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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**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 9, 2022

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**AZIYO BIOLOGICS, INC.**

(Exact name of registrant as specified in its charter)

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**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)

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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 Symbol(s)	Name of each exchange on which 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

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.

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**Item 2.02. Results of Operation and Financial Condition.**

On May 9, 2022, Aziyo Biologics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 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

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release of Aziyo Biologics, Inc., May 9, 2022</a>
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: May 9, 2022

By: /s/ Ronald Lloyd

Ronald Lloyd

President and Chief Executive Officer

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## Aziyo Biologics Provides Business Update and Reports First Quarter 2022 Financial Results

**SILVER SPRING, Md.** – May 9, 2022 – 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 provided a business update and reported financial results for the first quarter March 31, 2022.

### Recent Highlights

- Submitted 510(k) application and subsequently received acceptance for review by the FDA for CanGaroo RM, the company's next-generation biomaterial envelope for use with implantable electronic devices
- Total net sales of \$11.5 million, an 11% decrease compared to \$12.9 million in the first quarter of 2021
  - CanGaroo and SimpliDerm first quarter revenue growth over 25% for each product compared to the prior year
  - Excluding the contribution of FiberCel sales, which were discontinued by the product's distributor in the second quarter of 2021, achieved 14% revenue growth over the first quarter of 2021

“Our first quarter results reflected another strong quarter as the Aziyo team continued to execute on our commercial initiatives and to track according to plan against key product milestones. We were especially pleased to see our CanGaroo and SimpliDerm product lines each grow greater than 25% over the first quarter of 2021, reflecting both new accounts as well as expanded usage,” said Ron Lloyd, Chief Executive Officer. “Our contract manufacturing business also demonstrated particular strength in the first quarter, as our partners continued to leverage our tissue processing and development capabilities.”

“Additionally, our 510(k) application with the FDA for our next generation biomaterial envelope, CanGaroo RM, was accepted for review. This product has the potential to be the main driver of our business in the coming years, addressing an estimated \$600 million annual market. Pending FDA clearance, we remain on track for launch in the latter half of 2022 to set up a strong 2023 and beyond,” added Lloyd.

### First Quarter 2022 Financial Results

Net sales for the first quarter of 2022 were \$11.5 million, a decrease of 11%, compared to the first quarter of 2021. Net sales of core products were \$8.1 million in the first quarter of 2022, compared to \$10.7 million for the first quarter of 2021, and net sales of non-core products were \$3.4 million in the first quarter of 2022, compared to \$2.2 million in the first quarter of 2021. Excluding sales of FiberCel, which were \$2.8 million in the first quarter of 2021, total net sales for the first quarter of 2022 increased 14% compared to the first quarter of 2021.

Gross profit for the first quarter of 2022 was \$4.3 million and gross margin was 37%, as compared to \$6.3 million and 49%, 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% for the first quarter of 2022, as compared to 56% in the first

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quarter of 2021. The decline in gross margin compared to the prior-year quarter primarily related to product mix and reduced yields in the Company's viable bone product line.

Total operating expenses were \$11.2 million for the first quarter of 2022, as compared to \$10.0 million in the corresponding prior-year period, representing an increase of 12%, primarily due to increased expenses related to the development of CanGaroo RM.

Net loss was \$8.1 million in the first quarter of 2022, as compared to \$5.1 million in the corresponding period of the prior year. Loss per share in the first quarter of 2022 was \$0.60 per share, compared to a loss of \$0.50 per share in the first quarter of 2021.

Aziyo's cash balance as of March 31, 2022, was \$22.2 million, and total liquidity including available capacity under the Company's working capital line of credit was \$23.1 million.

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

Aziyo is confirming its expectation that total net sales for the full year 2022 will range between \$47 to \$50 million. Excluding approximately \$4.9 million of FiberCel sales in 2021, this range represents expected growth of 11% to 18%. The low end of this range implies no contribution from CanGaroo RM by year end and the high end assumes clearance and commercial availability of CanGaroo RM by the fourth quarter of 2022.

### **Conference Call**

Aziyo will host a conference call at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time on Monday, May 9, 2022, to discuss its first quarter 2022 financial results. A link to the webcast will be available on the Aziyo Biologics, Inc. website at [www.aziyo.com](http://www.aziyo.com) under the investor relations section and will be archived for future reference. The call may be accessed through an operator by calling (833) 665-0667 for domestic callers and (914) 987-7319 for international callers using conference ID number 9975003.

### **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

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position, opportunities and deliverables, goals, strategies, priorities and initiatives, including expectations regarding the Company's partnerships, pipeline, and anticipated new product launches, including platform opportunities and advancement with respect to CanGaroo RM, and the potential results thereof. 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 March 31, 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)

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

<b>Assets</b>	<u>March 31, 2022</u>	<u>December 31, 2021</u>
Current assets:		
Cash	\$ 22,175	\$ 30,428
Accounts receivable, net	6,010	5,996
Inventory	9,863	9,554
Prepaid expense and other assets	<u>3,030</u>	<u>1,450</u>
Total current assets	41,078	47,428
Property and equipment, net	1,155	1,200
Intangible assets, net	17,617	18,466
Other assets	<u>76</u>	<u>76</u>
<b>Total assets</b>	<u>\$ 59,926</u>	<u>\$ 67,170</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 10,349	\$ 10,424
Current portion of long-term debt and revenue interest obligation	10,809	10,809
Revolving line of credit	6,160	4,763
Other current liabilities	<u>-</u>	<u>5</u>
Total current liabilities	27,318	26,001
Long-term debt	8,758	10,410
Long-term revenue interest obligation	16,520	16,540
Other long-term liabilities	<u>771</u>	<u>698</u>
Total liabilities	<u>53,367</u>	<u>53,649</u>
Stockholders' equity (deficit):		
Common stock	13	13
Additional paid-in capital	119,786	118,599
Accumulated deficit	<u>(113,240)</u>	<u>(105,091)</u>
Total stockholders' equity	<u>6,559</u>	<u>13,521</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 59,926</u>	<u>\$ 67,170</u>

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

	Three months ended March 31,	
	2022	2021
Net sales	\$ 11,495	\$ 12,884
Cost of goods sold	7,214	6,555
Gross profit	4,281	6,329
Operating expenses:		
Sales and marketing	4,818	4,703
General and administrative	4,113	3,605
Research and development	2,272	1,720
Total operating expenses	11,203	10,028
Loss from operations	(6,922)	(3,699)
Interest expense	1,215	1,355
Loss before provision of income taxes	(8,137)	(5,054)
Provision for income taxes	12	13
Net loss	(8,149)	(5,067)
Net loss per share - basic and diluted	\$ (0.60)	\$ (0.50)
Weighted average common shares outstanding - basic and diluted	13,574,058	10,226,152

### 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).

	<u>Three months ended March 31,</u>	
	<u>2021</u>	<u>2020</u>
Net sales	\$ 11,495	\$ 12,884
Gross profit	4,281	6,329
Intangible asset amortization expense	849	849
Gross profit, excluding intangible asset amortization	\$ 5,130	\$ 7,178
Gross margin	37.2%	49.1%
Gross margin percentage, excluding intangible asset amortization	44.6%	55.7%

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