

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): August 14, 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>
Class A Common Stock, \$0.001 par value per share	AZYO	The Nasdaq Capital 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 2.02 Results of Operations and Financial Condition.

On August 14, 2023, Aziyo Biologics, Inc. (the “Company” or “Aziyo”) issued a press release announcing its results for the second quarter ended June 30, 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 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Number</u>	<u>Description</u>
99.1	Press Release of Aziyo Biologics, Inc., dated August 14, 2023
104	Cover Page Interactive Data File (formatted as an 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.
(Registrant)

Date: August 14, 2023

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



Aziyo Biologics Reports Second Quarter 2023 Financial Results - Transformation Continues to Drug-Eluting Biomatrix Company

Negotiating multiple LOIs to divest Orthopedic business

CanGaroo[®] RM 510(k) resubmission to the FDA remains on track

SimpliDerm[®] quarterly net sales up 32% year-over-year

Successful transfer of Cardiovascular product distribution to LeMaitre Vascular

SILVER SPRING, Md., Aug. 14, 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 second quarter ended June 30, 2023.

“Our strategy to transform Aziyo into a high growth drug-eluting biomatrix product company continues to move forward,” said Dr. Randy Mills, President and Chief Executive Officer of Aziyo Biologics. “We are in discussions with several interested parties to divest our Orthopedic business and have made significant progress in preparing our resubmission of CanGaroo RM for 510(k) clearance with the FDA. Furthermore, SimpliDerm had a strong quarter with sales up 32%, and we are pleased with higher sales volume of our Cardiovascular segment following our product distribution agreement with LeMaitre Vascular.”

“Regarding the voluntary recall of our viable bone matrix products, we continue to work closely with the FDA and the CDC to fully investigate the matter. Patients are at the center of everything we do at Aziyo and their safety will continue to be our foremost priority,” added Dr. Mills.

Second Quarter 2023 Financial Results

Net sales for the second quarter of 2023 were \$10.3 million, compared to \$12.6 million in the second quarter of 2022. The decrease was primarily due to the viable bone matrix recall and market withdrawal in July 2023, which resulted in the reversal of \$3.0 million of second quarter revenue.

While the voluntary recall and market withdrawal of the Company’s viable bone matrix products negatively impacted the Orthopedic segment, the Women’s Health segment and its SimpliDerm product experienced 32% growth in the second quarter of 2023 compared to the corresponding prior-year period. Device Protection revenue during the second quarter was relatively consistent compared to the prior-year period, and net sales from the Cardiovascular segment declined due to the commencement of the Company’s distribution agreement with LeMaitre Vascular, which resulted in increased sales volume but at distributor transfer pricing rather than the previous end-user pricing.

Gross profit for the second quarter of 2023 was \$1.0 million and gross margin was 9.5%, as compared to \$4.9 million and 38.8%, 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 17.8% for the second quarter of 2023, as compared to 45.5% in the second quarter of 2022. The decline in gross margin was due to the impact of the viable bone matrix recall and market withdrawal, which decreased second quarter gross profit by \$5.0 million and gross margin by 35%.

Total operating expenses were \$10.1 million for the second quarter of 2023, as compared to \$13.1 million in the corresponding prior-year period.

Net loss was \$10.6 million in the second quarter of 2023, as compared to \$9.4 million in the corresponding prior year period. Net loss per share in the second quarter of 2023 was \$0.65 per share, as compared to a loss of \$0.69 per share in the second quarter of 2022.

Aziyo’s cash balance as of June 30, 2023, was \$9.3 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 second 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.

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 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, our expectations regarding the potential disposition of our Orthopedics business 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 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 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

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

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
Assets		
Current assets:		
Cash	\$ 9,296	\$ 16,989
Accounts receivable, net	6,317	6,830
Inventory	9,274	10,052
Receivables of FiberCel litigation costs	8,876	13,813
Prepaid expense and other assets	2,363	3,015
Total current assets	<u>36,126</u>	<u>50,699</u>
Property and equipment, net	1,467	1,403
Intangible assets, net	13,370	15,069
Operating lease right-of-use assets, and other	1,366	1,670
Total assets	<u>\$ 52,329</u>	<u>\$ 68,841</u>
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses and other current liabilities	\$ 17,411	\$ 15,583
Current portion of long-term debt and revenue interest obligation	10,366	8,990
Contingent liability for FiberCel litigation	14,470	17,360
Current operating lease liabilities	620	682
Total current liabilities	<u>42,867</u>	<u>42,615</u>
Long-term debt	24,927	24,260
Long-term revenue interest obligation	5,601	5,916
Long-term operating lease liabilities	711	956
Other long-term liabilities	351	127
Total liabilities	<u>74,457</u>	<u>73,874</u>
Stockholders' equity (deficit):		
Common stock	16	16
Additional paid-in capital	134,439	132,939
Accumulated deficit	(156,583)	(137,988)
Total stockholders' equity (deficit)	<u>(22,128)</u>	<u>(5,033)</u>
Total liabilities and stockholders' equity	<u>\$ 52,329</u>	<u>\$ 68,841</u>

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

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Net sales	\$ 10,296	\$ 12,638	\$ 23,346	\$ 24,133
Cost of goods sold	9,316	7,740	16,035	14,954
Gross profit	<u>980</u>	<u>4,898</u>	<u>7,311</u>	<u>9,179</u>
Operating expenses:				
Sales and marketing	3,618	5,406	8,974	10,224
General and administrative	4,005	4,711	7,684	8,736
Research and development	1,171	2,617	2,974	4,889
FiberCel litigation costs	1,271	346	3,182	434
Total operating expenses	<u>10,065</u>	<u>13,080</u>	<u>22,814</u>	<u>24,283</u>
Loss from operations	(9,085)	(8,182)	(15,503)	(15,104)
Interest expense	1,524	1,204	3,068	2,419
Loss before provision of income taxes	(10,609)	(9,386)	(18,571)	(17,523)
Provision for income taxes	12	12	24	24
Net loss	<u>(10,621)</u>	<u>(9,398)</u>	<u>(18,595)</u>	<u>(17,547)</u>
Net loss attributable to common stockholders	<u>(10,621)</u>	<u>(9,398)</u>	<u>(18,595)</u>	<u>(17,547)</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (0.65)</u>	<u>\$ (0.69)</u>	<u>\$ (1.15)</u>	<u>\$ (1.29)</u>
Weighted average common shares outstanding - basic and diluted	<u>16,223,919</u>	<u>13,620,196</u>	<u>16,208,905</u>	<u>13,597,243</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 June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Net sales	\$ 10,296	\$ 12,638	\$ 23,346	\$ 24,133
Gross profit	980	4,898	7,311	9,179
Intangible asset amortization expense	849	849	1,698	1,698
Gross profit, excluding intangible asset amortization	\$ 1,829	\$ 5,747	\$ 9,009	\$ 10,877
Gross margin	9.5%	38.8%	31.3%	38.0%
Gross margin percentage, excluding intangible asset amortization	17.8%	45.5%	38.6%	45.1%