

**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): March 22, 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
(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 March 22, 2023, Aziyo Biologics, Inc. (the “Company” or “Aziyo”) issued a press release announcing its results for the fourth quarter and full year ended December 31, 2022. 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

Exhibit No. Description

[99.1](#) [Press Release of Aziyo Biologics, Inc., dated March 22, 2023](#)

104 Cover Page Interactive Data File (formatted as 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.

Date: March 22, 2023

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



Aziyo Biologics Reports Record Full Year 2022 Revenues

SILVER SPRING, Md., March 22, 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 fourth quarter and full year ended December 31, 2022.

Business Highlights:

- Reported \$49.2 million of net sales for full year 2022
- Fourth quarter 2022 net sales of \$12.7 million, representing an increase of 17% in Q4 2022 compared to Q4 2021
- Continued strong growth in sales of CanGaroo® and SimpliDerm® which, on an aggregate basis, increased 30% in Q4 2022 compared to Q4 2021
- Improved gross margin 8 percentage points to 39% in Q4 2022 compared to Q4 2021
- Entered into a U.S. distribution agreement with Sientra for the sale of SimpliDerm

“We are pleased to have closed the year with record revenues and thrilled to have helped more than 50,000 patients with our products in 2022,” said Dr. Randy Mills, President and Chief Executive Officer of Aziyo Biologics. “We believe we are on a path for continued growth in key markets where there remains significant unmet need. We are excited about our long-term potential and the opportunity to accelerate growth and enhance efficiency through strategic partnerships, as evidenced by the distribution agreement with Sientra for SimpliDerm announced earlier today.

“At the same time, following the recent feedback from the FDA delaying the market clearance of our CanGaroo RM Antibacterial Envelope, we recognize the need to extend our cash runway and have implemented significant measures to eliminate or defer expenses as we transition to a more capital efficient business model,” continued Dr. Mills. “Nevertheless, we remain committed to our CanGaroo RM development program and are confident we will be able to address the FDA’s outstanding questions.”

Fourth Quarter 2022 Financial Results

Net sales for the fourth quarter of 2022 were \$12.7 million, an increase of 17% compared to the fourth quarter of 2021. This growth was led by CanGaroo and SimpliDerm, which on an aggregate basis, grew by 30% in the fourth quarter of 2022, compared to the fourth quarter of 2021.

Gross profit for the fourth quarter of 2022 was \$5.0 million and gross margin was 39%, as compared to \$3.4 million and 31%, 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 46% for the fourth quarter of 2022, as compared to 39% in the fourth quarter of 2021. The increase in gross margin was primarily due to efficiency improvements in the Company’s Orthobiologics and Women’s Health business units.

Total operating expenses were \$13.8 million for the fourth quarter of 2022, as compared to \$11.2 million in the corresponding prior-year period, representing an increase of 24%. The increase was primarily due to legal expenses and updated estimates of contingent liabilities in excess of currently available insurance coverage related to the 2021 recall of a single donor lot of the Company's FiberCel Viable Bone Matrix ("FiberCel"). Increased sales and marketing also contributed to higher operating expenses, partially offset by a decrease in research and development.

Operating results for the fourth quarter of 2022 included \$5.0 million of other income related to a reduction of the Company's revenue interest obligation, which is based on the forecasted timing and extent of net sales for the Company's CanGaroo and cardiovascular product lines and the associated royalty and milestone payments. The Company's revenue interest obligation terminates in May 2027.

Net loss was \$5.4 million in the fourth quarter of 2022, as compared to \$9.1 million in the corresponding period of the prior year. Net loss per share in the fourth quarter of 2022 was \$0.38 per share, compared to a loss of \$0.82 per share in the fourth quarter of 2021.

Aziyo's cash balance as of December 31, 2022 was \$17.0 million, which included \$10.2 million in net proceeds from the follow-on public offering completed in December 2022 and additional borrowings of \$4.0 million under an existing term loan facility.

Full Year 2022 Financial Results

Net sales for the full year 2022 were \$49.2 million, an increase of 4% compared to the full year 2021 net sales of \$47.4 million. Excluding 2021 sales of \$4.9 million from the discontinued product, FiberCel, net sales from current products increased 16% in the full year 2022 compared to the prior year.

Gross profit for the full year 2022 was \$19.2 million and gross margin was 39%, as compared to \$19.0 million and 40%, respectively, in the prior year. Gross margin, excluding intangible asset amortization (a non-GAAP financial measure) was 46% for the full year 2022, as compared to 47% in the full year 2021.

Total operating expenses were \$51.0 million for the full year 2022, as compared to \$42.1 million in the prior year, representing an increase of 21%. The increase was primarily due to higher expenses related to litigation, general and administrative and sales and marketing expenses.

Net loss was \$32.9 million in the full year 2022, as compared to \$24.8 million in the prior year. Loss per share in the full year 2022 was \$2.38 per share, unchanged from the prior year.

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 fourth quarter 2022 and full year 2022 financial results, performance and vision for the future.

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 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, and overall business strategy and expected success; expectations regarding the Company’s operational position, opportunities and deliverables, goals, strategies, priorities and initiatives; 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 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. These include, but are not limited to, risks relating to: the Company’s inability to generate sufficient revenue to achieve or sustain profitability; adverse changes in economic conditions and instability and disruption of credit markets; the Company’s ability to continue as a going concern; the Company’s products and its ability to enhance, expand, develop and commercialize its product offerings; 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; 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, 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, 2021, as such factors have been updated by Aziyo’s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022 and may be updated from time to time in Aziyo’s other filings with the SEC, including without limitation, Aziyo’s Annual Report on Form 10-K for the year ended December 31, 2022 to be filed with the SEC, 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

matt.steinberg@finnpartners.com

Media:

Courtney Guyer

Aziyo Biologics, Inc.

PR@aziyo.com

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

	<u>December 31, 2022</u>	<u>December 31, 2021</u>
Assets		
Current assets:		
Cash	\$ 16,989	\$ 30,428
Accounts receivable, net	6,830	5,996
Inventory	10,052	9,554
Receivables of FiberCel litigation costs	13,813	-
Prepaid expense and other assets	3,015	1,450
Total current assets	<u>50,699</u>	<u>47,428</u>
Property and equipment, net	1,403	1,200
Intangible assets, net	15,069	18,466
Operating lease right-of-use assets, and other	1,670	76
Total assets	<u>\$ 68,841</u>	<u>\$ 67,170</u>
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 15,583	\$ 10,424
Current portion of long-term debt and revenue interest obligation	8,990	10,809
Revolving line of credit	-	4,763
Contingent liability for FiberCel litigation	17,360	-
Current operating lease liabilities and other	682	5
Total current liabilities	<u>42,615</u>	<u>26,001</u>
Long-term debt	24,260	10,410
Long-term revenue interest obligation	5,916	16,540
Long-term operating lease liabilities	956	-
Other long-term liabilities	127	698
Total liabilities	<u>73,874</u>	<u>53,649</u>
Stockholders' equity (deficit):		
Common stock	16	13
Additional paid-in capital	132,939	118,599
Accumulated deficit	(137,988)	(105,091)
Total stockholders' equity (deficit)	<u>(5,033)</u>	<u>13,521</u>
Total liabilities and stockholders' equity	<u>\$ 68,841</u>	<u>\$ 67,170</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>	
	2022	2021	2022	2021
Net sales	\$ 12,665	\$ 10,861	\$ 49,187	\$ 47,390
Cost of goods sold	7,671	7,471	29,965	28,368
Gross profit	<u>4,994</u>	<u>3,390</u>	<u>19,222</u>	<u>19,022</u>
Operating expenses:				
Sales and marketing	5,056	4,540	20,195	18,825
General and administrative	3,404	3,186	16,627	13,687
Research and development	2,085	3,376	8,940	9,266
FiberCel litigation costs	3,292	50	5,200	276
Total operating expenses	<u>13,837</u>	<u>11,152</u>	<u>50,962</u>	<u>42,054</u>
Loss from operations	(8,843)	(7,762)	(31,740)	(23,032)
Interest expense	1,561	1,290	5,282	5,324
Other (income) expense, net	(4,962)	-	(4,159)	(3,579)
Loss before provision of income taxes	(5,442)	(9,052)	(32,863)	(24,777)
Provision for income taxes	(2)	12	34	55
Net loss	(5,440)	(9,064)	(32,897)	(24,832)
Net loss attributable to common stockholders	<u>(5,440)</u>	<u>(9,064)</u>	<u>(32,897)</u>	<u>(24,832)</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (0.38)</u>	<u>\$ (0.82)</u>	<u>\$ (2.38)</u>	<u>\$ (2.38)</u>
Weighted average common shares outstanding - basic and diluted	<u>14,468,823</u>	<u>11,082,141</u>	<u>13,832,887</u>	<u>10,444,767</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 December 31,		Twelve months ended December 31,	
	2022	2021	2022	2021
Net sales	\$ 12,665	\$ 10,861	\$ 49,187	\$ 47,390
Gross profit	4,994	3,390	19,222	19,022
Intangible asset amortization expense	850	849	3,398	3,396
Gross profit, excluding intangible asset amortization	\$ 5,844	\$ 4,239	\$ 22,620	\$ 22,418
Gross margin	39.4%	31.2%	39.1%	40.1%
Gross margin percentage, excluding intangible asset amortization	46.1%	39.0%	46.0%	47.3%