
**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 1, 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 March 1, 2021, Aziyo Biologics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and year ended December 31, 2020. 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 March 1, 2021

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 1, 2021

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



Aziyo Biologics Reports Fourth Quarter and Full Year 2020 Financial Results

SILVER SPRING, Md. – March 1, 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 fourth quarter and full year ended December 31, 2020.

Financial Highlights

- Despite continuing impact from COVID-19, total net sales of \$12.5 million for the fourth quarter of 2020, representing a 3% increase over the fourth quarter of 2019
 - o Core Products net sales of \$10.3 million in the fourth quarter of 2020, a 10% increase over the fourth quarter of 2019
- Total net sales of \$42.7 million for the full year 2020, down 0.5% compared to the full year 2019
 - o Core Products net sales of \$36.2 million for full year 2020, a 17% increase over the full year 2019
- Cash balance of \$39.5 million as of December 31, 2020

Recent Operational Highlights

- Received CE Mark approval for updated labeling of CanGaroo® Envelope to allow for the addition of the antibiotic gentamicin in European markets
- Completed product design for next-generation CanGaroo Envelope with antibiotics
- Enrolled first patient in the HEAL study, a 100-patient, multi-center study designed to identify and compare the characteristics of soft tissue healing surrounding cardiovascular implantable electronic device implants, including those used with CanGaroo

“Despite the unprecedented landscape of 2020, the Aziyo team made meaningful progress throughout the year, resulting in robust top line revenue growth for our core products and continued gross margin improvement. We were also successful in driving forward our strategic priorities, including the advancement of our orthobiologic products and CanGaroo platform, increased clinical data, and the expansion of key partnerships that we believe will enable us to broaden our reach in the regenerative medicine markets. We have also begun to see the benefit of our contract manufacturing business, which leverages our operational capabilities and contributes positively to our bottom line,” said Ron Lloyd, Chief Executive Officer. “We look forward to building on this traction, as I am encouraged that we are taking the steps necessary to foster continued success during 2021 and beyond.”

Fourth Quarter 2020 Financial Results

Net sales for the fourth quarter of 2020 were \$12.5 million, an increase of 3%, compared to the fourth quarter of 2019. Core products sales were \$10.3 million, an increase of 10% compared to the fourth quarter of 2019.

Gross profit for the fourth quarter of 2020 was \$6.0 million and gross margin was 48%, as compared to \$4.9 million and 41%, 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 55% for the fourth quarter of 2020, as compared to 48% in the fourth quarter of 2019. The increase in gross margin in the fourth quarter of 2020 primarily resulted from growth in our higher-margin proprietary products and improvements in production and inventory management.

Total operating expenses were \$10.0 million for the fourth quarter of 2020, as compared to \$8.1 million in the corresponding prior-year period, representing an increase of 23%. The increase primarily resulted from costs related to operating as a public company and development costs associated with our program to add antibiotics to our CanGaroo Envelope.

Net loss was \$5.4 million in the fourth quarter of 2020, as compared to \$2.8 million in the corresponding period of the prior year. Loss per share in the fourth quarter of 2020 was \$0.57 per share, compared to a loss of \$4.30 per share in the fourth quarter of 2019.

The Company’s cash balance as of December 31, 2020 was \$39.5 million.

Full Year 2020 Financial Results

Net sales for the full year 2020 were \$42.7 million, a decline of 0.5% compared to full year 2019 net sales of \$42.9 million.

Gross profit for the full year 2020 was \$20.6 million and gross margin was approximately 48%, as compared to \$19.8 million and approximately 46% in the prior year. Gross margin, excluding intangible asset amortization (a non-GAAP financial measure) was approximately 56% for the full year 2020, as compared to 54% in the full year 2019.

Total operating expenses were \$34.2 million for the full year 2020, as compared to \$28.2 million in the corresponding prior year, representing an increase of 21%.

Net loss was \$21.8 million in the full year 2020, as compared to \$11.9 million in the prior year. Loss per share in the full year 2020, which includes the accretion of deemed dividends to the preferred stockholders, was \$8.88 per share, compared to a loss of \$18.48 per share in the full year 2019.

Guidance for Full Year 2021

While COVID-19 continues to pose a risk of uncertainty to the Company’s operating results, Aziyo expects total net sales for the full year 2021 to range between \$50 million and \$52 million, representing growth of approximately 17% to 22% compared to total net sales for 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 Monday, March 1, 2021 to discuss its fourth quarter and full year 2020 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 4158569. A live and archived webcast of the conference call will be available at <https://investors.aziyo.com>. The archived replay will be available until February 28, 2022.

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. 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. 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 2021 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, and the potential results thereof. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results to differ materially from those contemplated in this press release include, but are not limited to, our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings; our dependence on our commercial partners and independent sales agents to generate a substantial portion of our net sales; our failure to maintain our relationships with our existing contract manufacturing customers and enter into agreements with new contract manufacturing customers, or if existing contract manufacturing customers reduce purchases of our products; our ability to successfully expand, manage and maintain our direct sales force; our ability to achieve or sustain profitability; the adverse impacts of the novel strain of coronavirus disease, COVID-19 or any other future pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide; adverse changes in general domestic and global economic conditions and instability and disruption of credit markets, including as a result of the current COVID-19 pandemic or any other outbreak of an infectious disease; physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products; the continued and future acceptance of our products by the medical community; our ability to obtain regulatory approval or other marketing authorizations by the FDA and comparable foreign authorities for our products and product candidates; and our ability to obtain, maintain and adequately protect our 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, 2020, 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, 2020 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. Except to the extent required by law, the Company undertakes no obligation to update or review any estimate, projection, or forward-looking statement. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in the Company's business.

Investors:

Leigh Salvo
Gilmartin Group
investors@aziyo.com

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

	<u>December 31, 2020</u>	<u>December 31, 2019</u>
Assets		
Current assets:		
Cash	\$ 39,532	\$ 2,590
Accounts receivable, net	7,166	7,229
Inventory	10,117	7,190
Prepaid expense and other assets	2,892	1,437
Total current assets	<u>59,707</u>	<u>18,446</u>
Property and equipment, net	1,162	988
Intangible assets, net	21,865	25,262
Other assets	76	76
Total assets	<u>\$ 82,810</u>	<u>\$ 44,772</u>
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	\$ 10,672	\$ 8,955
Current portion of long-term debt and revenue interest obligation	9,060	4,442
Revolving line of credit	6,514	4,227
Deferred revenue and other current liabilities	533	650
Total current liabilities	<u>26,779</u>	<u>18,274</u>
Long-term debt	17,811	19,612
Long-term revenue interest obligation	16,633	16,596
Deferred revenue and other long-term liabilities	756	952
Total liabilities	<u>61,979</u>	<u>55,434</u>
Convertible preferred stock	-	44,449
Stockholders' equity (deficit):		
Common stock	10	1
Additional paid-in capital	101,080	1,826
Accumulated deficit	(80,259)	(56,938)
Total stockholders' equity (deficit)	<u>20,831</u>	<u>(55,111)</u>
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 82,810</u>	<u>\$ 44,772</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>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Net sales	\$ 12,466	\$ 12,054	\$ 42,682	\$ 42,901
Cost of goods sold	6,445	7,161	22,121	23,133
Gross profit	6,021	4,893	20,561	19,768
Operating expenses:				
Sales and marketing	4,374	4,569	16,845	16,161
General and administrative	4,338	2,875	13,232	9,616
Research and development	1,272	658	4,083	2,400
Total operating expenses	9,984	8,102	34,160	28,177
Loss from operations	(3,963)	(3,209)	(13,599)	(8,409)
Interest expense	1,385	1,446	5,633	5,381
Other expense, net	-	(1,881)	2,567	(1,881)
Loss before provision of income taxes	(5,348)	(2,774)	(21,799)	(11,909)
Provision for income taxes	8	9	26	30
Net loss	(5,356)	(2,783)	(21,825)	(11,939)
Accretion of Convertible Preferred Stock	-	-	3,510	-
Net loss attributable to common stockholders	\$ (5,356)	\$ (2,783)	\$ (25,335)	\$ (11,939)
Net loss per share attributable to common stockholders - basic and diluted	\$ (0.57)	\$ (4.30)	\$ (8.88)	\$ (18.48)
Weighted average common shares outstanding - basic and diluted	9,393,301	647,767	2,852,541	645,994

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,	
	2020	2019	2020	2019
Net sales	\$ 12,466	\$ 12,054	\$ 42,682	\$ 42,901
Gross profit	6,021	4,893	20,561	19,768
Intangible asset amortization expense	849	849	3,398	3,398
Gross profit, excluding intangible asset amortization	\$ 6,870	\$ 5,742	\$ 23,959	\$ 23,166
Gross margin	48.3%	40.6%	48.2%	46.1%
Gross margin percentage, excluding intangible asset amortization	55.1%	47.6%	56.1%	54.0%