
**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): November 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 November 9, 2021, Aziyo Biologics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 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	Press release of Aziyo Biologics, Inc., dated November 9, 2021
104	Cover Page Interactive Data File (formatted as Inline XBRL)

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: November 9, 2021

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



Aziyo Biologics Reports Third Quarter 2021 Financial Results

SILVER SPRING, Md. – November 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 nine months ended September 30, 2021.

“Despite the challenges faced during the quarter, the long-term value proposition of our regenerative medicine portfolio remains intact, as evidenced by continued customer adoption, improving productivity within our direct sales organization and partnerships with key market participants,” said Ron Lloyd, Chief Executive Officer.

“Our team is energized by the growth catalysts on the horizon. In particular, we are especially excited about the growing awareness and adoption of our CanGaroo envelope, as well as the progress made on our next generation product, CanGaroo RM. We continue to track towards CanGaroo RM FDA submission in the first quarter of 2022. In parallel, we anticipate new clinical data, greater market access and continued growth within our SimpliDerm product line. Within our orthopedic and spine business, we are working towards adding partners, as well as expanding existing relationships, while launching new viable bone matrix products. We are also implementing new screening and testing procedures that we believe will further support the safety of these products and set a new standard for the industry,” concluded Lloyd.

Third Quarter 2021 Financial Results

Net sales for the third quarter of 2021 were \$11.5 million, compared to \$11.8 million in the third quarter of 2020. Year to date at September 30, 2021, net sales were \$36.5 million, a 21% increase over the same period in 2020. Net sales of core products were \$8.6 million in the third quarter of 2021, compared to \$10.3 million for the third quarter of 2020, and net sales of non-core products were \$2.9 million in the third quarter of 2021, compared to \$1.4 million in the third quarter of 2020. The decrease in core products was driven primarily by the discontinuation of sales of FiberCel Fiber Viable Bone Matrix, as well as lower procedure volumes in certain geographies due to the resurgence of Covid-19 hospitalizations. These decreases were partially offset by growth in the CanGaroo and SimpliDerm product lines. The increase in non-core products was driven primarily by one contract manufacturing customer building inventory for a new product launch.

Gross profit for the third quarter of 2021 was \$3.7 million, and gross margin was 32.1%, as compared to \$5.5 million and 47.1% 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 39.5% for the third quarter of 2021, as compared to 54.3% in the third quarter of 2020. The decrease in gross margin was primarily due to lower yields in the Company’s viable bone products related to heightened donor screening criteria ahead of the implementation of enhanced product testing, as well as write-downs of inventory in certain categories. Together these factors impacted



margins by approximately 12 percentage points. The Company does not expect these costs to continue at similar levels going forward.

Total operating expenses were \$10.7 million for the third quarter of 2021, as compared to \$8.2 million in the corresponding prior-year period, an increase of 30%. The increase in total operating expense was primarily driven by R&D expenses related to the development of the next-generation CanGaroo product and increased G&A expenses associated with operating as a public company.

Net loss was \$8.3 million in the third quarter of 2021, as compared to \$6.7 million in the corresponding prior-year period.

Loss per share in the third quarter of 2021 was \$0.81, compared to a loss of \$15.79 per share in the third 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 September 30, 2021, was \$22.6 million, with an additional \$4.5 million available for borrowing under the Company's working capital line of credit, resulting in total liquidity of \$27.1 million.

Guidance

Aziyo expects net sales for the full year 2021 to be in a range of \$47 million to \$48 million, representing growth of 10% to 12.5% over the full year 2020.

Conference Call

Aziyo will host a conference call at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time on Tuesday, November 9, 2021 to discuss its third 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 1677709. 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 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 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 suspension 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 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 the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 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
Gilmartin Group
investors@aziyo.com



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

Assets	September 30, 2021	December 31, 2020
Current assets:		
Cash	\$ 22,626	\$ 39,532
Accounts receivable, net	5,519	7,166
Inventory	9,832	10,117
Prepaid expense and other assets	1,277	2,892
Total current assets	39,254	59,707
Property and equipment, net	1,257	1,162
Intangible assets, net	19,316	21,865
Other assets	76	76
Total assets	\$ 59,903	\$ 82,810
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 9,635	\$ 10,672
Current portion of long-term debt and revenue interest obligation	10,809	9,060
Revolving line of credit	1,956	6,514
Deferred revenue and other current liabilities	110	533
Total current liabilities	22,510	26,779
Long-term debt	12,046	17,811
Long-term revenue interest obligation	16,552	16,633
Deferred revenue and other long-term liabilities	936	756
Total liabilities	52,044	61,979
Stockholders' equity (deficit):		
Common stock	10	10
Additional paid-in capital	103,876	101,080
Accumulated deficit	(96,027)	(80,259)
Total stockholders' equity	7,859	20,831
Total liabilities and stockholders' equity	\$ 59,903	\$ 82,810



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

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Net sales	\$ 11,485	\$ 11,774	\$ 36,529	\$ 30,216
Cost of goods sold	7,796	6,233	20,897	15,676
Gross profit	<u>3,689</u>	<u>5,541</u>	<u>15,632</u>	<u>14,540</u>
Operating expenses:				
Sales and marketing	4,783	4,301	14,285	12,845
General and administrative	3,593	2,667	10,727	7,350
Research and development	2,289	1,264	5,890	3,981
Total operating expenses	<u>10,665</u>	<u>8,232</u>	<u>30,902</u>	<u>24,176</u>
Loss from operations	<u>(6,976)</u>	<u>(2,691)</u>	<u>(15,270)</u>	<u>(9,636)</u>
Interest expense	1,328	1,465	4,034	4,248
Other (income) expense, net	-	2,567	(3,579)	2,567
Loss before provision of income taxes	<u>(8,304)</u>	<u>(6,723)</u>	<u>(15,725)</u>	<u>(16,451)</u>
Provision for income taxes	<u>12</u>	<u>8</u>	<u>43</u>	<u>18</u>
Net loss	<u>(8,316)</u>	<u>(6,731)</u>	<u>(15,768)</u>	<u>(16,469)</u>
Accretion of Convertible Preferred Stock	-	3,510	-	3,510
Net loss attributable to common stockholders	<u>\$ (8,316)</u>	<u>\$ (10,241)</u>	<u>\$ (15,768)</u>	<u>\$ (19,979)</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (0.81)</u>	<u>\$ (15.79)</u>	<u>\$ (1.54)</u>	<u>\$ (30.82)</u>
Weighted average common shares outstanding - basic and diluted	<u>10,235,350</u>	<u>648,436</u>	<u>10,229,974</u>	<u>648,331</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 September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Net sales	\$ 11,485	\$ 11,774	\$ 36,529	\$ 30,216
Gross profit	3,689	5,541	15,632	14,540
Intangible asset amortization expense	849	849	2,548	2,548
Gross profit, excluding intangible asset amortization	\$ 4,538	\$ 6,390	\$ 18,180	\$ 17,088
Gross margin	32.1%	47.1%	42.8%	48.1%
Gross margin percentage, excluding intangible asset amortization	39.5%	54.3%	49.8%	56.6%