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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): March 3, 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 Symbols	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 March 3, 2022, Aziyo Biologics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and year ended December 31, 2021. 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., March 3, 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: March 3, 2022

By: /s/ Ronald Lloyd  
Ronald Lloyd  
President and Chief Executive Officer

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## Aziyo Biologics Reports Fourth Quarter and Full Year 2021 Financial Results

**SILVER SPRING, Md.** – March 3, 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 reported financial results for the fourth quarter and full year ended December 31, 2021.

### Highlights

- Fourth quarter 2021
  - Total net sales of \$10.9 million, a 13% decrease compared to \$12.5 million in the fourth quarter of 2020
  - Excluding the contribution of FiberCel sales, which were discontinued by the product's distributor in the second quarter of 2021, achieved 6% revenue growth over the fourth quarter of 2020
- Full Year 2021
  - Total net sales of \$47.4 million, an 11% increase as compared to \$42.7 million for the full year 2020
  - Excluding the contribution of FiberCel sales, achieved 19% revenue growth over the full year 2020
- Completed PIPE financing resulting in gross proceeds of approximately \$13.8 million, bringing the Company's cash position to \$30.4 million at December 31, 2021
- A 510(k) application for CanGaroo RM, the company's next generation envelope, remains on track for submission by the end of the first quarter 2022

"Throughout the year, our team made great progress, meeting a number of critical milestones to set up 2022 as a breakout year for Aziyo. We also saw year-over-year revenue growth for the full year, with our CanGaroo and SimpliDerm product lines bolstering the fourth quarter," said Ron Lloyd, Chief Executive Officer. "Despite the headwinds of 2021, our timeline for FDA submission of CanGaroo RM, the next generation of our flagship product, remains on track as we plan, subject to FDA clearance, for commercial launch in the second half of 2022.

"In addition, anticipated new product introductions to augment our other regenerative medicine portfolios, emerging opportunities to expand our orthopedic and spine repair partnerships, as well as increasing clinical data gives us further confidence that the milestones we anticipate achieving this year set us up for an even stronger 2023. We are also pursuing efficiencies throughout our entire business that we expect will increase our margins and improve productivity," added Lloyd.

#### **Fourth Quarter 2021 Financial Results**

Net sales for the fourth quarter of 2021 were \$10.9 million, a decrease of 13%, compared to the fourth quarter of 2020. Net sales of core products were \$8.4 million in the fourth quarter of 2021, compared to \$10.3 million for the fourth quarter of 2020, and net sales of non-core products were \$2.5 million in the fourth quarter of 2021, compared to \$2.2 million in the fourth quarter of 2020. The decrease in total net sales was primarily due to the discontinuation of sales of FiberCel by its distributor in the second quarter of 2021. Excluding sales of FiberCel, which were \$2.2 million in the fourth quarter of 2020, total net sales for the fourth quarter of 2021 increased 6% compared to the fourth quarter of 2020.

Gross profit for the fourth quarter of 2021 was \$3.4 million and gross margin was 31.2%, as compared to \$6.0 million and 48.3%, 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 39.0% for the fourth quarter of 2021, as compared to 55.1% in the fourth quarter of 2020. Gross profit and gross margin percent for the quarter were negatively impacted by approximately \$1.1 million and 10%, respectively, due to increased reserves for excess inventories in the Company's human tissue business. Gross margin, excluding intangible asset amortization, is expected to return to 50% or better during 2022.

Total operating expenses were \$11.2 million for the fourth quarter of 2021, as compared to \$10.0 million in the corresponding prior-year period, representing an increase of 11.7%.

Net loss was \$9.1 million in the fourth quarter of 2021, as compared to \$5.4 million in the corresponding period of the prior year. Loss per share in the fourth quarter of 2021 was \$0.82 per share, compared to a loss of \$0.57 per share in the fourth quarter of 2020.

Aziyo's cash balance as of December 31, 2021, was \$30.4 million. On December 8, 2021, the Company completed a PIPE financing that yielded net proceeds of approximately \$13.8 million, supporting Aziyo's efforts to further scale its commercial activities, generate data through ongoing clinical studies and support certain development costs associated with the launch of CanGaroo RM.

#### **Full Year 2021 Financial Results**

Net sales for the full year 2021 were \$47.4 million, an increase of 11% compared to full year 2020 net sales of \$42.7 million. Net sales of core products were \$37.6 million for the full year 2021, compared to \$36.2 million for the full year 2020, and net sales of non-core products were \$9.8 million for the full year 2021, compared to \$6.5 million for the full year 2020. Excluding sales of FiberCel, which were \$7.1 million in 2020 and \$4.9 million in 2021, total net sales for the full year 2021 increased 19% compared to the full year 2020.

Gross profit for the full year 2021 was \$19.0 million and gross margin was approximately 40.1%, as compared to \$20.6 million and approximately 48.2% in the prior year. Gross margin, excluding intangible asset amortization (a non-GAAP financial measure) was approximately 47.3% for the full year 2021, as compared to 56.1% in the full year 2020.

Total operating expenses were \$42.1 million for the full year 2021, as compared to \$34.2 million in the corresponding prior year, representing an increase of 23.1%.

Net loss was \$24.8 million in the full year 2021, as compared to \$21.8 million in the prior year. Loss per share in the full year 2021 was \$2.38 per share, compared to a loss of \$8.88 per share in the full year 2020, which includes the accretion of deemed dividends to the preferred stockholders.

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

Aziyo expects total net sales for the full year 2022 to 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 Q4.

### **Conference Call**

Aziyo will host a conference call at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time on Thursday, March 3, 2022, to discuss its fourth quarter and full year 2021 financial results. 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 2796569. A live and archived webcast of the conference call will be available 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, 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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021, as such factors may be updated from time to time in Aziyo's other filings with the SEC, including, Aziyo's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 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)

<b>Assets</b>	<u>December 31, 2021</u>	<u>December 31, 2020</u>
Current assets:		
Cash	\$ 30,428	\$ 39,532
Accounts receivable, net	5,996	7,166
Inventory	9,554	10,117
Prepaid expense and other assets	1,450	2,892
Total current assets	<u>47,428</u>	<u>59,707</u>
Property and equipment, net	1,200	1,162
Intangible assets, net	18,466	21,865
Other assets	76	76
<b>Total assets</b>	<u><u>\$ 67,170</u></u>	<u><u>\$ 82,810</u></u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 10,424	\$ 10,672
Current portion of long-term debt and revenue interest obligation	10,809	9,060
Revolving line of credit	4,763	6,514
Deferred revenue and other current liabilities	5	533
Total current liabilities	<u>26,001</u>	<u>26,779</u>
Long-term debt	10,410	17,811
Long-term revenue interest obligation	16,540	16,633
Other long-term liabilities	698	756
Total liabilities	<u>53,649</u>	<u>61,979</u>
Stockholders' equity (deficit):		
Common stock	13	10
Additional paid-in capital	118,599	101,080
Accumulated deficit	(105,091)	(80,259)
Total stockholders' equity	<u>13,521</u>	<u>20,831</u>
<b>Total liabilities and stockholders' equity</b>	<u><u>\$ 67,170</u></u>	<u><u>\$ 82,810</u></u>



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

	<u>Three months ended December 31,</u>		<u>Twelve months ended December 31,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Net sales	\$ 10,861	\$ 12,466	\$ 47,390	\$ 42,682
Cost of goods sold	7,471	6,445	28,368	22,121
Gross profit	<u>3,390</u>	<u>6,021</u>	<u>19,022</u>	<u>20,561</u>
Operating expenses:				
Sales and marketing	4,540	4,720	18,825	17,565
General and administrative	3,236	3,291	13,963	10,641
Research and development	<u>3,376</u>	<u>1,973</u>	<u>9,266</u>	<u>5,954</u>
Total operating expenses	<u>11,152</u>	<u>9,984</u>	<u>42,054</u>	<u>34,160</u>
Loss from operations	(7,762)	(3,963)	(23,032)	(13,599)
Interest expense	1,290	1,385	5,324	5,633
Other (income) expense, net	<u>-</u>	<u>-</u>	<u>(3,579)</u>	<u>2,567</u>
Loss before provision of income taxes	(9,052)	(5,348)	(24,777)	(21,799)
Provision for income taxes	<u>12</u>	<u>8</u>	<u>55</u>	<u>26</u>
Net loss	(9,064)	(5,356)	(24,832)	(21,825)
Accretion of Convertible Preferred Stock	<u>-</u>	<u>-</u>	<u>-</u>	<u>3,510</u>
Net loss attributable to common stockholders	<u>(9,064)</u>	<u>(5,356)</u>	<u>(24,832)</u>	<u>(25,335)</u>
Net loss per share attributable to common stockholders -				
basic and diluted	<u>\$ (0.82)</u>	<u>\$ (0.57)</u>	<u>\$ (2.38)</u>	<u>\$ (8.88)</u>
Weighted average common shares outstanding -				
basic and diluted	<u>11,082,141</u>	<u>9,393,301</u>	<u>10,444,767</u>	<u>2,852,541</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).

	<u>Three months ended December 31,</u>		<u>Twelve months ended December 31,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Net sales	\$ 10,861	\$ 12,466	\$ 47,390	\$ 42,682
Gross profit	3,390	6,021	19,022	20,561
Intangible asset amortization expense	849	849	3,396	3,396
Gross profit, excluding intangible asset amortization	\$ 4,239	\$ 6,870	\$ 22,418	\$ 23,957
Gross margin	31.2%	48.3%	40.1%	48.2%
Gross margin percentage, excluding intangible asset amortization	39.0%	55.1%	47.3%	56.1%