
**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 9, 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 August 9, 2021, Aziyo Biologics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 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
99.1	<u>Press release of Aziyo Biologics, Inc., dated August 9, 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: August 9, 2021

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

Aziyo Biologics Reports Second Quarter 2021 Financial Results

SILVER SPRING, Md. – August 9, 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 and six months ended June 30, 2021.

Recent Highlights

- Recorded net sales of \$12.2 million for the second quarter of 2021, representing a 42% increase over the second quarter of 2020
 - Core Product sales were \$10.0 million in the second quarter of 2021, representing 35% growth over the second quarter of 2020
- Recorded gross margin of 46.2% in the second quarter of 2021, a 210 basis point improvement over the second quarter of 2020
- Achieved next milestone towards FDA submission of next generation CanGaroo Envelope with the recent completion of manufacturing validation

“We were pleased to see strong second quarter results that not only significantly increased over the second quarter of 2020, but importantly, rose well above pre-COVID levels. Strong growth in our core product portfolio demonstrates the increased awareness and further validation of the remodeling benefits of our regenerative medicine products,” said Ron Lloyd, Chief Executive Officer. “We were also delighted to see continued progress in our program to add antibiotics to the CanGaroo Envelope with completion of manufacturing validation, and we believe we remain on track to reach FDA submission in the first quarter of 2022.”

“Regarding the recall of a single lot of our FiberCel product, we have thoroughly reviewed our procedures for screening donors and producing FiberCel and have not identified any deviations from our established protocols, which are based on industry standards and government requirements. The FDA has also completed an inspection of our manufacturing facility and quality control records and made no 483 observations. Nevertheless, we continue to seek enhancements to our processes, and we believe this experience can be a catalyst for further advancing the state of the art for all products in this category,” concluded Lloyd.

Second Quarter 2021 Financial Results

Net sales for the second quarter of 2021 were \$12.2 million, an increase of 42%, compared to the second quarter of 2020. The increase was driven primarily by a return to more normal surgical procedure volumes compared to the second quarter of 2020, which was severely impacted by the COVID-19 pandemic.

Gross profit for the second quarter of 2021 was \$5.6 million, and gross margin was 46.2%, as compared to \$3.8 million and 44.1% in the corresponding prior-year period. The increase in gross margin was



primarily due to increased efficiency associated with higher production volumes and other operational improvements compared to the year-ago quarter, offset by the impact of costs related to the FiberCel recall and the lower margin contribution of net sales from non-core products. Gross margin, excluding intangible asset amortization (a measure not presented in accordance with U.S. generally accepted accounting principles ("GAAP")), was 53.1% for the second quarter of 2021, as compared to 54.0% in the second quarter of 2020.

Total operating expenses were \$10.2 million for the second quarter of 2021, as compared to \$7.5 million in the corresponding prior-year period, an increase of 35%. The increase in total operating expense was primarily driven by growth in commercial spending associated with higher net sales, expenses associated with operating as a public company and development costs from the Company's program to develop a CanGaroo Envelope with antibiotics.

Net loss was \$2.4 million in the second quarter of 2021, as compared to \$5.2 million in the corresponding prior-year period. Net loss in the second quarter of 2021 included 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 2021 was \$0.23, compared to a loss of \$7.99 per share in the second 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 June 30, 2021, was \$28.4 million, with an additional \$5.1 million available for borrowing under the Company's working capital line of credit, resulting in total liquidity of \$33.5 million.

Guidance

Aziyo expects net sales in the third quarter of 2021 to range from \$11 million to \$12 million. This represents a year-over-year change ranging from (7)% to 2% and assumes FiberCel sales will not have resumed under the existing distribution agreement by the end of the quarter. Excluding sales of FiberCel from the third quarter of 2020, this guidance range represents growth of 14% to 24%. This outlook also assumes the recent resurgence of COVID-19 cases in the U.S., including impacts from Delta and other variants, does not result in a significant reduction in surgical procedure volumes in August and September.

Conference Call

Aziyo will host a conference call at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time on Monday, August 9, 2021 to discuss its second quarter 2021 financial results and provide a business update. The call may be accessed through an operator by dialing (833) 665-0667 (US/Canada) and (914) 987-7319 (International)



using conference ID number 9977823. 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, expected financial results for the third quarter of 2021 and the effect of COVID-19 cases on surgical procedure volumes. 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; the impact on our business of the recall of a single lot of our FiberCel product and the suspension of its sales by our distribution partner; 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 updated by the section titled "Risk Factors" included in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021 to be filed with the 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
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AZIYO BIOLOGICS, INC.
CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in thousands)

Assets	<u>June 30, 2021</u>	<u>December 31, 2020</u>
Current assets:		
Cash	\$ 28,368	\$ 39,532
Accounts receivable, net	7,749	7,166
Inventory	10,341	10,117
Prepaid expense and other assets	<u>1,759</u>	<u>2,892</u>
Total current assets	48,217	59,707
Property and equipment, net	1,243	1,162
Intangible assets, net	20,166	21,865
Other assets	<u>76</u>	<u>76</u>
Total assets	<u>\$ 69,702</u>	<u>\$ 82,810</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 10,187	\$ 10,672
Current portion of long-term debt and revenue interest obligation	10,254	9,060
Revolving line of credit	2,904	6,514
Deferred revenue and other current liabilities	<u>251</u>	<u>533</u>
Total current liabilities	23,596	26,779
Long-term debt	13,682	17,811
Long-term revenue interest obligation	16,587	16,633
Deferred revenue and other long-term liabilities	<u>870</u>	<u>756</u>
Total liabilities	<u>54,735</u>	<u>61,979</u>
Stockholders' equity (deficit):		
Common stock	10	10
Additional paid-in capital	102,668	101,080
Accumulated deficit	<u>(87,711)</u>	<u>(80,259)</u>
Total stockholders' equity	<u>14,967</u>	<u>20,831</u>
Total liabilities and stockholders' equity	<u>\$ 69,702</u>	<u>\$ 82,810</u>



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

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Net sales	\$ 12,160	\$ 8,579	\$ 25,044	\$ 18,442
Cost of goods sold	<u>6,546</u>	<u>4,795</u>	<u>13,101</u>	<u>9,443</u>
Gross profit	5,614	3,784	11,943	8,999
Operating expenses:				
Sales and marketing	4,799	4,062	9,502	8,544
General and administrative	3,529	2,077	7,134	4,683
Research and development	<u>2,029</u>	<u>1,408</u>	<u>3,749</u>	<u>2,717</u>
Total operating expenses	<u>10,209</u>	<u>7,547</u>	<u>20,237</u>	<u>15,944</u>
Loss from operations	(4,595)	(3,763)	(8,294)	(6,945)
Interest expense	1,351	1,410	2,706	2,783
Other (income) expense, net	<u>(3,579)</u>	<u>-</u>	<u>(3,579)</u>	<u>-</u>
Loss before provision of income taxes	(2,367)	(5,173)	(7,421)	(9,728)
Provision for income taxes	<u>18</u>	<u>5</u>	<u>31</u>	<u>10</u>
Net loss	<u>(2,385)</u>	<u>(5,178)</u>	<u>(7,452)</u>	<u>(9,738)</u>
Net loss per share attributable to common stockholders -				
basic and diluted	<u>\$ (0.23)</u>	<u>\$ (7.99)</u>	<u>\$ (0.73)</u>	<u>\$ (15.02)</u>
Weighted average common shares outstanding - basic and diluted	<u>10,228,296</u>	<u>648,277</u>	<u>10,227,240</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).

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Net sales	\$ 12,160	\$ 8,579	\$ 25,044	\$ 18,442
Gross profit	5,614	3,784	11,943	8,999
Intangible asset amortization expense	849	849	1,699	1,699
Gross profit, excluding intangible asset amortization	\$ 6,463	\$ 4,633	\$ 13,642	\$ 10,698
Gross margin	46.2%	44.1%	47.7%	48.8%
Gross margin percentage, excluding intangible asset amortization	53.1%	54.0%	54.5%	58.0%