



Aziyo Biologics Reports Strong Third Quarter 2022 Revenue

November 14, 2022

Positive meeting with FDA provides clarity for CanGaroo® RM clearance

SILVER SPRING, Md., Nov. 14, 2022 (GLOBE NEWSWIRE) -- Aziyo Biologics, Inc. (Nasdaq: AZYO), a biologics company with a portfolio of regenerative products aimed at improving compatibility between medical devices and the patients they treat, today provided a business update and reported financial results for the third quarter ended September 30, 2022.

Recent Highlights

- Positive meeting with FDA provided clarity on path for first quarter 2023 clearance of the CanGaroo® RM Antibacterial Envelope
- Strong growth with net sales of \$12.4 million, an 8% increase over third quarter of 2021
- Device compatibility business units (SimpliDerm® and CanGaroo®) achieved record sales with 18% year-over-year growth, further validating the Company's strategy
- Former Shire head of business development, David Colpman, added to Board of Directors
- Company raises lower end of FY22 revenue guidance range to \$48 million to \$50 million

"Aziyo's strong revenue performance reflects both our unique strategy and the team's exceptional efforts," said Dr. Randy Mills, Chief Executive Officer of Aziyo Biologics. "We are leveraging regenerative medicine to address the most frequent causes of implant procedure failure by improving compatibility between the medical devices and the patients they treat."

Dr. Mills added, "During the quarter, we made excellent progress towards clearance of the CanGaroo® RM Antibacterial Envelope, the only biomaterial envelope designed to mitigate complications in implantable pacemaker procedures. We are pleased to report that we held a positive meeting with the FDA to clarify outstanding items with our 510(k) submission. Based on Agency feedback, we believe we will be able to complete our responses to the FDA in time for an anticipated CanGaroo® RM marketing clearance in the first quarter of 2023."

"Looking ahead, our team is laser-focused on achieving further organic growth, while pursuing strategic relationships in areas where we believe such transactions would create significant shareholder value," said Dr. Mills. "I want to thank the entire Aziyo team for another great quarter."

Third Quarter 2022 Financial Results

Net sales for the third quarter of 2022 were \$12.4 million, an increase of 8%, compared to the third quarter of 2021. Net sales of core products were \$8.9 million in the third quarter of 2022, compared to \$8.6 million for the third quarter of 2021, and net sales of non-core products were \$3.4 million in the third quarter of 2022, compared to \$2.9 million in the third quarter of 2021.

Gross profit for the third quarter of 2022 was \$5.0 million and gross margin was 41%, as compared to \$3.7 million and 32%, 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 48% for the third quarter of 2022, as compared to 40% in the third quarter of 2021. The increase in gross margin was primarily due to recent production efficiencies and improved inventory management.

Total operating expenses were \$12.8 million for the third quarter of 2022, as compared to \$10.7 million in the corresponding prior-year period, representing an increase of 20%. The increase was primarily due to \$1.5 million in litigation expense associated with the 2021 recall of a single donor lot of the Company's FiberCel Viable Bone Matrix. This amount includes the difference between the current estimate of the Company's contingent liability and receivables from insurers and other parties. Additionally, there was a one-time \$0.8 million charge related to the CEO transition.

Net loss was \$9.9 million in the third quarter of 2022, as compared to \$8.3 million in the corresponding period of the prior year. Net loss per share in the third quarter of 2022 was \$0.73 per share, compared to a net loss of \$0.81 per share in the third quarter of 2021. Aziyo's cash balance as of September 30, 2022, was \$8.1 million.

Guidance for Full Year 2022

Aziyo updated its expectation that total net sales for the full year 2022 will be in the range of \$48 million to \$50 million. Excluding approximately \$4.9 million of FiberCel sales in 2021, this range represents expected growth of 13% to 18%. This updated guidance compares favorably to the previous guidance range of \$47 million to \$50 million

Conference Call

Aziyo will host a conference call today at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time to discuss its third quarter 2022 financial results, performance and vision for the future.

Individuals interested in listening to the conference call are required to register online. Participants are required to register at least 15 minutes before the start of the call. A live and archived webcast of the event and the accompanying presentation materials will be available on the “Investors” section of the Aziyo website at <https://investors.aziyo.com/>.

About Aziyo Biologics

Aziyo Biologics is a regenerative medicine company with a commercial portfolio of differentiated products focused on improving outcomes in patients undergoing a range of surgical procedures, primarily for 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 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 2022 and overall business strategy and expected success; expectations regarding the Company's operational position, opportunities and deliverables, goals, strategies, priorities and initiatives; and the timing of regulatory clearance and product launch. 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 discontinuation 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 can be found in the “Risk Factors” section of Aziyo's public filings with the Securities and Exchange Commission (“SEC”), including Aziyo's Annual Report on Form 10-K for the year ended December 31, 2021, as such factors may be updated from time to time in Aziyo's other filings with the SEC, including, Aziyo's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022 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.

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

Assets	September 30, 2022	December 31, 2021
Current assets:		
Cash	\$ 8,101	\$ 30,428
Accounts receivable, net	7,159	5,996
Inventory	10,192	9,554
Receivables of FiberCel litigation costs	17,234	-
Prepaid expense and other assets	970	1,450
Total current assets	<u>43,656</u>	<u>47,428</u>
Property and equipment, net	1,359	1,200
Intangible assets, net	15,918	18,466
Other assets	89	76
Total assets	<u>\$ 61,022</u>	<u>\$ 67,170</u>

Liabilities and Stockholders' Equity

Current liabilities:		
Accounts payable and accrued expenses	\$ 14,763	\$ 10,424
Current portion of long-term debt and revenue interest obligation	7,750	10,809
Revolving line of credit	-	4,763
Contingent liability for FiberCel litigation	17,643	-

Other current liabilities	12	5
Total current liabilities	40,168	26,001
Long-term debt	20,000	10,410
Long-term revenue interest obligation	11,449	16,540
Deferred revenue and other long-term liabilities	86	698
Total liabilities	71,703	53,649
Stockholders' equity (deficit):		
Common stock	13	13
Additional paid-in capital	121,854	118,599
Accumulated deficit	(132,548)	(105,091)
Total stockholders' equity (deficit)	(10,681)	13,521
Total liabilities and stockholders' equity	\$ 61,022	\$ 67,170

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Net sales	\$ 12,389	\$ 11,485	\$ 36,522	\$ 36,529
Cost of goods sold	7,340	7,796	22,294	20,897
Gross profit	5,049	3,689	14,228	15,632
Operating expenses:				
Sales and marketing	4,915	4,783	15,139	14,285
General and administrative	4,487	3,516	13,223	10,501
Research and development	1,966	2,289	6,855	5,890
FiberCel litigation costs	1,474	77	1,908	226
Total operating expenses	12,842	10,665	37,125	30,902
Loss from operations	(7,793)	(6,976)	(22,897)	(15,270)
Interest expense	1,302	1,328	3,721	4,034
Other (income) expense, net	803	-	803	(3,579)
Loss before provision of income taxes	(9,898)	(8,304)	(27,421)	(15,725)
Provision for income taxes	12	12	36	43
Net loss	(9,910)	(8,316)	(27,457)	(15,768)
Accretion of Convertible Preferred Stock	-	-	-	-
Net loss attributable to common stockholders	(9,910)	(8,316)	(27,457)	(15,768)
Net loss per share attributable to common stockholders - basic and diluted	\$ (0.73)	\$ (0.81)	\$ (2.02)	\$ (1.54)
Weighted average common shares outstanding - basic and diluted	13,660,555	10,235,350	13,618,580	10,229,974

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 September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Net sales	\$ 12,389	\$ 11,485	\$ 36,522	\$ 36,529
Gross profit	5,049	3,689	14,228	15,632
Intangible asset amortization expense	849	849	2,548	2,547
Gross profit, excluding intangible asset amortization	\$ 5,898	\$ 4,538	\$ 16,776	\$ 18,179
Gross margin	40.8%	32.1%	39.0%	42.8%
Gross margin percentage, excluding intangible asset amortization	47.6%	39.5%	45.9%	49.8%