

**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 11, 2022

**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:

Title of each class	Trading Symbols	Name of each exchange on which registered
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 Operation and Financial Condition.**

On August 11, 2022, Aziyo Biologics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2022. The full text 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 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.

**Exhibit No. Description**

[99.1](#) [Press Release of Aziyo Biologics, Inc., dated August 11, 2022.](#)

104 Cover Page Interactive Data File (formatted as 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.

Date: August 11, 2022

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

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## **Aziyo Biologics Announces Second Quarter 2022 Financial Results and Recent Business Achievements, Including Robust Revenue Growth and Strengthened Balance Sheet**

**SILVER SPRING, Md.** – August 11, 2022 – Aziyo Biologics, Inc. (Nasdaq: AZYO), a commercial-stage regenerative medicine company, today provided a business update and reported financial results for the second quarter June 30, 2022.

### **Recent Highlights**

- Total net sales of \$12.6 million, a 3.9% increase compared to \$12.2 million in the second quarter of 2021
  - o Net sales growth from existing products of 20.3%, after excluding Q2 2021 sales of discontinued product FiberCel
- Co-founder and board member C. Randal Mills, Ph.D. named Chief Executive Officer
  - o Follows appointment as Interim CEO in June 2022
- Closed \$25 million loan facility with SWK Corporation (“SWK Holdings”)

“First, I want to thank the outstanding team at Aziyo for another great performance,” said Dr. Randy Mills, CEO. “You make possible everything we do and will accomplish going forward.”

Dr. Mills continued, “Since June I have been meeting with our partners, physicians and Aziyo team members. During this time, three things have become crystal clear to me. One, there exists remarkably favorable market dynamics for which we have domain expertise. Two, our existing technology platform uniquely enables us to capture this demand with best-in-class products, including CanGaroo<sup>®</sup> RM, which is currently under review at FDA. And three, we are well positioned to leverage strategic partnerships to grow quickly and efficiently, better serving our patient’s needs.”

### **Second Quarter 2022 Financial Results**

Net sales for the second quarter of 2022 were \$12.6 million, an increase of 3.9%, compared to the second quarter of 2021. Net sales of core products were \$9.1 million in the second quarter of 2022, compared to \$10.0 million for the second quarter of 2021, and net sales of non-core products were \$3.6 million in the second quarter of 2022, compared to \$2.2 million in the second quarter of 2021. Net sales from current products increased 20.3% in the second quarter of 2022 compared to the corresponding prior year quarter, after excluding second quarter 2021 sales of \$1.7 million from discontinued product FiberCel.

Gross profit for the second quarter of 2022 was \$4.9 million and gross margin was 38.8%, as compared to \$5.6 million and 46.2%, 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 45.5% for the second quarter of 2022, as compared to 53.1% in the second quarter of 2021. The decline in gross margin was primarily due to higher net sales of non-core products net sales in the second quarter of 2022, which had lower gross margins.

Total operating expenses were \$13.1 million for the second quarter of 2022, as compared to \$10.2 million in the corresponding prior-year period, representing an increase of 28.1%. The increase was primarily due to higher stock-based compensation, legal expenses, the Company’s CEO transition and CanGaroo RM development.

Net loss was \$9.4 million in the second quarter of 2022, as compared to \$2.4 million in the corresponding period of the prior year. Net loss in the second quarter of 2021 included non-recurring other income related to forgiveness of \$3.0 million of indebtedness under the Paycheck Protection Program of the CARES Act, as well as a payment to Aziyo of \$550,000 in accordance with the terms of a settlement agreement related to a 2015 corporate transaction.

Loss per share in the second quarter of 2022 was \$0.69 per share, compared to a loss of \$0.23 per share in the second quarter of 2021.

Aziyo’s cash balance as of June 30, 2022, was \$16.5 million, and total liquidity including available capacity under the Company’s working capital line of credit was \$17.5 million.

### **Debt Refinancing**

On August 10, 2022, the Company entered into a \$25 million credit facility with SWK Holdings. The facility included an initial term loan of \$21 million that the Company intends to use to fund its on-going commercial and product development initiatives and through which it repaid the outstanding balances under its previous term loan and working capital credit facility. The new facility also provides for an additional term loan of \$4 million, subject to the achievement of specified operational and financial metrics by September 30, 2023. In addition, the loan facility allows for the establishment of a new asset-based revolving loan facility of up to \$8 million.

### **Guidance for Full Year 2022**

Aziyo confirmed its expectation that total net sales for the full year 2022 will be in the range of \$47 million to \$50 million. Excluding approximately \$4.9 million of FiberCel sales in 2021, this range represents expected growth of 11% to 18%.

### **Conference Call**

Aziyo will host a conference call at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time on Thursday, August 11, 2022, to discuss its second quarter 2022 financial results, performance and vision for the future. Individuals interested in listening to the conference call are required to [register online](#). Participants are required 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 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](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. 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 Company's anticipated financial performance; possible or assumed future results of operations, including descriptions of the Company's revenues, profitability, outlook, guidance for the full year 2022 and overall business strategy and expected success; expectations regarding the Company's operational position, opportunities and deliverables, goals, strategies, priorities and initiatives; and the timing of regulatory clearance and product launch. 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, risks regarding the Company's products and its ability to enhance, expand and develop its products; 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 its distribution partner; the Company's dependence on its commercial partners; the adverse impacts of COVID-19 or adverse changes in economic conditions; 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; and the Company's intellectual property rights, and other important factors 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, 2021, as such factors may be updated from time to time in Aziyo's other filings with the SEC, including, Aziyo's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022 to be filed with the SEC, 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. 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  
[investors@aziyo.com](mailto:investors@aziyo.com)

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

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
<b>Assets</b>		
Current assets:		
Cash	\$ 16,511	\$ 30,428
Accounts receivable, net	6,646	5,996
Inventory	9,699	9,554
Prepaid expense and other assets	1,828	1,450
<b>Total current assets</b>	<u>34,684</u>	<u>47,428</u>
Property and equipment, net	1,326	1,200
Intangible assets, net	16,768	18,466
Other assets	76	76
<b>Total assets</b>	<u>\$ 52,854</u>	<u>\$ 67,170</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 12,480	\$ 10,424
Current portion of long-term debt and revenue interest obligation	15,809	10,809
Revolving line of credit	6,452	4,763
Other current liabilities	8	5
<b>Total current liabilities</b>	<u>34,749</u>	<u>26,001</u>
Long-term debt	7,106	10,410
Long-term revenue interest obligation	11,469	16,540
Deferred revenue and other long-term liabilities	899	698
<b>Total liabilities</b>	<u>54,223</u>	<u>53,649</u>
Stockholders' equity (deficit):		
Common stock	13	13
Additional paid-in capital	121,256	118,599
Accumulated deficit	(122,638)	(105,091)
<b>Total stockholders' equity (deficit)</b>	<u>(1,369)</u>	<u>13,521</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 52,854</u>	<u>\$ 67,170</u>

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

	<b>Three months ended June 30,</b>		<b>Six months ended June 30,</b>	
	<b>2022</b>	<b>2021</b>	<b>2022</b>	<b>2021</b>
Net sales	\$ 12,638	\$ 12,160	\$ 24,133	\$ 25,044
Cost of goods sold	7,740	6,546	14,954	13,101
Gross profit	<u>4,898</u>	<u>5,614</u>	<u>9,179</u>	<u>11,943</u>
Operating expenses:				
Sales and marketing	5,406	4,799	10,224	9,502
General and administrative	5,057	3,529	9,170	7,134
Research and development	2,617	1,881	4,889	3,601
Total operating expenses	<u>13,080</u>	<u>10,209</u>	<u>24,283</u>	<u>20,237</u>
Loss from operations	(8,182)	(4,595)	(15,104)	(8,294)
Interest expense	1,204	1,351	2,419	2,706
Other (income) expense, net	-	(3,579)	-	(3,579)
Loss before provision of income taxes	<u>(9,386)</u>	<u>(2,367)</u>	<u>(17,523)</u>	<u>(7,421)</u>
Provision for income taxes	12	18	24	31
Net loss	<u>(9,398)</u>	<u>(2,385)</u>	<u>(17,547)</u>	<u>(7,452)</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (0.69)</u>	<u>\$ (0.23)</u>	<u>\$ (1.29)</u>	<u>\$ (0.73)</u>
Weighted average common shares outstanding - basic and diluted	<u>13,620,196</u>	<u>10,228,296</u>	<u>13,597,243</u>	<u>10,227,240</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. 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. 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.

Although we use gross margin, excluding intangible asset amortization, as described above, this metric has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information 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,	
	2022	2021	2022	2021
Net sales	\$ 12,638	\$ 12,160	\$ 24,133	\$ 25,044
Gross profit	4,898	5,614	9,179	11,943
Intangible asset amortization expense	849	849	1,698	1,698
Gross profit, excluding intangible asset amortization	\$ 5,747	\$ 6,463	\$ 10,877	\$ 13,641
Gross margin	38.8%	46.2%	38.0%	47.7%
Gross margin percentage, excluding intangible asset amortization	45.5%	53.1%	45.1%	54.5%