
**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 19, 2020

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 19, 2020, Aziyo Biologics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 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
<u>99.1</u>	<u>Press release of Aziyo Biologics, Inc., dated November 19, 2020</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: November 19, 2020

By: /s/ Ronald Lloyd

Ronald Lloyd
President and Chief Executive Officer



Aziyo Biologics Reports Third Quarter 2020 Financial Results

SILVER SPRING, Md. – November 19, 2020 – 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, 2020.

Recent Highlights

- Recorded net sales of \$11.8 million for the third quarter of 2020, representing a 6% increase over the third quarter of 2019
 - o 31% growth in Core Products over Q3 2019
- Completed initial public offering, raising approximately \$43.0 million in net proceeds, after deducting underwriting fees and other expenses
- Awarded “breakthrough technology” designation and subsequent group purchasing agreement from Premier Inc. to provide its alliance of approximately 4,100 U.S. hospitals and 200,000 other providers with access to Aziyo’s CanGaroo® Envelope
- Expanded partnership with Surgalign Holdings to include the distribution of Aziyo’s ViBone® Moldable, a next generation moldable cellular bone matrix product

“Our third quarter results reflect the strong performance of our Core Products, which showed year-over-year growth in sales over 30%,” said Ron Lloyd, Chief Executive Officer. “Following our initial public offering in October, we are now better positioned financially and operationally to deliver on the opportunity we have in three large markets within regenerative medicine: implantable electronic devices, orthopedic and spine repair, and soft tissue reconstruction. Today, we are addressing this estimated \$3 billion market with a comprehensive and growing portfolio of next-generation products driven by an expanding commercial team and partnerships with industry leaders.

“Looking ahead, we’re especially excited about our strong pipeline of anticipated new product launches, including a growing platform opportunity with CanGaroo to potentially reduce complications associated with a range of implantable electronic devices,” concluded Lloyd.

Third Quarter 2020 Financial Results

Net sales for the third quarter of 2020 were \$11.8 million, an increase of 6%, compared to the third quarter of 2019. The increase was driven primarily by growth of the company’s proprietary Core Products, which delivered sales of \$10.3 million, a 31% increase over Q3 2019.

Gross profit for the third quarter of 2020 was \$5.5 million and gross margin was 47%, as compared to 50% in the corresponding prior-year period. Gross margin, excluding intangible asset amortization (a non-GAAP financial measure) was 54% for the third quarter of 2020, as compared to 57% in the third quarter of 2019. The decrease in gross margin in Q3 2020 primarily resulted from a two-week shutdown of the company’s main production facility, resulting in plant costs being charged directly to cost of goods sold during this shutdown period rather than being a component of inventory, which allowed for the early completion of maintenance activities that would otherwise take place closer to year-end.

Total operating expenses were \$8.2 million for the third quarter of 2020, as compared to \$7.4 million in the corresponding prior year period, an increase of 11%. The increase was driven primarily by investments in research and development and increased general and administrative expenses in anticipation of the company's initial public offering.

Net loss was \$6.7 million in the third quarter of 2020, as compared to \$3.1 million in the corresponding period of the prior year. Loss per share in the third quarter of 2020, which includes the accretion of deemed dividends to the preferred stockholders, was \$15.79 per share, compared to a loss of \$4.81 per share in the third quarter of 2019.

Cash and cash equivalents were \$1.6 million as of September 30, 2020. However, following the end of the third quarter of 2020, Aziyo completed its initial public offering, raising approximately \$43.0 million of net proceeds, after deducting underwriting fees and other expenses.

Conference Call

Aziyo will host a conference call at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time on Thursday November 19, 2020 to discuss its third quarter 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 7952289. 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. 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 and overall business strategy; expectations regarding the Company's operational position, opportunities and deliverables, goals, strategies, priorities and initiatives, including the expansion of the Company's commercial team and partnerships; and expectations regarding the Company's pipeline and anticipated new product launches, including platform opportunities with 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 can be found in the Risk Factors section of Aziyo's public filings with the Securities and Exchange Commission ("SEC"), including Aziyo's 424(b)(4) filed on October 8, 2020 in connection with the company's initial public offering, as updated in Aziyo's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020 to be filed with the SEC, and as such 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. 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 or Caroline Paul
Gilmartin Group
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AZIYO BIOLOGICS, INC.
CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in thousands)

Assets	September 30, 2020	December 31, 2019
Current assets:		
Cash	\$ 1,644	\$ 2,590
Accounts receivable, net	7,096	7,229
Inventory	9,788	7,190
Prepaid expense and other assets	3,685	1,437
Total current assets	\$ 22,213	\$ 18,446
Property and equipment, net	1,140	988
Intangible assets, net	22,714	25,262
Other assets	76	76
Total assets	\$ 46,143	\$ 44,772
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 13,542	\$ 8,955
Current portion of long-term debt and revenue interest obligation	5,640	4,442
Revolving line of credit	5,866	4,227
Deferred revenue and other current liabilities	537	650
Total current liabilities	25,585	18,274
Long-term debt	21,201	19,612
Long-term revenue interest obligation	16,667	16,596
Deferred revenue and other long-term liabilities	1,001	952
Total liabilities	64,454	55,434
Convertible preferred stock	56,593	44,449
Stockholders' deficit:		
Common stock	1	1
Additional paid-in capital	-	1,826
Accumulated deficit	(74,905)	(56,938)
Total stockholders' deficit	(74,904)	(55,111)
Total liabilities, convertible preferred stock and stockholders' deficit	\$ 46,143	\$ 44,772

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

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Net sales	\$ 11,774	\$ 11,138	\$ 30,216	\$ 30,847
Cost of goods sold	6,233	5,595	15,676	15,972
Gross profit	5,541	5,543	14,540	14,875
Operating expenses:				
Sales and marketing	4,174	4,435	12,471	11,592
General and administrative	3,195	2,448	8,894	6,741
Research and development	863	507	2,811	1,742
Total operating expenses	8,232	7,390	24,176	20,075
Loss from operations	(2,691)	(1,847)	(9,636)	(5,200)
Interest expense	1,465	1,249	4,248	3,935
Other expense, net	2,567	-	2,567	-
Loss before provision of income taxes	(6,723)	(3,096)	(16,451)	(9,135)
Provision for income taxes	8	8	18	21
Net loss	(6,731)	(3,104)	(16,469)	(9,156)
Accretion of Convertible Preferred Stock	3,510	-	3,510	-
Net loss attributable to common stockholders	\$ (10,241)	\$ (3,104)	\$ (19,979)	\$ (9,156)
Net loss per share attributable to common stockholders - basic and diluted	\$ (15.79)	\$ (4.81)	\$ (30.82)	\$ (14.19)
Weighted average common shares outstanding - basic and diluted	648,436	645,142	648,331	645,142

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 U.S. generally accepted accounting principles, (“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 September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Net sales	\$ 11,774	\$ 11,138	\$ 30,216	\$ 30,847
Gross profit	5,541	5,543	14,540	14,875
Intangible asset amortization expense	849	849	2,548	2,548
Gross profit, excluding intangible asset amortization	\$ 6,390	\$ 6,392	\$ 17,089	\$ 17,424
Gross margin	47%	50%	48%	48%
Gross margin percentage, excluding intangible asset amortization	54%	57%	57%	56%