
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q**

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2022

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number: 001-39577

Aziyo Biologics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

47-4790334
(I.R.S. Employer Identification No.)

12510 Prosperity Drive, Suite 370
Silver Spring, MD 20904
(Address of principal executive offices and Zip Code)

(240) 247-1170
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Class A Common Stock, par value \$0.001 per share	AZYO	The Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 11, 2022, there were 9,460,964 shares of the registrant's Class A common stock and 4,313,406 shares of the registrant's Class B common stock outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (the “Quarterly Report”) contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements other than statements of historical facts contained in this Quarterly Report, including, without limitation, statements regarding our results of operations, financial position, projected growth in our net sales, increases in expenses, seasonality, business strategy, policies and approach, including, without limitation: expectations regarding our products and their targeted effects; plans for our sales and marketing growth and anticipated expansion of our product development and clinical and research activities; expectations regarding competition, our competitive advantages, regulations that impact our business, and overall clinical and commercial success; expectations regarding the pending lawsuits and claims related to our recall of a single lot of Fiber Viable Bone Matrix (“FiberCel”), amounts recoverable under insurance, indemnity and contribution agreements and the impact of such lawsuits and claims on our future financial position; results of operations or business; our expectations and plans regarding pursuit of any strategic transactions; our expectations relating to the FDA regulatory process for the CanGaroo RM Antibacterial Envelope; the potential impact of the pandemic related to COVID-19 and variants thereof on our business; plans for meeting our current or future cash requirements are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

Without limiting the foregoing, the words “aim”, “believe,” “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential,” “seeks,” or “continue” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words.

These forward-looking statements are not a guarantee of future results, performance, or achievements, and one should avoid placing undue reliance on such statements.

These forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to us. Such beliefs and assumptions may or may not prove to be correct. Additionally, such forward-looking statements are subject to a number of known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied in the forward-looking statements, including, but not limited to the following:

- 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 ability 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 and variants thereof 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, or any impacts of Russia's war with Ukraine;
- 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 continue as a going concern;
- our ability to obtain regulatory approval or other marketing authorizations by the U.S. Food and Drug Administration ("FDA") and comparable foreign authorities for our products and product candidates;
- our dependence on a limited number of third-party suppliers;
- our ability to defend against the various lawsuits related to our recall of a single lot of FiberCel and avoid a material adverse financial consequence; and
- our ability to obtain, maintain and adequately protect our intellectual property rights.

These and other important factors discussed in Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Part II, Item 1A. "Risk Factors" in this Quarterly Report, in Part I, Item 1A. "Risk Factors" and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (the "Annual Report") and in our other filings with the Securities and Exchange Commission (the "SEC"), each of which filings are accessible on the SEC's website at www.sec.gov and the Investor Relations page of our website at <https://investors.aziyo.com/financials/sec-filings>, could cause actual results to differ materially from those indicated by the forward-looking statements made in this Quarterly Report.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Quarterly Report and the documents that we reference in this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

As used in this Quarterly Report, unless otherwise specified or the context otherwise requires, references to "we," "us," "our," the "Company" and "Aziyo" refer to the operations of Aziyo Biologics, Inc. and its consolidated subsidiaries.

WEBSITE DISCLOSURE

We may use our website as a distribution channel of material information about the Company. Financial and other important information regarding the Company is routinely posted on and accessible through the Investor Relations sections of its website at www.aziyo.com. In addition, you may automatically receive email alerts and other information about the Company when you enroll your email address by visiting the "Email Alerts" option under the IR Resources menu of the Investor Relations of our website at www.aziyo.com. The reference to our website address does not constitute incorporation by reference of the information contained on or available through our website, and you should not consider such information to be a part of this Quarterly Report.

TRADEMARKS, TRADE NAMES AND SERVICE MARKS

This Quarterly Report includes our trademarks, trade names and service marks, including, without limitation, “Aziyo®,” “CanGaroo®,” “ProxiCor®,” “Tyke®,” “VasCure®,” “ViBone®,” “OsteGro®,” “SimpliDerm®” and our logo, which are our property and are protected under applicable intellectual property laws. This Quarterly Report also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks may appear in this Quarterly Report without the ®, TM and SM symbols, but such references are not intended to indicate, in any way, that we or the applicable owner forgo or will not assert, to the fullest extent permitted under applicable law, our rights or the rights of any applicable licensors to these trademarks, trade names and service marks. We do not intend our use or display of other parties’ trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

INDUSTRY AND OTHER DATA

Unless otherwise indicated, information contained in this Quarterly Report concerning our industry and the markets in which we operate, including our general expectations, market position and market opportunity, is based on our management’s estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties. We believe the information from these third-party publications, research, surveys and studies included in this Quarterly Report is reliable. Management’s estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in this Quarterly Report under “Forward-Looking Statements” and Part I, Item 1A. “Risk Factors” in our Annual Report which can be found at <https://investors.aziyo.com/financials/sec-filings>. These and other factors could cause our future performance to differ materially from our assumptions and estimates.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

AZIYO BIOLOGICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In Thousands, Except for Share and Per Share Data)

(UNAUDITED)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash	\$ 8,101	\$ 30,393
Restricted cash	—	35
Accounts receivable, net	7,159	5,996
Inventory	10,192	9,554
Receivables of FiberCel litigation costs	17,234	—
Prepaid expenses and other current assets	970	1,450
Total current assets	43,656	47,428
Property and equipment, net	1,359	1,200
Intangible assets, net	15,918	18,466
Other assets	89	76
Total assets	\$ 61,022	\$ 67,170
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,618	\$ 1,582
Accrued expenses	8,935	6,375
Payables to tissue suppliers	3,210	2,467
Current portion of long-term debt	—	8,059
Current portion of revenue interest obligation	7,750	2,750
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
Other long-term liabilities	86	698
Total liabilities	71,703	53,649
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Class A Common stock, \$0.001 par value, 200,000,000 shares authorized as of September 30, 2022 and December 31, 2021, and 9,460,964 and 9,245,146 shares issued and outstanding, as of September 30, 2022 and December 31, 2021, respectively	9	9
Class B Common stock, \$0.001 par value, 20,000,000 shares authorized, as of September 30, 2022 and December 31, 2021 and 4,313,406 issued and outstanding as of September 30, 2022 and December 31, 2021	4	4
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

The accompanying notes are an integral part of these condensed consolidated financial statements.

AZIYO BIOLOGICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In Thousands, Except Share and Per Share Data)

(UNAUDITED)

	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
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 for income taxes	(9,898)	(8,304)	(27,421)	(15,725)
Income tax expense	12	12	36	43
Net loss	\$ (9,910)	\$ (8,316)	\$ (27,457)	\$ (15,768)
Net loss per share - 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

The accompanying notes are an integral part of these condensed consolidated financial statements.

AZIYO BIOLOGICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
(In Thousands, Except Share Amounts)

(UNAUDITED)

	Class A Common Stock		Class B Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount			
Balance, June 30, 2022	9,306,838	\$ 9	4,313,406	\$ 4	\$ 121,256	\$ (122,638)	\$ (1,369)
Proceeds from stock option exercises	1,881	—	—	—	10	—	10
Proceeds from sale of common stock through Employee Stock Purchase Plan	32,063	—	—	—	126	—	126
Vesting of restricted stock units, net of shares withheld and taxes paid	120,182	—	—	—	(395)	—	(395)
Issuance of warrants in connection with debt financing	—	—	—	—	560	—	560
Stock-based compensation	—	—	—	—	297	—	297
Net loss	—	—	—	—	—	(9,910)	(9,910)
Balance, September 30, 2022	9,460,964	\$ 9	4,313,406	\$ 4	\$ 121,854	\$ (132,548)	\$ (10,681)
Balance, June 30, 2021	7,095,265	\$ 7	3,134,162	\$ 3	\$ 102,668	\$ (87,711)	\$ 14,967
Proceeds from sale of common stock through Employee Stock Purchase Plan	27,244	—	—	—	208	—	208
Stock-based compensation	—	—	—	—	1,000	—	1,000
Net loss	—	—	—	—	—	(8,316)	(8,316)
Balance, September 30, 2021	7,122,509	\$ 7	3,134,162	\$ 3	\$ 103,876	\$ (96,027)	\$ 7,859

	Class A Common Stock		Class B Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount			
Balance, December 31, 2021	9,245,146	\$ 9	4,313,406	\$ 4	\$ 118,599	\$ (105,091)	\$ 13,521
Proceeds from stock option exercises	1,881	—	—	—	10	—	10
Additional issuance costs in connection with Private Placement	—	—	—	—	(110)	—	(110)
Proceeds from sale of common stock through Employee Stock Purchase Plan	74,408	—	—	—	317	—	317
Vesting of restricted stock units, net of shares withheld and taxes paid	139,529	—	—	—	(395)	—	(395)
Issuance of warrants in connection with debt financing	—	—	—	—	560	—	560
Stock-based compensation	—	—	—	—	2,873	—	2,873
Net loss	—	—	—	—	—	(27,457)	(27,457)
Balance, September 30, 2022	9,460,964	\$ 9	4,313,406	\$ 4	\$ 121,854	\$ (132,548)	\$ (10,681)
Balance, December 31, 2020	7,091,960	\$ 7	3,134,162	\$ 3	\$ 101,080	\$ (80,259)	\$ 20,831
Proceeds from stock option exercises	3,305	—	—	—	26	—	26
Proceeds from sale of common stock through Employee Stock Purchase Plan	27,244	—	—	—	208	—	208
Stock-based compensation	—	—	—	—	2,562	—	2,562
Net loss	—	—	—	—	—	(15,768)	(15,768)
Balance, September 30, 2021	7,122,509	\$ 7	3,134,162	\$ 3	\$ 103,876	\$ (96,027)	\$ 7,859

The accompanying notes are an integral part of these condensed consolidated financial statements

AZIYO BIOLOGICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In Thousands)
(UNAUDITED)

	Nine Months Ended September 30,	
	2022	2021
Net loss	\$ (27,457)	\$ (15,768)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,796	2,797
(Gain) loss on extinguishment of debt	311	(3,029)
Amortization of deferred financing costs and debt discount	63	91
Interest expense recorded as additional revenue interest obligation	1,983	1,987
Stock-based compensation	2,873	2,562
Changes in operating assets and liabilities:		
Accounts receivable	(1,163)	1,647
Inventory	(638)	285
Receivables of FiberCel litigation costs	(17,234)	—
Prepaid expenses and other	467	1,615
Accounts payable and accrued expenses	4,029	(1,456)
Obligations to tissue suppliers	743	419
Contingent liability for FiberCel litigation	17,643	—
Deferred revenue and other liabilities	(605)	(209)
Net cash used in operating activities	(16,189)	(9,059)
INVESTING ACTIVITIES:		
Expenditures for property, plant and equipment	(406)	(344)
Net cash used in investing activities	(406)	(344)
FINANCING ACTIVITIES:		
Additional issuance costs in connection with Private Placement	(110)	—
Net borrowings (repayments) under revolving line of credit	(4,763)	(4,558)
Proceeds from stock option exercises	10	26
Proceeds from long-term debt	21,000	—
Deferred financing costs	(468)	—
Repayments of long-term debt	(18,615)	(1,111)
Costs related to the extinguishment of debt	(633)	—
Payments on revenue interest obligation	(2,075)	(2,068)
Payments for taxes upon vesting of restricted stock units	(395)	—
Proceeds from sales of common stock through Employee Stock Purchase Plan	317	208
Net cash used in financing activities	(5,732)	(7,503)
Net decrease in cash and restricted cash	(22,327)	(16,906)
Cash and restricted cash, beginning of period	30,428	39,532
Cash and restricted cash, end of period	\$ 8,101	\$ 22,626
Supplemental Cash Flow and Non-Cash Financing Activities Disclosures:		
Cash paid for interest	\$ 5,047	\$ 3,788
Fair value of warrants issued	\$ 560	\$ —
Forgiveness of SBA PPP loan	\$ -	\$ 3,029

The accompanying notes are an integral part of these condensed consolidated financial statements.

AZIYO BIOLOGICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Note 1. Organization and Description of Business

Aziyo Biologics, Inc. (together with its consolidated subsidiaries, "Aziyo" or the "Company") is a regenerative medicine company, with a focus on patients receiving implantable medical devices. The Company has developed a portfolio of regenerative products using both human and porcine tissue that are designed to be as close to natural biological material as possible. Aziyo's portfolio of core products spans the implantable electronic devices/cardiovascular-related market, the orthopedic/spinal repair market and the soft tissue reconstruction market ("Core Products"). These products are primarily sold to healthcare providers or commercial partners. The Company also sells human tissue products under contract manufacturing and certain other arrangements ("Non-Core Products") with corporate customers.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation and Liquidity

The unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's consolidated financial statements and accompanying notes included in the Company's annual report on Form 10-K ("Annual Report") for the fiscal year ended December 31, 2021. The financial information as of September 30, 2022 and for the three and nine months ended September 30, 2022 and 2021 is unaudited, but in the opinion of management, all adjustments considered necessary for a fair statement of the results for these interim periods have been included. The condensed consolidated balance sheet data as of December 31, 2021 was derived from audited financial statements but does not include all disclosures required by GAAP. The results of the Company's operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or any future year or period.

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. Intercompany accounts and transactions have been eliminated in consolidation.

In accordance with Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. For the nine months ended September 30, 2022, the Company incurred a net loss of \$27.5 million, and as of September 30, 2022, the Company had an accumulated deficit of \$132.5 million. In addition, during the nine months ended September 30, 2022, the Company used \$16.2 million and \$5.7 million of cash in operating and financing activities, respectively, and expects to continue to incur cash outflows for the remainder of the year. Because of the numerous risks and uncertainties associated with the Company's commercialization and development efforts, the Company is unable to predict when it will become profitable, and it may never become profitable. The Company's inability to achieve and then maintain profitability would negatively affect its business, financial condition, results of operations and cash flows.

In order to mitigate the current and potential future liquidity issues caused by the matters noted above, the Company may seek to raise capital through the issuance of common stock or debt, restructure its Revenue Interest Obligation (as such term is defined, and further described, in Note 7), or pursue asset sale or licensing transactions. However, such transactions may not be successful and the Company may not be able to raise additional equity or debt, restructure its Revenue Interest Obligation, or sell or license assets on acceptable terms, or at all. As such, based on its current operating plans, the Company believes there is uncertainty as to whether its future cash flows along with its existing cash, potential availability under the SWK Loan Facility (described in Note 6), issuances of additional equity and cash

generated from expected future sales will be sufficient to meet the Company's anticipated operating needs through twelve months from the financial statement issuance date. Due to these factors, there is substantial doubt about the Company's ability to continue as a going concern within one year after the issuance of the financial statements.

The accompanying condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. That is, the accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, realization of assets, and satisfaction of liabilities in the ordinary course of business.

Reclassifications

Certain reclassifications have been made to prior year amounts to conform to current year financial statement presentation. The reclassifications relate to the separate presentation of prior year costs related to the FiberCel Litigation (see Note 8 for further discussion). Such costs were formerly shown as a component of general and administrative expenses in the accompanying condensed consolidated statements of operations.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates and assumptions relating to inventory, receivables, long-lived assets, the valuation of stock-based awards, the valuation of the Revenue Interest Obligation and deferred income taxes are made at the end of each financial reporting period by management. Management continually re-evaluates its estimates, judgments and assumptions, and management's evaluation could change. Actual results could differ from those estimates.

Impact of COVID-19

The Company continues to closely monitor the impact of the COVID-19 pandemic and its variants on its business. In March 2020, the World Health Organization declared COVID-19 a global pandemic and recommended various containment and mitigation measures worldwide. Since that time, the number of procedures performed using the Company's products has intermittently decreased, as governmental authorities in the United States have recommended, and in certain cases required, that elective, specialty and other non-emergency procedures and appointments be suspended or canceled in order to avoid patient exposure to medical environments and the risk of potential infection with COVID-19, and to focus limited resources and personnel capacity on the treatment of COVID-19 patients. As a result, beginning in March 2020, a significant number of procedures using the Company's products have intermittently been postponed or cancelled, which has negatively impacted sales of its products. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and may reduce the Company's net sales in the future and negatively impact its business, financial condition and results of operations while the pandemic continues.

Net Loss per Share Attributable to Common Stockholders

Our common stock has a dual class structure, consisting of Class A common stock, \$0.001 par value per share (the "Class A common stock) and Class B common stock, \$0.001 par value per share (the "Class B common stock). Other than voting rights, the Class B common stock has the same rights as the Class A common stock, and therefore both are treated as the same class of stock for purposes of the earnings per share calculation. Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average shares outstanding during the period. For purposes of the diluted net income (loss) per share attributable to common stockholders calculation, stock options and restricted stock units ("RSUs") are considered to be common stock equivalents. All common stock equivalents have been excluded from the calculation of diluted net loss per share attributable to common stockholders, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for both periods presented.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability of fair value measures, the following hierarchy prioritizes the inputs to valuation methodologies used to measure fair value:

Level 1 - Valuations based on quoted prices for identical assets and liabilities in active markets.

Level 2 - Valuations based on observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.

Level 3 - Valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

The estimated fair value of financial instruments disclosed in the financial statements has been determined by using available market information and appropriate valuation methodologies. The carrying value of all current assets and current liabilities approximates fair value because of their short-term nature.

Cash and Restricted Cash

The Company maintains its cash balances at banks and financial institutions. The balances are insured up to the legal limit. The Company maintains cash balances that may, at times, exceed this insured limit.

Under the provisions of the Company's former revolving credit facility, the MidCap Credit Facility (as such term is defined, and further described in Note 6), the Company had a lockbox arrangement with the banking institution whereby daily lockbox receipts were contractually utilized to pay down outstanding balances on the MidCap Credit Facility debt. Lockbox receipts that had not yet been applied to the MidCap Credit Facility were classified as restricted cash in the accompanying condensed consolidated balance sheets. The following table provides a reconciliation of cash and restricted cash included in the condensed consolidated balance sheets to the amounts included in the statements of cash flows (in thousands).

	September 30,	
	2022	2021
Cash	\$ 8,101	\$ 22,543
Restricted cash	—	83
Total cash and restricted cash shown in statements of cash flows	<u>\$ 8,101</u>	<u>\$ 22,626</u>

Accounts Receivable and Allowances

Accounts receivable in the accompanying balance sheets are presented net of allowances for doubtful accounts and other credits. The Company grants credit to customers in the normal course of business, but generally does not require collateral or any other security to support its receivables.

The Company evaluates the collectability of accounts receivable based on a combination of factors. In circumstances where a specific customer is unable to meet its financial obligations to the Company, a provision to the allowance for doubtful accounts is recorded to reduce the net recognized receivable to the amount that is reasonably expected to be collected. For all other customers, a provision to the allowance for doubtful accounts is recorded based on factors including the length of time the receivables are past due, the current business environment and the Company's historical experience. Provisions to the allowance for doubtful accounts are recorded to general and administrative expenses. Account balances are charged off against the allowance when it is probable that the receivable will not be recovered.

Inventory

Inventory, consisting of purchased materials, direct labor and manufacturing overhead, is stated at the lower of cost or net realizable value, with cost determined generally using the average cost method. Inventory write-downs for unprocessed and certain processed donor tissue are recorded based on the estimated amount of inventory that will not pass the quality control process based on historical data. At each balance sheet date, the Company also evaluates inventory for excess quantities, obsolescence or shelf life expiration. This evaluation includes analysis of the Company's current and future strategic plans, historical sales levels by product, projections of future demand, the risk of technological or competitive obsolescence for products, general market conditions and a review of the shelf life expiration dates for products. To the extent that management determines there is excess or obsolete inventory or quantities with a shelf life that is too near its expiration for the Company to reasonably expect that it can sell those products prior to their expiration, the Company adjusts the carrying value to estimated net realizable value.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed on the straight-line method over the following estimated useful lives of the assets:

Processing and research equipment	5 to 10 years
Office equipment and furniture	3 to 5 years
Computer hardware and software	3 years

Leasehold improvements are amortized on the straight-line method over the shorter of the lease term or the estimated useful life of the asset.

Repairs and maintenance costs are expensed as incurred.

Long-Lived Assets

Purchased intangible assets with finite lives are carried at acquired fair value, less accumulated amortization. Amortization is computed over the estimated useful lives of the respective assets.

The Company periodically evaluates the period of depreciation or amortization for long-lived assets to determine whether current circumstances warrant revised estimates of useful lives. The Company reviews its property and equipment and intangible assets for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. Impairment exists when the carrying value of the company's asset exceeds the related estimated undiscounted future cash flows expected to be derived from the asset. If impairment exists, the carrying value of that asset is adjusted to its fair value. A discounted cash flow analysis is used to estimate an asset's fair value, using assumptions that market participants would apply. The results of impairment tests are subject to management's estimates and assumptions of projected cash flows and operating results. Changes in assumptions or market conditions could result in a change in estimated future cash flows and could result in a lower fair value and therefore an impairment, which could impact reported results. There were no impairment losses for the three and nine months ended September 30, 2022 or 2021.

Revenue Recognition

The Company's revenue is generated from contracts with customers in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 606. The core principle of ASC 606 is that the Company recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The ASC 606 revenue recognition model consists of the following five steps: (1) identify the contracts with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

As noted above, the Company enters into contracts to sell and distribute products to healthcare providers or commercial partners, or produce and sell products under contract manufacturing arrangements with corporate customers, and in all such cases, customers are billed under ship and bill contract terms. Revenue is recognized when the Company has met its performance obligations pursuant to its contracts with its customers in an amount that the Company expects to be entitled to in exchange for the transfer of control of the products to the Company's customers. For all product sales, the Company has no further performance obligations and revenue is recognized at the point control transfers which occurs either when: (i) the product is shipped via common carrier; or (ii) the product is delivered to the customer or distributor, in accordance with the terms of the agreement.

A portion of the Company's product revenue is generated from consigned inventory maintained at hospitals and from inventory physically held by direct sales representatives. For these types of product sales, the Company retains control until the product has been used or implanted, at which time revenue is recognized.

The Company elected to account for shipping and handling activities as a fulfillment cost rather than a separate performance obligation. Amounts billed to customers for shipping and handling are included as part of the transaction price and recognized as revenue when control of the underlying products is transferred to the customer. The related shipping and freight charges incurred by the Company are included in sales and marketing costs.

Contracts with customers state the final terms of the sale, including the description, quantity, and price of each implant distributed. The payment terms and conditions in the Company's contracts vary; however, as a common business practice, payment terms are typically due in full within 30 to 60 days of delivery. The Company, at times, extends volume discounts to customers.

The Company permits returns of its products in accordance with the terms of contractual agreements with customers. Allowances for returns are provided based upon analysis of the Company's historical patterns of returns matched against the revenues from which they originated. The Company records estimated returns as a reduction of revenue in the same period revenue is recognized.

Deferred Rent

The Company recognizes rent expense by the straight-line method over the lease term. Funds received from the lessor used to reimburse the Company for the cost of leasehold improvements are recorded as a deferred credit resulting from a lease incentive and are amortized over the lease term as a reduction of rent expense.

Stock-Based Compensation Plans

The Company accounts for its stock-based compensation plans in accordance with FASB ASC 718, *Accounting for Stock Compensation*. FASB ASC 718 requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors, including employee stock options and restricted stock. Stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense on a straight-line basis over the requisite service period of the entire award.

Research and Development Costs

Research and development costs, which include mainly salaries, outside services and supplies, are expensed as incurred.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash. At September 30, 2022, the Company maintained \$7.8 million in bank deposit accounts that are in excess of the \$0.25 million insurance provided by the Federal Deposit Insurance Corporation in one federally insured financial institution. The Company has not experienced any losses in such accounts.

Significant Customers

The Company sells certain of its products under large contract manufacturing or distribution arrangements. The following table presents percentage of total revenues derived from the Company's largest customers as well as their respective percentage of total accounts receivable:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Percent of revenues derived from:				
ACE Surgical Supply	11%	9%	10%	4%
Surgalign Holdings	11%	9%	11%	10%
Medtronic Sofamor Danek USA	-	3%	-	13%
	September 30,		December 31,	
	2022	2021	2022	2021
Percent of accounts receivable derived from:				
ACE Surgical Supply		5%		3%
Surgalign Holdings		13%		12%
Medtronic Sofamor Danek USA		-		-

Comprehensive Income (Loss)

Comprehensive income (loss) comprises net income (loss) and other changes in equity that are excluded from net income (loss). For the three and nine months ended September 30, 2022 and 2021, the Company's net loss equaled its comprehensive loss and accordingly, no additional disclosure is presented.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred income taxes are recorded to reflect the tax consequences on future years for differences between the tax basis of assets and liabilities and their financial reporting amounts at each year-end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to amounts that are more likely than not to be realized.

The Company is subject to income taxes in the federal and state jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. In accordance with the authoritative guidance on accounting for uncertainty in income taxes, the Company recognizes tax liabilities for uncertain tax positions when it is more likely than not that a tax position will not be sustained upon examination and settlement with various taxing authorities. Liabilities for uncertain tax positions are measured based upon the largest amount of benefit that is more likely than not (greater than 50%) of being realized upon settlement. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense.

Note 3. Recently Issued Accounting Standards

In November 2019, the FASB issued ASU 2019-10, "Financial Instruments - Credit Losses (Topic 326), Derivative and Hedging (Topic 815), and Leases (Topic 842), Effective Dates." The FASB deferred the effective dates of the new credit losses standard for all entities except filers with the Securities and Exchange Commission (the "SEC") that are not smaller reporting companies ("SRCs") to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The FASB also aligned the effective dates of ASU 2017-04 on goodwill impairment with the new effective dates of the credit losses standard. The FASB deferred the effective dates of its new standards on hedging and leases for entities that are not public business entities ("PBEs") (and for leases, for entities that are not non-for-profit ("NFP") entities that have issues, or are conduit bond obligors for, certain securities; and are not employee benefit plans ("EBPs") that file or furnish financial statements with or to the SEC) to fiscal years beginning after December 15, 2020, and interim periods in the following year. The FASB is also reconsidering its philosophy on establishing effective dates

for major standards for private companies, NFPs, EBPs and smaller public companies. The FASB has developed a two-bucket approach that would give these entities more time to implement major new standards. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases. The standard requires that lessees recognize a right-of-use asset and a lease liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be based on the liability subject to certain adjustments. For income statement purposes, the FASB retained a dual model, requiring leases to be classified as either operating or finance. Operating leases will result in straight-line expense (similar to current operating leases) while finance leases will result in a front-loaded expense pattern (similar to current capital leases). In November 2019, the FASB issued 2019-10 which extended the adoption of ASU 2016-02 for the Company to be effective for periods ending after December 15, 2022. While early adoption is permitted, the Company will adopt the standard in the fourth quarter of 2022 for the full 2022 year, and expects to recognize right-of-use assets and lease liabilities for operating leases of approximately \$2.4 million.

Note 4. Stock-Based Compensation

In 2015, the Company established the Aziyo Biologics, Inc. 2015 Stock Option/Stock Issuance Plan, as amended (the "2015 Plan") which provided for the granting of incentive and non-qualified stock options to employees, directors and consultants of the Company. On October 7, 2020, in connection with the Company's initial public offering ("IPO"), the Company adopted the Aziyo Biologics, Inc. 2020 Incentive Award Plan (the "2020 Plan"), which authorizes the grant of incentive and non-qualified stock options, restricted stock, restricted stock units and stock appreciation rights to employees, directors and consultants. Shares of Class A common stock totaling 1,636,000 were initially reserved for issuance pursuant to the 2020 Plan. In addition, the shares reserved for issuance under the 2020 Plan will also include shares reserved but not issued under the 2015 Plan as well as an annual increase as set forth in the 2020 Plan. As of September 30, 2022, the Company had 756,809 shares of Class A common stock available for issuance under the 2020 Plan.

On June 21, 2022, C. Randal Mills, Ph.D., a member of the Board of Directors (the "Board") of the Company, was appointed as the Company's Interim President and Chief Executive Officer, succeeding Ronald Lloyd, who stepped down as the Company's President and Chief Executive Officer and as a member of the Board. In connection with his appointment as the Interim President and Chief Executive Officer, Dr. Mills and the Company entered into an employment agreement for an initial term of 90 days (such period, the "Interim Period"). On August 9, 2022, Dr. Mills was appointed to the role of President and Chief Executive Officer of the Company, thereby ending the Interim Period, and his employment agreement was extended pursuant to the terms thereof.

In accordance with the terms of his employment agreement, Dr. Mills (1) received a stock option award to purchase 456,278 shares of Class A common stock of the Company (the "Option Grant") on June 21, 2022; three-fifths of such Option Grant is subject to time-based vesting (the "Time-Based Options") and two-fifths of such Option Grant is subject to performance-based vesting (the "Performance Based Options") and (2) is eligible to receive 224,734 restricted stock units (the "RSU Grant"); three-fifths of such RSU Grant is subject to time-based vesting (the "Time-Based RSUs") and two-fifths of such RSU Grant is subject to performance-based vesting (the "Performance-Based RSUs"). One-third of the Time-Based Options vested on August 9, 2022 (end of the Interim Period), and two-thirds of the Time-Based Options vest over a four-year vesting schedule with 25% vesting on the first anniversary of June 21, 2022 and the remaining portion vesting in twelve equal quarterly installments. One-third of the Time-Based RSUs vest on the grant date, and two-thirds of the Time-Based RSUs vest over a four-year vesting schedule in equal annual installments. The Performance-Based Options and Performance-Based RSUs each vest in equal installments upon the achievement of certain share price thresholds for twenty consecutive days of trading at each respective threshold. Pursuant to the terms of the employment agreement, all of these awards were deemed granted on June 21, 2022, for purposes of and in accordance with ASC 718, *Accounting for Stock Based Compensation*; however, the RSUs had not been legally granted as of September 30, 2022. It is anticipated that such RSUs will be legally granted prior to December 31, 2022, and the vested shares underlying the award will be deemed outstanding as of such time.

In connection with his resignation as President and Chief Executive Officer, Mr. Lloyd and the Company entered into a separation agreement, pursuant to which Mr. Lloyd remained a full-time, non-officer employee of the Company through September 30, 2022 to assist with the transition of his duties to his successor. On September 30, 2022, Mr. Lloyd received: (i) cash severance in an amount equal to his base salary for a period of 12 months and 100% of his annual target bonus and (ii) the COBRA benefits, during the 12-month period following September 30, 2022. The Company recognized Mr. Lloyd's severance costs totaling approximately \$0.6 million over the period from June 21, 2022 through September 30, 2022, and as of September 30, 2022, all such expenses were included in Accrued Expenses in the accompanying condensed consolidated balance sheets.

Stock Options

The Company's policy is to grant stock options at an exercise price equal to 100% of the market value of a share of Class A common stock at closing on the date of the grant. The Company's stock options have contractual terms of seven to ten years, and generally vest over a four-year period from the date of grant.

A summary of stock option activity under the Company's 2015 Plan and 2020 Plan for the nine months ended September 30, 2022 is as follows:

	<u>Number of Shares</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted-Average Remaining Contractual Term (years)</u>	<u>Aggregate Intrinsic Value (in thousands)</u>
Outstanding, December 31, 2021	1,386,811	\$ 13.28	7.8	\$ 179
Granted	1,075,858	\$ 5.77		
Exercised	(1,881)	\$ 5.58		
Forfeited	(705,341)	\$ 10.83		
Outstanding, September 30, 2022	<u>1,755,447</u>	<u>\$ 9.68</u>	7.2	\$ 1,329
Vested and exercisable, September 30, 2022	<u>688,632</u>	<u>\$ 10.40</u>	4.2	\$ 419

The weighted average grant date fair value of options granted during the nine months ended September 30, 2022 was \$3.15. As of September 30, 2022, there was approximately \$4.1 million of total unrecognized compensation expense related to unvested stock options. These costs are expected to be recognized over a weighted-average period of 2.5 years.

The Company uses the Black-Scholes model to value its time-based stock option grants and expenses the related compensation cost using the straight-line method over the vesting period. The fair value of stock options is determined on the grant date using assumptions for the estimated fair value of the underlying common stock, expected term, expected volatility, dividend yield, and the risk-free interest rate. Before the completion of the Company's IPO, the Board determined the fair value of common stock considering the state of the business, input from management, third party valuations and other considerations. The Company uses the simplified method for estimating the expected term used to determine the fair value of options. The expected volatility of the Class A common stock is primarily based on the historical volatility of comparable companies in the industry whose share prices are publicly available. The Company uses a zero-dividend yield assumption as the Company has not paid dividends since inception nor does it anticipate paying dividends in the future. The risk-free interest rate approximates recent U.S. Treasury note auction results with a similar life to that of the option. The period expense is then determined based on the valuation of the options, and is recognized on a straight-line basis over the requisite service period for the entire award.

The following weighted-average assumptions were used to determine the fair value of options granted during the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,	
	2022	2021
Expected term (years)	6.2	6.0
Risk-free interest rate	2.0 %	1.0 %
Volatility factor	53 %	64 %
Dividend yield	—	—

For the Performance-Based Options granted as described above, the Company accounted for the awards as market condition awards and used an option pricing model, the Monte Carlo model, to determine the fair value of the respective equity instruments and an expense recognition term of approximately three years.

Restricted Stock Units

Restricted stock units (“RSUs”) represent rights to receive common shares at a future date. There is no exercise price and no monetary payment is required for receipt of restricted stock units or the shares issued in settlement of the award. The Company’s RSUs generally vest over a three to four year period from the date of grant.

A summary of the RSU activity under the Company’s 2020 Plan for the nine months ended September 30, 2022 is as follows:

	Number of Shares Underlying RSUs	Weighted- Average Grant Date Fair Value
Unvested, December 31, 2021	235,985	\$ 15.98
Granted	586,083	\$ 4.08
Vested	(238,142)	\$ 6.64
Forfeited	(210,594)	\$ 11.42
Unvested, September 30, 2022	<u>373,332</u>	<u>\$ 5.89</u>

The total fair value of the RSUs granted during the nine months ended September 30, 2022 was \$2.4 million.

During the nine months ended September 30, 2022, the Company granted 289,282 Performance-Based RSUs. All such RSUs, including those granted to Dr. Mills and described above, vest only if or when the Company’s Class A common stock closing price is at or exceeds a defined share price for a defined period of time. As such, all of these awards have been accounted for as market condition awards. Given the nature of these market condition arrangements, an option pricing model, the Monte Carlo model, was used to determine the fair value of these RSUs as well as the expense recognition term of two to three years using the graded vesting method.

As of September 30, 2022, \$1.7 million of unrecognized compensation costs related to RSUs is expected to be recognized over a weighted average period of two years.

Employee Stock Purchase Plan

The Company makes shares of its Class A common stock available for purchase under the Aziyo Biologics, Inc. 2020 Employee Stock Purchase Plan (the “ESPP”). The ESPP provides for separate six-month offering periods that begin in March and September of each year. Under the ESPP, employees may purchase a limited number of shares of Aziyo Class A common stock at 85% of the fair market value on either the first day of the offering period or the purchase date, whichever is lower. The ESPP is considered compensatory for purposes of stock-based compensation expense. The number of shares reserved under the ESPP will automatically increase on the first day of each fiscal year through January 1, 2030, in an amount as set forth in the ESPP. As of September 30, 2022, the total shares of Class A common stock

authorized for issuance under the ESPP was 380,997, of which 279,345 remained available for future issuance. During the nine months ended September 30, 2022, 74,408 shares of Class A common stock were issued under the ESPP.

Stock-Based Compensation Expense

Stock-based compensation expense recognized during the three and nine months ended September 30, 2022 and 2021 was comprised of the following (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Sales and marketing	\$ 343	\$ 185	\$ 841	\$ 488
General and administrative	(120)	622	1,465	1,557
Research and development	8	139	432	391
Cost of goods sold	66	53	135	126
Total stock-based compensation expense	<u>\$ 297</u>	<u>\$ 999</u>	<u>\$ 2,873</u>	<u>\$ 2,562</u>

Note 5. Inventory

Inventory was comprised of the following (in thousands):

	September 30,	December 31,
	2022	2021
Raw materials	\$ 2,055	\$ 1,880
Work in process	617	834
Finished goods	7,520	6,840
Total	<u>\$ 10,192</u>	<u>\$ 9,554</u>

Note 6. Long-Term Debt

On May 31, 2017, in connection with the Company’s acquisition of CorMatrix described in Note 7, Aziyo entered into a \$12 million term loan facility (the “MidCap Loan Facility”) and an \$8.0 million asset-backed revolving line of credit (the “MidCap Credit Facility”), under which the Company’s borrowing capacity was limited by certain qualifying assets, with a financial institution (the “May 2017 Financing”). The MidCap Loan Facility was amended in December 2017, February 2018 and July 2019 (all amendments being considered modifications) such that an additional \$1.5 million, \$3.0 million, and \$3.5 million, respectively were received by the Company bringing the total aggregate principal amount outstanding under the MidCap Loan Facility to \$20 million. The borrowings under the MidCap Loan Facility and the MidCap Credit Facility were fully repaid with a portion of the proceeds from the SWK Loan Facility (as defined below) as more fully described below.

On August 10, 2022 (the “Closing Date”), the Company entered into a senior, secured term loan facility with SWK Funding LLC, as agent, and other lenders party thereto (the “SWK Loan Facility”) for an aggregate principal amount of \$25 million, with \$21 million drawn on the Closing Date (the “Initial Term Loan”) and \$4 million that becomes available, subject to the achievement of specified operational and financial metrics by September 30, 2023 (the “Additional Term Loan”). The SWK Loan Facility also allows for the establishment of a separate, new asset-based revolving loan facility of up to \$8 million, which had not been entered into as of September 30, 2022. The SWK Loan Facility matures on August 10, 2027 and accrues interest, payable quarterly in arrears. Principal amortization of the SWK Loan Facility starts on November 15, 2024, which amortization may be extended to November 17, 2025 if conditions to draw the Additional Term Loan have been satisfied. Principal payments during the amortization period will be limited based on revenue-based caps. As of September 30, 2022, quarterly principal payments are scheduled to begin on November 15, 2024, in an amount equal to 5% of the Initial Term Loan with the balance paid at maturity. The SWK Loan Facility also includes both revenue and liquidity covenants, restrictions as to payment of dividends, and is secured by all assets of the Company, subject to certain customary exceptions. As of September 30, 2022, Aziyo was in compliance with its financial covenants under the agreement governing the SWK Loan Facility (the “SWK Loan Facility Agreement”).

All of the SWK Loan Facility borrowings take the form of Secured Overnight Financing Rate (“SOFR”) loans and bear interest at a rate per annum equal to the sum of an applicable margin of (i) 8.75% and the “Term SOFR Rate” (based upon an interest period of 3 months), or (ii) if the Company has elected the PIK Interest option (as defined below), 4.75% and the “Term SOFR Rate.” The Company may elect a portion of the interest due, to be paid in-kind at a rate per annum of 4.5% (“PIK Interest”), and such election may be made (x) until November 15, 2024 if the conditions to draw the Additional Term Loan have not been met, or (y) if such conditions to draw the Additional Term Loan have been satisfied, until November 17, 2025. The “Term SOFR Rate” is subject to a floor of 2.75%. The agreement governing the SWK Loan Facility also includes an exit fee equal to 6.5% of the aggregate principal amount funded prior to termination and prepayment penalties equal to: (i) if such prepayment occurs prior to the first anniversary of the Closing Date, 2% of the aggregate principal amount funded prior to the termination plus remaining unpaid interest payments scheduled to be paid during the first year of the loan or (ii) if such prepayment occurs after the first anniversary of the Closing Date but prior to the second anniversary of the Closing Date, 2% of the aggregate principal amount funded prior to the termination. The weighted average interest rate on the SWK Loan Facility was 11.7% for the period from August 10, 2022 through September 30, 2022.

On August 10, 2022, the Company issued to SWK Funding LLC a warrant (the “Warrant”) to purchase, in the aggregate, up to 187,969 shares of Class A common stock of the Company, \$0.001 par value per share at an exercise price of \$6.65 per share. The Warrant is immediately exercisable for up to 157,894 shares of Class A common stock from time to time on or after the Closing Date. Subject to and effective upon the borrowing of the Additional Term Loan, the Warrant will be exercisable for up to an additional 30,075 shares of Class A common stock. The exercise price and number of shares of Class A common stock issuable upon exercise of the Warrant are subject to adjustment in the event of stock dividends, stock splits and certain other events affecting the Class A common stock. Unless earlier exercised or terminated in accordance with its terms, the Warrant will expire on the seventh anniversary of the Closing Date. Upon issuance, the Company valued the Warrant at approximately \$0.6 million using the Black Scholes model. The recognition of the Warrant as well as deferred financing costs of approximately \$0.5 million incurred in securing the SWK Loan Facility served to reduce the recorded value of the associated debt. The debt discount and deferred financing costs will be recognized as interest expense through the maturity of the loan.

The Company used \$16 million of the proceeds of the SWK Loan Facility to repay all outstanding obligations on the MidCap Loan Facility and MidCap Credit Facility. Such payment included (i) \$12.8 million to repay all outstanding principal and accrued interest on the MidCap Loan Facility, (ii) \$1.7 million to pay the prepayment and exit fees on the MidCap Loan Facility and (iii) \$1.5 million to repay the outstanding balance, accrued interest and exit fees on the MidCap Credit Facility. The prepayment fees, payment of unaccrued exit fees and the write-off of unamortized deferred financing costs resulted in a loss to the Company of approximately \$1.2 million which has been recorded as other expense in the accompanying condensed consolidated statements of operations for the three and nine months ended September 30, 2022.

The SWK Loan Facility Agreement requires certain mandatory prepayments, subject to certain exceptions, with: (1) 100% of any net casualty proceeds in excess of \$250,000 and (2) for non-ordinary course asset sales, an amount equal to the difference between (x) the proportion of divested gross profit (as defined in the SWK Loan Facility Agreement) to the Company’s total gross profit (as defined in the SWK Loan Facility Agreement) multiplied by the outstanding loans under the SWK Loan Facility and (y) the difference between \$1,000,000 and the aggregate sale proceeds of any assets previously sold during the fiscal year. No such mandatory prepayments were required during the three and nine months ended September 30, 2022.

Borrowings under the MidCap Loan Facility, as amended, bore interest at a rate per annum equal to the sum of (x) the greater of (i) 2.25% and (ii) the applicable London Interbank Offered Rate for U.S. dollar deposits divided by 1.00 minus the maximum effective reserve percentage for Eurocurrency funding (“LIBOR”) plus (y) 7.25%. The weighted average interest rate on MidCap Loan Facility was 9.5% from January 1, 2022 through August 10, 2022 (the “Repayment Date”) and July 1, 2022 through the Repayment Date. The weighted average interest rate on the MidCap Loan Facility was 9.5% for both the three and nine months ended September 30, 2021.

Borrowings under the MidCap Credit Facility bore interest at a rate per annum equal to the sum of (x) the greater of (i) 2.25% and (ii) LIBOR plus (y) 4.95%. The weighted average interest rate on MidCap Credit Facility was 7.2% from

January 1, 2022 through the Repayment Date and July 1, 2022 through the Repayment Date. The weighted average interest rate on MidCap Credit Facility was 7.2% for both the three and nine months ended September 30, 2021.

During 2017, the Company restructured certain of its liabilities with a tissue supplier and entered into an unsecured promissory note totaling \$2.1 million. The note bears interest at 5% and includes quarterly interest-only payments in 2017 and quarterly interest and principal payments from March 31, 2018 through August 31, 2021. The Company used \$1.4 million of the proceeds from the SWK Loan Facility to repay the remaining balance on the promissory note; however the accrued interest on the promissory note was forgiven by the lender. Such forgiveness resulted in a gain to the Company of approximately \$0.4 million which has been recorded as other income in the accompanying condensed consolidated statements of operations for the three and nine months ended September 30, 2022.

In May 2020, Aziyo entered into a promissory note with Silicon Valley Bank that provided for the receipt by the Company of loan proceeds totaling approximately \$3.0 million (the "PPP Loan") pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). In September 2021, Aziyo was notified by the U.S. Small Business Administration that the entire balance of the Company's PPP Loan and all related accrued interest was forgiven. Such forgiveness resulted in a gain to the Company of approximately \$3.0 million which has been recorded as other income in the accompanying condensed consolidated statements of operations for the nine months ended September 30, 2021.

Long-term debt was comprised of the following (in thousands):

	September 30, 2022	December 31, 2021
SWK/MidCap Loan Facility, net of unamortized discount and deferred financing costs	\$ 20,000	\$ 17,077
Note to Tissue Supplier	—	1,392
Total	20,000	18,469
Current Portion	—	(8,059)
Long-Term Debt	<u>\$ 20,000</u>	<u>\$ 10,410</u>

The fair value of all debt instruments, which is based on inputs considered to be Level 2 under the fair value hierarchy, approximates the respective carrying values as of September 30, 2022 and December 31, 2021.

Note 7. Revenue Interest Obligation

On May 31, 2017, the Company completed an asset purchase agreement with CorMatrix Cardiovascular, Inc. ("CorMatrix") and acquired all CorMatrix commercial assets and related intellectual property (the "CorMatrix Acquisition"). As part of the CorMatrix Acquisition, the Company assumed a restructured, long-term obligation (the "Revenue Interest Obligation") to Ligand Pharmaceuticals ("Ligand") with an estimated present value on the acquisition date of \$27.7 million. Subject to annual minimum payments of \$2.75 million per year, the terms of the Revenue Interest Obligation require Aziyo to pay Ligand, 5% of future sales of the products Aziyo acquired from CorMatrix, including CanGaroo, ProxiCor, Tyke and VasCure, as well as products substantially similar to those products, such as the version of CanGaroo Aziyo is currently developing that is designed to include antibiotics.

Furthermore, a \$5.0 million payment will be due to Ligand if cumulative sales of these products exceed \$100 million and a second \$5.0 million will be due if cumulative sales exceed \$300 million during the ten-year term of the agreement which expires on May 31, 2027.

The Company recorded the present value of the estimated total future payments under the Revenue Interest Obligation as a long-term obligation, with the annual minimum payments, along with the expected payment timing of the first \$5.0 million sales milestone payment noted above, serving to establish the short-term portion. At each reporting period, the value of the Revenue Interest Obligation is re-measured based on current estimates of future payments, with changes to be recorded in the condensed consolidated statements of operations using the catch-up method. There was no change to estimated future payments during the three and nine months ended September 30, 2022 and 2021, and thus, no re-measurement gain or loss was recognized. Interest expense related to the Revenue Interest Obligation of approximately

\$0.7 million was recorded for both the three months ended September 30, 2022 and 2021 and approximately \$2.0 million for both the nine months ended September 30, 2022 and 2021.

Note 8. Commitments and Contingencies

Operating Leases

The Company leases two production facilities and one administrative and research facility under non-cancelable operating lease arrangements that expire through November 2025. Each of these leases contain renewal options and escalation clauses based upon increases in the lessors' operating expenses and other charges. The Company also has a short-term lease for a small administrative-only facility.

The Company records rent expense on a straight-line basis over the life of the lease and the difference between the average rent expense and cash payments for rent is recorded as deferred rent and is included in other current and long-term liabilities on the balance sheet. Rent expense was approximately \$0.3 million for both the three months ended September 30, 2022 and 2021, and was approximately \$0.9 million for both the nine months ended September 30, 2022 and 2021, and is included as a component of either cost of goods sold or general and administrative expenses.

Cook Biotech License and Supply Agreements

Aziyo has entered into a license agreement with Cook Biotech ("Cook") for an exclusive, worldwide license to the porcine tissue for use in the Company's Cardiac Patch and CanGaroo products, subject to certain co-exclusive rights retained by Cook (the "Cook License Agreement"). The term of such license is through the date of the last to expire of the licensed Cook patents, which is anticipated to be July 2031. Along with this license agreement, Aziyo entered into a supply agreement whereby Cook would be the exclusive supplier to Aziyo of the licensed porcine tissue. Under certain limited circumstances, Aziyo has the right to manufacture the licensed product and pay Cook a royalty of 3% of sales of the Aziyo-manufactured tissue. The supply agreement expires on the same date as the related license agreement. No royalties were paid to Cook during the three and nine months ended September 30, 2022 or 2021. Aziyo has also entered into an amendment to the Cook License Agreement (the "Cook Amendment") in order to add fields of exclusive use. Specifically, the Cook Amendment provides for a worldwide exclusive license to the porcine tissue for use with neuromodulation devices in addition to cardiovascular devices. The Cook Amendment includes license fee payments of \$0.1 million per year in each of the years 2021 through 2026. Such license payments would accelerate if a change in control, as defined in the Cook Amendment, occurs within Aziyo. The Company, in its sole discretion, can terminate the Cook License Agreement at any time.

Legal Proceedings

From time to time, the Company may be involved in claims and proceedings arising in the course of the Company's business. The outcome of any such claims or proceedings, regardless of the merits, is inherently uncertain. The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available.

FiberCel Litigation

In June 2021, the Company announced a voluntary recall of a single lot of FiberCel fiber viable bone matrix. Since September 2021, 55 lawsuits in Indiana, Delaware, Florida, Maryland, Colorado, Michigan, Ohio, Kentucky, Oregon, North Carolina and Louisiana have been filed against Aziyo Biologics Inc., certain Medtronic entities, and others alleging that the plaintiffs were exposed to and/or contracted tuberculosis and/or suffered substantial symptoms and complications following the implantation of FiberCel during spinal fusion operations. Such lawsuits were filed in Indiana state court (collectively, the "Indiana State Complaints"); the Superior Court of the State of Delaware (collectively, the "Delaware State Complaints"); the Circuit Court of Maryland (collectively, the "Maryland State Complaints"); the Court of Common Pleas of Ohio ("Ohio State Complaint"); the Northern District of Ohio ("Ohio Federal Complaint"); the U.S. District Court for the Western District of North Carolina ("North Carolina Federal Complaint"); the U.S. District Court

for the Northern District of Florida (“Florida Federal Complaint”); U.S. District Court for the Eastern District of Michigan and the Eastern District of Michigan (collectively “Michigan Federal Complaints.”); the U.S. District Court for the District of Colorado (“Colorado Federal Complaint”); the U.S. District Court for the District of Oregon (“Oregon Federal Complaint”); the Fayette, Kentucky Circuit Court and the U.S. District Court for the Eastern District of Kentucky (collectively, “Kentucky Complaints.”); the U.S. District Court for the Western District of Louisiana (“Louisiana Federal Complaint”).

Plaintiffs in the Indiana State Complaints allege a cause of action under Indiana’s Product Liability Act, citing manufacturing defects, defective design and failure to properly warn and instruct, and several of the complaints allege loss of consortium. Plaintiffs in these actions assert that the defendants are strictly liable or have breached the duty of care owed to plaintiffs by failing to exercise reasonable care in designing, manufacturing, marketing and labeling FiberCel and are seeking various types of damages, including economic damages, non-economic damages and loss of consortium. Plaintiffs in one of the Indiana State Complaints allege causes of action for product liability, negligence, breach of express and implied warranties, and punitive damages. Each of the plaintiffs in the Delaware State Complaints alleges negligence, breach of implied warranty, breach of express warranty, and medical monitoring and punitive damages, and two also allege loss of consortium. Plaintiffs in the Delaware State Complaints are seeking economic, consequential, and punitive damages. The Maryland State Complaints assert claims of negligence, breach of implied warranty, breach of express warranty, medical monitoring, and loss of consortium. The Florida Federal Complaint contains three strict liability claims for defective design, defective manufacture, and failure to warn. A claim for punitive damages is also pled. The Ohio State Complaint alleges causes of action for product liability and negligence and seeks compensatory damages. The Colorado Federal Complaint asserts causes of action for strict product liability, misrepresentation, negligence, breach of express warranty, and breach of implied warranty of merchantability. The Michigan Federal Complaints assert causes of action for negligence, gross negligence breach of implied warranty, breach of express warranty, intentional infliction of emotional distress, and liability under the *res ipsa loquitur* doctrine. The Michigan Federal Complaints seek compensatory damages and punitive damages. The North Carolina Federal Complaint alleges causes of action for negligence, defective design, breach of implied warranty, breach of express warranty, and loss of consortium, and seeks both compensatory and punitive damages. The Oregon Federal Complaint asserts strict liability claims for defective design, defective manufacture, and failure to warn, and seeks compensatory damages. The Ohio Federal Complaint asserts strict liability claims for defective manufacturing, inadequate warning, nonconformance with representations, and also alleges loss of consortium and seeks compensatory damages. The Kentucky Complaints assert strict liability claims based on manufacturing defect, design defect, failure to warn, negligence, breach of implied warranty, breach of express warranty, and seek recovery for medical monitoring, loss of consortium, compensatory damages, and punitive damages. The Louisiana Federal Complaint asserts claims of violation of the Louisiana products liability act, negligence and gross negligence, breach of implied warranty, breach of express warranty and seek recovery for medical monitoring.

In addition to the above, there have been 42 claims related to the FiberCel recall that have not yet resulted in a lawsuit. The Company refers to all of the aforementioned litigation, or claim notices, collectively as the “FiberCel Litigation.”

In October 2022, the Company engaged in a process to negotiate and attempt to resolve many of the cases in the FiberCel Litigation. The Company also mediated and resolved a Maryland lawsuit in August 2022. In total, Aziyo’s liability in 24 of the cases was settled (23 of which are pending finalization of the related settlement agreements) for a total of approximately \$7.2 million. The settled matters included cases from the Indiana State Complaints, Ohio State Complaint, Florida Federal Complaint, Colorado Federal Complaint, Delaware State Complaints and Maryland Complaint, along with claims in six states. Of these settled matters, one case was both settled and paid as of September 30, 2022 for a total cash outlay of \$1.3 million. For the remaining 73 cases, the Company estimated a probable loss related to each case and has recorded a liability at an estimated amount of \$11.7 million bringing the total estimated liability at September 30, 2022 to \$17.6 million, which is recorded as Contingent Liability for FiberCel Litigation in the accompanying condensed consolidated balance sheets. Although we believe there is a possibility that a loss in excess of the amount recognized exists, we are unable to estimate the possible loss or range of loss in excess of the amount recognized at this time. In order to reasonably estimate the liability for the unsettled FiberCel Litigation cases, the Company, along with outside legal counsel, has assessed a variety of factors, including (i) the extent of the injuries incurred, (ii) recent experience on the settled claims, (iii) settlement offers made to the other parties to the litigation and (iv) any other factors that may have a material effect on the FiberCel Litigation. While the Company believes its estimated liability to be reasonable, the actual

loss amounts are highly variable and turn on a case-by-case analysis of the relevant facts. As more information is learned about asserted claims and potential future trends, adjustments may be made to this Contingent Liability for FiberCel Litigation as appropriate.

Defense costs are recognized in the accompanying condensed consolidated statements of operations as incurred.

The Company has purchased insurance coverage that, subject to common contract exclusions, provided coverage for the FiberCel Litigation product liability losses as well as legal defense costs. Additionally, the Company has various potential indemnity and/or contribution rights against third party sources with respect to certain product liability losses. When settlements are reached and/or amounts are recorded in the related Contingent Liability for FiberCel Litigation, the Company calculates amounts due to be reimbursed pursuant to the terms of the coverage and related agreements, and pursuant to other indemnity or contribution claims, in respect of product liability losses and related defense costs. The amounts probable of reimbursement or recovery from this calculation are recorded as receivables. The determination that the recorded receivables are probable of collection is based on the terms of agreements reached in respect of indemnity and contribution claims as well as the advice of the Company's outside legal counsel. These receivables at September 30, 2022 totaled \$17.2 million and are recorded as Receivables of FiberCel Litigation Costs in the accompanying condensed consolidated balance sheets.

The indemnity and contribution receivables amount at September 30, 2022 represents amounts that are not believed to be subject to any current dispute. At September 30, 2022, the Company continues to pursue up to \$3.8 million or more in additional amounts in respect of such indemnity and contribution claims and as such, has not been reflected as part of this receivable. The Company will vigorously pursue its position with respect to this amount and while uncertain, does expect to be successful in recovering at least an additional \$3.8 million or more.

As of both September 30, 2022 and December 31, 2021, the Company was not a party to, or aware of, any material legal matters or claims except for the FiberCel Litigation.

Note 9. Net Loss Per Share Attributable to Common Stockholders

(in thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net loss attributable to common stockholders	\$ (9,910)	\$ (8,316)	\$ (27,457)	\$ (15,768)
Denominator:				
Weighted average number of common shares, basic and diluted	13,660,555	10,235,350	13,618,580	10,229,974
Net loss per common share attributable to common stockholders, basic and diluted	\$ (0.73)	\$ (0.81)	\$ (2.02)	\$ (1.54)

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at period end, from the computation of diluted net loss per share attributable to common stockholders:

	September 30,	
	2022	2021
Options to purchase common stock	1,755,447	1,390,234
Restricted stock units	373,332	235,885
Total	2,128,779	1,626,119

Note 10. Related Party Transactions

As part of the contribution of assets transacted from Tissue Banks International, now KeraLink International (“KeraLink”), to Aziyo upon formation of the Company, a provision existed which guaranteed a certain level of working capital, as defined, on the opening balance sheet of Aziyo. Such guarantee was largely finalized in 2016; however, an additional \$0.4 million was received by the Company in connection with a settlement reached in 2018. Furthermore, as part of the 2018 settlement, it was agreed that when KeraLink sells its Aziyo common shares for net proceeds greater than \$550,000, KeraLink is obligated to pay Aziyo \$550,000 within three days of such cash being received. In May 2021, KeraLink sold Aziyo common shares for proceeds in excess of \$550,000, and as such, remitted \$550,000 to Aziyo in full satisfaction of the 2018 settlement. Amounts received in connection with this settlement were recorded as other income in the accompanying condensed consolidated statements of operations for the nine months ended September 30, 2021.

Note 11. Segment Information

The Company operates as one segment, regenerative medicines. The segment is based on financial information that is utilized by the Company’s Chief Operating Decision Maker (“CODM”), who is the Company’s Chief Executive Officer, to assess performance and allocate resources.

For the three and nine months ended September 30, 2022 and 2021, the Company’s net sales disaggregated by the major sources - Core Products and Non-Core Products (see Note 1) - were as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Sales by product				
Core Products	\$ 8,949	\$ 8,588	\$ 26,141	\$ 29,230
Non-Core Products	3,440	2,897	10,381	7,299
Total Net Sales	<u>\$ 12,389</u>	<u>\$ 11,485</u>	<u>\$ 36,522</u>	<u>\$ 36,529</u>

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report, as well as the audited financial statements and the related notes thereto, and the discussion under Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report. This discussion contains forward-looking statements reflecting our current expectations, estimates, plans and assumptions concerning events and financial trends that involve risks and may affect our future operating results and financial position. Actual results and the timing of events may differ materially from those contained in these forward-looking statements due to a number of factors, including those discussed in the sections entitled “Forward-Looking Statements” and Part II, Item 1A. “Risk Factors” of this Quarterly Report and in the section entitled “Risk Factor Summary” and in Part I, Item 1A. “Risk Factors” of our Annual Report.

Overview

We are 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. From our proprietary tissue processing platforms, we have developed a portfolio of advanced regenerative medical products that are designed to be very similar to natural biological material. Our proprietary products, which we refer to as our Core Products, are designed to address the implantable electronic device/cardiovascular, orthopedic/spinal repair and soft tissue reconstruction markets, which represented a combined \$3 billion market opportunity in the United States in 2020. To expand our commercial reach, we have commercial relationships with major medical device companies, such as Boston Scientific and Biotronik, to promote and sell some of our Core Products. We believe our focus on our unique regenerative medicine platforms and our Core Products will ultimately maximize our probability of continued clinical and commercial success and will create a long-term competitive advantage for us.

We estimate that, over the past two years, approximately two million patients per year in the United States are implanted with either medical devices, such as pacemakers, defibrillators, neuro-stimulators, spinal fusion and trauma fracture hardware or tissue expanders for breast reconstruction. This number is driven by advances in medical device technologies and an aging population with a growing incidence of comorbidities, including diabetes, obesity and cardiovascular and peripheral vascular diseases. These comorbidities can exacerbate various immune responses and other complications that can be triggered by a device implant.

Our Core Products are targeted to address unmet clinical needs with the goal of promoting healthy tissue formation and avoiding complications associated with medical device implants, such as scar-tissue formation, capsular contraction, erosion, migration, non-union of implants and implant rejection. We believe that we have developed the only biomaterial envelope, which is covered by a number of patents that forms a natural, systemically vascularized pocket for holding implanted electronic devices. We have a proprietary processing technology for manufacturing bone regenerative products for use in orthopedic/spinal repair that preserves a cell’s ability to regenerate bone and decelerates cell apoptosis or programmed cell death. We have a patented cell removal technology that produces undamaged extracellular matrices for use in soft tissue reconstruction.

Our Non-Core Products are those fulfilled through tissue processing contracts at our Richmond, California facility. These contracts serve to utilize as much as possible of the starting human biological material from which we produce our orthopedic/spinal repair and soft tissue reconstruction products, leverage our existing overhead and improve our cash flow. The resulting processed materials, including particulate bone, precision milled bone, cellular bone matrix, acellular dermis and other soft tissue products, are sold to medical/surgical companies as finished products and as a subcomponent of their products. Additionally, we process amniotic membrane as finished product for selected customers.

We process all of our products at our two manufacturing facilities in Roswell, Georgia and Richmond, California, and stock inventory of raw materials, components and finished goods at those locations. We rely on a single or limited number of suppliers for certain raw materials and components. Except for the porcine tissue supplier of our raw materials for our CanGaroo and cardiovascular products, which is Cook Biotech, we generally have no long-term supply agreements with our suppliers, as we obtain supplies on a purchase order basis. Specifically, we acquire donated human tissue directly

through tissue procurement firms engaged by us. We primarily ship our Core Products from our facilities directly to hospital customers.

Since inception, we have financed our operations primarily through private placements of our convertible preferred stock, amounts borrowed under our credit facilities, sales of our products and, more recently, with proceeds from our initial public offering (“IPO”) and a private placement of our common stock. We have devoted the majority of our resources to acquisitions and integration, manufacturing and administrative costs, general and administrative, research and development, clinical activity, purchase of property and equipment used in the production activities of our Richmond, California facility and investing in our commercial infrastructure through our direct sales force and our commercial partners in order to expand our presence and to promote awareness and adoption of our products. As of September 30, 2022, we had 166 employees, of which 26 were direct sales representatives.

For the nine months ended September 30, 2022, we incurred a net loss of \$27.5 million, and as of September 30, 2022, we had an accumulated deficit of \$132.5 million. In addition, during the nine months ended September 30, 2022, we used \$16.2 million and \$5.7 million of cash in operating and financing activities, respectively. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we expand our product development and clinical and research activities and to the extent we grow our sales organization to coincide with product launches. Because of the numerous risks and uncertainties associated with our commercialization and development efforts, we are unable to predict when we will become profitable, and we may never become profitable. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows.

Our ability to achieve profitability will depend on our ability to generate sales from existing or new products sufficient to exceed our ongoing operating expenses and capital requirements. Because of the numerous risks and uncertainties affecting product sales and our ongoing commercialization and product development efforts, we are unable to predict with any certainty whether we will be able to increase sales of our products or the timing or amount of ongoing expenditures we will be required to incur. Accordingly, even if we are able to increase sales of our products, we may not become profitable.

In order to mitigate the current and potential future liquidity issues caused by the matters noted above, we may seek to raise capital through the issuance of common stock, restructure our Revenue Interest Obligation, or pursue asset sale or licensing transactions. However, such transactions may not be successful and we may not be able to raise additional equity, refinance or restructure our debt instruments, or sell assets on acceptable terms, or at all. As such, based on our current operating plans, we believe there is uncertainty as to whether our future cash flows along with our existing cash, potential availability under our SWK Loan Facility (described below under “– Liquidity and Capital Resources – Credit Facilities”), issuances of additional equity and cash generated from expected future sales will be sufficient to meet our anticipated operating needs through twelve months from the financial statement issuance date. Due to these factors, there is substantial doubt about our ability to continue as a going concern within one year after the issuance of the financial statements.

Impact of COVID-19

We continue to closely monitor the impact of the COVID-19 pandemic and its variants on our business. In March 2020, the World Health Organization declared COVID-19 a global pandemic and recommended various containment and mitigation measures worldwide. Since that time, the number of procedures performed using our products has intermittently decreased, as governmental authorities in the United States have recommended, and in certain cases required, that elective, specialty and other non-emergency procedures and appointments be suspended or canceled in order to avoid patient exposure to medical environments and the risk of potential infection with COVID-19, and to focus limited resources and personnel capacity on the treatment of COVID-19 patients. As a result, beginning in March 2020, a significant number of procedures using our products have intermittently been postponed or cancelled, which has negatively impacted sales of our products. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and may reduce our net sales in the future and negatively impact our business, financial condition and results of operations while the pandemic continues.

In addition, numerous state and local jurisdictions, including those where our facilities are located, imposed, and others in the future may impose or re-impose, “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Such orders or restrictions resulted in reduced operations at our manufacturing facilities and service providers, travel restrictions and cancellation of events, and have restricted the ability of our sales representatives and those of our commercial partners and independent sales agents to attend procedures in which our products are used, among other effects, thereby negatively impacting our operations.

While access to procedures for our sales representatives and independent sales agents have improved, the extent to which the COVID-19 pandemic impacts our future financial condition and results of operations will depend on future events and developments, which are highly uncertain and cannot be predicted, including the severity and spread of the disease and the effectiveness of actions to contain the disease or treat its impact, among others. As new information regarding COVID-19 continues to emerge, and, as variants of COVID-19 emerge, it is difficult to predict the degree to which this disease will ultimately affect our business.

FiberCel Recall

In June 2021, we issued a voluntary recall pertaining to a single donor lot of our FiberCel, a bone repair product formerly distributed by Medtronic, after learning of postsurgical infections reported in several patients treated with the product, including some patients that tested positive for tuberculosis. For information about the FiberCel Litigation in which we are involved, the impact of such proceedings on our financial statements included in this Quarterly Report, and the possible future financial implications, see Note 8 to the condensed consolidated financial statements included elsewhere in this Quarterly Report. The impact of FiberCel Litigation on our results of operations for the periods covered by this Quarterly Report are discussed below under “ – Results of Operations.”

Strategic Transactions

We operate four distinct business units – Device Protection, Cardiovascular, Women’s Health, and Orthobiologics. We have received interest and are actively considering material strategic transactions in each of these business units. The types of transactions under consideration include exclusive supply agreements, co-promotion arrangements, exclusive distribution partnerships, and whole business unit divestitures. The most advanced of these potential transactions are based on written statements of interest with detailed terms that include cash offers for acquisition of the unit, and partnership opportunities with significant upfront payments and purchase commitments.

Each business unit has at least one contemplated transaction with the potential, we believe, to be consummated, add non-dilutive capital, and enhance shareholder value. However, we intend to be selective and only execute agreements that we believe are in the best long-term interest of shareholders. As a result, it is possible that we do not execute any of the aforementioned. Moreover, if we do execute one or more of these transactions, there can be no assurance that the terms of any such transaction would be favorably received by the market.

CanGaroo RM Status

A 510(k) submission for pre-market clearance of the CanGaroo RM Antibacterial Envelope, the only biomaterial envelope designed to mitigate complications in implantable electronic device procedures, is currently under review by the U.S. FDA. We recently held a positive meeting with the FDA that clarified certain information requirements related to our 510(k) submission. We will be able to complete our responses to outstanding questions from FDA in time for an anticipated CanGaroo RM marketing clearance in the first quarter of 2023.

Impact of Inflation

Inflationary factors, such as increases in our cost of goods sold or other operating expenses, may adversely affect our operating results. While it is difficult to accurately measure the impact of inflation due to the imprecise nature of the estimates required, we do not believe inflation had a material effect on our financial condition or results of operations during the nine months ended September 30, 2022 and 2021. We cannot assure you, however, that we will be able to

increase the selling prices of our products or reduce our operating expenses in an amount sufficient to offset the effects future inflationary pressures may have on our gross margin. Accordingly, we cannot assure you that our financial condition and results of operations will not be materially impacted by inflation in the future.

Components of Our Results of Operations

Net Sales

We recognize revenue on the sale of our Core Products and our Non-Core Products. With respect to our Core Products, CanGaroo and our cardiovascular products are sold to hospitals and other healthcare facilities primarily through our direct sales force, commercial partners or independent sales agents. Our orthopedic/spinal repair products are sold through commercial partners. Our soft tissue reconstruction product SimpliDerm is sold directly to hospitals and other healthcare facilities through independent sales agents. Our contract manufacturing products are sold directly to corporate customers. Gross to net sales adjustments include sales returns and prompt payment and volume discounts.

Expenses

In recent years, we have incurred significant costs in the operation of our business. We expect that our recurring operating costs will largely stabilize, or increase at modest rates, in the near future through the identification of efficiencies as we grow. We may, however, still experience more significant expense increases as we expand our product development and clinical and research activities and to the extent we grow our sales organization to coincide with product launches. As a result, we will need to generate significant net sales in order to achieve profitability. Below is a breakdown of our main expense categories and the related expenses incurred in each category:

Cost of Goods Sold

Our cost of goods sold relate to purchased raw materials and the processing and conversion costs of such raw materials consisting primarily of salaries and benefits, supplies, quality control testing and the manufacturing overhead incurred at our processing facilities in Richmond, California and Roswell, Georgia. Both facilities have additional capacity, which if utilized, would further leverage our fixed overhead. Cost of goods sold also includes the amortization of intangibles generated from the CorMatrix Acquisition in 2017.

Sales and Marketing Expenses

Sales and marketing expenses are primarily related to our direct sales force, consisting of salaries, commission compensation, fringe benefits, meals and other expenses. Auto and travel costs have also historically contributed to sales and marketing expenses, albeit to a lesser extent due to the COVID-19 pandemic. Outside of our direct sales force, we incur significant expenses relating to commissions to our CanGaroo commercial partners and independent sales agents. Additionally, this expense category includes distribution costs as well as market research, trade show attendance, advertising and public relations related to our products, and customer service expenses.

General and Administrative Expenses

General and administrative (“G&A”) expenses consist primarily of compensation, consulting, legal, human resources, information technology, accounting, insurance and general business expenses. Our G&A expenses have increased as a result of operating as a public company, especially as a result of hiring additional personnel and incurring greater director and officer insurance premiums, greater investor relations costs, and additional costs associated with accounting, legal, tax-related and other services associated with maintaining compliance with exchange listing and SEC requirements.

Research and Development Expenses

Research and development (“R&D”) expenses consist primarily of salaries and fringe benefits, laboratory supplies, clinical trials and outside service costs. Our product development efforts primarily relate to new offerings in

support of the orthopedic/spinal repair market and activities associated with the development of a CanGaroo Envelope with antibiotics. We also conduct clinical trials to validate the performance characteristics of our products and to capture patient data necessary to support our commercial efforts.

FiberCel Litigation Costs

FiberCel litigation costs consist primarily of legal fees and the estimated costs to resolve the outstanding FiberCel litigation cases offset by the estimated amounts recoverable under insurance, indemnity and contribution agreements for such costs.

Results of Operations

Comparison of the Three Months Ended September 30, 2022 and 2021

<i>(in thousands, except percentages)</i>	Three Months Ended September 30,				Change 2021 / 2022	
	2022		2021		\$	%
	Amount	% of Net Sales	Amount	% of Net Sales		
Net sales	\$ 12,389	100.0 %	\$ 11,485	100.0 %	\$ 904	7.9 %
Cost of goods sold	7,340	59.2 %	7,796	67.9 %	(456)	(5.8)%
Gross profit	5,049	40.8 %	3,689	32.1 %	1,360	36.9 %
Sales and marketing	4,915	39.7 %	4,783	41.6 %	132	2.8 %
General and administrative	4,487	36.2 %	3,516	30.6 %	971	27.6 %
Research and development	1,966	15.9 %	2,289	19.9 %	(323)	(14.1)%
FiberCel litigation costs	1,474	11.9 %	77	0.7 %	1,397	NM
Total operating expenses	12,842	103.7 %	10,665	92.9 %	2,177	20.4 %
Loss from operations	(7,793)	(62.9)%	(6,976)	(60.7)%	(817)	11.7 %
Interest expense	1,302	10.5 %	1,328	11.6 %	(26)	(2.0)%
Other (income) expense, net	803	6.5 %	—	— %	803	NM
Loss before provision of income taxes	(9,898)	(79.9)%	(8,304)	(72.3)%	(1,594)	19.2 %
Income tax expense	12	0.1 %	12	0.1 %	—	— %
Net loss	\$ (9,910)	(80.0)%	\$ (8,316)	(72.4)%	\$ (1,594)	19.2 %

Net Sales

Net sales increased \$0.9 million, or 7.9%, to \$12.4 million in the three months ended September 30, 2022 compared to \$11.5 million in the three months ended September 30, 2021. The improvement in net sales was due to growth in net sales of our Core Products of \$0.4 million and Non-Core Products of \$0.5 million.

Net sales information for our Core Products and Non-Core Products is summarized as follows:

<i>(in thousands, except percentages)</i>	Three Months Ended September 30,				Change 2021 / 2022	
	2022		2021		\$	%
	Amount	% of Net Sales	Amount	% of Net Sales		
Products:						
Core Products	\$ 8,949	72.2 %	\$ 8,588	74.8 %	\$ 361	4.2 %
Non-Core Products	3,440	27.8 %	2,897	25.2 %	543	18.7 %
Total Net Sales	\$ 12,389	100.0 %	\$ 11,485	100.0 %	\$ 904	7.9 %

Net sales generated by our Core Products increased \$0.4 million, or 4.2%, to \$8.9 million in the three months ended September 30, 2022 compared to \$8.6 million in the three months ended September 30, 2021. The Core Products net sales growth can be attributed to sales volume increases in our CanGaroo and SimpliDerm products.

Net sales generated by our Non-Core Products increased \$0.5 million, or 18.7%, to \$3.4 million in the three months ended September 30, 2022 compared to \$2.9 million in the three months ended September 30, 2021. The increase was primarily driven by a growth in the revenue from several contract manufacturing customers.

Cost of Goods Sold

Cost of goods sold decreased \$0.5 million, or 5.8%, to \$7.3 million in the three months ended September 30, 2022 compared to \$7.8 million in the three months ended September 30, 2021, and included, in each case, \$0.8 million of intangible asset amortization expenses. Gross margin in the three months ended September 30, 2022 was 40.8%, an increase from 32.1% in the corresponding prior year period. Gross margin, excluding intangible asset amortization, in the three months ended September 30, 2022 was 47.6%, an increase from 39.5% in the corresponding prior year period. Gross margin, excluding intangible asset amortization, is a non-GAAP financial measure. See "Non-GAAP Financial Measures" for a discussion regarding our use of gross margin, excluding intangible asset amortization, including its limitations and a reconciliation to the most directly comparable GAAP financial measure. The increase in gross margin and decrease in cost of goods sold was primarily due to recent production efficiencies and improved inventory management in the three months ended September 30, 2022.

Operating Expenses

Sales and Marketing

Sales and marketing expenses increased \$0.1 million, or 2.8%, to \$4.9 million in the three months ended September 30, 2022 compared to \$4.8 million in the three months ended September 30, 2021. As a percentage of sales, sales and marketing expenses declined to 39.7% in the three months ended September 30, 2022 from 41.6% in the three months ended September 30, 2021. The decrease as a percentage of sales was the result of the growth during the three months ended September 30, 2022 of revenues from sales to contract manufacturing customers as such revenues have lower selling costs than our sales directly to end users.

General and Administrative

G&A expenses increased \$1.0 million, or 27.6%, to \$4.5 million in the three months ended September 30, 2022 compared to \$3.5 million in the three months ended September 30, 2021. As a percentage of net sales, G&A expenses increased to 36.2% in the three months ended September 30, 2022 from 30.6% in the three months ended September 30, 2021. The increase in expense was primarily due to certain non-recurring charges associated with legal fees on various corporate matters and the Chief Executive Officer transition described in Note 4 to the condensed consolidated financial statements.

Research and Development

R&D expenses decreased to \$2.0 million in the three months ended September 30, 2022 compared to \$2.3 million in the three months ended September 30, 2021. We continue to focus our R&D efforts on the development of our pipeline products and the decline in R&D expenses in the three months ended September 30, 2022 was largely attributable to the lessening of work needed to finalize the development and testing of our CanGaroo with antibiotics.

FiberCel Litigation Costs

FiberCel litigation costs increased to \$1.5 million in the three months ended September 30, 2022 compared to \$0.1 million in the three months ended September 30, 2021. The increase in expense was primarily due to the settlements reached in a significant number of FiberCel Litigation cases in the three months ended September 30, 2022 as well as the estimation of contingent liabilities for the unsettled cases. The total of such settlement and estimated settlement values was recorded (net of estimated insurance, indemnity and contribution agreement recoveries) in the three months ended September 30, 2022. See further discussion in Note 8 to condensed consolidated financial statements included elsewhere in this Quarterly Report.

Interest Expense

Interest expense was approximately \$1.3 million in both the three months ended September 30, 2022 and 2021. See “- Liquidity and Capital Resources - Credit Facilities” below for a discussion of our borrowings related to these interest expenses and Note 7 to the condensed consolidated financial statements included elsewhere in this Quarterly Report for a description of our Revenue Interest Obligation and the interest expense related thereto.

Other (Income) Expense, net

Other (income) expense, net was approximately \$0.8 million of expense in the three months ended September 30, 2022. Such other expense relates to our debt refinancing in August 2022 and the associated prepayment fees, payment of unaccrued exit fees and write-off of unamortized deferred financing costs which collectively resulted in a loss of \$1.2 million. Such loss was offset by other income of \$0.4 million related to the forgiveness of interest accrued on the promissory note to a tissue supplier upon repayment of such note in August 2022. See Note 6 to the accompanying condensed consolidated statements of operations for the three and nine months ended September 30, 2022 for further discussion of these transactions.

Comparison of the Nine Months Ended September 30, 2022 and 2021

(in thousands, except percentages)	Nine Months Ended September 30,				Change 2021 / 2022	
	2022		2021		\$	%
	Amount	% of Net Sales	Amount	% of Net Sales		
Net sales	\$ 36,522	100.0 %	\$ 36,529	100.0 %	\$ (7)	(0.0)%
Cost of goods sold	22,294	61.0 %	20,897	57.2 %	1,397	6.7 %
Gross profit	14,228	39.0 %	15,632	42.8 %	(1,404)	(9.0)%
Sales and marketing	15,139	41.5 %	14,285	39.1 %	854	6.0 %
General and administrative	13,223	36.2 %	10,501	28.7 %	2,722	25.9 %
Research and development	6,855	18.8 %	5,890	16.1 %	965	16.4 %
FiberCel litigation costs	1,908	5.2 %	226	0.6 %	1,682	NM
Total operating expenses	37,125	101.7 %	30,902	84.6 %	6,223	20.1 %
Loss from operations	(22,897)	(62.7)%	(15,270)	(41.8)%	(7,627)	49.9 %
Interest expense	3,721	10.2 %	4,034	11.0 %	(313)	(7.8)%
Other (income) expense, net	803	2.2 %	(3,579)	(9.8)%	4,382	NM
Loss before provision of income taxes	(27,421)	(75.1)%	(15,725)	(43.0)%	(11,696)	74.4 %
Income tax expense	36	0.1 %	43	0.1 %	(7)	(16.3)%
Net loss	\$ (27,457)	(75.2)%	\$ (15,768)	(43.2)%	\$ (11,689)	74.1 %

Net Sales

Net sales were \$36.5 million in both the nine months ended September 30, 2022 and 2021. Net sales information for our Core Products and Non-Core Products is summarized as follows:

(in thousands, except percentages)	Nine Months Ended September 30,				Change 2021 / 2022	
	2022		2021		\$	%
	Amount	% of Net Sales	Amount	% of Net Sales		
Products:						
Core Products	\$ 26,141	71.6 %	\$ 29,230	80.0 %	\$ (3,089)	(10.6)%
Non-Core Products	10,381	28.4 %	7,299	20.0 %	3,082	42.2 %
Total Net Sales	\$ 36,522	100.0 %	\$ 36,529	100.0 %	\$ (7)	(0.0)%

Net sales generated by our Core Products declined \$3.1 million, or 10.6%, to \$26.1 million in the nine months ended September 30, 2022 compared to \$29.2 million in the nine months ended September 30, 2021. The decrease in Core Products net sales can be attributed to the cessation of purchases by Medtronic of FiberCel following our recall of a single

lot of FiberCel in June 2021 partially offset by sales volume increases in our CanGaroo and SimpliDerm products. Sales of FiberCel to Medtronic were \$4.9 million in the nine months ended September 30, 2021.

Net sales generated by our Non-Core Products increased \$3.1 million, or 42.2%, to \$10.4 million in the nine months ended September 30, 2022 compared to \$7.3 million in the nine months ended September 30, 2021. The increase was primarily driven by a growth in the revenue from several contract manufacturing customers.

Cost of Goods Sold

Cost of goods sold increased \$1.4 million, or 6.7%, to \$22.3 million in the nine months ended September 30, 2022 compared to \$20.9 million in the nine months ended September 30, 2021, and included, in each case, \$2.5 million of intangible asset amortization expenses. Gross margin in the nine months ended September 30, 2022 was 39.0%, a decrease from 42.8% in the corresponding prior year period. Gross margin, excluding intangible asset amortization, in the nine months ended September 30, 2022 was 45.9%, a decline from 49.8% in the corresponding prior year period. Gross margin, excluding intangible asset amortization, is a non-GAAP financial measure. See "Non-GAAP Financial Measures" for a discussion regarding our use of gross margin, excluding intangible asset amortization, including its limitations and a reconciliation to the most directly comparable GAAP financial measure. The decrease in gross margin and increase to cost of goods sold was primarily due to product mix (higher Non-Core revenues in 2022 with lower gross margins).

Operating Expenses

Sales and Marketing

Sales and marketing expenses increased \$0.8 million, or 6.0%, to \$15.1 million in the nine months ended September 30, 2022 compared to \$14.3 million in the nine months ended September 30, 2021. As a percentage of sales, sales and marketing expenses grew to 41.5% in the nine months ended September 30, 2022 from 39.1% in the nine months ended September 30, 2021. The increase as a percentage of sales was the result of higher stock-based compensation and travel costs related to our sales force.

General and Administrative

G&A expenses increased \$2.7 million, or 25.9%, to \$13.2 million in the nine months ended September 30, 2022 compared to \$10.5 million in the nine months ended September 30, 2021. As a percentage of net sales, G&A expenses increased to 36.2% in the nine months ended September 30, 2022 from 28.7% in the nine months ended September 30, 2021. The increase in expense was primarily due to higher stock-based compensation as well as non-recurring charges totaling \$1.7 million associated with legal fees on various corporate matters and the Chief Executive Officer transition described in Note 4 to the condensed consolidated financial statements.

Research and Development

R&D expenses increased to \$6.9 million in the nine months ended September 30, 2022 compared to \$5.9 million in the nine months ended September 30, 2021. We continue to focus our R&D efforts on the development of our pipeline products and the growth in R&D expenses in the nine months ended September 30, 2022 was largely attributable to the work performed on the final development and testing of our CanGaroo with antibiotics.

FiberCel Litigation Costs

FiberCel litigation costs increased to \$1.9 million in the nine months ended September 30, 2022 compared to \$0.2 million in the nine months ended September 30, 2021. The increase in expense was primarily due to the settlements reached in a significant number of FiberCel Litigation cases in the nine months ended September 30, 2022 as well as the estimation of contingent liabilities for the unsettled cases. The total of such settlement and estimated settlement values was recorded (net of estimated insurance, indemnity and contribution agreement recoveries) in the nine months ended September 30, 2022. See further discussion in Note 8 to condensed consolidated financial statements included elsewhere in this Quarterly Report.

Interest Expense

Interest expense was approximately \$3.7 million in the nine months ended September 30, 2022 compared to \$4.0 million in the nine months ended September 30, 2021. The decrease was due to lower draws on our formerly outstanding MidCap Credit Facility (as defined, and further described, in Note 6 to the condensed consolidated financial statements included elsewhere in this Quarterly Report) and lower outstanding principal on our formerly outstanding MidCap Loan Facility (as defined, and further described, in Note 6 to the condensed consolidated financial statements included elsewhere in this Quarterly Report) due to the commencement of principal payments in August 2021. See “ - Liquidity and Capital Resources - Credit Facilities” below for a further discussion of these debt agreements and Note 6 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

Other (Income) Expense, net

Other (income) expense, net was approximately \$0.8 million of expense in the nine months ended September 30, 2022. Such other expense relates to our debt refinancing in August 2022 and the associated prepayment fees, payment of unaccrued exit fees and the write-off of unamortized deferred financing costs, which collectively resulted in a loss of \$1.2 million. Such loss was offset by other income of \$0.4 million related to the forgiveness of interest accrued on the promissory note to a tissue supplier upon repayment of such note in August 2022. See Note 6 to the accompanying condensed consolidated statements of operations for the three and nine months ended September 30, 2022 for further discussion of these transactions.

Other (income) expense, net was approximately \$3.6 million of income in the nine months ended September 30, 2021. Such other income relates to the forgiveness of our PPP Loan totaling approximately \$3.0 million and the Company’s receipt of \$550,000 in satisfaction of a 2018 settlement with Keralink. For further discussion on these items, see Notes 6 and 10 to the condensed consolidated financial statements shown elsewhere in this Quarterly Report.

Non-GAAP Financial Measures

This Quarterly Report presents our gross margin, excluding intangible asset amortization, for the three and nine months ended September 30, 2022 and 2021. We calculate gross margin, excluding intangible asset amortization, as gross profit, excluding amortization expense relating to intangible assets we acquired in the CorMatrix Acquisition, 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. 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, for the three and nine months ended September 30, 2022 and 2021 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
Cost of goods sold	7,340	7,796	22,294	20,897
Gross profit	5,049	3,689	14,228	15,632
Intangible asset amortization expense	849	849	2,548	2,548
Gross profit, excluding intangible asset amortization	\$ 5,898	\$ 4,538	\$ 16,776	\$ 18,180
Gross margin	40.8 %	32.1 %	39.0 %	42.8 %
Gross margin, excluding intangible asset amortization	47.6 %	39.5 %	45.9 %	49.8 %

Seasonality

Historically, we have experienced seasonality, with lower sales in our first and second quarters and higher sales in our fourth quarter, and we expect this trend to continue. We have experienced and may in the future experience, higher sales in the fourth quarter as a result of hospitals in the United States increasing their purchases of our products to coincide with the end of their budget cycles. Satisfaction of patient deductibles throughout the course of the year also results in increased sales later in the year, once patients have paid their annual insurance deductibles in full, which reduces their out-of-pocket costs. Conversely, our first quarter generally has lower sales than the preceding fourth quarter as patient deductibles are re-established with the new year, which increases their out-of-pocket costs.

Liquidity and Capital Resources

As of September 30, 2022, we had cash of approximately \$8.1 million. In August 2022, we refinanced our debt as described below under “— Credit Facilities.” Since inception, we have financed our operations primarily through private placements of our convertible preferred stock, amounts borrowed under our credit facilities, sales of our products and more recently, proceeds from our IPO and a private placement of our common stock. Our historical cash outflows have primarily been associated with acquisitions and integration, manufacturing and administrative costs, general and marketing, research and development, clinical activity, purchase of property and equipment used in the production activities of our Richmond, California facility and investing in our commercial infrastructure through our direct sales force and our commercial partners in order to expand our presence and to promote awareness and adoption of our products. As of September 30, 2022, our accumulated deficit was \$132.5 million.

On December 8, 2021, we closed on a private investment in public equity (PIPE) financing, thereby receiving net proceeds of approximately \$13.8 million, after deducting offering costs. The PIPE investors purchased an aggregate of 2,122,637 shares of the Company’s Class A common stock and an aggregate of 1,179,244 shares of the Company’s Class B common stock (which are convertible on a one-for-one basis into shares of Class A common stock), in each case, at a price of \$4.24 per share.

We expect our losses to continue for the foreseeable future and these losses will continue to have an adverse effect on our financial position. Because of the numerous risks and uncertainties associated with our commercialization and development efforts, we are unable to predict when we will become profitable, and we may never become profitable. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows.

In order to mitigate the current and potential future liquidity issues caused by the matters noted above, we may seek to raise capital through the issuance of common stock, restructure our Revenue Interest Obligation, or pursue asset sale or licensing transactions. However, such transactions may not be successful and we may not be able to raise additional equity, refinance our debt instruments, or sell assets on acceptable terms, or at all. As such, based on our current operating plans, we believe there is uncertainty as to whether our future cash flows along with our existing cash, availability under

the SWK Loan Facility (described below under “—Credit Facilities”), issuances of additional equity and cash generated from expected future sales will be sufficient to meet our anticipated operating needs through twelve months from the financial statement issuance date. Due to these factors, there is substantial doubt about our ability to continue as going concern within one year after the issuance of the financial statements.

Cash Flows for the Nine Months Ended September 30, 2022 and 2021

	<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>
	(in thousands)	
Net cash used in:		
Operating activities	\$ (16,189)	\$ (9,059)
Investing activities	(406)	(344)
Financing activities	(5,732)	(7,503)
Net decrease in cash	\$ (22,327)	\$ (16,906)

Net Cash Used in Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2022 was \$16.2 million compared to \$9.1 million for the nine months ended September 30, 2021. The year-over-year increase was primarily due to a gain on extinguishment of debt in the three months ended September 30, 2021 versus a loss experienced in the three months ended September 30, 2022. Additionally, due to timing, accounts payable increases in the current period increased cash and offset a portion of the cash used in operating cash activities when compared to the prior period.

Net Cash Used in Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2022 was \$0.4 million compared to \$0.3 million for the nine months ended September 30, 2021. In both periods, the use of cash related to the purchase of property and equipment, the majority of which were used in the production activities of our Richmond, California facility.

Net Cash Used in Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2022 was \$5.7 million compared to \$7.5 million for the nine months ended September 30, 2021. The year-over-year net decrease was caused primarily by the net cash infusion from the proceeds of the August 2022 debt refinancing, less all debt repayments and refinancing costs incurred during the nine months ended September 30, 2022. See “Credit Facilities” below for further discussion.

Credit Facilities

General

On August 10, 2022 (the “Closing Date”), we entered into a senior secured term loan facility with SWK Funding LLC, as agent, and other lenders party thereto (the “SWK Loan Facility”) for an aggregate principal amount of \$25 million, with \$21 million drawn on the Closing Date (the “Initial Term Loan”) and \$4 million that becomes available, subject to the achievement of specified operational and financial metrics by September 30, 2023 (the “Additional Term Loan”). The SWK Loan Facility also allows for the establishment of a separate, new asset-based revolving loan facility of up to \$8 million, which had not been entered into as of September 30, 2022. We used \$16 million of the proceeds of the SWK Loan Facility to pay all outstanding obligations on the formerly outstanding MidCap Loan Facility and MidCap Credit Facility. Such payment included (i) \$12.8 million to repay all outstanding principal and accrued interest on the MidCap Loan Facility, (ii) \$1.7 million to pay the prepayment and exit fees on the MidCap Loan Facility and (iii) \$1.5 million to repay the outstanding balance, accrued interest and exit fees on the MidCap Credit Facility.

As of September 30, 2022, we had \$20.0 million of indebtedness outstanding under our SWK Loan Facility (net of \$1.0 million of unamortized discount and deferred financing costs).

Interest Rates

All of the SWK Loan Facility borrowings take the form of Secured Overnight Financing Rate (“SOFR”) loans and will bear interest at a rate per annum equal to the sum of an applicable margin of (i) 8.75% and the “Term SOFR Rate” (based upon an interest period of 3 months), or (ii) if we have elected the PIK Interest option (as defined below), 4.75% and the “Term SOFR Rate.” We may elect a portion of the interest due, to be paid in-kind at a rate per annum of 4.5% (“PIK Interest”), and such election may be made (x) until November 15, 2024 if the conditions to draw the Additional Term Loan have not been met, or (y) if such conditions to draw the Additional Term Loan have been satisfied, until November 17, 2025. The “Term SOFR Rate” is subject to a floor of 2.75%.

Mandatory Prepayments

The SWK Loan Facility Agreement requires certain mandatory prepayments, subject to certain exceptions, with: (1) 100% of any net casualty proceeds in excess of \$250,000 and (2) for non-ordinary course asset sales, an amount equal to the difference between (x) the proportion of divested gross profit (as defined in the SWK Loan Facility Agreement) to the Company’s total gross profit (as defined in the SWK Loan Facility Agreement) multiplied by the outstanding loans under the SWK Loan Facility, and (y) the difference between \$1,000,000 and the aggregate sale proceeds of any assets previously sold during the fiscal year. No such mandatory prepayments were required during the three and nine months ended September 30, 2022.

Optional Prepayment

The SWK Loan Facility Agreement also includes an exit fee equal to: (i) if such prepayment occurs prior to the first anniversary of the Closing Date, 2% of the aggregate principal amount funded prior to the termination plus remaining unpaid interest payments scheduled to be paid during the first year of the loan or (ii) if such prepayment occurs after the first anniversary of the Closing Date but prior to the second anniversary of the Closing Date, 2% of the aggregate principal amount funded prior to termination.

Amortization and Final Maturity

The SWK Loan Facility matures on August 10, 2027 and accrues interest, payable quarterly in arrears. Principal amortization of the SWK Loan Facility starts on November 15, 2024, which amortization may be extended to November 17, 2025 if conditions to draw the Additional Term Loan have been satisfied. Principal payments during the amortization period will be limited based on revenue-based caps. As of September 30, 2022, quarterly principal payments are scheduled to begin on November 15, 2024, in an amount equal to 5% of the Initial Term Loan with the balance paid at maturity.

Security

All obligations under the SWK Loan Facility are, and any future guarantees of those obligations will be, secured by, among other things, and in each case subject to certain exceptions, a first priority lien on and security interest in, upon, and to all of our assets, whether now owned or hereafter acquired, wherever located.

Covenants and Other Matters

The SWK Loan Facility Agreement that governs the SWK Loan Facility contains a number of covenants that, among other things and subject to certain exceptions, restrict our ability to:

- incur additional indebtedness;
- incur certain liens;
- pay dividends or make other distributions on equity interests;
- redeem, repurchase or refinance subordinated indebtedness;

- consolidate, merge or sell or otherwise dispose of their assets;
- make investments, loans, advances, guarantees and acquisitions;
- enter into transactions with affiliates;
- amend or modify their governing documents;
- amend or modify certain material agreements; and
- alter the business conducted by them and their subsidiaries.

In addition, the SWK Loan Facility Agreement contains two financial covenants. The first covenant, which is measured quarterly, requires us to achieve a specified Minimum Aggregate Revenue (as defined in the SWK Loan Facility Agreement) for the preceding 12-month period. The second covenant requires us to maintain a minimum liquidity (as defined in the SWK Loan Facility Agreement) of \$5.0 million until November 21, 2022 (as amended from the previous compliance date of November 10, 2022, which had been previously amended from the compliance date of October 10, 2022) and thereafter, the greater of (a) \$5.0 million and (b) the sum of the operating cash burn (as defined in the SWK Loan Facility Agreement) for the two prior consecutive fiscal quarters then ended (the “Liquidity Covenant”).

The SWK Loan Facility Agreement contains events of default, including, most significantly, a failure to timely pay interest or principal, insolvency, or an action by the FDA or such other material adverse event impacting the operations of Aziyo. As of September 30, 2022, we were in compliance with the financial covenant and all other covenants.

Funding Requirements

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we expand our product development and clinical and research activities and to the extent we grow our sales organization to coincide with product launches. In addition, we expect to continue to incur significant costs and expenses associated with operating as a public company.

As of September 30, 2022, we had \$20.0 million of indebtedness outstanding, consisting of \$21.0 million outstanding under our SWK Loan Facility (net of \$1.0 million of unamortized discount and deferred financing costs). In addition, as further described in Note 7 to the condensed consolidated financial statements included elsewhere in this Quarterly Report, we are party to a royalty agreement with Ligand Pharmaceuticals Incorporated (“Ligand”) pursuant to which we assumed a restructured, long-term obligation to Ligand (the “Revenue Interest Obligation”), that requires us to pay Ligand 5.0% of future sales of the products we acquired from CorMatrix (as well as products substantially similar to those products), subject to annual minimum payments of \$2.75 million. Furthermore, a \$5.0 million payment will be due to Ligand if cumulative sales of these products exceed \$100 million and a second \$5.0 million will be due if cumulative sales exceed \$300 million during the ten-year term of the agreement which expires on May 31, 2027. We are currently forecasting that the initial \$5.0 million milestone payment will become payable in mid-2023.

If our available cash balances and cash flow from operations, if any, are insufficient to satisfy our liquidity requirements, we may seek to raise additional capital through equity offerings, debt financings, or asset sale or licensing transactions. However, such transactions may not be successful and we may not be able to raise additional equity or debt, or sell or license assets on acceptable terms, or at all. We may also consider raising additional capital in the future to expand our business, pursue strategic investments or take advantage of financing opportunities. Our present and future funding requirements will depend on many factors, including, among other things:

- continued patient, physician and market acceptance of our products;
- the scope, rate of progress and cost of our current and future pre-clinical and clinical studies;

- the cost of our research and development activities and the cost and timing of commercializing new products or technologies;
- the cost and timing of expanding our sales and marketing capabilities;
- the cost of filing and prosecuting patent applications and maintaining, defending and enforcing our patent or other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights;
- the costs of defending against or the damages payable in connection with the FiberCel Litigation and any future litigation that we may be subject to (to the extent above the applicable insurance coverage);
- the cost and timing of additional regulatory approvals;
- costs associated with any product recall that may occur;
- the effect of competing technological and market developments;
- the expenses we incur in manufacturing and selling our products;
- the extent to which we acquire or invest in products, technologies and businesses, although we currently have no commitments or agreements relating to any of these types of transactions;
- the costs of operating as a public company;
- unanticipated general, legal and administrative expenses; and
- the effects on any of the above of the current COVID-19 pandemic or any other pandemic, epidemic or outbreak of infectious disease.

In addition, our operating plans may change as a result of any number of factors, including those set forth above and other factors currently unknown to us, and we may need additional funds sooner than anticipated. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming shares of our common stock and/or declaring dividends. If we raise funds through collaborations, licensing agreements or other strategic alliances, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay the development or commercialization of our products, license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize and reduce marketing, customer support or other resources devoted to our products or cease operations. See our Annual Report, Part I, Item 1A. “Risk Factors — Risks Related to Our Business — Our future capital needs are uncertain and we may need to raise funds in the future, and such funds may not be available on acceptable terms or at all.”

Based on our current operating plans, we believe there is uncertainty as to whether our future cash flows along with our existing cash, availability under the SWK Loan Facility, issuances of additional equity and cash generated from expected future sales will be sufficient to meet our anticipated operating needs through twelve months from the financial statement issuance date. Due to these factors, there is substantial doubt about our ability to continue as going concern within one year after the issuance of the financial statements.

Critical Accounting Policies and Estimates

The preparation of our unaudited condensed consolidated financial statements in accordance with GAAP requires us to make estimates and assumptions that affect reported amounts and related disclosures. We have discussed the policies and estimates that we believe are critical and require the use of complex judgment in their application in our Annual Report, and, during the nine months ended September 30, 2022, there were no material changes to those previously disclosed, except as noted below. Refer to Note 2, “Summary of Significant Accounting Policies,” to our condensed consolidated financial statements included elsewhere in this Quarterly Report for information regarding our critical accounting estimates and policies.

Contingent Liability for FiberCel Litigation

We believe the determination of our Contingent Liability for FiberCel Litigation is a critical accounting policy. We review every lawsuit and claim and are in contact with outside counsel on an ongoing basis. An accrual is established for each lawsuit and claim, when appropriate, based on the nature of each such lawsuit or claim. The provision for FiberCel Litigation claims are based upon many factors, which vary for each case. These factors include (i) the extent of the injuries incurred, (ii) recent experience on settled claims, (iii) settlement offers made to the other parties to the litigation and (iv) any other factors that may have a material effect on the estimated liability. While we believe our estimated liability to be reasonable, the actual loss amounts are highly variable and turn on a case-by-case analysis of the relevant facts. As such, actual settlement amounts may differ from our estimates and such differences may be material.

Recent Accounting Pronouncements

Refer to Note 3, “Recently Issued Accounting Standards,” to our condensed consolidated financial statements included elsewhere in this Quarterly Report for information regarding recently issued accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business, including risks relating to changes in interest rates, foreign currency and inflation. The following discussion provides additional information regarding these risks.

Interest Rate Risk

Our primary exposure to market risk relates to changes in interest rates. Borrowings under our SWK Loan Facility bear interest at variable rates, subject to an interest rate floor. Interest rate risk is highly sensitive due to many factors, including U.S. monetary and tax policies, U.S. and international economic factors and other factors beyond our control. A hypothetical 10% relative change in interest rates on our variable rate indebtedness outstanding at September 30, 2022 would not have had a material effect on our financial statements. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

Credit Risk

As of September 30, 2022, our cash and cash equivalents were maintained with one financial institution in the United States. While our deposit accounts are insured up to the legal limit, the balances we maintain may, at times, exceed this insured limit. We believe this financial institution has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Our accounts receivable relate to sales to customers. To minimize credit risk, ongoing credit evaluations of all customers’ financial condition are performed. One customer represented 10% or more of our accounts receivable as of September 30, 2022.

Foreign Currency Risk

Our business is primarily conducted in U.S. dollars. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our financial condition, results of operations or cash flows. As we grow our operations, our exposure to foreign currency risk could become more significant.

JOBS Act

Section 107 of the JOBS Act permits us, as an “emerging growth company,” to take advantage of an extended transition period for adopting new or revised accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, as a result, for so long as we remain an emerging growth company, unless we subsequently choose to affirmatively and irrevocably opt out of the extended transition period, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable.

We will remain an emerging growth company until the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues are \$1.235 billion or more; (ii) the last day of 2025; (iii) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common equity held by non-affiliates is \$700 million or more as of the last business day of our most recently completed second fiscal quarter; or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the previous three years.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

The Company’s management has evaluated, with the participation of the Chief Executive Officer and the Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report. Based on this evaluation, management concluded that the Company’s disclosure controls and procedures were effective as of September 30, 2022.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may be involved in claims and proceedings arising in the course of our business. The outcome of any such claims or proceedings, regardless of the merits, is inherently uncertain. For information about legal proceedings in which we are involved, see Note 8 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

Item 1A. Risk Factors.

Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described as risk factors, any one or more of which could, directly or indirectly, cause our actual operating results and financial condition to vary materially from past, or anticipated future, operating results and financial condition. For a discussion of these potential risks and uncertainties, see Part I, Item 1A. “Risk Factors” of our Annual Report. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and the price of our common stock. Except as set forth below, there have been no material changes in our risk factors to those included in our Annual Report.

We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.

As of September 30, 2022, we had \$8.1 million in cash. Based on our existing cash, availability under the SWK Loan Facility, issuances of additional equity and cash generated from expected future sales, we believe that we do not have sufficient cash on hand to support current operations and our payment obligations under our Revenue Interest Obligation for at least one year from the date of issuance of the unaudited condensed consolidated financial statements appearing within this Quarterly Report. This condition raises substantial doubt about our ability to continue as a going concern for at least one year from the date that our unaudited condensed consolidated financial statements for the period ended September 30, 2022 were issued.

In order to mitigate the current and potential future liquidity issues, we may seek to raise capital through the issuance of common stock, restructure our Revenue Interest Obligation or pursue asset sale or licensing transactions. However, such transactions may not be successful and we may not be able to raise additional equity, refinance our Revenue Interest Obligation, or sell or license assets on acceptable terms, or at all. As such, there can be no assurance that we will be able to continue as a going concern.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

On November 10, 2022, the Company entered into an amendment to the SWK Loan Facility Agreement that further extended the minimum liquidity step-up date of November 10, 2022 to November 21, 2022. As amended, the Company is required to maintain a minimum liquidity of \$5.0 million until November 21, 2022 and thereafter, the greater of (i) \$5.0 million or (ii) the sum of the Operating Burn (as defined in the SWK Loan Facility Agreement) for the two prior, consecutive fiscal quarters then ended.

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Item 6. Exhibits.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
3.1	Restated Certificate of Incorporation of Aziyo Biologics, Inc.	8-K	001-39577	3.1	10/13/2020	
3.2	Amended and Restated Bylaws of Aziyo Biologics, Inc.	8-K	001-39577	3.2	10/13/2020	
4.1	Second Amended and Restated Investor Rights Agreement, dated as of September 14, 2020, among the Registrant and the investors named therein	S-1	333-248788	4.1	09/14/2020	
4.2	Specimen stock certificate evidencing the shares of Class A common stock	S-1	333-248788	4.2	09/14/2020	
4.3	Specimen stock certificate evidencing the shares of Class B common stock	S-1/A	333-248788	4.3	09/30/2020	
4.4	Warrant to Purchase Stock, issued on August 10, 2022, by Aziyo Biologics, Inc. to SWK Funding LLC.	8-K	001-39577	4.1	08/15/2022	
10.1#	Credit Agreement, dated as of August 10, 2022, between Aziyo Biologics, Inc. and SWK Funding LLC, as Agent and the Lenders from time to time party thereto	8-K	001-39577	10.1	08/15/2022	
10.2	Amendment Letter, dated as of October 9, 2022 to Credit Agreement, dated as of August 10, 2022, between Aziyo Biologics, Inc. and SWK Funding LLC, as Agent and the Lenders from time to time party thereto	8-K	001-39577	10.1	10/13/2022	
10.3	Amendment Letter, dated as of November 10, 2022 to Credit Agreement, dated as of August 10, 2022, between Aziyo Biologics, Inc. and SWK Funding LLC, as Agent and the Lenders from time to time party thereto (as amended by the Amendment Letter dated as of October 9, 2022)					*
10.4	Form of Restricted Stock Unit Award Agreement (approved August 2022)					*
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*

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32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	**
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	**
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	*
101.SCH	Inline XBRL Taxonomy Extension Schema Document	*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	*

* Filed herewith.

** Furnished herewith.

Annexes, schedules and exhibits have been omitted pursuant to Item 601(a)(5)(b)(2) of Regulation S-K. The Registrant hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the SEC upon request.

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 thereunto duly authorized.

AZIYO BIOLOGICS, INC.

Date: November 14, 2022

By: /s/ C. Randal Mills
C. Randal Mills
President and Chief Executive Officer
(principal executive officer)

Date: November 14, 2022

By: /s/ Matthew Ferguson
Matthew Ferguson
Chief Financial Officer
(principal financial officer and principal accounting officer)

November 10, 2022

Aziyo Biologics, Inc.
12510 Prosperity Drive, Suite 370
Silver Spring, MD 20904
Email: jhamet@aziyo.com

RE: **Amendment Letter**

Ladies and Gentlemen:

Reference is made to that certain Credit Agreement, dated as of August 10, 2022, by and among Aziyo Biologics, Inc., a Delaware corporation (the "Borrower"), each of the undersigned financial institutions (individually each a "Lender" and collectively the "Lenders") and SWK Funding LLC, a Delaware limited liability company, in its capacity as administrative agent for the other Lenders (in such capacity, "Agent") (as amended, restated, supplemented or otherwise modified from time to time, the "Credit Agreement"). All capitalized terms used in this amendment letter (this "Amendment Letter") and not otherwise defined herein, shall have the respective meanings given such terms in the Credit Agreement.

Borrower has requested of Agent and Lenders, and in consideration of the premises herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Agent and Lenders, intending to be legally bound, hereby agree that each reference to the date "November 10, 2022" in Section 7.13.1 of the Credit Agreement be replaced with "November 21, 2022."

Except for the amendments expressly set forth above, all of the terms, provisions and conditions of the Credit Agreement and the other Loan Documents shall remain and continue in full force and effect. This Amendment Letter shall not apply to any other past, present or future deviations from the Credit Agreement or any other Loan Document. Except as expressly provided herein, Agent or any Lender's failure to exercise any right, privilege or remedy as a result of the matters set forth above shall not directly or indirectly in any way whatsoever either: (a) impair, prejudice or otherwise adversely affect Agent or any Lender's right at any time to exercise any right, privilege, or remedy in connection with the Credit Agreement, the other Loan Documents, any other agreement, or any other contract or instrument in connection therewith, or (b) amend or alter any provision of the Credit Agreement, the other Loan Documents, any other agreement, or any other contract or instrument in connection therewith, or (c) constitute any course of dealing or other basis for altering any obligations of Borrower or any right, privilege, or remedy of Agent or any Lender under the Credit Agreement, the other Loan Documents, any other agreement, or any other contract or instrument in connection therewith. Agent and each Lender hereby reserve all rights granted under the Credit Agreement, the other Loan Documents, this Amendment Letter and any other contract or instrument between Borrower, Agent or any Lender in connection therewith. Except as expressly stated herein, Agent and each Lender reserve all of their respective rights, privileges and remedies under the Credit Agreement, the other Loan Documents, each other

agreement and any other contracts or instruments executed by Borrower for the benefit of Agent or such Lender in connection therewith.

Borrower hereby represents and warrants that (i) each of the representations and warranties contained in the Credit Agreement, is true, correct and complete in all material respects as of the date hereof; provided, however, that those representations and warranties expressly referring to a specific date shall be true, correct and complete in all material respects as of such date and (ii) no Default or Event of Default exists.

This Amendment Letter shall not become effective until Agent has received an executed and delivered signature page to this Amendment Letter by the Borrower.

Borrower represents that it has discussed this Agreement with its counsel.

THE TERMS AND PROVISIONS OF SECTION 10.17 (GOVERNING LAW) AND 10.18 (FORUM SELECTION; CONSENT TO JURISDICTION) OF THE CREDIT AGREEMENT ARE HEREBY INCORPORATED HEREIN BY REFERENCE, AND SHALL APPLY TO THIS AMENDMENT LETTER *MUTATIS MUTANDIS* AS IF FULLY SET FORTH HEREIN.

This Amendment Letter may be executed in multiple counterparts, each of which shall constitute an original hereof, and all of which taken together shall constitute one and the same agreement. One or more counterparts of this Amendment Letter may be delivered by facsimile or electronic (including "PDF") transmission, with the intention that delivery by such means shall have the same effect as delivery of an original counterpart thereof.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS HEREOF, as of the date above-written, the undersigned hereby agree to the terms and conditions set forth in this Amendment Letter.

Very truly yours,

AGENT AND LENDER:

SWK FUNDING LLC

As Agent and a Lender

By: SWK Holdings Corporation
its sole manager

By: /s/ Joe D. Staggs

Name: Joe D. Staggs

Title: President

[Additional signature pages follow]

ACCEPTED AND AGREED TO:

AZIYO BIOLOGICS, INC.

By: /s/ Matt Ferguson
Name: Matt Ferguson
Title: Chief Financial Officer

**AZIYO BIOLOGICS, INC.
2020 INCENTIVE AWARD PLAN**

RESTRICTED STOCK UNIT AWARD GRANT NOTICE AND RESTRICTED STOCK UNIT AGREEMENT

Aziyo Biologics, Inc., a Delaware corporation (the “Company”), pursuant to its 2020 Incentive Award Plan, as amended from time to time (the “Plan”), in connection with its initial public offering, hereby grants to the holder listed below (“Participant”) the number of Restricted Stock Units set forth below (the “RSUs”). The RSUs are subject to the terms and conditions set forth in this Restricted Stock Unit Grant Notice (the “Grant Notice”), the Restricted Stock Unit Agreement attached hereto as Exhibit A (the “Agreement”) and the Plan, each of which is incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in the Grant Notice and the Agreement.

Participant: _____
Grant Date: _____
Number of RSUs: [_____]
Type of Shares Issuable: Class A Common Stock
Vesting Date: [_____]

By Participant’s signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and the Grant Notice. Participant has reviewed the Plan, the Agreement and the Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing the Grant Notice and fully understands all provisions of the Plan, the Agreement and the Grant Notice. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, the Agreement and the Grant Notice.

AZIYO BIOLOGICS, INC.

PARTICIPANT

By: _____
 Print Name: _____
 Title: _____

By: _____
 Print Name: _____



EXHIBIT A
TO RESTRICTED STOCK UNIT AWARD GRANT NOTICE

RESTRICTED STOCK UNIT AWARD AGREEMENT

Pursuant to the Grant Notice to which this Agreement is attached, the Company has granted to Participant the number of RSUs set forth in the Grant Notice.

ARTICLE I.

GENERAL

Section 1.1 Defined Terms. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan or the Grant Notice. For purposes of this Agreement,

(a) “Change in Control” shall mean a Change in Control (as defined under the Plan) that constitutes a “change in control event” as defined in Treasury Regulation Section 1.409A-3(i)(5).

(b) “Company Group” shall mean the Company and its Affiliates.

(c) “Company Group Member” shall mean each member of the Company Group.

(d) “Disability” shall mean any disability or incapacity that (i) renders Participant unable to substantially perform his duties hereunder for ninety (90) days during any 12-month period or (ii) would reasonably be expected to render Executive unable to substantially perform his or her duties for ninety (90) days during any 12-month period, in each case as determined by the Board in its good faith judgment.

Section 1.2 Incorporation of Terms of Plan. The RSUs and the shares of Common Stock issued to Participant hereunder (“Shares”) are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

ARTICLE II.

AWARD OF RESTRICTED STOCK UNITS

Section 2.1 Award of RSUs

(a) In consideration of Participant’s past and/or continued employment with or service to a Company Group Member and for other good and valuable consideration, effective as of the grant date set forth in the Grant Notice (the “Grant Date”), the Company has granted to Participant the number of RSUs set forth in the Grant Notice, upon the terms and conditions set forth in the Grant Notice, the Plan and this Agreement, subject to adjustment as provided in Section 12.2 of the Plan. Each RSU represents the right to receive one Share at the times and subject to the conditions set forth herein. However, unless and until the RSUs have vested, Participant will have no right to the payment of any Shares subject thereto. Prior to the actual delivery of any Shares, the RSUs will represent an unsecured obligation of the Company, payable only from the general assets of the Company.

Section 2.2 Vesting of RSUs.

(a) Subject to Participant's continued employment with or service to a Company Group Member on the Vesting Date, and subject to the terms of this Agreement, including, without limitation, Section 2.2(d), the RSUs shall vest on the Vesting Date as set forth in the Grant Notice.

(b) In the event Participant incurs a Termination of Service prior to the Vesting Date, except as may be otherwise provided herein or by the Administrator or as set forth in a written agreement between Participant and the Company, Participant shall immediately forfeit any and all RSUs granted under this Agreement, and Participant's rights in any such RSUs shall lapse and expire.

(c) Notwithstanding the Grant Notice or the provisions of Section 2.2(a) and Section 2.2(b), in the event of Participant's death or in the event Participant incurs a Disability prior to the Vesting Date, the RSUs shall become vested with respect to all Shares covered thereby on the date of such Termination of Service.

(d) Notwithstanding the Grant Notice or the provisions of Section 2.2(a) and Section 2.2(b), in the event of the occurrence of a Change in Control prior to the Vesting Date, the RSUs shall become vested with respect to all Shares covered thereby on the date of the consummation of such Change in Control, subject to Participant's continued employment with or service to a Company Group Member through such Change in Control.

Section 2.3

(a) Distribution or Payment of RSUs. Participant's RSUs shall be distributed in Shares (either in book-entry form or otherwise) on or within two business days following the Vesting Date. Notwithstanding the foregoing, the Company may delay a distribution or payment in settlement of RSUs if it reasonably determines that such payment or distribution will violate federal securities laws or any other Applicable Law, *provided* that such distribution or payment shall be made at the earliest date at which the Company reasonably determines that the making of such distribution or payment will not cause such violation, as required by Treasury Regulation Section 1.409A-2(b)(7)(ii), and *provided further* that no payment or distribution shall be delayed under this Section 2.3(a) if such delay will result in a violation of Section 409A.

(b) All distributions shall be made by the Company in the form of whole Shares, and any fractional share shall be distributed in cash in an amount equal to the value of such fractional share determined based on the Fair Market Value as of the date immediately preceding the date of such distribution.

Section 2.4 Conditions to Issuance of Certificates. The Company shall not be required to issue or deliver any certificate or certificates for any Shares or to cause any Shares to be held in book-entry form prior to the fulfillment of all of the following conditions: (a) the admission of the Shares to listing on all stock exchanges on which such Shares are then listed, (b) the completion of any registration or other qualification of the Shares under any state or federal law or under rulings or regulations of the Securities and Exchange Commission or other governmental regulatory body, which the Administrator shall, in its absolute discretion, deem necessary or advisable, (c) the obtaining of any approval or other clearance from any state or federal governmental agency that the Administrator shall, in its absolute discretion, determine to be necessary or advisable, (d) the receipt by the Company of full payment for such Shares, which may be in one or more of the forms of consideration permitted under Section 2.5, and (e) the receipt of full payment of any applicable withholding tax in accordance with Section 2.5 by the Company Group Member with respect to which the applicable withholding obligation arises.

Section 2.5 Tax Withholding. Notwithstanding any other provision of this Agreement:

(a) As set forth in Section 10.2 of the Plan, the Company shall have the authority and the right to deduct or withhold, or to require the Participant to remit to the Company, an amount sufficient to satisfy all applicable federal, state and local taxes required by law to be withheld with respect to any taxable event arising in connection with the RSUs. Without limiting Section 10.2 of the Plan, the Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the RSUs as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Award.

(b) In the event any tax withholding obligation arising in connection with the RSUs will be satisfied under Section 10.2 of the Plan, then the Company may elect to instruct any brokerage firm determined acceptable to the Company for such purpose to sell on Participant's behalf a whole number of shares from those shares of Stock then issuable to Participant pursuant to the RSUs as the Company determines to be appropriate to generate cash proceeds sufficient to satisfy the tax withholding obligation and to remit the proceeds of such sale to the Participating Company with respect to which the withholding obligation arises. Participant's acceptance of this Award constitutes Participant's instruction and authorization to the Company and such brokerage firm to complete the transactions described in this Section 2.5(b), including the transactions described in the previous sentence, as applicable.

(c) The Company shall not be obligated to deliver any certificate representing Shares issuable with respect to the RSUs to, or to cause any such Shares to be held in book-entry form by, Participant or his or her legal representative unless and until Participant or his or her legal representative shall have paid or otherwise satisfied in full the amount of all federal, state, local and foreign taxes applicable with respect to the taxable income of Participant resulting from the vesting or settlement of the RSUs or any other taxable event related to the RSUs.

(d) Participant is ultimately liable and responsible for all taxes owed in connection with the RSUs, regardless of any action the Company or any other Company Group Member takes with respect to any tax withholding obligations that arise in connection with the RSUs. No Company Group Member makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the RSUs or the subsequent sale of Shares. The Participating Companies do not commit and are under no obligation to structure the RSUs to reduce or eliminate Participant's tax liability.

Section 2.6 Rights as Stockholder. Neither Participant nor any Person claiming under or through Participant will have any of the rights or privileges of a stockholder of the Company in respect of any Shares deliverable hereunder unless and until certificates representing such Shares (which may be in book-entry form) will have been issued and recorded on the records of the Company or its transfer agents or registrars and delivered to Participant (including through electronic delivery to a brokerage account). Except as otherwise provided herein, after such issuance, recordation and delivery, Participant will have all the rights of a stockholder of the Company with respect to such Shares, including, without limitation, the right to receipt of dividends and distributions on such Shares.

Section 2.7 Restrictive Covenants. Participant agrees to comply with the restrictive covenants set forth in Sections 7 through 10 in the employment agreement between Participant and a Company Group Member (the "Restrictive Covenants"), which are hereby incorporated by reference, and Participant acknowledges and agrees that the grant of the RSUs shall be in material part in consideration of Participant's reaffirmation of Participant's agreement to comply with the covenants set forth therein. In the event the Participant materially breaches the Restrictive Covenants or any other written covenants between such

Participant and any Company Group Member, the Participant shall immediately forfeit any and all RSUs granted under this Agreement (whether or not vested), and Participant's rights in any such RSUs shall lapse and expire.

ARTICLE III.

OTHER PROVISIONS

Section 3.1 Administration. The Administrator shall have the power to interpret the Plan, the Grant Notice and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan, the Grant Notice and this Agreement as are consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator will be final and binding upon Participant, the Company and all other interested Persons. To the extent allowable pursuant to Applicable Law, no member of the Committee or the Board will be personally liable for any action, determination or interpretation made with respect to the Plan, the Grant Notice or this Agreement.

Section 3.2 RSUs Not Transferable. The RSUs may not be sold, pledged, assigned or transferred in any manner other than by will or the laws of descent and distribution, unless and until the Shares underlying the RSUs have been issued, and all restrictions applicable to such Shares have lapsed. No RSUs or any interest or right therein or part thereof shall be liable for the debts, contracts or engagements of Participant or his or her successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempted disposition thereof shall be null and void and of no effect, except to the extent that such disposition is permitted by the preceding sentence. Notwithstanding the foregoing, with the consent of the Administrator, the RSUs may be transferred to Permitted Transferees, pursuant to any such conditions and procedures the Administrator may require.

Section 3.3 Adjustments. The Administrator may accelerate the vesting of all or a portion of the RSUs in such circumstances as it, in its sole discretion, may determine. Participant acknowledges that the RSUs and the Shares subject to the RSUs are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan, including Section 12.2 of the Plan.

Section 3.4 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to Participant shall be addressed to Participant at Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 3.4, either party may hereafter designate a different address for notices to be given to that party. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service or similar foreign entity.

Section 3.5 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

Section 3.6 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

Section 3.7 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement, are intended to conform to the extent necessary with all Applicable Laws, including, without limitation, the provisions of the Securities Act and the Exchange Act, and any and all regulations and rules promulgated thereunder by the Securities and Exchange Commission, and state securities laws and regulations. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the RSUs are granted, only in such a manner as to conform to Applicable Law. To the extent permitted by Applicable Law, the Plan, the Grant Notice and this Agreement, shall be deemed amended to the extent necessary to conform to Applicable Law.

Section 3.8 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board, *provided* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the RSUs in any material way without the prior written consent of Participant.

Section 3.9 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in Section 3.2 and the Plan, this Agreement shall be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

Section 3.10 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the RSUs, the Grant Notice and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

Section 3.11 Not a Contract of Employment. Nothing in this Agreement or in the Plan shall confer upon Participant any right to continue to serve as an employee or other service provider of any Company Group Member or shall interfere with or restrict in any way the rights of any Company Group Member, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent (i) expressly provided otherwise in a written agreement between a Company Group Member and Participant or (ii) where such provisions are not consistent with applicable foreign or local laws, in which case such applicable foreign or local laws shall control.

Section 3.12 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

Section 3.13 Section 409A. The intent of the parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (collectively, "Section 409A") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

Section 3.14 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held invalid or unenforceable, such provision will be severable from, and such invalidity or

unenforceability will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

Section 3.15 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant shall have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the RSUs.

Section 3.16 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which shall be deemed an original and all of which together shall constitute one instrument.

* * * * *

CERTIFICATIONS

I, C. Randal Mills, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022 of Aziyo Biologics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) [omitted];
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2022

By: _____
/s/ C. Randal Mills
C. Randal Mills
President and Chief Executive Officer
(principal executive officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Aziyo Biologics, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2022

By: _____
/s/ C. Randal Mills
C. Randal Mills
President and Chief Executive Officer
(principal executive officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.
