE SHEET DATA**  
(Unaudited, in thousands)

<b>Assets</b>	<b>March 31, 2023</b>	<b>December 31, 2022</b>
<b>Current assets:</b>		
Cash	\$ 11,789	\$ 16,989
Accounts receivable, net	7,334	6,830
Inventory	11,055	10,052
Receivables of FiberCel litigation costs	10,921	13,813
Prepaid expense and other assets	2,367	3,015
<b>Total current assets</b>	<b>43,466</b>	<b>50,699</b>
Property and equipment, net	1,488	1,403
Intangible assets, net	14,220	15,069
Operating lease right-of-use assets, and other	1,456	1,670
<b>Total assets</b>	<b>\$ 60,630</b>	<b>\$ 68,841</b>
<b>Liabilities and Stockholders' Deficit</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 15,527	\$ 15,583
Current portion of long-term debt and revenue interest obligation	9,678	8,990
Revolving line of credit	-	-
Contingent liability for FiberCel litigation	15,631	17,360
Current operating lease liabilities and other	588	682
<b>Total current liabilities</b>	<b>41,424</b>	<b>42,615</b>
Long-term debt	24,589	24,260
Long-term revenue interest obligation	5,750	5,916
Long-term operating lease liabilities	835	956
Other long-term liabilities	207	127
<b>Total liabilities</b>	<b>72,805</b>	<b>73,874</b>
<b>Stockholders' equity (deficit):</b>		
Common stock	16	16
Additional paid-in capital	133,771	132,939
Accumulated deficit	(145,962)	(137,988)
<b>Total stockholders' equity (deficit)</b>	<b>(12,175)</b>	<b>(5,033)</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 60,630</b>	<b>\$ 68,841</b>

**AZIYO BIOLOGICS, INC.**  
**CONSOLIDATED STATEMENT OF OPERATIONS**  
(Unaudited, in thousands, except share and per share data)

	<b>Three months ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
Net sales	\$ 13,050	\$ 11,495
Cost of goods sold	6,719	7,214
Gross profit	<u>6,331</u>	<u>4,281</u>
Operating expenses:		
Sales and marketing	5,356	4,818
General and administrative	3,679	4,025
Research and development	1,803	2,272
FiberCel litigation costs	1,911	88
Total operating expenses	<u>12,749</u>	<u>11,203</u>
Loss from operations	(6,418)	(6,922)
Interest expense	1,544	1,215
Loss before provision of income taxes	(7,962)	(8,137)
Provision for income taxes	12	12
Net loss	<u>(7,974)</u>	<u>(8,149)</u>
Net loss per share - basic and diluted	<u>\$ (0.49)</u>	<u>\$ (0.60)</u>
Weighted average common shares outstanding - basic and diluted	<u>16,149,567</u>	<u>13,574,058</u>

## Non-GAAP Financial Measures

This press release presents our gross margin, excluding intangible asset amortization. We calculate gross margin, excluding intangible asset amortization, as gross profit, excluding amortization expense relating to intangible assets we acquired in our acquisition of all of the commercial assets of CorMatrix Cardiovascular, Inc. in 2017, divided by net sales.

We present gross margin, excluding intangible asset amortization, because we believe that it provides meaningful supplemental information regarding our operating performance by removing the impact of amortization expense, which is not indicative of our overall operating performance. We believe this provides our management and investors with useful information to facilitate period-to-period comparisons of our operating results. Our management uses this metric in assessing the health of our business and our operating performance, and we believe investors' understanding of our operating performance is similarly enhanced by our presentation of this metric.

Gross margin, excluding intangible asset amortization, is a supplemental measure of our performance, is not defined by or presented in accordance GAAP, has limitations as an analytical tool and should not be considered in isolation or as an alternative to our GAAP gross margin, gross profit or any other financial performance measure presented in accordance with GAAP. In addition, other companies, including companies in our industry, may use other measures to evaluate their performance, which could reduce the usefulness of this non-GAAP financial measure as a tool for comparison.

The following table presents a reconciliation of our gross margin, excluding intangible asset amortization, to the most directly comparable GAAP financial measure, which is our GAAP gross margin (in thousands).

	Three months ended March 31,	
	2023	2022
Net sales	\$ 13,050	\$ 11,495
Gross profit	6,331	4,281
Intangible asset amortization expense	849	849
Gross profit, excluding intangible asset amortization	\$ 7,180	\$ 5,130
Gross margin	48.5%	37.2%
Gross margin percentage, excluding intangible asset amortization	55.0%	44.6%

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