

**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): May 4, 2021

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 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.

Item 2.02. Results of Operation and Financial Condition.

On May 4, 2021, Aziyo Biologics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 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

Exhibit No.	Description
<u>99.1</u>	<u>Press release of Aziyo Biologics, Inc., dated May 4, 2021</u>

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 4, 2021

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



Aziyo Biologics Reports First Quarter 2021 Financial Results and Increases 2021 Revenue Guidance

SILVER SPRING, Md. – May 4, 2021 – 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 three months ended March 31, 2021.

Recent Highlights

- Recorded net sales of \$12.9 million for the first quarter of 2021, representing a 31% increase over the first quarter of 2020
- Commenced a multi-center study to evaluate outcomes in patients receiving a CanGaroo® Envelope vs. no envelope with de novo cardiovascular implantable electronic device procedures
- Increased full year 2021 guidance for net sales to \$52 million to \$54 million, representing anticipated year-over-year growth of 22% to 27%

“Our first quarter results illustrate a strong start to the year despite some ongoing COVID-related headwinds. Encouragingly, we saw a continued high level of commercial traction and growth in our Core Product portfolio, which grew 29% over the first quarter of 2020,” said Ron Lloyd, Chief Executive Officer. “We were also pleased with the level of non-core contract manufacturing revenue, which grew 36% year over year, further leveraging our operational capabilities and contributing positively to our bottom line. With several exciting catalysts on the horizon, including the anticipated launch of our next-generation CanGaroo platform next year, we believe that Aziyo is well-positioned to continue to deliver consistent organic growth and to execute on a pipeline of new products that can augment that growth well into the future.”

First Quarter 2021 Financial Results

Net sales for the first quarter of 2021 were \$12.9 million, an increase of 31%, compared to the first quarter of 2020. The increase was driven primarily by growth of the Company’s proprietary Core Products, which resulted in sales of \$10.7 million, a 29% increase over the first quarter of 2020.

Gross profit for the first quarter of 2021 was \$6.3 million, and gross margin was 49%, as compared to 53% in the corresponding prior-year period and 48% in the fourth quarter of 2020. The decrease in gross margin in the first quarter of 2021 compared to the first quarter of 2020 was primarily due to non-recurring margin gains in the first quarter of 2020, resulting from high production volumes of the recently launched SimpliDerm product, and the increase compared to the fourth quarter of 2020 resulted from operational efficiency improvements. Gross margin, excluding intangible asset amortization (a measure not presented in accordance with U.S. generally accepted accounting principles (GAAP)) was 56% for the first quarter of 2021, as compared to 61% in the first quarter of 2020 and 55% in the fourth quarter of 2020.



Total operating expenses were \$10.0 million for the first quarter of 2021, as compared to \$8.4 million in the corresponding prior-year period, an increase of 19%. The increase was driven primarily by costs related to operating as a public company and development costs associated with the Company's program to add antibiotics to the CanGaroo Envelope.

Net loss was \$5.1 million in the first quarter of 2021, as compared to \$4.6 million in the corresponding period of the prior year. Loss per share in the first quarter of 2021 was \$0.50 per share, compared to a loss of \$7.03 per share in the first quarter of 2020, which was prior to the conversion of the Company's preferred stock into common stock in connection with the Company's initial public offering in the fourth quarter of 2020.

The Company's cash balance as of March 31, 2021 was \$30.5 million, with an additional \$4.5 million available for borrowing under the Company's working capital line of credit.

Updated Guidance for Full Year 2021

While COVID-19 continues to pose a risk of uncertainty to the Company's operating results, Aziyo now expects total net sales for the full year 2021 to be a range of \$52 million to \$54 million, representing growth of approximately 22% to 27% compared to total net sales for the full year 2020. This compares to previous full year 2021 guidance of \$50 million to \$52 million provided on March 1, 2021.

Conference Call

Aziyo will host a conference call at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time on Tuesday, May 4, 2021 to discuss its first quarter 2021 financial results and provide a business update. The call may be accessed through an operator by dialing (800) 708-4539 (US/Canada) and (847) 619-6396 (International) using conference ID number 50150586. A live and archived webcast of the event 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.



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 growth of its current products, execution on products in the pipeline, timing of the next-generation CanGaroo platform and expected financial results for full year 2021. 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 our products and our ability to enhance, expand and develop our products; our dependence on our 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 our products; our ability to obtain regulatory approval or other marketing authorizations; and our intellectual property rights, and other important factors discussed under the caption "Risk Factors" in Aziyo's Annual Report on Form 10-K for the annual period ended December 31, 2020 filed with the Securities and Exchange Commission ("SEC"), as such risk factors may be updated from time to time in Aziyo's other filings with the SEC, which are accessible on the SEC's website at www.sec.gov and the Investor Relations page of Aziyo's website at www.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



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

	<u>March 31, 2021</u>	<u>December 31, 2020</u>
Assets		
Current assets:		
Cash	\$ 30,501	\$ 39,532
Accounts receivable, net	8,762	7,166
Inventory	10,218	10,117
Prepaid expense and other assets	2,427	2,892
Total current assets	<u>51,908</u>	<u>59,707</u>
Property and equipment, net	1,210	1,162
Intangible assets, net	21,015	21,865
Other assets	76	76
Total assets	<u>\$ 74,209</u>	<u>\$ 82,810</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 9,561	\$ 10,672
Current portion of long-term debt and revenue interest obligation	11,368	9,060
Revolving line of credit	3,450	6,514
Deferred revenue and other current liabilities	392	533
Total current liabilities	<u>24,771</u>	<u>26,779</u>
Long-term debt	15,533	17,811
Long-term revenue interest obligation	16,631	16,633
Deferred revenue and other long-term liabilities	830	756
Total liabilities	<u>57,765</u>	<u>61,979</u>
Stockholders' equity (deficit):		
Common stock	10	10
Additional paid-in capital	101,760	101,080
Accumulated deficit	(85,326)	(80,259)
Total stockholders' equity	<u>16,444</u>	<u>20,831</u>
Total liabilities and stockholders' equity	<u>\$ 74,209</u>	<u>\$ 82,810</u>



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

	Three months ended March 31,	
	2021	2020
Net sales	\$ 12,884	\$ 9,863
Cost of goods sold	6,555	4,648
Gross profit	<u>6,329</u>	<u>5,215</u>
Operating expenses:		
Sales and marketing	4,703	4,482
General and administrative	3,605	2,606
Research and development	1,720	1,309
Total operating expenses	<u>10,028</u>	<u>8,397</u>
Loss from operations	(3,699)	(3,182)
Interest expense	1,355	1,373
Loss before provision of income taxes	<u>(5,054)</u>	<u>(4,555)</u>
Provision for income taxes	13	5
Net loss	<u>\$ (5,067)</u>	<u>\$ (4,560)</u>
Net loss per share - basic and diluted	<u>\$ (0.50)</u>	<u>\$ (7.03)</u>
Weighted average common shares outstanding - basic and diluted	<u>10,226,152</u>	<u>648,277</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 with 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 (unaudited, in thousands).

	Three months ended March 31,	
	2021	2020
Net sales	\$ 12,884	\$ 9,863
Gross profit	6,329	5,215
Intangible asset amortization expense	849	849
Gross profit, excluding intangible asset amortization	\$ 7,178	\$ 6,064
Gross margin	49.1%	52.9%
Gross margin percentage, excluding intangible asset amortization	55.7%	61.5%