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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 March 31, 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	**47-4790334**
(State or other jurisdiction of incorporation or organization)	(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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Common Stock, par value $0.001 per share	AZYO	The Nasdaq Global 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 May 9, 2022, there were 9,306,738 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 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 lawsuits currently pending related to our recall of a single lot of Fiber Viable Bone Matrix ("FiberCel") and the potential impact of the pandemic related to COVID-19 and variants thereof, or Russia's war with Ukraine, on our business 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, in some cases, you can identify forward-looking statements by terms such as "aim", "believe," "may," "will," "should," "expect," "exploring," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," "seeks," or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. No forward-looking statement is a guarantee of future results, performance, or achievements, and one should avoid placing undue reliance on such statements.

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 assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, the other important factors identified 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. These risks and uncertainties include, but are not limited to:

- our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings;
- our dependence on our commercial partners and independent sales agents to generate a substantial portion of our net sales;
- our 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.

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.

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)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash	$ 22,066	$ 30,393
Restricted cash	109	35
Accounts receivable, net	6,010	5,996
Inventory	9,863	9,554
Prepaid expenses and other current assets	3,030	1,450
Total current assets	41,078	47,428
Property and equipment, net	1,155	1,200
Intangible assets, net	17,617	18,466
Other assets	76	76
Total assets	**$ 59,926**	**$ 67,170**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,715	$ 1,582
Accrued expenses	5,750	6,375
Payables to tissue suppliers	2,884	2,467
Current portion of long-term debt	8,059	8,059
Current portion of revenue interest obligation	2,750	2,750
Revolving line of credit	6,160	4,763
Other current liabilities	-	5
Total current liabilities	27,318	26,001
Long-term debt	8,758	10,410
Long-term revenue interest obligation	16,520	16,540
Other long-term liabilities	771	698
Total liabilities	53,367	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 March 31, 2022 and December 31, 2021, and 9,306,738 and 9,245,146 shares issued and outstanding, as of March 31, 2022 and December 31, 2021, respectively	9	9
Class B Common stock, $0.001 par value, 20,000,000 shares authorized, as of March 31, 2022 and December 31, 2021 and 4,313,406 issued and outstanding as of March 31, 2022 and December 31, 2021	4	4
Additional paid-in capital	119,786	118,599
Accumulated deficit	(113,240)	(105,091)
Total stockholders' equity	6,559	13,521
Total liabilities and stockholders' equity	**$ 59,926**	**$ 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 March 31,	
	2022	2021
Net sales	$ 11,495	$ 12,884
Cost of goods sold	7,214	6,555
Gross profit	4,281	6,329
Sales and marketing	4,818	4,703
General and administrative	4,113	3,605
Research and development	2,272	1,720
Total operating expenses	11,203	10,028
Loss from operations	(6,922)	(3,699)
Interest expense	1,215	1,355
Loss before provision for income taxes	(8,137)	(5,054)
Income tax expense	12	13
Net loss	**$ (8,149)**	**$ (5,067)**
Net loss per share - basic and diluted	**$ (0.60)**	**$ (0.50)**
Weighted average common shares outstanding - basic and diluted	13,574,058	10,226,152

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				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance, December 31, 2021	**9,245,146**	**$ 9**	**4,313,406**	**$ 4**	**$ 118,599**	**$ (105,091)**	**$ 13,521**
Additional issuance costs in connection with Private Placement	—	—	—	—	(110)	—	(110)
Proceeds from sale of common stock through Employee Stock Purchase Plan	42,345	—	—	—	192	—	192
Vesting of restricted stock units	19,247	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	1,105	—	1,105
Net loss	—	—	—	—	—	(8,149)	(8,149)
Balance, March 31, 2022	**9,306,738**	**$ 9**	**4,313,406**	**$ 4**	**$ 119,786**	**$ (113,240)**	**$ 6,559**
Balance, December 31, 2020	**7,091,960**	**$ 7**	**3,134,162**	**$ 3**	**$ 101,080**	**$ (80,259)**	**$ 20,831**
Proceeds from stock option exercises	561	—	—	—	3	—	3
Stock-based compensation	—	—	—	—	677	—	677
Net loss	—	—	—	—	—	(5,067)	(5,067)
Balance, March 31, 2021	**7,092,521**	**$ 7**	**3,134,162**	**$ 3**	**$ 101,760**	**$ (85,326)**	**$ 16,444**

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)

	Three Months Ended March 31,	
	2022	2021
Net loss	$ (8,149)	$ (5,067)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	929	933
Amortization of deferred financing costs	15	30
Interest expense recorded as additional revenue interest obligation	660	663
Stock-based compensation	1,105	677
Changes in operating assets and liabilities:		
Accounts receivable	(14)	(1,596)
Inventory	(309)	(101)
Prepaid expenses and other	(1,580)	465
Accounts payable and accrued expenses	(492)	(1,387)
Obligations to tissue suppliers	417	276
Deferred revenue and other liabilities	68	(67)
Net cash used in operating activities	**(7,350)**	**(5,174)**
INVESTING ACTIVITIES:		
Expenditures for property, plant and equipment	(34)	(131)
Net cash used in investing activities	**(34)**	**(131)**
FINANCING ACTIVITIES:		
Additional issuance costs in connection with Private Placement	(110)	—
Net borrowings (repayments) under revolving line of credit	1,397	(3,064)
Proceeds from stock option exercises	—	3
Repayments of long-term debt	(1,667)	—
Payments on revenue interest obligation	(681)	(665)
Proceeds from sales of common stock through Employee Stock Purchase Plan	192	—
Net cash used in financing activities	**(869)**	**(3,726)**
Net decrease in cash and restricted cash	**(8,253)**	**(9,031)**
Cash and restricted cash, beginning of period	**30,428**	**39,532**
Cash and restricted cash, end of period	**$ 22,175**	**$ 30,501**
Supplemental Cash Flow and Non-Cash Financing Activities Disclosures:		
Cash paid for interest	$ 1,162	$ 1,243

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 March 31, 2022 and for the three months ended March 31, 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 three months ended March 31, 2022, the Company incurred a net loss of $8.1 million, and as of March 31, 2022, the Company had an accumulated deficit of $113.2 million. In addition, during the three months ended March 31, 2022, the Company used $7.4 million and $0.9 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, either refinance or restructure its Term Loan Facility and Revolving Credit Facility (as such terms are defined, and further described, in Note 6), restructure its Revenue Interest Obligation (as such term is defined, and further described, in Note 7), or pursue asset sale transactions. However, such transactions may not be successful and the Company may not be able to raise additional equity, refinance or restructure its debt instruments, or sell 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, availability under

the Revolving Credit Facility 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.

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 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 and 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 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 Revolving Credit Facility (see Note 6), the Company has a lockbox arrangement with the banking institution whereby daily lockbox receipts are contractually utilized to pay down outstanding balances on the Revolving Credit Facility debt. Lockbox receipts that have not yet been applied to the Revolving Credit Facility are 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).

	March 31,	
	2022	2021
Cash	$ 22,066	$ 30,410
Restricted cash	109	91
Total cash and restricted cash shown in statements of cash flows	$ 22,175	$ 30,501

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 months ended March 31, 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 primarily sell and distribute products to healthcare providers or commercial partners, or are produced and sold under contract manufacturing arrangements with corporate customers which 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 March 31, 2022, the Company maintained $22.1 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 March 31,	
	2022	2021
Percent of revenues derived from:		
Medtronic Sofamor Danek USA	-	22%
Surgalign Holdings	10%	10%

	March 31, 2022	December 31, 2021
Percent of accounts receivable derived from:		
Surgalign Holdings	11%	12%

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 months ended March 31, 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 March 2020, the Financial Accounting Standards Board ("FASB") issued ASU 2020-04, Reference Rate Reform (Topic 848), Facilitation of the Effects of Reference Rate Reform on Financial Reporting. The ASU provides temporary relief from some of the existing rules governing contract modifications when the modification is related to the replacement of the London Interbank Offered Rate ("LIBOR") or other reference rates discontinued as a result of reference rate reform. The ASU specifically provides optional practical expedients for contract modification accounting related to contracts subject to ASC 310, Receivables, ASC 470, Debt, ASC 842, Leases, and ASC 815, Derivatives and Hedging. The ASU also establishes a general contract modification principle that entities can apply in other areas that may be affected by reference rate reform and certain elective hedge accounting expedients. For eligible contract modifications, the principle generally allows an entity to account for and present modifications as an event that does not require contract remeasurement at the modification date or reassessment of a previous accounting determination. That is, the modified contract is accounted for as a continuation of the existing contract. The standard was effective upon issuance on March 12, 2020, and the optional practical expedients can generally be applied to contract modifications made and hedging relationships entered into on or before December 31, 2024. Borrowings under the Company's term loan facility and

revolving line of credit bear interest based on LIBOR or an alternate rate. Provisions currently provide the Company with the ability to replace LIBOR with a different reference rate in the event that LIBOR ceases to exist.

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 Board 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 board 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 intends to adopt in the fourth quarter of 2022 for the full 2022 year. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.

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 March 31, 2022, the Company had 481,195 shares of Class A common stock available for issuance under the 2020 Plan.

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 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 three months ended March 31, 2022 is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2021	1,386,811	$ 13.28	7.8	$ 179
Granted	499,130	$ 5.08		
Exercised	—	$ —		
Forfeited	(28,850)	$ 12.26		
Outstanding, March 31, 2022	1,857,091	$ 11.10	8.2	$ 524
Vested and exercisable, March 31, 2022	477,322	$ 11.04	5.7	$ 87

As of March 31, 2022, there was approximately $7.3 million of total unrecognized compensation expense related to unvested stock options. These costs are expected to be recognized over a weighted-average period of 2.9 years. The weighted average grant date fair value of options granted during the three months ended March 31, 2022 was $3.03.

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.

A summary of the RSU activity under the Company's 2020 Plan for the three months ended March 31, 2022 is as follows:

	Number of Shares Underlying RSUs	Weighted-Average Grant Date Fair Value
Unvested, December 31, 2021	235,985	$ 15.98
Granted	356,349	$ 3.58
Vested	(19,247)	$ 14.53
Forfeited	(8,928)	$ 8.66
Unvested, March 31, 2022	564,159	$ 8.31

The total fair value of the RSUs granted during the three months ended March 31, 2022 of $1.3 million, of which nearly all was based on the fair market value of the Company's Class A common stock on the date of grant and such fair value at the time of the grant is amortized to expense on a straight-line basis over the vesting period of three to four years. The Company granted RSUs totaling 199,388 during the three months ended March 31, 2022, pursuant to which such RSUs will only vest if or when the Company's Class A common stock closing price is at or exceeds $10 per share for 30 consecutive days by March 8, 2024, subject to the grantee's continued employment with the Company. Given the nature of this arrangement, an option pricing model, the Monte Carlo model, was used to determine the fair value of the RSUs granted and an expense recognition on a straight-line basis over two years. As of March 31, 2022, $3.3 million of unrecognized compensation costs related to RSUs is expected to be recognized over a weighted average period of 1.7 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 March 31, 2022, the total shares of Class A common stock authorized for issuance under the ESPP was 380,997, of which 311,408 remained available for future issuance. During the three months ended March 31, 2022, 42,345 shares of Class A common stock were issued under the ESPP.

Stock-Based Compensation Expense

Stock-based compensation expense recognized during the three months ended March 31, 2022 and 2021 was comprised of the following (in thousands):

	Three Months Ended March 31,	
	2022	2021
Sales and marketing	$ 195	$ 128
General and administrative	682	411
Research and development	178	109
Cost of goods sold	50	29
Total stock-based compensation expense	$ 1,105	$ 677

The Company uses the Black-Scholes model to value its 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 of Directors 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 during the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,	
	2022	2021
Expected term (years)	6.2	6.1
Risk-free interest rate	1.8 %	1.0 %
Volatility factor	64 %	64 %
Dividend yield	—	—

Note 5. Inventory

Inventory was comprised of the following (in thousands):

	March 31, 2022	December 31, 2021
Raw materials	$ 1,872	$ 1,880
Work in process	568	834
Finished goods	7,423	6,840
Total	$ 9,863	$ 9,554

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 "Term Loan Facility") and an $8.0 million asset-backed revolving line of credit (the "Revolving Credit Facility"), under which the Company's borrowing capacity is limited by certain qualifying assets, with a financial institution (the "May 2017 Financing"). As of March 31, 2022 and 2021, the Company's borrowing capacity under its Revolving Credit Facility was $7.0 million and $8.0 million, respectively. The Term 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 Term Loan Facility to $20 million. Borrowings under the Term Loan Facility, as amended, bear 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 Term Loan Facility borrowings was 9.5% for both the three months ended March 31, 2022 and 2021. The agreement governing the Term Loan Facility provides for interest only payments through January 2021 and interest and equal monthly principal payments from February 2021 through maturity in July 2024. However, the Term Loan Facility also provides that if certain conditions were satisfied prior to December 1, 2020 (including the completion of a qualified initial public offering and no continuing default or event of default), interest only payments may, upon the Company's request, be extended to August 1, 2021. Accordingly, based on the Company's successful completion of its IPO, Aziyo exercised this interest-only period extension right and as such, interest and equal principal payments commenced on August 1, 2021 and will continue through maturity in July 2024.

The agreement that governs the Term Loan Facility, as amended, requires certain mandatory prepayments, subject to certain exceptions, with: (1) 100% of any net casualty proceeds in excess of $250,000 with respect to assets upon which the agent maintains a lien and (2) 100% of the net cash proceeds of non-ordinary course asset sales or sales pertaining to collateral upon which the borrowing base of the Revolving Credit Facility is calculated. In addition, the Company is required to prepay all outstanding obligations under the Term Loan Facility upon the termination of all commitments under the Revolving Credit Facility and the repayment of the outstanding borrowings thereunder. No such mandatory prepayments were required during the three months ended March 31, 2022 and 2021.

The agreement governing the Term Loan Facility also includes an exit fee of 6.5% of the aggregate principal amount and prepayment penalties which, based on an amendment to the Term Loan Facility executed in January 2022, shall be equal to the amount prepaid multiplied by 3.0% until January 21, 2023 and 2.0% thereafter.

Borrowings under the Revolving Credit Facility bear 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 agreement governing the Revolving Credit Facility includes an unused line fee in an amount equal to 0.5% per annum of the unused borrowing capacity and based on an amendment to the Revolving Credit Facility executed in January 2022, prepayment penalties equal to $8.0 million multiplied by 3.0% until January 21, 2023 and 2.0% thereafter. The weighted average interest rate on Revolving Credit Facility borrowings was 7.2% for the three months ended March 31, 2022 and 2021. Both debt instruments contain events of default, including, most significantly, a failure to timely pay interest or principal, insolvency, or an action by the United States Food and Drug Administration or such other material adverse event impacting the operations of Aziyo.

The debt instruments also include a financial covenant based on cumulative minimum net product revenue, as defined, restrictions as to payment of dividends, and are secured by all assets of the Company. As of March 31, 2022, Aziyo was in compliance with this financial covenant.

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 notes are subordinated in payment to the Term Loan Facility and Revolving Credit Facility and in both 2022 and 2021, the Company's senior lender restricted payment of the amounts due.

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

	March 31, 2022	December 31, 2021
Term Loan Facility, net of unamortized discount and deferred financing costs	$ 15,425	$ 17,077
Note to Tissue Supplier	1,392	1,392
Total	16,817	18,469
Current Portion	(8,059)	(8,059)
Long-Term Debt	$ 8,758	$ 10,410

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 March 31, 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 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 months ended March 31, 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 March 31, 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. All leases contain renewal options and escalation clauses based upon increases in the lessors' operating expenses and other charges.

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 March 31, 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 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 months ended March 31, 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, occurs within Aziyo. The Company, in its sole discretion, can terminate the 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.

In June 2021, the Company announced a voluntary recall of a single lot of FiberCel. Between June 21, 2021 and May 9, 2022, forty-seven lawsuits in Indiana, Delaware, Florida, Maryland, Colorado, Michigan, Ohio, Kentucky, Oregon, and North Carolina have been filed against Aziyo Biologics Inc., certain Medtronic entities, and others alleging that the plaintiffs contracted tuberculosis and/or suffered substantial symptoms and complications following the implantation of FiberCel during spinal fusion operations. Twenty lawsuits were filed in Indiana state court, captioned, respectively: (1) John Dukes and Kimberly Smith v. Aziyo Biologics, Inc., et al., Case No. 49D02-2109-CT-032234 (case dismissed without prejudice on 09/16/2021 and re-filed on 09/24/2021); (2) Tamara and Richard Marksberry v. Aziyo Biologics, Inc., et al., Case No. 49D04-2106-CT-021649 (consolidated); (3) Ramon Cabello v. Aziyo Biologics, Inc., et al., Case No. 49D13-2106-CT-021650 (consolidated); (4) Luis Caban v. Aziyo Biologics, Inc., Case No. 49D13-2107-CT-022413 (consolidated); (5) Machell and Samuel Hargrave v. Aziyo Biologics, Inc., et al., Case No. 49D01-2106-CT-021275 (consolidated); (6) Georgia Flinn as Personal Representative of the Estate of Gregory Flinn v. Aziyo Biologics, Inc., et al., Case No. 49D12-2107-CT-024051 (consolidated); (7) Ruth and William Flynn v. v. Aziyo Biologics, Inc., et al., Case No. 49D12-2107-CT-024624 (consolidated); (8) Tracy Warner and Kristin Foate v. v. Aziyo Biologics, Inc., et al., Case No. 49D04-2107-CT-024631 (consolidated); (9) Donna Schilling v. v. Aziyo Biologics, Inc., et al., Case No. 49D04-2107-CT-024443 (consolidated); (10) Robby and Stephanie Anderson v. v. Aziyo Biologics, Inc., et al., Case No. 49D13-2107-CT-025221 (consolidated); (11) Max Shepard v. v. Aziyo Biologics, Inc., et al., Case No. 49D11-2108-CT-025984 (consolidated); (12) Leon Chew v. Aziyo Biologics, Inc., et al., Case No. 49D12-2108-CT-025967 (consolidated); (13) Candace Kozor, Kenneth Largin and Anthony Young v. Aziyo Biologics, Inc., et al., Case No. 49D04-2107-CT-024626 (consolidated); (14) James and Lauri Ann Jackson v. v. Aziyo Biologics, Inc., et al., Case No. 49D02-2108-CT-028321 (re-filed in state court and consolidated); (15) James and Kathy Shaw v. Aziyo Biologics, Inc., et al, Case No. 49D11-2108-CT-028669 (consolidated); (16) Larry Szynski v. Aziyo Biologics, Inc., et al., Case No. 49D05-2108-CT-029225 (consolidated); (17) Jerrold Jenkins v. Aziyo Biologics, Inc., et al., Case No. 49D03-2108-CT-029367 (consolidated; (18) Hon Vien v. Aziyo Biologics, Inc., et al., Case No. 49D01-2202-CT-004812; (19) Jayson Hartman v. Aziyo Biologics, et al., Case No. 49D12-2202-CT-004835; and (20) Randy Smith v. Aziyo Biologics, Inc., et al., Case No. 49D01-2202-CT-005184 (collectively, the "Indiana State Complaints"). Fifteen lawsuits were filed in the Superior Court of the State of Delaware, captioned respectively: (1) Richard Williams v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-166 EMD; (2) Jean and Shante Georges v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-256-DJB; (3) Marjorie Hitchens v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-214-DJB; (4) Larry and Joanne Fortner v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-215-DJB; (5) Nancy and John Smith v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-219-DJB; (6) Joan Trincia v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-220-DJB; (7) Bernadette Burgess v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-264-DJB; (8) Summer Fitzhugh v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-221-DJB; (9) Linda Shields v. Aziyo, Biologics Inc., et al., C.A. No. N21C-06-166-DJB; and (10) Sharon Riddick v. Aziyo, Biologics Inc., et al., C.A. No. N21C-07-005-EMD; (11) Carl Stevens v. Aziyo, Biologics Inc., et al., C.A. No. N21C-08-149-DJB; (12) Joel and Melissa Stanton v. Aziyo, Biologics Inc., et al., C.A. No. N21C-08-212-AML; (13) Bruce and Beverly Carroll v. Aziyo, Biologics Inc., et al., C.A. No. N21C-08-130-DJB; (14) Margaret Cook v. Aziyo, Biologics Inc., et al.,

C.A. No. N21C-08-131-DJB; (15) Robert Jr. and Kelly Aspinall v. Aziyo, Biologics Inc., et al., C.A. No. N21C-09-065-DJB (collectively, the "Delaware State Complaints"). One lawsuit has been re-filed in the Circuit Court of Maryland (previously filed on 07/21/2021 and dismissed without prejudice on 08/12/2021 in the U.S. District Court of Maryland), captioned: Diana and James Hanson v. Aziyo Biologics, Inc., et al., Case No. C-02-CV-21-001094 ("Maryland State Complaint"). One lawsuit has been filed in the Court of Common Pleas of Ohio, captioned: Michelle and Charles Weethee v. Aziyo, Biologics Inc., et al., Case No. 2021 CV 03621 ("Ohio State Complaint"). One lawsuit was filed in the Northern District of Ohio, captioned: Heath Raker and Neal Raker v. Aziyo Biologics, Inc., et al., Case No. 1:22-cv-54 ("Ohio Federal Complaint"). One lawsuit filed in the Superior Court of North Carolina, captioned: Aurelia and Belvin Sherrill v. Aziyo Biologics, Inc., et al., Case No. 21-cvs-2797 has since been removed to the U.S. District Court for the Western District of North Carolina ("North Carolina Federal Complaint"). One lawsuit has been filed in the U.S. District Court for the Northern District of Florida, captioned Deborah Rice v. Aziyo Biologics, Inc., et al., Case No. 5:21-cv-00135-MW-MJF ("Florida Federal Complaint"). Two lawsuits were filed in the U.S. District Court for the Eastern District of Michigan, captioned: (1) Karrold Dudley v. Aziyo, Biologics Inc., et al., Case No. 2:21-cv-11813-GAD-EAS and (2) Diane Parron v. Aziyo Biologics Inc., et al., Case No. 2:22-cv-10522-NGE-EAS. A third lawsuit originally filed in the Circuit Court of Michigan, captioned: (3) Ilona and Christian Hildebrandt v. Aziyo Biologics, Inc., Case No. 2021-003804-NP has since been removed to the Eastern District of Michigan (collectively "Michigan Federal Complaints.") One lawsuit has been filed in the U.S. District Court for the District of Colorado, captioned Christopher and Julie Buri v. Aziyo Biologics, Inc., et al., Case No. 1:21-cv-02789-SKC ("Colorado Federal Complaint"). One lawsuit has been filed in the U.S. District Court for the District of Oregon, captioned Christy Bryant v. Aziyo Biologics, Inc., et al., Case No. 1:21-cv-01759-AA ("Oregon Federal Complaint"). Two lawsuits have been filed in Fayette, Kentucky Circuit Court, captioned: (1) Earl Wesley Robinson and Joyce Ann Robinson v. Aziyo Biologics, Inc., Case No. 21-CI-03842 and (2) Horace B. Nelson, Sr. v. Aziyo Biologics, Inc., et al., Case No. 22-CI-00895 (collectively "Kentucky State Complaints"). Lastly, two lawsuits have been dismissed: (1) in the state court of Maryland, captioned Tracey and Stan Gearhart v. Aziyo Biologics, Inc., et al., Case No. C-02-CV-21-000997(dismissed without prejudice on 09/14/2021), and (2) in the U.S. District Court for the Northern District of Indiana, captioned: David Hahn v. Aziyo Biologics, Inc., et al., Case No. 2:21-cv-00265-PPS-JEM (dismissed without prejudice on 09/30/2021).

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 allege negligence, breach of implied warranty, breach of express warranty, 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 Complaint asserts 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 State 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. In addition to the above, there have been forty-four claims related to the FiberCel recall, which 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 order to reasonably estimate a loss or range of loss for the FiberCel Litigation, the Company must assess a variety of factors, including, (i) what claims, if any, will survive dispositive motion practice, (ii) the extent of the claims, particularly when damages are not specified or are indeterminate, (iii) how the discovery process will affect the litigation, (iv) the settlement posture of the other parties to the litigation and (v) any other factors that may have a material effect on the litigation. At present, it is not possible for Aziyo to estimate a range of probable loss in the FiberCel Litigation; however, while unknown, the probable loss could have a material effect on the Company's financial position and results of operations.

Should Aziyo be required to pay claims related to the FiberCel Litigation, the Company believes that certain settlements and judgments, as well as legal defense costs, may be covered in whole or in part under the Company's insurance policies. In certain circumstances, insurance carriers reserve their rights to contest or deny coverage. The Company intends to contest vigorously any disputes with its insurance carriers and to enforce its rights under the terms of its insurance policies. Accordingly, the Company will record receivables with respect to amounts due under these policies only when the realization of the potential claim for recovery is considered probable. Amounts recovered under the Company's insurance policies could be materially less than stated coverage limits and may not be adequate to cover damages, other relief and/or costs relating to claims. In addition, there is no guarantee that insurers will pay claims or that coverage will otherwise be available.

As of both March 31, 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 March 31,	
	2022	2021
Numerator:		
Net loss attributable to common stockholders	$ (8,149)	$ (5,067)
Denominator:		
Weighted average number of common shares, basic and diluted	13,574,058	10,226,152
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.60)	$ (0.50)

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:

	March 31,	
	2022	2021
Options to purchase common stock	1,857,091	1,238,548
Restricted stock units	564,159	232,098
Total	2,421,250	1,470,646

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.

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 months ended March 31, 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 March 31,	
	2022	2021
Sales by product		
Core Products	$ 8,140	$ 10,664
Non-Core Products	3,355	2,220
Total Net Sales	$ 11,495	$ 12,884

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 IA. "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 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, research and development, clinical activity 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 March 31, 2022, we had 157 employees, of which 26 were direct sales representatives.

For the three months ended March 31, 2022, we incurred net losses of $8.1 million, and as of March 31, 2022, we had an accumulated deficit of $113.2 million. In addition, during the three months ended March 31, 2022, we used $7.4 million and $0.9 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 seek to grow our sales organization to coincide with product launches and expand our product development and clinical and research activities. 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, either refinance or restructure our Term Loan Facility and Revolving Credit Facility, restructure our Revenue Interest Obligation, or pursue asset sale 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, availability under our Revolving Credit Facility 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.

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.

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 Fiber Viable Bone Matrix, 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 legal proceedings in which we are involved and the possible future financial implications, see Note 8 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

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 expenses will increase in the foreseeable future as we grow our sales and marketing organization to coincide with new product launches and expand our product development and clinical activities to support our current and pipeline products. 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:

Costs 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 and customer service expenses. We expect sales and marketing expenses to grow

commensurate with sales increases, and to an even larger degree in the near-term to the extent we grow our direct sales force and increase marketing activities to coincide with new product launches.

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 and public 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.

Results of Operations

Comparison of the Three Months Ended March 31, 2022 and 2021

	Three Months Ended March 31,					
	2022		2021		Change 2021 / 2022	
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Net sales	$ 11,495	100.0 %	$ 12,884	100.0 %	$ (1,389)	(10.8)%
Cost of goods sold	7,214	62.8 %	6,555	50.9 %	659	10.1 %
Gross profit	4,281	37.2 %	6,329	49.1 %	(2,048)	(32.4)%
Sales and marketing	4,818	41.9 %	4,703	36.5 %	115	2.4 %
General and administrative	4,113	35.8 %	3,605	28.0 %	508	14.1 %
Research and development	2,272	19.8 %	1,720	13.3 %	552	32.1 %
Total operating expenses	11,203	97.5 %	10,028	77.8 %	1,175	11.7 %
Loss from operations	(6,922)	(60.2)%	(3,699)	(28.7)%	(3,223)	87.1 %
Interest expense	1,215	10.6 %	1,355	10.5 %	(140)	(10.3)%
Loss before provision of income taxes	(8,137)	(70.8)%	(5,054)	(39.2)%	(3,083)	61.0 %
Income tax expense	12	0.1 %	13	0.1 %	(1)	(8)%
Net loss	**$ (8,149)**	**(70.9)%**	**$ (5,067)**	**(39.3)%**	**$ (3,082)**	**60.8 %**

Net Sales

Net sales decreased $1.4 million, or 10.8%, to $11.5 million in the three months ended March 31, 2022 compared to $12.9 million in the three months ended March 31, 2021. The decline in net sales was due to reductions in the net sales of our Core Products of $2.5 million, partially offset by growth in the net sales of our Non-Core Products of $1.1 million.

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

	Three Months Ended March 31,					
	2022		2021			
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	Change 2021 / 2022 $	Change 2021 / 2022 %
Products:						
Core Products	$ 8,140	70.8 %	$ 10,664	82.8 %	$ (2,524)	(23.7)%
Non-Core Products	3,355	29.2 %	2,220	17.2 %	1,135	51.1 %
Total Net Sales	**$ 11,495**	**100.0 %**	**$ 12,884**	**100.0 %**	**$ (1,389)**	**(10.8)%**

Net sales generated by our Core Products declined $2.5 million, or 23.7%, to $8.1 million in the three months ended March 31, 2022 compared to $10.6 million in the three months ended March 31, 2021. The Core Products net sales reduction can be attributed to the cessation of purchases by Medtronic of FiberCel following our recall of a single lot of FiberCel in June 2021. Sales of FiberCel to Medtronic were $2.8 million in the three months ended March 31, 2021.

Net sales generated by our Non-Core Products increased $1.1 million, or 51.1%, to $3.4 million in the three months ended March 31, 2022 compared to $2.2 million in the three months ended March 31, 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 was $7.2 million and $6.6 million in the three months ended March 31, 2022 and 2021, respectively, and included, in each case, $0.8 million of intangible asset amortization expenses. Gross margin in the three months ended March 31, 2022 was 37.2%, a decrease from 49.1% in the corresponding prior year period. Gross margin, excluding intangible asset amortization, in the three months ended March 31, 2022 was 44.6%, a decline from 55.7% 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 was primarily due to product mix (higher Non-Core revenues in 2022 with lower gross margins) and lower yields in our orthopedic and spinal repair product lines related to heightened donor screening criteria ahead of the implementation of enhanced product testing.

Operating Expenses

Sales and Marketing

Sales and marketing expenses increased $0.1 million, or 2.4%, to $4.8 million in the three months ended March 31, 2022 compared to $4.7 million in the three months ended March 31, 2021. As a percentage of sales, sales and marketing expenses grew to 41.9% in the three months ended March 31, 2022 from 36.5% in the three months ended March 31, 2021. The increase as a percentage of sales was the result of the growth during the three months ended March 31, 2022 of revenues from sales by us directly to the end user as such revenues have higher selling costs than our “business to business” revenues.

General and Administrative

G&A expenses increased $0.5 million, or 14.1%, to $4.1 million in the three months ended March 31, 2022 compared to $3.6 million in the three months ended March 31, 2021. As a percentage of net sales, G&A expenses increased to 35.8% in the three months ended March 31, 2022 from 28.0% in the three months ended March 31, 2021. The increase in expense was primarily due to higher stock-based compensation as well as costs associated with FiberCel Litigation that we did not incur in the 2021 period.

Research and Development

R&D expenses increased to $2.3 million in the three months ended March 31, 2022 compared to $1.7 million in the three months ended March 31, 2021. We continue to focus our R&D efforts on the development of our pipeline products with the growth in R&D expenses in the three months ended March 31, 2022 largely attributable to the work performed on the final development and testing of our CanGaroo with antibiotics.

Interest Expense

Interest expense was approximately $1.2 million in the three months ended March 31, 2022 compared to $1.4 million in the three months ended March 31, 2021. The decrease was due to lower draws on our Revolving Credit Agreement and lower outstanding principal on our Term Loan Credit Agreement (as defined below) due to the commencement of principal payments in the three months ended September 30, 2021. See "Credit Facilities" below for further discussion of these debt agreements 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.

Non-GAAP Financial Measures

This Quarterly Report presents our gross margin, excluding intangible asset amortization, for the three months ended March 31, 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 months ended March 31, 2022 and 2021 to the most directly comparable GAAP financial measure, which is our GAAP gross margin (in thousands).

	Three Months Ended March 31,	
	2022	2021
Net sales	$ 11,495	$ 12,884
Cost of goods sold	7,214	6,555
Gross profit	4,281	6,329
Intangible asset amortization expense	849	849
Gross profit, excluding intangible asset amortization	$ 5,130	$ 7,178
Gross margin	37.2 %	49.1 %
Gross margin, excluding intangible asset amortization	44.6 %	55.7 %

Seasonality

Historically, we have experienced seasonality, with lower sales in our first and second quarter 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 March 31, 2022, we had cash and restricted cash of approximately $22.2 million and availability under our Revolving Credit Facility of $0.9 million. 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 acquisition and integration, manufacturing 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 March 31, 2022, our accumulated deficit was $113.2 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. Additionally, as discussed below under "--- Credit Facilities," in August 2021, we commenced the principal repayment of our Term Debt with such repayments totaling approximately $556,000 per month through July 2024.

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, either refinance or restructure our Term Loan Facility and Revolving Credit Facility, restructure our Revenue Interest Obligation, or pursue asset sale 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 our Revolving Credit Facility 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 Three Months Ended March 31, 2022 and 2021

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
Net cash used in:		
Operating activities	$ (7,350)	$ (5,174)
Investing activities	(34)	(131)
Financing activities	(869)	(3,726)
Net decrease in cash	**$ (8,253)**	**$ (9,031)**

Net Cash Used in Operating Activities

Net cash used in operating activities for the three months ended March 31, 2022 was $7.4 million compared to $5.2 million for the three months ended March 31, 2021. The year-over-year increase was primarily due to a higher net loss (after adjustment for non-cash charges and gains) as well as the timing of certain annual insurance prepayments.

Net Cash Used in Investing Activities

Net cash used in investing activities for the three months ended March 31, 2022 was $0.03 million and approximately $0.1 million for the three months ended March 31, 2021. In both periods, the use of cash related to the purchase of property and equipment, the majority of which are used in the production activities of our Richmond, California facility.

Net Cash Used in Financing Activities

Net cash used in financing activities for the three months ended March 31, 2022 totaled $0.9 million compared to $3.7 million for the three months ended March 31, 2021. The year-over-year net decrease was caused by net borrowings of $1.4 million on our Revolving Credit Facility during the three months ended March 31, 2022 compared to net repayments of $3.1 million during the three months ended March 31, 2021. This change in the Revolving Credit Facility activity was offset by principal payments of $1.7 million on our Term Loan Credit Agreement as such payments commenced in August 2021.

Credit Facilities

General

On July 15, 2019, Aziyo and Aziyo Med, LLC, which we refer to collectively as the Borrowers, entered into an amended and restated term loan credit agreement (the "Term Loan Credit Agreement"), with Midcap Financial Trust, as agent and lender, and the other lenders party thereto, which provided for the conversion of our existing term loans into borrowing under the Term Loan Credit Agreement (consisting of a $8.5 million tranche ("Term Loan Tranche 1"), a $5.0 million tranche ("Term Loan Tranche 2") and a $3.0 million tranche ("Term Loan Tranche 3"), and established a new $3.5 million tranche ("Term Loan Tranche 4"). We refer to Term Loan Tranche 1, Term Loan Tranche 2, Term Loan Tranche 3 and Term Loan Tranche 4 collectively as the "Term Loan Facility".

On July 15, 2019, the Borrowers also entered into an amended and restated revolving credit agreement (the "Revolving Credit Agreement"), with Midcap Funding IV Trust, as agent and lender, and the other lenders party thereto, which provided for an $8.0 million asset-based revolving credit facility (the "Revolving Credit Facility").

As of March 31, 2022, we had $15.4 million of indebtedness outstanding under our Term Loan Facility (net of $0.1 million of unamortized discount and deferred financing costs), and $6.2 million outstanding under our Revolving Credit Facility (with $0.9 million of additional borrowings available thereunder).

Interest Rates and Fees

Borrowings under the Term Loan Facility accrue interest at a rate per year equal to the LIBOR Rate (as defined below) plus a margin of 7.25%. Borrowings under the Revolving Credit Facility bear interest at the per annum rate equal to the LIBOR Rate plus a margin of 4.95%. The LIBOR Rate is defined as the greater of 2.25% and the applicable London Interbank Offered Rate for U.S. dollar deposits divided by 1.00 minus the maximum effective reserve percentage for Eurocurrency funding.

Under the terms of the Revolving Credit Facility, we can borrow up to an amount (the "Borrowing Base"), equal to (1) 85.0% of the aggregate net amount at such time of the Eligible Accounts (as defined in the Revolving Credit Agreement), plus (2) 50% of the value of the Eligible Inventory (as defined in the Revolving Credit Agreement), valued at the lower of first-in-first-out cost or market cost, and after factoring in all rebates, discounts and other incentives or

rewards associated with the purchase of the applicable Eligible Inventory (provided that the Borrowing Base will be automatically adjusted down, if necessary, such that the aggregate availability from Eligible Inventory shall never exceed the lesser of (x) an amount equal to 40% of the Borrowing Base and (y) $2,000,000). The amount available for borrowing under the Revolving Credit Facility may also be reduced by certain reserve amounts that may be established by the administrative agent from time to time.

In addition to paying interest on the principal amounts outstanding under the Revolving Credit Facility, we are required to pay an unused line fee to the lenders under the Revolving Credit Facility in respect of the unutilized commitments thereunder equal to 0.50% multiplied by the lesser of (1) the unutilized commitments and (2) $8,000,000 minus 40% of the Borrowing Base.

Mandatory Prepayments

The Term Loan Credit Agreement requires the Borrowers to prepay amounts outstanding under the Term Loan Facility, subject to certain exceptions, with: (1) 100% of any net casualty proceeds in excess of $250,000 with respect to assets upon which the agent maintains a lien and (2) 100% of the net cash proceeds of non-ordinary course asset sales or sales pertaining to collateral upon which the Borrowing Base is calculated. In addition, the Borrowers are required to prepay all outstanding obligations under the Term Loan Facility upon the termination of all commitments under the Revolving Credit Facility and the repayment of the outstanding borrowings thereunder. No such mandatory prepayments were required during the three months ended March 31, 2022 and 2021.

The Revolving Credit Agreement requires the Borrowers to prepay amounts outstanding under the Revolving Credit Facility (or provide cash collateral up to the amount of any outstanding letter of credit obligations) to the extent outstanding borrowings under the Revolving Credit Facility exceed the lesser of (1) $8,000,000 and (2) the Borrowing Base.

Optional Prepayment

The Borrowers may prepay the Term Loan Facility, in whole but not in part, at any time with at least 10 business days' prior written notice, provided, however, that such prepayment shall be accompanied by a portion of the Exit Fee (as defined below) equal to the amount prepaid divided by the then-outstanding principal amount of borrowings outstanding under the Term Loan Facility, and a prepayment fee which, based on the amendment to the Term Loan Credit Agreement executed in January 2022, shall be equal to the amount prepaid multiplied by 3.0% until January 21, 2023 and 2.0% thereafter. The "Exit Fee" is defined as an amount equal to 6.5% multiplied by the aggregate principal amount of all borrowings advanced to the Borrowers under the Term Loan Facility.

The Borrowers may prepay the Revolving Credit Facility in whole or in part at any time, provided, however, that any such partial prepayment shall be in an amount equal to $100,000 or a higher integral multiple of $25,000. Should the Revolving Credit Facility be terminated prior to its final maturity (see below), based on the amendment to the Revolving Credit Agreement executed in January 2022, the Borrowers must pay a fee equal to an amount determined by multiplying the amount of the Revolving Credit Facility so terminated by 3.0% until January 21, 2023 and 2.0% thereafter.

Amortization and Final Maturity

The Borrowers are required to make interest-only payments prior to the principal amortization start date. The Term Loan Facility provided that if certain conditions were satisfied prior to December 1, 2020 (including our completion of a qualified initial public offering and no continuing default or event of default), the principal amortization start date may, upon our request, be extended to August 1, 2021 (from the previous principal amortization start date of February 1, 2021). Based on the completion of our IPO, in January 2021, we exercised this interest-only period extension right and, as such, the principal payments in respect of borrowings under the Term Loan Facility commenced on August 1, 2021. Such principal payments shall be in an amount equal to the total principal amount of borrowings under the Term Loan Facility divided by 36, for a 36-month straight-line amortization of equal monthly principal payments. The remaining unpaid balance on the Term Loan Facility, together with all accrued and unpaid interest thereon and any remaining unpaid amount of the Exit Fee, is due and payable on July 15, 2024.

Outstanding borrowings under the Revolving Credit Facility do not amortize and are due and payable on July 15, 2024.

Security

All obligations under the Term Loan Facility and the Revolving Credit 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 each Borrower's assets, including all goods, equipment, inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, general intangibles, commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts, securities accounts, fixtures, letter of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located.

Covenants and Other Matters

The Term Loan Credit Agreement and the Revolving Credit Agreement each contain a number of covenants that, among other things and subject to certain exceptions, restrict the ability of the Borrowers to:

- incur additional indebtedness;
- incur certain liens;
- pay dividends or make other distributions on equity interests;
- enter into agreements restricting their subsidiaries' ability to pay dividends;
- 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;
- alter the business conducted by them and their subsidiaries; and
- enter into sale and leaseback transactions.

In addition, the Term Loan Credit Agreement and the Revolving Credit Agreement contain a financial covenant, which is tested on a monthly basis, and requires us to achieve a specified Minimum Net Product Revenue (as defined in the applicable credit agreement) for the preceding 12-month period. In January 2022, the Term Loan Credit Agreement and Revolving Credit Agreement were amended and all future Minimum Net Product Revenue covenant amounts were reset.

The Term Loan Credit Agreement and the Revolving Credit Agreement each 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 March 31, 2022, Aziyo was in compliance with the financial covenant and all other covenants.

The Term Loan Credit Agreement and the Revolving Credit Agreement also contain certain customary representations and warranties and affirmative covenants, and certain reporting obligations. In addition, the lenders will be permitted to accelerate all outstanding borrowings and other obligations, terminate outstanding commitments and exercise other specified remedies upon the occurrence of certain events of default (subject to certain grace periods and exceptions), which include, among other things, payment defaults, breaches of representations and warranties, covenant defaults, certain cross-defaults and cross-accelerations to other indebtedness, certain events of bankruptcy and insolvency, certain judgments and changes of control.

Supplier Promissory Note

During 2017, we restructured certain of our liabilities with a tissue supplier and entered into an unsecured promissory note. As of March 31, 2022, the balance of this promissory note totaled $1.4 million plus accrued interest. The note bears interest at 5% and is currently due in full; however, the notes are subordinated in payment to the Term Loan Facility and Revolving Credit Facility and in both 2021 and 2020, the Company's senior lender restricted payment of the amounts due.

Funding Requirements

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

As of March 31, 2022, we had $23.0 million of indebtedness outstanding, consisting of $15.4 million outstanding under our Term Loan Facility (net of $0.1 million of unamortized deferred financing costs), $6.2 million outstanding under our Revolving Credit Facility (with $0.9 million of additional borrowings available thereunder), and a $1.4 million promissory note payable to one of our suppliers. 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 transactions. However, such transactions may not be successful and we may not be able to raise additional equity, refinance our Term Debt and Revolver, or sell 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 (to the extent above the applicable insurance coverage), for example, in connection with claims involving the recall of FiberCel;
- 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 our Revolver 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 three months ended March 31, 2022, there were no material changes to those previously disclosed. 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.

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 Term Loan Facility and Revolving Credit 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 March 31, 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 March 31, 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 March 31, 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.

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 three months ended March 31, 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.

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 $1.07 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 March 31, 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 March 31, 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 March 31, 2022, we had $22.2 million in cash and restricted cash. Based on our existing cash, availability under our Revolving Credit Facility 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 Term Loan Facility, Revolving Credit Facility and 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 on Form 10-Q. 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 March 31, 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, either refinance or restructure our Term Loan Facility and Revolving Credit Facility, restructure our Revenue Interest Obligation or pursue asset sale transactions. However, such transactions may not be successful and we may not be able to raise additional equity, refinance our Term Loan Facility and Revolving Credit Facility, or sell 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.

None.

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	
10.1	Second Amendment, dated January 21, 2022, to Amended and Restated Credit and Security Agreement (Revolving Loan), dated as of July 15, 2019, by and among the Registrant and Aziyo Med, LLC, as Borrowers, Midcap Funding IV Trust, as Agent and as a Lender, and the additional Lenders from time to time party thereto, as amended	10-K	001-39577	10.3	03/08/2022	
10.2	Second Amendment, dated January 21, 2022, to Amended and Restated Credit and Security Agreement (Term Loan), dated as of July 15, 2019, by and among the Registrant and Aziyo Med, LLC, as Borrowers, Midcap Funding IV Trust, as Agent and as a Lender, and the additional Lenders from time to time party thereto, as amended	10-K	001-39577	10.4	03/08/2022	
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.					*
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.

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: May 10, 2022

By: /s/ Ronald Lloyd
Ronald Lloyd
President and Chief Executive Officer
(principal executive officer)

Date: May 10, 2022

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

Exhibit 31.1

CERTIFICATIONS

I, Ronald Lloyd, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended March 31, 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: May 10, 2022

By: /s/ Ronald Lloyd
Ronald Lloyd
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS

I, Matthew Ferguson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended March 31, 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: May 10, 2022

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

Exhibit 32.1

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 March 31, 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: May 10, 2022

By: /s/ Ronald Lloyd
Ronald Lloyd
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.

Exhibit 32.2

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 March 31, 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: May 10, 2022

By: /s/ Matthew Ferguson
Matthew Ferguson
Chief Financial Officer
(principal financial 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.