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

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(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 30, 2021

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

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**Aziyo Biologics, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation or organization)

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

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

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

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

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Class A Common Stock, par value \$0.001 per share	AZYO	The Nasdaq 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of November 9, 2021, there were 7,122,509 shares of the registrant's Class A common stock and 3,134,162 shares of the registrant's Class B common stock outstanding.

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## 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, 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 such as Delta 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, 2020 (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](http://www.sec.gov) and the Investor Relations page of our website at <https://investors.aziyo.com/reports>. 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 failure to maintain our relationships with our existing contract manufacturing customers and enter into agreements with new contract manufacturing customers, or if existing contract manufacturing customers reduce purchases of our products;
- our ability to successfully expand, manage and maintain our direct sales force;
- our ability to achieve or sustain profitability;
- the adverse impacts of the novel strain of coronavirus disease, COVID-19 and variants thereof such as Delta or any other future pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide;

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- adverse changes in general domestic and global economic conditions and instability and disruption of credit markets;
- physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products;
- the continued and future acceptance of our products by the medical community;
- our ability to obtain regulatory approval or other marketing authorizations by the U.S. Food and Drug Administration (“FDA”) and comparable foreign authorities for our products and product candidates;
- 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](http://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](http://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®,” “FiberCel®,” “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 “Risk Factors” and Part I, Item 1A. “Risk Factors” in our Annual Report which can be found at <https://investors.aziyo.com/reports>. These and other factors could cause our future performance to differ materially from our assumptions and estimates.

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## PART I – FINANCIAL INFORMATION

## Item 1. Financial Statements.

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

(UNAUDITED)

	September 30, 2021	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash	\$ 22,543	\$ 39,150
Restricted cash	83	382
Accounts receivable, net	5,519	7,166
Inventory	9,832	10,117
Prepaid expenses and other current assets	1,277	2,892
Total current assets	39,254	59,707
Property and equipment, net	1,257	1,162
Intangible assets, net	19,316	21,865
Other assets	76	76
<b>Total assets</b>	<b>\$ 59,903</b>	<b>\$ 82,810</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,689	\$ 2,054
Accrued expenses	5,232	6,323
Payables to tissue suppliers	2,714	2,295
Current portion of long-term debt	8,059	6,310
Current portion of revenue interest obligation	2,750	2,750
Revolving line of credit	1,956	6,514
Deferred revenue and other current liabilities	110	533
Total current liabilities	22,510	26,779
Long-term debt	12,046	17,811
Long-term revenue interest obligation	16,552	16,633
Deferred revenue and other long-term liabilities	936	756
Total liabilities	52,044	61,979
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Class A Common stock, \$0.001 par value, 200,000,000 shares authorized as of September 30, 2021 and December 31, 2020, and 7,122,509 and 7,091,960 shares issued and outstanding, as of September 30, 2021 and December 31, 2020, respectively	7	7
Class B Common stock, \$0.001 par value, 20,000,000 shares authorized, as of September 30, 2021 and December 31, 2020 and 3,134,162 issued and outstanding as of September 30, 2021 and December 31, 2020	3	3
Additional paid-in capital	103,876	101,080
Accumulated deficit	(96,027)	(80,259)
Total stockholders' equity	7,859	20,831
<b>Total liabilities and stockholders' equity</b>	<b>\$ 59,903</b>	<b>\$ 82,810</b>

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

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

**(UNAUDITED)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net sales	\$ 11,485	\$ 11,774	\$ 36,529	\$ 30,216
Cost of goods sold	7,796	6,233	20,897	15,676
Gross profit	3,689	5,541	15,632	14,540
Sales and marketing	4,783	4,301	14,285	12,845
General and administrative	3,593	2,667	10,727	7,350
Research and development	2,289	1,264	5,890	3,981
Total operating expenses	10,665	8,232	30,902	24,176
Loss from operations	(6,976)	(2,691)	(15,270)	(9,636)
Interest expense	1,328	1,465	4,034	4,248
Other (income) expense, net	—	2,567	(3,579)	2,567
Loss before provision for income taxes	(8,304)	(6,723)	(15,725)	(16,451)
Income tax expense	12	8	43	18
<b>Net loss</b>	<b>(8,316)</b>	<b>(6,731)</b>	<b>(15,768)</b>	<b>(16,469)</b>
Accretion of Convertible Preferred Stock	—	3,510	—	3,510
<b>Net loss attributable to common stockholders</b>	<b>\$ (8,316)</b>	<b>\$ (10,241)</b>	<b>\$ (15,768)</b>	<b>\$ (19,979)</b>
<b>Net loss per share - basic and diluted</b>	<b>\$ (0.81)</b>	<b>\$ (15.79)</b>	<b>\$ (1.54)</b>	<b>\$ (30.82)</b>
Weighted average common shares outstanding - basic and diluted	10,235,350	648,436	10,229,974	648,331

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

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

(UNAUDITED)

	Convertible Preferred Stock		Common Stock		Class A Common Stock		Class B Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount			
<b>Balance, June 30, 2021</b>	—	\$ —	—	\$ —	7,095,265	\$ 7	3,134,162	\$ 3	\$ 102,668	\$ (87,711)	\$ 14,967
Proceeds from sale of common stock through Employee Stock Purchase Plan	—	—	—	—	27,244	—	—	—	208	—	208
Stock-based compensation	—	—	—	—	—	—	—	—	1,000	—	1,000
Net loss	—	—	—	—	—	—	—	—	—	(8,316)	(8,316)
<b>Balance, September 30, 2021</b>	—	\$ —	—	\$ —	7,122,509	\$ 7	3,134,162	\$ 3	\$ 103,876	\$ (96,027)	\$ 7,859
<b>Balance, June 30, 2020</b>	45,000,000	\$44,899	648,277	\$ 1	—	\$ —	—	\$ —	\$ 1,952	\$ (66,676)	\$ (64,723)
Issuance of Convertible Preferred Stock, net of issuance costs of \$9	5,414,427	8,184	—	—	—	—	—	—	—	—	—
Proceeds from stock option exercises	—	—	402	—	—	—	—	—	2	—	2
Accretion of Convertible Preferred Stock	—	3,510	—	—	—	—	—	—	(2,012)	(1,498)	(3,510)
Stock-based compensation	—	—	—	—	—	—	—	—	58	—	58
Net loss	—	—	—	—	—	—	—	—	—	(6,731)	(6,731)
<b>Balance, September 30, 2020</b>	<u>50,414,427</u>	<u>\$56,593</u>	<u>648,679</u>	<u>\$ 1</u>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ (74,905)</u>	<u>\$ (74,904)</u>

	Convertible Preferred Stock		Common Stock		Class A Common Stock		Class B Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount			
<b>Balance, December 31, 2020</b>	—	\$ —	—	\$ —	7,091,960	\$ 7	3,134,162	\$ 3	\$ 101,080	\$ (80,259)	\$ 20,831
Proceeds from stock option exercises	—	—	—	—	3,305	—	—	—	26	—	26
Proceeds from sale of common stock through Employee Stock Purchase Plan	—	—	—	—	27,244	—	—	—	208	—	208
Stock-based compensation	—	—	—	—	—	—	—	—	2,562	—	2,562
Net loss	—	—	—	—	—	—	—	—	—	(15,768)	(15,768)
<b>Balance, September 30, 2021</b>	—	\$ —	—	\$ —	7,122,509	\$ 7	3,134,162	\$ 3	\$ 103,876	\$ (96,027)	\$ 7,859
<b>Balance, December 31, 2019</b>	44,550,230	\$44,449	648,277	\$ 1	—	\$ —	—	\$ —	\$ 1,826	\$ (56,938)	\$ (55,111)
Issuance of Convertible Preferred Stock, net of issuance costs of \$9	5,864,197	8,634	—	—	—	—	—	—	—	—	—
Proceeds from stock option exercises	—	—	402	—	—	—	—	—	2	—	2
Accretion of Convertible Preferred Stock	—	3,510	—	—	—	—	—	—	(2,012)	(1,498)	(3,510)
Stock-based compensation	—	—	—	—	—	—	—	—	184	—	184
Net loss	—	—	—	—	—	—	—	—	—	(16,469)	(16,469)
<b>Balance, September 30, 2020</b>	<u>50,414,427</u>	<u>\$56,593</u>	<u>648,679</u>	<u>\$ 1</u>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ (74,905)</u>	<u>\$ (74,904)</u>

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

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

	Nine Months Ended September 30,	
	2021	2020
Net loss	\$ (15,768)	\$ (16,469)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,797	2,921
(Gain) loss on (forgiveness)/early extinguishment of debt	(3,029)	2,340
Gain on revaluation of revenue interest obligation and other	—	227
Amortization of deferred financing costs	91	91
Interest expense recorded as additional revenue interest obligation	1,987	2,011
Interest expense recorded as Convertible Preferred Stock	—	39
Stock-based compensation	2,562	184
Operating expense satisfied through Convertible Preferred Stock issuance	—	814
Changes in operating assets and liabilities:		
Accounts receivable	1,647	134
Inventory	285	(2,598)
Prepaid expenses and other	1,615	(2,248)
Accounts payable and accrued expenses	(1,456)	4,641
Obligations to tissue suppliers	419	(55)
Deferred revenue and other liabilities	(209)	(290)
<b>Net cash used in operating activities</b>	<b>(9,059)</b>	<b>(8,258)</b>
<b>INVESTING ACTIVITIES:</b>		
Expenditures for property, plant and equipment	(344)	(525)
<b>Net cash used in investing activities</b>	<b>(344)</b>	<b>(525)</b>
<b>FINANCING ACTIVITIES:</b>		
Proceeds from issuance of Convertible Promissory Note	—	2,000
Net borrowings (repayments) under revolving line of credit	(4,558)	1,639
Proceeds from Convertible Preferred Stock issuance, net	—	3,441
Proceeds from stock option exercises	26	2
Proceeds from long-term debt	—	2,995
Repayments of long-term debt	(1,111)	(300)
Payments on revenue interest obligation	(2,068)	(1,940)
Proceeds from sales of common stock through Employee Stock Purchase Plan	208	—
<b>Net cash (used in) provided by financing activities</b>	<b>(7,503)</b>	<b>7,837</b>
<b>Net decrease in cash and restricted cash</b>	<b>(16,906)</b>	<b>(946)</b>
<b>Cash and restricted cash, beginning of period</b>	<b>39,532</b>	<b>2,590</b>
<b>Cash and restricted cash, end of period</b>	<b>\$ 22,626</b>	<b>\$ 1,644</b>
<b>Supplemental Cash Flow and Non-Cash Financing Activities Disclosures:</b>		
Cash paid for interest	\$ 3,788	\$ 3,769
Cash paid for taxes	\$ 37	\$ 32
Conversion of Convertible Promissory Note to Convertible Preferred Stock	\$ —	\$ 2,000
Forgiveness of SBA PPP loan	\$ 3,029	\$ —

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

**AZIYO BIOLOGICS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 1. Organization and Description of Business**

Aziyo Biologics, Inc. (together with its consolidated subsidiaries, "Aziyo" or the "Company") is a regenerative medicine company, with a focus on patients receiving implantable medical devices. The Company has developed a portfolio of regenerative products using both human and porcine tissue that are designed to be as close to natural biological material as possible. Aziyo's portfolio of core products span 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.

***Reverse Stock Split and Initial Public Offering***

On September 25, 2020, the Company's Board of Directors and stockholders approved an amendment to the Company's amended and restated certificate of incorporation to effect a 1-for-13.9549 reverse stock split of the Company's common stock, which was effected on September 29, 2020. The par value of the common stock was not adjusted as a result of the reverse stock split. Accordingly, all share and share-related information presented in these condensed consolidated financial statements and the accompanying notes has been retroactively adjusted for all periods presented to give effect to the reverse stock split.

On October 13, 2020, in connection with the Company's initial public offering ("IPO"), the Company issued and sold 2,941,176 shares of common stock, consisting of 2,205,882 shares of Class A common stock and 735,294 shares of Class B common stock, at a price to the public of \$17.00 per share, resulting in net proceeds to the Company of approximately \$43.0 million, after deducting the underwriting discount of approximately \$3.5 million and offering expenses of approximately \$3.5 million.

**Note 2. Summary of Significant Accounting Policies**

***Basis of Presentation***

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, 2020. The financial information as of September 30, 2021 and for the three and nine months ended September 30, 2021 and 2020 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, 2020 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 and nine

months ended September 30, 2021, the Company incurred net losses of \$8.3 million and \$15.8 million, respectively, and as of September 30, 2021, the Company had an accumulated deficit of \$96.0 million. 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.

As further described in Note 6, the Company's Term Debt Facility ("Term Debt") and Revolving Line of Credit (the "Revolver") include monthly revenue covenants, the non-compliance of which would permit our lenders to accelerate the repayment of these outstanding borrowings. In October 2021, the Company was informed by Medtronic that they would no longer be distributing cellular bone products such as FiberCel and, as such, the two companies are working towards a mutual termination of the associated FiberCel distribution agreement ("FiberCel Agreement"). Such termination will follow the suspension of all FiberCel purchases by Medtronic after Aziyo's voluntary recall pertaining to a single donor lot of FiberCel in June 2021. Given the associated revenues derived from the FiberCel Agreement, its suspension and then termination may negatively affect the Company's future revenues. As such, while Aziyo is currently in compliance with all revenue covenants, the Company's ability to comply with these covenants in the future is uncertain. Additionally, in August 2021, the Company commenced the principal repayment of its Term Debt with such repayments totaling approximately \$556,000 per month.

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 and to either refinance or restructure its Term Debt and Revolver. However, the Company may not be able to raise additional equity or refinance its Term Debt and Revolver 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 its Revolver 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 Aziyo's ability to continue as a going concern within one year after the issuance of the financial statements.

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

### **Reclassifications**

Certain reclassifications have been made to prior year amounts to conform with current year financial statement presentation. The reclassifications relate to certain executive compensation costs and technical operations expenses at the Company's Richmond, California plant. As follows are the total amounts reclassified for the three and nine months ended September 30, 2020 along with the line items in the condensed consolidated statement of operations that were impacted (in thousands).

	<b>Increase (Decrease) From Previously Reported Amounts</b>	
	<b>Three Months Ended</b>	<b>Nine Months Ended</b>
	<b>September 30,</b>	<b>September 30,</b>
	<b>2020</b>	<b>2020</b>
Sales and marketing	\$ 127	\$ 374
General and administrative	(528)	(1,544)
Research and development	401	1,170

These reclassifications did not impact the Company's consolidated earnings or assets for the three and nine months ended September 30, 2020.

### **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 preferred stock warrant liability 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 decreased significantly, 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 been postponed or cancelled and the access of Aziyo's sales representatives to the associated healthcare facilities has been curtailed, all of 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 will likely continue to reduce the Company's net sales and negatively impact its business, financial condition and results of operations while the pandemic continues.

### ***Net Loss per Share Attributable to Common Stockholders***

The Company calculates basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for participating securities. The Convertible Preferred Stock was considered a participating security through the completion of the IPO. The two-class method requires income (loss) available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to share in the earnings as if all income (loss) for the period had been distributed. Under the two-class method, the net loss attributable to common stockholders is not allocated to the Convertible Preferred Stock as the holders of the preferred stock do not have a contractual obligation to share in losses.

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, Convertible Preferred Stock, stock options, and preferred and common stock warrants 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).

	<u>September 30,</u>	
	<u>2021</u>	<u>2020</u>
Cash	\$ 22,543	\$ 1,544
Restricted cash	83	100
Total cash and restricted cash shown in statements of cash flows	<u>\$ 22,626</u>	<u>\$ 1,644</u>

#### ***Accounts Receivable and Allowances***

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

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

#### ***Inventory***

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

### **Property and Equipment**

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

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

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

Repairs and maintenance costs are expensed as incurred.

### **Long-Lived Assets**

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

The Company periodically evaluates the period of depreciation or amortization for long-lived assets to determine whether current circumstances warrant revised estimates of useful lives. The Company reviews its property and equipment and intangible assets for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. Impairment exists when the carrying value of the company's asset exceeds the related estimated undiscounted future cash flows expected to be derived from the asset. If impairment exists, the carrying value of that asset is adjusted to its fair value. A discounted cash flow analysis is used to estimate an asset's fair value, using assumptions that market participants would apply. The results of impairment tests are subject to management's estimates and assumptions of projected cash flows and operating results. Changes in assumptions or market conditions could result in a change in estimated future cash flows and could result in a lower fair value and therefore an impairment, which could impact reported results. There were no impairment losses for the three and nine months ended September 30, 2021 or 2020.

### **Revenue Recognition**

The Company's revenue is generated from contracts with customers in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) No. 606, "Revenue from Contracts with Customers." 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 products 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 Accounting Standards Codification ("ASC") 718, *Accounting for Stock Compensation*. FASB ASC 718 requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors, including employee stock options and restricted stock. Stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense on a straight-line basis over the requisite service period of the entire award.

#### ***Research and Development Costs***

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

#### ***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash. At September 30, 2021, the Company maintained \$23.3 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.

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:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
Percent of revenues derived from:				
Medtronic Sofamor Danek USA	3%	18%	14%	16%
Surgalign Holdings	9%	10%	10%	9%

	September 30, 2021	December 31, 2020
Percent of accounts receivable derived from:		
Medtronic Sofamor Danek USA	0%	34%
Surgalign Holdings	12%	13%

### ***Comprehensive Income (Loss)***

Comprehensive income (loss) comprises net income (loss) and other changes in equity that are excluded from net income (loss). For the three and nine months ended September 30, 2021 and 2020, 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, 2022. 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 December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740), Simplifying the Accounting for Income Taxes*, which clarifies and simplifies certain aspects of the accounting for income taxes. The standard is effective for years beginning after December 15, 2020, and interim periods within annual periods beginning after December 15, 2020. The adoption of this standard on January 1, 2021 did not have a material impact on the Company's consolidated financial statements.

In November 2019, the FASB issued ASU 2019-10, "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 accordance with the revised timeline provided by the FASB. 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 IPO, the Company adopted the Aziyo Biologics, Inc. 2020 Incentive Award Plan (the “2020 Plan”), which authorizes the grant of incentive and non-qualified stock options, restricted stock, restricted stock units and stock appreciation rights to employees, directors and consultants. Shares of Class A common stock totaling 1,636,000 were initially reserved for issuance pursuant to the 2020 Plan. In addition, the shares reserved for issuance under the 2020 Plan will also include shares reserved but not issued under the 2015 Plan as well as an annual increase as set forth in the 2020 Plan. As of September 30, 2021, the Company had 343,999 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 nine months ended September 30, 2021 is as follows:

	<u>Number of Shares</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted-Average Remaining Contractual Term (years)</u>	<u>Aggregate Intrinsic Value (in thousands)</u>
Outstanding, December 31, 2020	917,437	\$ 13.68	8.1	\$ 2,070
Granted	492,017	\$ 12.71		
Exercised	(3,305)	\$ 7.91		
Forfeited	(15,915)	\$ 15.92		
Outstanding, September 30, 2021	<u>1,390,234</u>	<u>\$ 13.32</u>	8.1	\$ 328
Vested and exercisable, September 30, 2021	<u>222,652</u>	<u>\$ 6.05</u>	3.3	\$ 282

As of September 30, 2021, 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 3.1 years. The weighted average grant date fair value of options granted during the nine months ended September 30, 2021 was \$7.31.

### **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 nine months ended September 30, 2021 is as follows:

	<b>Number of Shares Underlying RSUs</b>	<b>Weighted- Average Grant Date Fair Value</b>
Unvested, December 31, 2020	147,883	\$ 17.00
Granted	91,182	\$ 14.40
Vested	—	\$ —
Forfeited	(3,180)	\$ 13.86
Unvested, September 30, 2021	<u>235,885</u>	<u>\$ 16.08</u>

The total fair value of the RSUs granted during the nine months ended September 30, 2021 of \$1.3 million was based on the fair market value of the Company’s Class A common stock on the date of grant. The 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. As of September 30, 2021, \$2.8 million of unrecognized compensation costs related to RSUs is expected to be recognized over a weighted average period of 2.6 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 equal to the lesser of (i) 1% of the total shares of Class A common stock outstanding on the final day of the immediately preceding calendar year; or (ii) a lesser number of shares determined by our board of directors. As of September 30, 2021, the total shares of Class A common stock authorized for issuance under the ESPP was 214,069, of which 186,825 remained available for future issuance. During the nine months ended September 30, 2021, 27,244 shares of Class A common stock were issued under the ESPP.

### **Stock-Based Compensation Expense**

Stock-based compensation expense recognized during the three and nine months ended September 30, 2021 and 2020 was comprised of the following (in thousands):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
Sales and marketing	\$ 185	\$ —	\$ 488	\$ —
General and administrative	622	59	1,557	186
Research and development	139	—	391	—

Cost of goods sold	53	—	126	—
Total stock-based compensation expense	<u>\$ 1,000</u>	<u>\$ 59</u>	<u>\$ 2,562</u>	<u>\$ 186</u>

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 nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,	
	2021	2020
Expected term (years)	6.0	5.0
Risk-free interest rate	0.96 %	1.89 %
Volatility factor	64 %	55 %
Dividend yield	—	—

**Note 5. Inventory**

Inventory was comprised of the following (in thousands):

	September 30, 2021	December 31, 2020
Raw materials	\$ 1,944	\$ 1,507
Work in process	1,098	708
Finished goods	6,790	7,902
Total	<u>\$ 9,832</u>	<u>\$ 10,117</u>

**Note 6. Long-Term Debt**

On May 31, 2017, in connection with the Company’s acquisition of CorMatrix described in Note 7, Aziyo entered into a \$10 million term loan facility (the “Term Loan Facility”) and an \$8 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 September 30, 2021 and December 31, 2020, the Company’s borrowing capacity under its Revolving Credit Facility was \$6.4 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%. In January 2021, based on its IPO, the Company exercised its right to extend the interest-only payment period for the Term Loan Facility to August 1, 2021 and, accordingly, interest and equal principal payments of approximately \$556,000 per month began 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 and nine months ended September 30, 2021 and 2020.

Both the Term Loan Facility and the Revolving Credit Facility also permit optional prepayments.

The agreement governing the Term Loan Facility also includes an exit fee of 6.5% of the aggregate principal amount and prepayment penalties of 2% to 4% if repaid prior to maturity. The weighted average interest rate on Term Loan Facility borrowings was 7.3% and 7.4%, respectively, for the three months ended September 30, 2021 and 2020 and 7.4% and 7.9%, respectively for the nine months ended September 30, 2021 and 2020. 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 prepayment penalties of 2% to 4% on the \$8 million borrowing capacity if terminated by the Company prior to its expiration in July 2024. The weighted average interest rate on Revolving Credit Facility borrowings was 5.0% and 5.1%, respectively, for the three months ended September 30, 2021 and 2020 and 5.1% and 5.5%, respectively, for the nine months ended September 30, 2021 and 2020. 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 September 30, 2021, Aziyo was in compliance with this financial covenant and all other covenants. When finalized, the mutual termination of the Company's Supply Agreement for FiberCel with Medtronic referred to in Note 2 would have triggered an event of default; however, such event of default was waived by the Company's lenders.

In conjunction with the May 2017 Financing and the amendment thereto, the Company issued to the financial institution warrants to purchase 405,000 shares of Aziyo's Convertible Preferred Stock at \$1.00 per share. The warrants were exercisable through the first to occur of (a) May 31, 2027 (in the case of warrants to purchase 360,000 shares of Convertible Preferred Stock) or December 14, 2027 (in the case of warrants to purchase 45,000 shares of Convertible Preferred Stock), and (b) the earlier of (i) a Sale Transaction (as defined in the Company's Certificate of Incorporation) or (ii) an initial public offering of the Company's common stock. All warrants were exercised in connection with the IPO noted in Note 1. Upon issuance, the Company valued such warrants at \$286,267. The recognition of these warrants served to reduce the recorded value of the associated Term Loan Facility borrowings. This resulting debt discount will be recognized as interest expense through the maturity of the Term Loan Facility.

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, 2020. 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.

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

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

	September 30, 2021	December 31, 2020
Term Loan Facility, net of unamortized discount and deferred financing costs	\$ 18,713	\$ 19,734
Note to Tissue Supplier	1,392	1,392
PPP loan	—	2,995
Total	20,105	24,121
Current Portion	(8,059)	(6,310)
Long-Term Debt	<u>\$ 12,046</u>	<u>\$ 17,811</u>

The fair value of all debt instruments, which is based on inputs considered to be Level 2 under the fair value hierarchy, approximates the respective carrying values as of September 30, 2021 and December 31, 2020.

#### 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 have anti-infective properties.

Furthermore, a \$5.0 million payment will be due to Ligand if cumulative sales of these products exceed \$100.0 million and a second \$5.0 million will be due if cumulative sales exceed \$300.0 million during the ten-year term of the agreement which expires on May 31, 2027.

The Company has 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. Total future payments, including contingent milestone payments and estimated sales-based payments, are based on assumptions related to future sales of the acquired products. At each reporting period, the value of the Revenue Interest Obligation is re-measured based on current estimates of future payments, with changes to be recorded in the condensed consolidated statements of operations using the catch-up method. There was no change to estimated future payments during the three and nine months ended September 30, 2021 and 2020, and thus, no re-measurement gain or loss was recognized. Interest expense related to the Revenue Interest Obligation was approximately \$0.7 million for both the three months ended September 30, 2021 and 2020, respectively, and approximately \$2.0 million for both the nine months ended September 30, 2021 and 2020, respectively.

#### Note 8. Stockholders' Equity

At inception, Aziyo was capitalized through the sale of 19.5 million shares of Series A Convertible Preferred Stock, par value \$0.001 per share (the "Convertible Preferred Stock"). From inception through the Company's IPO, the Company issued an additional 30.9 million shares of Convertible Preferred Stock yielding proceeds of approximately \$30.4 million, which were used for general corporate purposes and the CorMatrix Acquisition. During the nine months ended September 30, 2020, Convertible Preferred Stock offerings totaled approximately \$5.4 million. The Convertible Preferred Stock issued during the nine months ended December 31, 2020 occurred primarily in September 2020 at which time the Company completed the sale of 3.0 million shares of Convertible Preferred Stock for net proceeds of approximately \$3.0 million. At the same time, the bridge notes of \$2.0 million (issued in April 2020), and related accrued interest, converted into approximately 2.0 million shares of Convertible Preferred Stock.

The fair value of the 3.0 million shares of Convertible Preferred Stock described above exceeded the purchase price of the Convertible Preferred Stock by \$3.5 million. Such excess was accounted for as a deemed dividend to the

Convertible Preferred Stock and was recorded as “Accretion of Convertible Preferred Stock” in the Consolidated Statements of Operations to arrive at “Net Loss Attributable to Common Shareholders” and was included in the numerator of basic Earnings Per Share. With respect to the Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders’ Deficit, these deemed dividends have been recorded such that Additional Paid-in Capital was first eliminated and any residual dividends served to reduce Accumulated Deficit. Additionally, the fair value of the 2.0 million shares of Convertible Preferred Stock issued upon conversion of Convertible Bridge Notes exceeded the face value of the Convertible Bridge Notes by \$2.3 million. Such excess has been recorded as Loss on Early Extinguishment of Debt within Other (income) expense, net in the accompanying Consolidated Statements of Operations.

As consideration for the advisory services provided to Aziyo in connection with the CorMatrix Acquisition, an agreement was executed between Aziyo and HighCape Partners Management, L.P. whereby upon consummation by Aziyo of a sale transaction, as defined in the Company’s Certificate of Incorporation, or an initial public offering of the Company’s common stock, Aziyo would be required to pay HighCape a fee totaling \$0.75 million. In September 2020, the Company’s obligation in respect of this fee was extinguished in connection with the issuance of 375,000 shares of Convertible Preferred Stock. Such Convertible Preferred Stock and the associated expense was recorded at its fair value of approximately \$0.8 million.

## **Note 9. 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 September 30, 2021 and 2020, respectively, and was approximately \$0.9 million for both the nine months ended September 30, 2021 and 2020, respectively, 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 and nine months ended September 30, 2021 or 2020. 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 2020 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, 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. 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.

Between June 21, 2021 and November 5, 2021, forty-one lawsuits in Indiana, Delaware, Florida, Maryland, Colorado, Michigan, Ohio, 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. Seventeen 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); and (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) (collectively, the “Indiana State Complaints”). On September 20, 2021, a motion was granted to consolidate the cases pending in the Marion Superior Court in the State of Indiana for purposes of discovery and pre-trial practice. 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 has been filed in the Circuit Court of Michigan, captioned: Ilona and Christian Hildebrandt v. Aziyo Biologics, Inc., Case No. 2021-003804-NP (“Michigan State Complaint”). One lawsuit has been filed in the Superior Court of North Carolina, captioned: Aurelia and Belvin Sherrill v. Aziyo Biologics, Inc., et al., Case No. 21cvs2797 (“North Carolina State 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”). One lawsuit has been filed in the U.S. District Court for the Eastern District of Michigan, captioned: Karrold Dudley v. Aziyo, Biologics Inc., et al., Case No. 2:21-cv-11813-GAD-EAS (“Michigan Federal Complaint”). 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”). 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 also 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 Michigan State Complaint asserts causes of action for product defect and breach of implied warranty, product defect and breach of express warranty, negligence, gross negligence, and possible knowledge of defect, and seeks compensatory and exemplary 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 Complaint asserts causes of action for 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 Complaint seeks compensatory damages and punitive damages. The North Carolina State 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. In addition to the above, there have been thirty-five claims related to the FiberCel recall, which have not yet resulted in a lawsuit. We refer 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 our insurance policies with two insurance carriers. In certain circumstances, insurance carriers reserve their rights to contest or deny coverage. We intend to contest vigorously any disputes with our insurance carriers and to enforce our rights under the terms of our insurance policies. Accordingly, we 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 our 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 September 30, 2021 and December 31, 2020, the Company was not a party to, or aware of, any material legal matters or claims except for the FiberCel Litigation.

**Note 10. Net Loss Per Share Attributable to Common Stockholders**

(in thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Numerator:</b>				
Net loss attributable to common stockholders	\$ (8,316)	\$ (10,241)	\$ (15,768)	\$ (19,979)
<b>Denominator:</b>				
Weighted average number of common shares, basic and diluted	10,235,350	648,436	10,229,974	648,331
Net loss per common share attributable to common stockholders, basic and diluted	\$ (0.81)	\$ (15.79)	\$ (1.54)	\$ (30.82)

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

	September 30,	
	2021	2020
Convertible Preferred Stock	—	3,612,668
Options to purchase common stock	1,390,234	287,996
Restricted stock units	235,885	—
Common stock warrants	—	7,656
Preferred stock warrants	—	29,022
Total	1,626,119	3,937,342

**Note 11. Related Party Transactions**

Prior to the IPO, the Company had a management services agreement with an affiliate of HighCape Partners through which strategic, operational and management consulting services are provided to the Company. During the three and nine months ended September 30, 2020, the Company recorded expenses totaling \$0.1 million and \$0.2 million, respectively. The management services agreement terminated upon completion of the IPO and all amounts due thereunder were paid as of December 31, 2020.

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

**Note 12. Segment Information**

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

For the three and nine months ended September 30, 2021 and 2020, 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Sales by product				
Core Products	\$ 8,588	\$ 10,345	\$ 29,230	\$ 25,956
Non-Core Products	2,897	1,429	7,299	4,260
Total Net Sales	<u>\$ 11,485</u>	<u>\$ 11,774</u>	<u>\$ 36,529</u>	<u>\$ 30,216</u>

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

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

### **Overview**

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

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

Our Core Products are targeted to address unmet clinical needs with the goal of promoting healthy tissue formation and avoiding complications associated with medical device implants, such as scar-tissue formation, capsular contraction, erosion, migration, non-union of implants and implant rejection. We believe that we have developed the only biological 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. In pre-clinical and clinical studies, our products have supported and, in some cases, accelerated tissue healing, and thereby improved patient outcomes.

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. 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 September 30, 2021, we had 176 employees, of which 34 were direct sales representatives.

For the three and nine months ended September 30, 2021, we incurred net losses of \$8.3 million and \$15.8 million, respectively, and as of September 30, 2021, we had an accumulated deficit of \$96.0 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we seek to grow our sales organization and expand our product development and clinical and research activities. In addition, we expect to continue to incur additional costs and expenses associated with operating as a public company.

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.

As further described in Note 6 to the condensed consolidated financial statements included elsewhere in this Quarterly Report, our Term Debt Facility (“Term Debt”) and Revolving Line of Credit (the “Revolver”) include monthly revenue covenants, the non-compliance of which would permit our lenders to accelerate the repayment of these outstanding borrowings. In October 2021, we were informed by Medtronic that they would no longer be distributing cellular bone products such as FiberCel and, as such, the two companies are working towards a mutual termination of the associated FiberCel distribution agreement (“FiberCel Agreement”). Such termination will follow the suspension of all FiberCel purchases by Medtronic after Aziyo’s voluntary recall pertaining to a single donor lot of FiberCel in June 2021 as described further below. Given the associated revenues derived from the FiberCel Agreement, its suspension and then termination may negatively affect our future revenues. As such, while we are currently in compliance with all revenue covenants, our ability to comply with these covenants in the future is uncertain. Additionally, in August 2021, we commenced the principal repayment of the Term Debt with such repayments totaling approximately \$556,000 per month.

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 and to either refinance or restructure the Term Debt and Revolver. However, we may not be able to raise additional equity or refinance the Term Debt and Revolver on acceptable terms, or at all. As such, based on our current operating plans, we believe there is uncertainty as to whether our future cash flows along with our existing cash, availability under the 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.

### **Impact of COVID-19**

We continue to closely monitor the impact of the pandemic related to COVID-19 and its variants such as Delta 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 decreased significantly, 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 and the access of our sales representatives to the associated healthcare facilities has been curtailed 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 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 will likely continue to reduce our net sales 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, 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 significantly and 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 Update**

As previously reported, we issued a voluntary recall on June 2, 2021 pertaining to a single donor lot of our FiberCel Fiber Viable Bone Matrix after learning of post-surgical infections reported in several patients treated with the product, including some patients that tested positive for tuberculosis.

Since issuing the recall, we have been working with the U.S. Food and Drug Administration (“FDA”) and the U.S. Centers for Disease Control and Prevention (“CDC”) to identify and secure all unused product, ascertain the medical status of patients treated with the recalled product, understand whether there is any relationship between the post-surgical infections and the recalled product lot and determine the medical cause of these infections.

At this time, we have identified the 154 units comprising the single product lot in question. Based on information from the CDC, 136 units within this product lot were implanted into 113 patients and the remaining 18 units were returned to either us or the CDC. Of these 113 patients, CDC has identified at least 75 patients who have exhibited clinical or diagnostic findings consistent with tuberculosis infection.

The CDC has advised us that the CDC, working with state health agencies, has contacted all patients treated with the recalled lot of FiberCel to help ensure they are directed to appropriate medical treatment and has informed us that all patients were started on standard four-drug treatment for tuberculosis. We have learned from the CDC that eight patients who received the product from the recalled lot have died; however, the cause of death for each patient is still being determined.

Samples of the recalled product have now undergone PCR analysis by a lab contracted by the CDC and tested positive for the presence of *Mycobacterium tuberculosis*. Cell culture testing of the recalled product was also conducted by the same lab that showed the presence of *Mycobacterium tuberculosis*, and this testing corroborated the PCR testing results. Eleven lots of FiberCel produced both before and after the single donor lot at issue have undergone PCR analysis and cell culture testing and have all tested negative for *Mycobacterium tuberculosis*. Based on these findings, we have no reason to believe that other units of FiberCel have been affected.

As part of our continuing cooperation with the FDA and CDC and our efforts to conduct a prompt and fulsome investigation into this matter, we have reviewed the processes for screening donors and producing FiberCel and have not identified any deviations from our established protocols, which are designed to comply with industry standards established by the American Association of Tissue Banks (“AATB”) as well as applicable FDA requirements and guidelines.

To date, our investigation into the available medical records for the donor at issue indicates: (1) the donor's emergency department documentation 10 days before his decease reported "Never had TB"; (2) the donor had a negative tuberculosis skin test approximately four months before decease; (3) a Tuberculosis Risk Assessment Questionnaire administered approximately four months before the donor deceased was reported as showing negative for clinical or physical evidence of a tuberculosis infection; (4) multiple chest x-rays taken during a period of approximately 33 months before the donor deceased were all interpreted as negative for tuberculosis; and (5) a CT abdominal scan taken prior to the donor deceasing was interpreted as showing no evidence of swelling of lymph nodes.

To help ensure the safety of future production lots, we are currently evaluating a number of potential safeguards against Mycobacterium tuberculosis that we believe exceed applicable industry standards and currently available FDA-approved testing. We have already implemented additional donor screening procedures to include screening for any donor utilizing hemodialysis for an extended period of time and to request additional background and information on any time spent by the donor outside the United States. In addition, we are actively developing a potential methodology for testing tissue products for Mycobacterium tuberculosis. As far as we are aware, there are no commercially available testing methods authorized by the FDA for detecting the presence of Mycobacterium tuberculosis in donor tissue. For an update on the legal proceedings related to the FiberCel Recall, see Part II, Item 1, "Legal Proceedings" and Note 9 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 direct sales and 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 our expenses to continue to increase for the foreseeable future as we grow our sales and marketing organization, expand our product development and clinical activities and increase our administrative infrastructure. 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 the continued expansion of our CanGaroo direct sales force.

#### *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. G&A expenses also include any expenses we incur associated with the FiberCel Litigation described in Note 9 to the condensed consolidated financial statements included elsewhere in this Quarterly Report. We expect our G&A expenses to increase 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. G&A expenses will also increase to the extent any future costs associated with the FiberCel Litigation are incurred.

#### *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 anti-infective properties. We also conduct clinical trials to validate the performance characteristics of our products and to capture patient data necessary to support our commercial efforts.

#### **Reclassifications**

Certain reclassifications have been made to prior year amounts to conform with current year financial statement presentation. The reclassifications relate to certain executive compensation costs and technical operations expenses at our Richmond, California plant. As follows are the total amounts reclassified for the three and nine months ended September 30, 2020 along with the line items in the condensed consolidated statement of operations that were impacted (in thousands).

	<b>Increase (Decrease) From Previously Reported Amounts</b>	
	<b>Three Months Ended</b>	<b>Nine Months Ended</b>
	<b>September 30,</b>	<b>September 30,</b>
	<b>2020</b>	<b>2020</b>
Sales and marketing	\$ 127	\$ 374
General and administrative	(528)	(1,544)
Research and development	401	1,170

These reclassifications did not impact our consolidated earnings or assets for the three and nine months ended September 30, 2020.

## Results of Operations

### Comparison of the Three Months Ended September 30, 2021 and 2020

(in thousands, except percentages)	Three Months Ended September 30,				Change 2020 / 2021	
	2021		2020		\$	%
	Amount	% of Net Sales	Amount	% of Net Sales		
Net sales	\$ 11,485	100.0 %	\$ 11,774	100.0 %	\$ (289)	(2.5)%
Cost of goods sold	7,796	67.9 %	6,233	52.9 %	1,563	25.1 %
Gross profit	3,689	32.1 %	5,541	47.1 %	(1,852)	(33.4)%
Sales and marketing	4,783	41.6 %	4,301	36.5 %	482	11.2 %
General and administrative	3,593	31.3 %	2,667	22.7 %	926	34.7 %
Research and development	2,289	19.9 %	1,264	10.7 %	1,025	81.1 %
Total operating expenses	10,665	92.9 %	8,232	69.9 %	2,433	29.6 %
Loss from operations	(6,976)	(60.7)%	(2,691)	(22.9)%	(4,285)	159.2 %
Interest expense	1,328	11.6 %	1,465	12.4 %	(137)	(9.4)%
Other (income) expense, net	—	— %	2,567	21.8 %	(2,567)	NM
Loss before provision of income taxes	(8,304)	(72.3)%	(6,723)	(57.1)%	(1,581)	23.5 %
Income tax expense	12	0.1 %	8	0.1 %	4	50 %
<b>Net loss</b>	<b>\$ (8,316)</b>	<b>(72.4)%</b>	<b>\$ (6,731)</b>	<b>(57.2)%</b>	<b>\$ (1,585)</b>	<b>23.5 %</b>
Accretion of Convertible Preferred Stock	—	— %	3,510	29.8 %	(3,510)	NM
<b>Net loss attributable to common stockholders</b>	<b>\$ (8,316)</b>	<b>(72.4)%</b>	<b>\$ (10,241)</b>	<b>(87.0)%</b>	<b>\$ 1,925</b>	<b>(18.8)%</b>

NM = not meaningful

### Net Sales

Net sales decreased \$0.3 million, or 2.5%, to \$11.5 million in the three months ended September 30, 2021 compared to \$11.8 million in the three months ended September 30, 2020. The decline in net sales was due to reductions in the net sales of our Core Products of \$1.8 million, partially offset by growth in the net sales of our Non-Core Products of \$1.5 million.

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

(in thousands, except percentages)	Three Months Ended September 30,				Change 2020 / 2021	
	2021		2020		\$	%
	Amount	% of Net Sales	Amount	% of Net Sales		
Products:						
Core Products	\$ 8,588	74.8 %	\$ 10,345	87.9 %	\$ (1,757)	(17.0)%
Non-Core Products	2,897	25.2 %	1,429	12.1 %	1,468	102.7 %
<b>Total Net Sales</b>	<b>\$ 11,485</b>	<b>100.0 %</b>	<b>\$ 11,774</b>	<b>100.0 %</b>	<b>\$ (289)</b>	<b>(2.5)%</b>

Net sales generated by our Core Products declined \$1.8 million, or 17.0%, to \$8.6 million in the three months ended September 30, 2021 compared to \$10.3 million in the three months ended September 30, 2020. 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. Excluding the FiberCel sales to Medtronic of \$0.4 million and \$2.1 million in the three months ended September 30, 2021 and 2020, respectively, net sales of our Core Products were essentially equal at \$8.2 and \$8.3 million, respectively.

Net sales generated by our Non-Core Products increased \$1.5 million, or 102.7%, to \$2.9 million in the three months ended September 30, 2021 compared to \$1.4 million in the three months ended September 30, 2020. The Non-Core Products net sales increase was primarily due to revenues associated with new contracts signed in the latter half of 2020 and by one contract manufacturing customer building inventory for a new product launch.

### ***Cost of Goods Sold***

Cost of goods sold was \$7.8 million and \$6.2 million in the three months ended September 30, 2021 and 2020, respectively, and included, in each case, \$0.8 million of intangible asset amortization expenses. Gross margin in the three months ended September 30, 2021 was 32.1%, a decrease from 47.1% in the corresponding prior year period. Gross margin, excluding intangible asset amortization, in the three months ended September 30, 2021 was 39.5%, a decline from 54.3% 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 lower yields in our orthopedic and spinal repair product lines related to heightened donor screening criteria ahead of the implementation of enhanced product testing, as well as write-downs of inventory in certain categories. Together these factors negatively impacted gross margins by approximately \$1.4 million or 12%. We do not expect these costs to continue at similar levels going forward.

### ***Operating Expenses***

#### ***Sales and Marketing***

Sales and marketing expenses increased \$0.5 million, or 11.2%, to \$4.8 million in the three months ended September 30, 2021 compared to \$4.3 million in the three months ended September 30, 2020. As a percentage of sales, sales and marketing expenses grew to 41.6% in the three months ended September 30, 2021 from 36.5% in the three months ended September 30, 2020. Along with slightly higher marketing costs, the increase as a percentage of sales was the result of the growth during the third quarter of 2021 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 \$0.9 million, or 34.7%, to \$3.6 million in the three months ended September 30, 2021 compared to \$2.7 million in the three months ended September 30, 2020. As a percentage of net sales, G&A expenses increased to 31.3% in the three months ended September 30, 2021 from 22.7% in the three months ended September 30, 2020. The increase in expense was primarily due to costs of being a public company, most notably increases in directors and officers insurance, legal fees and stock-based compensation.

#### ***Research and Development***

R&D expenses increased to \$2.3 million in the three months ended September 30, 2021 compared to \$1.3 million in the three months ended September 30, 2020. 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 September 30, 2021 largely attributable to the work performed on the development of our CanGaroo anti-infective product.

### ***Interest Expense***

Interest expense was approximately \$1.3 million in the three months ended September 30, 2021 compared to \$1.5 million in the three months ended September 30, 2020. 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 third quarter of 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.

### ***Other (Income) Expense, net***

Other (income) expense, net was \$2.6 million in the three months ended September 30, 2020 and was primarily attributable to the loss on early extinguishment of debt of \$2.3 million. This loss related to the conversion of Convertible Bridge Notes into Convertible Preferred Stock with such stock exceeding the face value of the Convertible Bridge Notes

by \$2.3 million. See Note 8 to the condensed consolidated financial statements included elsewhere in this Quarterly Report for further discussion.

**Comparison of the Nine Months Ended September 30, 2021 and 2020**

(in thousands, except percentages)	Nine Months Ended September 30,				Change 2020 / 2021	
	2021		2020		\$	%
	Amount	% of Net Sales	Amount	% of Net Sales		
Net sales	\$ 36,529	100.0 %	\$ 30,216	100.0 %	\$ 6,313	20.9 %
Cost of goods sold	20,897	57.2 %	15,676	51.9 %	5,221	33.3 %
Gross profit	15,632	42.8 %	14,540	48.1 %	1,092	7.5 %
Sales and marketing	14,285	39.1 %	12,845	42.5 %	1,440	11.2 %
General and administrative	10,727	29.4 %	7,350	24.3 %	3,377	45.9 %
Research and development	5,890	16.1 %	3,981	13.2 %	1,909	48.0 %
Total operating expenses	30,902	84.6 %	24,176	80.0 %	6,726	27.8 %
Loss from operations	(15,270)	(41.8)%	(9,636)	(31.9)%	(5,634)	58.5 %
Interest expense	4,034	11.0 %	4,248	14.1 %	(214)	(5.0)%
Other (income) expense, net	(3,579)	(9.8)%	2,567	8.5 %	(6,146)	NM
Loss before provision of income taxes	(15,725)	(43.0)%	(16,451)	(54.4)%	726	(4.4)%
Income tax expense	43	0.1 %	18	0.1 %	25	138.9 %
<b>Net loss</b>	<b>(15,768)</b>	<b>(43.2)%</b>	<b>(16,469)</b>	<b>(54.5)%</b>	<b>701</b>	<b>(4.3)%</b>
Accretion of Convertible Preferred Stock	—	— %	3,510	11.6 %	(3,510)	NM
<b>Net loss attributable to common stockholders</b>	<b>\$ (15,768)</b>	<b>(43.2)%</b>	<b>\$ (19,979)</b>	<b>(66.1)%</b>	<b>\$ 4,211</b>	<b>(21.1)%</b>

NM = not meaningful

**Net Sales**

Net sales grew \$6.3 million, or 20.9%, to \$36.5 million in the nine months ended September 30, 2021 compared to \$30.2 million in the nine months ended September 30, 2020. The increase in net sales was due to growth in both the net sales of our Core Products and of our Non-Core Products, which grew \$3.3 million and \$3.0 million, respectively.

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

(in thousands, except percentages)	Nine Months Ended September 30,				Change 2020 / 2021	
	2021		2020		\$	%
	Amount	% of Net Sales	Amount	% of Net Sales		
Products:						
Core Products	\$ 29,230	80.0 %	\$ 25,956	85.9 %	\$ 3,274	12.6 %
Non-Core Products	7,299	20.0 %	4,260	14.1 %	3,039	71.3 %
<b>Total Net Sales</b>	<b>\$ 36,529</b>	<b>100.0 %</b>	<b>\$ 30,216</b>	<b>100.0 %</b>	<b>\$ 6,313</b>	<b>84.0 %</b>

Net sales generated by our Core Products grew \$3.3 million, or 12.6%, to \$29.2 million in the nine months ended September 30, 2021 compared to \$26.0 million in the nine months ended September 30, 2020. The Core Products net sales growth can be largely attributed to the volume growth in all of our Core Product categories due to increased market demand along with the lessened revenue impact of COVID-19 in the nine months ended September 30, 2021 versus such impact in the nine months ended September 30, 2020. As noted above, in June 2021, Medtronic ceased the purchasing of FiberCel following our recall of a single lot of FiberCel in June 2021. Our sales of FiberCel to Medtronic were nearly equal during the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020.

Net sales generated by our Non-Core Products increased \$3.0 million, or 71.3%, to \$7.3 million in the nine months ended September 30, 2021 compared to \$4.3 million in the nine months ended September 30, 2020. The Non-Core Products net sales increase was primarily due to revenues associated with new contracts signed in the latter half of 2020

and by one contract manufacturing customer building inventory for a new product launch, along with the lessened revenue impact of COVID-19 in the nine months ended September 30, 2021 versus such impact in the nine months ended September 30, 2020.

### ***Cost of Goods Sold***

Cost of goods sold was \$20.9 million and \$15.7 million in the nine months ended September 30, 2021 and 2020, respectively, and included, in each case, \$2.5 million of intangible asset amortization expenses. Gross margin in the nine months ended September 30, 2021 was 42.8%, a decrease from 48.1% in the corresponding prior year period. Gross margin, excluding intangible asset amortization, in the nine months ended September 30, 2021 was 49.8%, a decline from 56.6% 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 lower yields in our orthopedic and spinal repair product lines related to heightened donor screening criteria ahead of the implementation of enhanced product testing, as well as write-downs of inventory in certain categories during the third quarter of 2021. Together these factors negatively impacted gross margins by approximately \$1.4 million or 4%. We do not expect these costs to continue at similar levels going forward.

### ***Operating Expenses***

#### *Sales and Marketing*

Sales and marketing expenses increased \$1.4 million, or 11.2%, to \$14.3 million in the nine months ended September 30, 2021 compared to \$12.8 million in the nine months ended September 30, 2020. As a percentage of sales, sales and marketing expenses fell to 39.1% in the nine months ended September 30, 2021 from 42.5% in the nine months ended September 30, 2020. Along with slightly lower marketing costs, the decrease as a percentage of sales is the result of the growth in our "business to business" orthopedic and spinal repair revenues during the nine months ended September 30, 2021, as such revenues have limited associated selling costs.

#### *General and Administrative*

G&A expenses increased \$3.4 million, or 45.9%, to \$10.7 million in the nine months ended September 30, 2021 compared to \$7.4 million in the nine months ended September 30, 2020. As a percentage of net sales, G&A expenses increased to 29.4% in the nine months ended September 30, 2021 from 24.3% in the nine months ended September 30, 2020. The dollar increase was primarily due to costs of being a public company, most notably increases in directors and officers insurance, legal fees and stock-based compensation.

#### *Research and Development*

R&D expenses increased to \$5.9 million in the nine months ended September 30, 2021 compared to \$4.0 million in the nine months ended September 30, 2020. We continue to focus our R&D efforts on the development of our pipeline products with the growth in R&D expenses in the nine months ended September 30, 2021 largely attributable to the work performed on the development of our CanGaroo anti-infective product which achieved its next development milestone in the nine months ended September 30, 2021 with the completion of manufacturing validation.

### ***Interest Expense***

Interest expense was approximately \$4.0 million and \$4.2 million in the nine months ended September 30, 2021 and 2020, respectively. The decrease was due to lower draws on our Revolving Credit Agreement during the nine months ended September 30, 2021 and lower outstanding principal on our Term Loan Credit Agreement due to the commencement of principal payments in the third quarter of 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.

**Other (Income) Expense, net**

Other (income) expense, net was approximately \$3.6 million of income in the nine months ended September 30, 2021. Such other income relates to the forgiveness of our PPP Loan totaling approximately \$3.0 million and our receipt of \$550,000 in satisfaction of a 2018 settlement with KeraLink. For further discussion on these items, see Notes 6 and 11 to the condensed consolidated financial statements included elsewhere in this Quarterly Report. Other (income) expense, net was \$2.6 million in the nine months ended September 30, 2020 and was primarily attributable to the loss on early extinguishment of debt of \$2.3 million. This loss related to the conversion of Convertible Bridge Notes into Convertible Preferred Stock during the 2020 period with such stock exceeding the face value of the Convertible Bridge Notes by \$2.3 million. See Note 8 to the condensed consolidated financial statements included elsewhere in this Quarterly Report for additional discussion.

**Non-GAAP Financial Measures**

This Quarterly Report presents our gross margin, excluding intangible asset amortization, for the three and nine months ended September 30, 2021 and 2020. We calculate gross margin, excluding intangible asset amortization, as gross profit, excluding amortization expense relating to intangible assets we acquired in the CorMatrix Acquisition, divided by net sales. Gross margin, excluding intangible asset amortization, is a supplemental measure of our performance, is not defined by or presented in accordance with U.S. generally accepted accounting principles (“GAAP”), has limitations as an analytical tool and should not be considered in isolation or as an alternative to our GAAP gross margin, gross profit or any other financial performance measure presented in accordance with GAAP. We present gross margin, excluding intangible asset amortization, because we believe that it provides meaningful supplemental information regarding our operating performance by removing the impact of amortization expense, which is not indicative of our overall operating performance. We believe this provides our management and investors with useful information to facilitate period-to-period comparisons of our operating results. Our management uses this metric in assessing the health of our business and our operating performance, and we believe investors’ understanding of our operating performance is similarly enhanced by our presentation of this metric. In addition, other companies, including companies in our industry, may use other measures to evaluate their performance, which could reduce the usefulness of this non-GAAP financial measure as a tool for comparison.

The following table presents a reconciliation of our gross margin, excluding intangible asset amortization, for the three and nine months ended September 30, 2021 and 2020 to the most directly comparable GAAP financial measure, which is our GAAP gross margin (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net sales	\$ 11,485	\$ 11,774	\$ 36,529	\$ 30,216
Cost of goods sold	7,796	6,233	20,897	15,676
Gross profit	3,689	5,541	15,632	14,540
Intangible asset amortization expense	849	849	2,548	2,548
Gross profit, excluding intangible asset amortization	<u>\$ 4,538</u>	<u>\$ 6,390</u>	<u>\$ 18,180</u>	<u>\$ 17,088</u>
Gross margin	32.1 %	47.1 %	42.8 %	48.1 %
Gross margin, excluding intangible asset amortization	39.5 %	54.3 %	49.8 %	56.6 %

**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 September 30, 2021, we had cash and restricted cash of approximately \$28.4 million and availability under our Revolving Credit Facility of \$5.1 million. We have historically financed our operations primarily through private placements of our convertible preferred stock, amounts borrowed under our credit facilities and sales of our products and, more recently, with proceeds from our IPO. 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 September 30, 2021, our accumulated deficit was \$96.0 million.

On October 13, 2020, in connection with our IPO, we issued and sold 2,941,176 shares of common stock, consisting of 2,205,882 shares of Class A common stock and 735,294 shares of Class B common stock, at a price to the public of \$17.00 per share, resulting in net proceeds to us of approximately \$43.0 million, after deducting the underwriting discount of approximately \$3.5 million and offering expenses of approximately \$3.5 million.

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. As discussed below under “— Funding Requirements,” we may need additional funding to support our continuing operations and pursue our growth strategy.

As further described in Note 6, our Term Debt Facility (“Term Debt”) and Revolving Line of Credit (the “Revolver”) include monthly revenue covenants, the non-compliance of which would permit our lenders to accelerate the repayment of these outstanding borrowings. In October 2021, we were informed by Medtronic that they would no longer be distributing cellular bone products such as FiberCel and, as such, the two companies are working towards a mutual termination of the associated FiberCel distribution agreement (“FiberCel Agreement”). Such termination will follow the suspension of all FiberCel purchases by Medtronic after Aziyo’s voluntary recall pertaining to a single donor lot of FiberCel in June 2021. Given the associated revenues derived from the FiberCel Agreement, its suspension and then termination may negatively affect our future revenues. As such, while Aziyo is currently in compliance with all revenue covenants, our ability to comply with these covenants in the future is uncertain. Additionally, in August 2021, we commenced the principal repayment of our Term Debt with such repayments totaling approximately \$556,000 per month.

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 and to either refinance or restructure its Term Debt and Revolver. However, we may not be able to raise additional equity or refinance our Term Debt and Revolver 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 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.

### *Cash Flows for the Nine Months Ended September 30, 2021 and 2020*

	<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
	<b>(in thousands)</b>	
Net cash (used in) provided by:		
Operating activities	\$ (9,059)	\$ (8,258)
Investing activities	(344)	(525)
Financing activities	(7,503)	7,837
<b>Net decrease in cash</b>	<b>\$ (16,906)</b>	<b>\$ (946)</b>

### *Net Cash Used in Operating Activities*

Net cash used in operating activities for the nine months ended September 30, 2021 was \$9.1 million compared to \$8.3 million for the nine months ended September 30, 2020. The year-over-year change was primarily due to a higher net loss (after adjustment for non-cash charges and gains) offset by improved working capital performance, particularly as it relates to our management of inventory levels.

### *Net Cash Used in Investing Activities*

Net cash used in investing activities for the nine months ended September 30, 2021 was \$0.3 million and approximately \$0.5 million for the nine months ended September 30, 2020. 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) Provided by Financing Activities*

Net cash used in financing activities for the nine months ended September 30, 2021 totaled \$7.5 million compared to \$7.8 million of cash provided by financing activities for the nine months ended September 30, 2020. The year-over-year net increase of \$15.3 million was primarily due to the capital raises in the 2020 period totaling approximately \$7.1 million necessary to fund our operations prior to the IPO in contrast to only the net repayments of \$4.6 million on our Revolving Credit Facility and \$1.1 million on our Term Loan Credit Agreement during the 2021 (post-IPO) period.

## **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) and a new \$5.0 million tranche (Term Loan Tranche 5). Commitments in respect of Term Loan Tranche 5 terminated without being borrowed on September 30, 2020. 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 September 30, 2021, we had \$18.7 million of indebtedness outstanding under our Term Loan Facility (net of \$0.2 million of unamortized discount and deferred financing costs), and \$2.0 million outstanding under our Revolving Credit Facility (with \$4.5 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 40.0% 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 nine months ended September 30, 2021 and 2020.

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 equal to the amount prepaid multiplied by, in the case of Term Loan Tranche 1, Term Loan Tranche 2 or Term Loan Tranche 3, 3.0% until July 15, 2021 and 2.0% thereafter, and, in the case of Term Loan Tranche 4, 4.0% until November 21, 2020, 3.0% until November 21, 2021 and 2.0% thereafter. The "Exit Fee" is defined as an amount equal to 6.50% 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.

#### *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.

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 September 30, 2021, Aziyo was in compliance with the financial covenant and all other covenants. When finalized, the mutual agreement to terminate our Supply Agreement for FiberCel with Medtronic, as described above, would have triggered an event of default under the Term Loan Credit Agreement; however, such event of default was waived by our lenders.

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.

### ***PPP Loan***

In May 2020, we entered into a promissory note with Silicon Valley Bank, or SVB, under the Paycheck Protection Program of the CARES Act pursuant to which SVB agreed to make a loan to us in the amount of approximately \$3.0 million. The PPP Loan bears interest at a rate of 1.0% per annum with monthly principal and interest payments beginning in March 2021 and ending on the maturity date of May 7, 2022; however such repayment commencement was deferred by the U.S. Small Business Administration while they evaluated our forgiveness application. In June 2021, we were notified by the U.S. Small Business Administration that the entire balance of our PPP Loan and all related accrued interest was forgiven. Such forgiveness resulted in a gain to us of approximately \$3.0 million which has been recorded as other income in the accompanying condensed consolidated statements of operations for the nine months ended September 30, 2021.

### ***2020 Bridge Notes***

In April 2020, we entered into a bridge note purchase agreement pursuant to which we issued approximately \$2.0 million in aggregate principal amount of convertible promissory notes (the “2020 Bridge Notes”), to HighCape Partners QP, HighCape Partners and Deerfield. The 2020 Bridge Notes had a maturity date of April 1, 2025 and accrued interest at a rate of 5.0% per year. The aggregate principal amount of, and accrued interest on, the 2020 Bridge Notes automatically converted into an aggregate of 2,039,427 shares of our Series A convertible preferred stock upon the closing of our Series A convertible preferred stock financing in September 2020.

### ***Funding Requirements***

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we grow our sales organization 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 noted above under “—Liquidity and Capital Resources,” without additional capital, there is substantial doubt about Aziyo’s ability to continue as going concern within one year after the issuance of the financial statements. As such, we may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. 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 studies and clinical trials;
- 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, including variants of the disease, 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.”

#### **Off-Balance Sheet Arrangements**

As of September 30, 2021, we did not have any off-balance sheet arrangements, as defined under SEC Regulation S-K Item 303(a)(4)(ii).

#### **Contractual Obligations**

Not applicable as permitted based on our classification as a “smaller reporting company” as defined in Rule 12b-2 of the Exchange Act.

### **Critical Accounting Policies and Estimates**

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 September 30, 2021 would not have had a material effect on our financial statements. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

#### ***Credit Risk***

As of September 30, 2021, our cash and cash equivalents were maintained with one financial institution in the United States. While our deposit accounts are insured up to the legal limit, the balances we maintain may, at times, exceed this insured limit. We believe this financial institution has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Our accounts receivable relate to sales to customers. To minimize credit risk, ongoing credit evaluations of all customers’ financial condition are performed. One customer represented 10% or more of our accounts receivable as of September 30, 2021.

#### ***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 nine months ended September 30, 2021 and 2020. 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 September 30, 2021.

#### **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 nine months ended September 30, 2021 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 9 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 as updated and supplemented by the risk factors below. 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.

### ***Risks Related to Our Business***

#### ***Our success depends on our ability to maintain the value and reputation of the Aziyo name.***

We believe that the “Aziyo” name is important to attracting and retaining customers, and enhancing our name depends largely on our ability to provide high-quality and safe products. Our name could be harmed if we fail to achieve these objectives or if our public image were to be tarnished by events yielding negative perceptions and publicity. For example, on June 2, 2021, we issued a voluntary recall pertaining to a single donor lot of our FiberCel Fiber Viable Bone Matrix (“FiberCel”), a bone repair product made from human tissue that is used in various orthopedic and spinal procedures. Notice of the voluntary recall was issued to hospitals that received products from this specific lot, following our learning of post-surgical infections in patients treated with FiberCel, including some patients who tested positive for tuberculosis, including eight cases that resulted in fatalities (the “FiberCel Recall”). Following the public announcement of our voluntary recall, there has been various media coverage surrounding the recall and patients impacted, as well as lawsuits filed against Aziyo, which are described in Part II, Item 1, “Legal Proceedings” and Note 9 to the condensed consolidated financial statements included elsewhere in this Quarterly Report. Such negative publicity related to the perceived quality and safety of our products could affect our brand image, decrease confidence in our products or have an adverse effect on our ability to retain existing and attract new customers, suppliers and distribution partners, any one of which could result in decreased revenue, having an adverse effect on our business, financial condition and operating results.

#### ***A substantial portion of our net sales is generated through our commercial partners and independent sales agents, which subjects us to various risks.***

We currently rely on the efforts of our commercial partners and independent sales agents to generate a substantial portion of our net sales, and we expect to continue to rely on these third parties to generate a substantial portion of our net sales in the future while we work to grow our direct sales force. As a result, the impairment or termination of these relationships for any reason, or the failure of these parties to diligently sell our products and comply with applicable laws and regulations, could materially and adversely affect our ability to generate revenue and profits. Because our commercial partners and independent sales agents control the relationships with our end customers, if our relationship with any commercial partner or independent sales agent ends, we will likely also lose our relationship with their customers. Furthermore, our success is partially dependent on the willingness and ability of the sales representatives and other employees of our commercial partners and independent sales agents to diligently sell our products. However, we cannot guarantee that they will be successful in marketing our products. In addition, because our commercial partners and independent sales agents do not sell our products exclusively, they may focus their sales efforts and resources on other products that produce better margins or greater commissions for them or are incorporated into a broader strategic relationship with a partner. Because we do not control the sales representatives and other employees of our commercial partners, we cannot guarantee that our sales processes, regulatory compliance and other priorities will be consistently communicated and executed. In addition, we do not have staff in many of the areas covered by our commercial partners and independent sales agents, which makes it particularly difficult for us to monitor their performance. While we may take steps to mitigate the risks associated with noncompliance by our commercial partners and independent sales agents, there remains a risk that they will not comply with regulatory requirements or our requirements and policies. Actions by the sales representatives and other employees of our commercial partners and independent sales agents that are beyond our control could result in flat or declining sales in that territory, harm to the reputation of our company or our products or legal liability, any of which could have a material adverse effect on our business, financial condition and results of operations. In addition to the risk of losing customers, the operation of local laws and our agreements with our commercial partners and independent sales agents would make it difficult for us to replace a commercial partner or independent sales agent we feel is underperforming.

In order to increase our sales, particularly with respect to our Core Products, we intend to develop relationships and arrangements with additional commercial partners and/or independent sales agents, which we may not be able to do on commercially reasonable terms or at all. If we are unable to establish new commercial partner and independent sales agent relationships and maintain our relationships with our existing commercial partners and independent sales agents, in each case, on commercially reasonable terms, we will be unable to increase sales of our products and our business, financial condition and results of operations could be materially and adversely affected.

In addition, certain of our commercial partners may, from time to time, account for a significant portion of our net sales and/or accounts receivable. Sales to Surgalign Spine Technologies, one of our commercial partners, accounted for 10% of our net sales during the nine months ended September 30, 2021 and represented 12% of our accounts receivable as of September 30, 2021. Sales to Medtronic accounted for 14% of our net sales during the nine months ended September 30, 2021 and represented none of our accounts receivable as of September 30, 2021. As more fully described elsewhere in this Quarterly Report, we issued a voluntary recall on June 2, 2021 pertaining to a single donor lot of our FiberCel product after learning of post-surgical infections in several patients treated with the product, including some of whom tested positive for tuberculosis, and eight of whom suffered a fatal outcome. FiberCel is distributed by Medtronic and, in June 2021, Medtronic notified us that sales of FiberCel as well as all such other Non-Core products supplied to Medtronic would be suspended until further notice. In October 2021, we were informed by Medtronic that they would no longer be distributing cellular bone products such as FiberCel and, as such, the two companies are working towards a mutual termination of the associated FiberCel distribution agreement.

The loss of one or more significant commercial partners, a material reduction in their purchases of our products, such as what we are currently experiencing with Medtronic, or their inability to perform their contractual obligations, including, for example, committed purchase requirements, could adversely affect our business, financial condition and results of operations. We are also subject to the risk that any such commercial partner will experience financial difficulties that prevent them from making payments to us on a timely basis or at all.

***We have incurred operating losses since our inception, expect to continue to incur significant expenses and operating losses in the future, and may not be able to achieve or sustain profitability.***

We have incurred net losses since our inception in 2015. For the nine months ended September 30, 2021, we had net losses of \$15.8 million and as of September 30, 2021, we had an accumulated deficit of \$96.0 million. To date, we have financed our operations primarily through private placements of our convertible preferred stock, amounts borrowed under our credit facilities and sales of our products and, more recently, with proceeds from our IPO. We have devoted the majority of our resources to acquisition and integration, manufacturing costs, research and development, clinical activity and investing in our commercial infrastructure through our direct sales force and commercial partners in order to expand our presence and to promote awareness and adoption of our products.

We expect that our operating expenses will continue to increase as we grow our sales organization, expand our product development and clinical and research activities, and incur additional costs associated with being a public company. Sales of our products or meaningful reductions or suspensions of such sales, such as the suspension of sales of FiberCel, may not offset our operating expenses. As a result, we expect to continue to incur operating losses in the future and may never achieve profitability. Furthermore, even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our Class A common stock to decline. In addition, failure of our products to significantly penetrate existing or new markets would negatively affect our business, financial condition and results of operations.

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

We anticipate our operating losses to continue for the foreseeable future due to, among other things, costs related to research and development of our product candidates, sales and marketing costs, and our administrative organization. We will require substantial additional financing to fund our operations and to continue to execute our strategy, and we will pursue a range of options to secure additional capital. As described in Note 2 to the condensed consolidated financial statements included elsewhere in this Quarterly Report, without additional capital, there is substantial doubt about our

ability to continue as going concern within one year after the issuance of the financial statements included in this Quarterly Report. We will need to raise additional capital to fund our future operations and remain as a going concern. There can be no assurance that we will be able to obtain additional funding on acceptable terms, if at all. To the extent that we raise additional capital through future equity offerings, the ownership interest of common stockholders will be diluted, which dilution may be significant. However, we cannot guarantee that we will be able to obtain any or sufficient additional funding or that such funding, if available, will be obtainable on terms satisfactory to us. In the event we are unable to obtain any or sufficient additional funding, there can be no assurance that we will be able to continue as going concern.

***Our future growth depends on physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products.***

We focus our sales, marketing and training efforts on physicians, surgeons and other healthcare professionals. The acceptance of our products depends in part on our ability to educate these individuals as to the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products compared to alternative products, procedures and therapies. We support our direct sales force, commercial partners and independent sales agents through in-person educational programs and online medical educational materials, among other things. We also produce marketing materials, including materials outlining our products, for our sales teams using printed, video and multimedia formats. However, our efforts to educate physicians, surgeons and other healthcare professionals regarding our products may not be successful, particularly with respect to our Bone Repair products in light of the recent events involving the FiberCel Recall, and in markets where we rely exclusively on the efforts of our commercial partners and independent sales agents. If we do not adequately educate physicians, surgeons and other healthcare professionals about our products, as well as any adverse events involving these products, our products may not gain or maintain market acceptance, which may adversely affect our business, financial condition and results of operations.

***Our success depends on the continued and future acceptance of our products by the medical community.***

Even if we are able to increase awareness of our products among healthcare professionals, there can be no assurance that this will translate into greater acceptance of our products by the medical community. We believe physicians, surgeons and other healthcare professionals will only adopt our products if they determine, based on experience, clinical data and published peer reviewed journal articles, that the use of our products in a particular procedure is a favorable alternative to other available methods. In light of the events surrounding the FiberCel Recall, described in Part II, Item 1, "Legal Proceedings" and Note 9 to the condensed consolidated financial statements included elsewhere in this Quarterly Report, such positive evaluation of our Bone Repair products may become more challenging. Physicians also are more interested in using cost-effective products as they face increasing cost-containment pressure. In general, physicians may be slow to change their medical treatment practices and adopt our products for a variety of reasons, including, among others:

- their lack of experience using our products;
- lack of evidence supporting additional patient benefits from use of our products over conventional methods;
- pressure to contain costs;
- preference for other treatment modalities or our competitors' products;
- perceived liability risks generally associated with the use of new products and procedures;
- limited availability of coverage and/or reimbursement from third-party payors; and
- the time that must be dedicated to learning how to use our products.

The degree of market acceptance of our products will continue to depend on a number of factors, some of which are outside of our control, including, among other things:

- the actual and perceived safety and efficacy of our products;

- the potential and perceived advantages of our products over alternative treatments;
- clinical data and the clinical indications for which our products are approved;
- product labeling or product insert requirements of the FDA, the European Union or other regulatory authorities, including any limitations or warnings contained in approved labeling;
- the cost of using our products relative to the use of our competitors' products or alternative treatment modalities;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- our reputation and the reputation of our products;
- the prevalence and severity of any adverse events patients experience involving our products;
- the shelf life of our products and our ability to manage the logistics of the end-user supply chain; and
- sufficient and readily accessible third-party insurance coverage and reimbursement for procedures incorporating our products.

In addition, we believe recommendations for, and support of our products by, influential physicians are essential for market acceptance and adoption. If we do not receive this support (e.g., because we are unable to demonstrate favorable long-term clinical data or otherwise), physicians and hospitals may not use our products, which would significantly impair our ability to increase our sales and prevent us from achieving and sustaining profitability.

***We face significant and continuing competition from other companies, some of which have longer operating histories, more established products and/or greater resources than we do, which could adversely affect our business, financial condition and results of operations.***

We operate in highly competitive markets that are characterized by intense competition, subject to rapid change and significantly affected by new product introductions, technological advancements and other market activities of industry participants. Our competitors have historically dedicated, and will continue to dedicate, significant resources to promote their products and to develop new products that compete with ours. Customers in our target markets consider many factors when selecting a product, including product efficacy, ease of use, price, availability of payor coverage and adequate third-party reimbursement for procedures using the product, customer support services for technical-, clinical- and reimbursement-related matters and customer preference for, and loyalty to, particular products or a particular manufacturer. We expect competition to remain intense as competitors introduce additional competing products and enhancements to their existing products, and continue expanding into geographic markets where we currently operate or plan to expand. Product introductions or enhancements by competitors, which may have advanced technology, better features or lower pricing, may make our products obsolete or less competitive. As a result, we will be required to devote continued efforts and financial resources to develop and commercialize new products and enhancements to our existing products, deliver cost-effective clinical outcomes, manage our costs and expand our geographic reach.

Many of our current and potential competitors have longer operating histories and substantially greater financial, technical, marketing, sales, distribution and other resources than we do, which may prevent us from achieving significant market penetration or improved operating results. Certain competitors' products, such as competitors of SimpliDerm, are subject to a simpler reimbursement process than are our products. Competitors may also be able to leverage their market

share and other resources to set prices at a level below that which is profitable for us. These companies may also enjoy other competitive advantages, including, without limitation:

- greater company, product and brand recognition;
- better quality and greater volume of clinical data;
- more effective marketing to and education of physicians and other healthcare professionals;
- greater control of key intellectual property and more expansive portfolios of intellectual property rights;
- more experience in obtaining and maintaining regulatory clearances or approvals for products and product enhancements;
- more established relationships with hospitals and other healthcare providers, physicians, suppliers, customers and third-party payors;
- additional lines of products, and the ability to bundle products to offer greater incentives to gain a competitive advantage;
- more established sales, marketing and worldwide distribution networks;
- better product support and service;
- superior reliability, durability and product safety, with such product safety particularly in light of the events involving the FiberCel Recall;
- more effective pricing and revenue strategies; and
- more effective clinical training programs.

Our ability to achieve and maintain profitability will depend, in part, on our ability to develop or acquire proprietary products that reach the market in a timely manner, receive adequate coverage and reimbursement for procedures using our products, and are safer and more effective than their alternatives, as well as our ability to otherwise compete effectively on the factors listed above. If we are unable to do so, our sales and/or margins will decrease, which could have a material adverse effect on our business, financial condition and results of operations.

***The processing of human and porcine tissue for our products is technically complex, requiring high levels of quality control and precision, which subjects us to increased production risks.***

We manufacture our human and porcine tissue products using technically complex processes requiring specialized facilities, highly specific raw materials, skill and diligence by our personnel and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture and storage of our products, subjects us to production risks. In addition to ongoing production risks, process deviations or unanticipated effects of approved process changes may result in non-compliance with regulatory requirements, including stability requirements or specifications. For example, our bone allograft products, such as ViBone and OsteGro V, must be shipped and maintained within a specified temperature range. If environmental conditions deviate from that range, our products' remaining shelf-lives could be impaired or their safety and efficacy could be adversely affected, making them unsuitable for use. The occurrence of this or any other actual or suspected production or distribution problem can lead to lost inventory, customer returns and, in some cases, recalls, with consequential damage to our reputation and customer relationships and the risk of product liability.

For example, on June 2, 2021, we issued a voluntary recall pertaining to a single donor lot of our FiberCel Fiber Viable Bone Matrix, a bone repair product made from human tissue that is used in various orthopedic and spinal procedures. Notice of the voluntary recall was issued to hospitals that received product from this specific lot following our learning of post-surgical infections in patients treated with FiberCel, including some patients that tested positive for

tuberculosis. The lot consisted of 154 units of FiberCel, all derived from a single donor, that were shipped to facilities in 20 states. We have investigated the source of the infections in coordination with our distributor, the FDA and the U.S. Centers for Disease Control and Prevention (“CDC”). The FDA inspected our Richmond, California production facility, and this inspection did not result in any Form-483 observations. Additionally, multiple product liability lawsuits have been filed against Aziyo. See *“We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance”* for additional information about these product liability lawsuits.

This investigation, as well as others that may occur in the future, and the remediation of any potential or identified problems can cause production delays and result in substantial additional expenses and lost revenue. In addition, we may experience difficulties in scaling up processing and production of our human and porcine tissue products, including problems related to yields, quality control and assurance, tissue availability, adequacy of control policies and procedures and availability of skilled personnel. Furthermore, developing and maintaining our production capabilities has required, and will continue to require, the investment of significant resources, and we cannot guarantee that we will be able to achieve economies of scale. If we are unable to process and produce our human tissue products on a timely basis, at acceptable quality and costs and in sufficient quantities, or if we experience technological problems, delays in production, failure in the storage of our products or other loss of supply, our business would be materially and adversely affected.

***We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance.***

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, processing, investigating and marketing of medical devices and human and animal tissue products. For example, since the voluntary recall pertaining to a single donor lot of our FiberCel Fiber Viable Bone Matrix was issued, we have received notice of 41 separate lawsuits alleging that the plaintiffs contracted tuberculosis and/or suffered substantial symptoms and complications following the implantation of FiberCel during spinal fusion operations. We have notified our insurers of the known lawsuits and claims and a defense has been tendered to us (with reservation of rights), and counsel has been retained to defend us in the litigation.

We are, and may in the future be, subject to product liability claims and lawsuits, including potential class actions or mass tort claims, alleging that our products have resulted or could result in an unsafe condition or injury. Product liability claims may be made by patients and their families, healthcare providers or others selling our products. Product liability claims may include, among other things, allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. For example, the Company and certain Medtronic entities have been named in complaints alleging that plaintiffs contracted tuberculosis following the implantation of FiberCel during spinal fusion operations and seeking unspecified compensatory and punitive damages and medical monitoring. See Part II, Item 1, “Legal Proceedings” and Note 9 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

Additionally, we may be subject to product liability claims, proceedings and lawsuits, even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on physicians and other healthcare providers to properly and correctly use our products. If these physicians or other healthcare providers are not properly trained or are negligent in using our products, the capabilities of our products may be diminished or the patient may suffer critical injury. In addition, we may be subject to product liability claims, as well as a number of other risks, as a result of physicians and other healthcare providers using our products “off-label.” See the risk factor entitled *“The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business”* included in our Annual Report on Form 10-K.

Defending any current or future claims, proceedings or lawsuits, regardless of merit, could be costly, divert management attention and result in adverse publicity, which could result in the withdrawal of, or reduced acceptance of, our products in the market. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- harm to our business reputation;

- investigations by regulators;
- significant legal costs;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- decreased demand for our products.

Our product liability insurance is subject to deductibles and coverage limitations, and we may not be able to maintain this insurance. It is also possible that claims could exceed the limits of, or be excluded from, coverage under our policy, and claims against us could also increase the cost of maintaining our coverage. If we are unable to maintain product liability insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect ourselves against potential product liability claims, or if we underestimate the amount of insurance we need, we could be exposed to significant liabilities, which may harm our business. One or more product liability claims could have a significant adverse effect on our business, financial condition and results of operations.

***We bear the risk of warranty claims on our products.***

We bear the risk of warranty claims on our products. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer, and any recovery from such supplier or vendor may not be adequate. Furthermore, we may not have any, or have an adequate, warranty provided by our supplier. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us. In addition, we have been, and in the future could be, subject to costs related to product recalls, and we could incur significant costs to correct any defects, warranty claims or other problems. Any such events could adversely affect our business, financial condition and results of operations.

***Defects, failures or quality issues associated with our products could lead to product recalls or safety alerts, adverse regulatory actions, litigation, including product liability claims, and negative publicity, any of which may erode our competitive advantage and market share and have a material adverse effect on our reputation, business, financial condition and results of operations.***

Quality is extremely important to us and our customers due to the serious and costly consequences of product failure. Quality and safety issues may occur with respect to any of our products, and our future operating results will depend on our ability to maintain an effective quality control system and effectively train and manage our workforce with respect to our quality system. The development, manufacture and control of our products are subject to extensive and rigorous regulation by numerous government agencies, including the FDA, the Competent Authorities of the European Union and similar foreign agencies. Compliance with these regulatory requirements, including but not limited to the QSR, current Good Manufacturing Practices (“GMPs”) and adverse events/recall reporting requirements in the United States and other applicable regulations worldwide, is subject to continual review and is monitored rigorously through periodic inspections by the FDA and foreign regulatory authorities. If we fail to comply with our reporting obligations, the FDA, the Competent Authorities of the European Union or other regulatory authority could take action, including issuance of warning letters and/or untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in the clearance of future products.

The FDA and foreign regulatory authorities may also require post-market testing and surveillance to monitor the performance of approved products. Our facilities and those of our suppliers, commercial partners and independent sales agents are also subject to periodic regulatory inspections. If the FDA or a foreign authority were to conclude that we have failed to comply with any of these requirements, it could institute a wide variety of enforcement actions, ranging from a

public warning letter to more severe sanctions, such as product recalls or seizures, withdrawals, monetary penalties, consent decrees, injunctive actions to halt the manufacture or distribution of products, import detentions of products made outside the United States, export restrictions, restrictions on operations or other civil or criminal sanctions. Civil or criminal sanctions could be assessed against our officers, employees, or us. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing and selling our products.

If our products do not function as designed, or are designed improperly, we or the third-party manufacturer of such products may withdraw such products from the market, whether by choice or as a result of regulatory requirements. In August 2019, we recalled and discarded certain production lots of CanGaroo from the market due to suture breakage. In January 2018, we recalled five of our allograft tissue implants because a pre-sterilized donor culture should have been disqualified, each of which had a negative effect on our business, financial condition and results of operations. Furthermore, 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 made from human tissue that is used in various orthopedic and spinal procedures, following our learning of post-surgical infections in patients treated with FiberCel, including some patients that tested positive for tuberculosis. This recall had a negative effect on our business, financial condition and results of operations. Any product recall we or a third-party manufacturer may conduct in the future, whether voluntary or required, may also negatively affect our business, financial condition and results of operations, and this effect may be material.

In addition, we cannot predict the results of future legislative activity or future court decisions, any of which could increase regulatory requirements, subject us to government investigations or expose us to unexpected litigation. Any regulatory action or litigation, regardless of the merits, may result in substantial costs, divert management's attention from other business concerns and place additional restrictions on our sales or the use of our products. In addition, negative publicity, including regarding a quality or safety issue, could damage our reputation, reduce market acceptance of our products, cause us to lose customers and decrease demand for our products. Any actual or perceived quality issues may also result in issuances of physician's advisories against our products or cause us to conduct voluntary recalls. Any product defects or problems, regulatory action, litigation, negative publicity or recalls could disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

***We face significant litigation related to FiberCel.***

We have been named in several lawsuits alleging that the plaintiffs contracted tuberculosis and are suffering substantial adverse symptoms following the implantation of FiberCel during spinal fusion operations. See Part II, Item 1, "Legal Proceedings" and Note 9 to the condensed consolidated financial statements included elsewhere in this Quarterly Report. We have incurred and will continue to incur costs to defend these lawsuits and are not currently able to estimate damage amounts, if any, that we may be required to pay in connection with these lawsuits. Furthermore, these proceedings are still expected to continue for the reasonably foreseeable future, and we cannot predict the course the proceedings will take or their ultimate outcome. Given the inherent difficulty of predicting the outcome of litigation and costs involved to defend against the claims, we are currently unable to reasonably estimate the possible loss or range of loss with respect to these lawsuits. Any unfavorable outcome that results in the payment of substantial damages could have a material adverse effect on our business, cash flow, results of operations, financial position and prospects.

***Our indebtedness and our Revenue Interest Obligation to Ligand Pharmaceuticals Incorporated may limit our flexibility in operating our business and adversely affect our financial health and competitive position.***

As of September 30, 2021, we had \$22.1 million of indebtedness outstanding, consisting of \$18.7 million outstanding under our Term Loan Facility (net of \$0.2 million of unamortized discount and deferred financing costs), \$2.0 million outstanding under our Revolving Credit Facility (with \$4.5 million of additional borrowings available thereunder), and a \$1.4 million promissory note payable to one of our suppliers. In addition, 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 and certain milestone payments if sales of the acquired products exceed certain thresholds. See Note 7 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

In order to service this indebtedness and our Revenue Interest Obligation, and any additional indebtedness or other long-term obligations we may incur in the future, we need to generate sufficient levels of cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient levels of cash from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness, satisfy our obligations under the Revenue Interest Obligation and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness and satisfy our obligations under the Revenue Interest Obligation instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This will place us at a competitive disadvantage compared to our competitors that have less indebtedness.

In addition, the agreements governing our Term Loan Facility and Revolving Credit Facility contain, and any agreements evidencing or governing other future indebtedness may also contain, certain covenants that limit our ability to engage in certain transactions that may be in our long-term best interests. Subject to certain limited exceptions, these covenants limit our ability to, among other things:

- incur additional indebtedness;
- incur certain liens;
- pay dividends or make other distributions on equity interests;
- enter into agreements restricting our subsidiaries' ability to pay dividends;
- redeem, repurchase or refinance subordinated indebtedness;
- consolidate, merge or sell or otherwise dispose of our assets;
- make investments, loans, advances, guarantees and acquisitions;
- enter into transactions with affiliates;
- amend or modify our governing documents;
- amend or modify certain material agreements;
- alter the business conducted by us and our subsidiaries; and
- enter into sale and leaseback transactions.

In addition to these covenants, the agreements governing our Term Loan Facility and Revolving Credit Facility also contain a financial covenant, which is tested on a monthly basis, and requires us to achieve a specified minimum net product revenue (as defined therein) for the preceding 12-month period. While we were in compliance with all covenants under these agreements as of September 30, 2021, we have had past breaches requiring waivers and there can be no guarantee that we will not breach these covenants in the future. To this end, when finalized, the mutual termination of our Supply Agreement for FiberCel with Medtronic referred to in Note 2 to the condensed consolidated financial statements included elsewhere in this Quarterly Report would have triggered an event of default; however, such event of default was waived by our lenders. Furthermore, the Supply Agreement's termination may negatively affect future revenues and as such, Aziyo's ability to comply with the revenue covenants in the future is uncertain.

Our ability to comply with these covenants may be affected by events and factors beyond our control. In the event that we breach one or more covenants, our lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding, terminate any commitment to extend further credit and foreclose on the

collateral granted to them to collateralize such indebtedness. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations.

In addition, we may be able to incur significant additional indebtedness in the future. Although the agreements governing our Term Loan Facility and Revolving Credit Facility contain restrictions on the incurrence of additional indebtedness by us, such restrictions are subject to a number of qualifications and exceptions, and the indebtedness incurred in compliance with these restrictions could be substantial. Also, these restrictions do not prohibit us from incurring obligations that do not constitute indebtedness as defined therein. To the extent that we incur additional indebtedness or such other obligations, the risks associated with our substantial indebtedness described above will increase.

Various events permit the lender under the Term Loan Facility and Revolving Credit Facility to terminate the agreement, following a cure period. Such events include, without limitation, legal proceedings which could be implicated based on the facts involving the FiberCel Recall and the FiberCel Litigation. If the lender were to terminate either the Term Loan Facility or the Revolving Credit Facility, the lender may declare all or any portion of these obligations to become immediately due and payable.

***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.***

Our future capital needs are uncertain and, as such, we may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. Any 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 studies and clinical trials;
- the cost of our research and development activities and the cost 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 damages payable (to the extent above the applicable insurance coverage), for example, in connection with claims involving the FiberCel Recall;
- 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 costs of developing and commercializing new products or technologies;
- 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 COVID-19 pandemic, including due to variants thereof, or any other pandemic, epidemic or outbreak of infectious disease.

In addition, our operating plan 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. Any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds by selling additional shares of our common stock or other securities convertible (directly or indirectly) into or exercisable or exchangeable for shares of our common stock, the issuance of such securities will result in dilution to our stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible into or exercisable or exchangeable for shares of our common stock, in future transactions may be higher or lower than the price per share paid by you. Furthermore, investors purchasing any securities we may issue in the future may have rights superior to your rights as a holder of our common stock.

In addition, any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us.

Furthermore, we cannot be certain that additional funding will be available to us on acceptable terms, if at all. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our business, financial condition and results of operations.

***Our estimates of market opportunity and forecasts of market and sales growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business could fail to grow at similar rates, if at all.***

Market opportunity estimates and growth forecasts are inherently uncertain. Our estimates of the annual total addressable markets for our products are based on a number of internal and third-party estimates and assumptions, including, without limitation, the number of implantable electronic device procedures and orthopedic/spinal repair procedures, as well as the number of procedures using biologic products annually in the United States. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for any of our products may prove to be incorrect. If the actual number of procedures, the price at which we are able to sell any of our products, or the annual total addressable market is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business, financial condition and results of operations.

***We may face additional issues associated with the voluntary recall of the single donor lot of FiberCel if we are unable to show that we initiated a timely recall and recalled all deficient lots.***

On June 2, 2021, we issued a voluntary recall pertaining to a single donor lot of FiberCel Fiber Viable Bone Matrix, a bone repair product made from human tissue that is used in various orthopedic and spinal procedures. Notice of the voluntary recall was issued to hospitals that received product from this specific lot following our learning of post-surgical infections in patients treated with FiberCel, including some patients who tested positive for tuberculosis. We investigated the source of the infections in coordination with our distributor of the product, the FDA and the CDC. The FDA has since inspected our Richmond, California production facility and this did not result in any Form-483 observations. At this time, we have identified the 154 units comprising the single product lot in question. Based on information from the CDC, 136 units within this product lot were implanted into 113 patients and the remaining 18 units were returned to either us or the CDC. Of these 113 patients, CDC has identified at least 75 patients who have exhibited clinical or diagnostic findings consistent with tuberculosis infection. The CDC has advised us that the CDC, working with state health agencies,

has contacted all patients treated with the recalled lot of FiberCel to help ensure they are directed to appropriate medical treatment and has informed us that all patients were started on standard four-drug treatment for tuberculosis. If it is determined that there are other lots that are similarly affected or we experience the same or similar circumstances in the future, this could adversely affect our ability to generate revenue and have an adverse effect on our financial condition and results of operations. Moreover, we may face additional issues associated with our voluntary recall if we are unable to show that we initiated a timely recall.

#### ***Risks Related to Government Regulation***

***Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.***

Some of our marketed products are subject to Medical Device Reporting (“MDR”) obligations, which require that we report to the FDA or the Competent Authorities of the European Union, any incident in which our products may have caused or contributed to a death or serious injury, or in which our products malfunctioned and, if the malfunction were to recur, it could likely cause or contribute to a death or serious injury. The timing of our obligation to report under the MDR regulations is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our product. If we fail to comply with our reporting obligations, the FDA, or the Competent Authorities of the European Union, could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products.

The FDA, the Competent Authorities of the European Union, and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA’s authority to require a recall for a medical device must be based on a finding that there is reasonable probability that the device could cause serious injury or death. With respect to human cells, tissues, and cellular and tissue-based products (“HCT/Ps”), the FDA may also require a recall where the conditions of manufacture of the HCT/P do not provide adequate protections against risks of communicable disease transmission, or where the HCT/P is infected or contaminated so as to be a source of dangerous infections to humans. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product’s deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls, and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

### ***Risks Related to Our Common Stock***

***We expect that the price of our Class A common stock will fluctuate substantially and you may not be able to sell the shares you purchase at or above the price you paid for such shares.***

The market price of our Class A common stock is likely to be highly volatile and may fluctuate substantially due to a variety of factors, many of which are outside of our control, including, among other things:

- the volume and timing of sales of our products;
- the introduction of new products or product enhancements by us or others in our industry;
- developments related to the COVID-19 pandemic;
- disputes or other developments with respect to our or others' intellectual property rights;
- our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis;
- changes or proposed changes in laws or regulations or differing interpretations or enforcement thereof affecting our business;
- product liability claims or damages related thereto, including those related to FiberCel described in this Quarterly Report, as well as other litigation or regulatory investigations;
- annual or quarterly variations in our results of operations or those of others in our industry, or results of operations that otherwise vary from those expected by securities analysts and investors;
- publications, reports or other media exposure of our products or those of others in our industry, or of our industry generally;
- announcements by us or others in our industry, or by our or their respective suppliers, distributors or other business partners, regarding, among other things, significant contracts, price reductions, capital commitments or other business developments, the entry into or termination of strategic transactions or relationships, securities offerings or other financing initiatives, and public reaction thereto;
- additions or departures of key management personnel;
- changes in governmental regulations or in reimbursement;
- changes in earnings estimates or recommendations by securities analysts, or other changes in investor perceptions of the investment opportunity associated with our common stock relative to other investment alternatives;
- the development and sustainability of an active trading market for our Class A common stock;
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors; and
- other factors discussed in Part II, Item 1A. "Risk Factors" of this Quarterly Report and Part I, Item 1A, "Risk Factors" of our Annual Report.

In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies, including, as a result of the pandemic related to COVID-19 and variants such as Delta. Broad market and industry factors may significantly affect the market price of our Class A common stock, regardless of our actual operating performance. If the market price of shares

of our Class A common stock does not ever exceed the price you paid for your shares, you may not realize any return on your investment in us and may lose some or all of your investment.

In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management's attention and resources away from our business.

***We are a "controlled company" within the meaning of the Nasdaq Stock Market LLC ("Nasdaq") and, as a result, qualify for, and may rely on, exemptions from certain corporate governance requirements.***

Affiliates of HighCape Partners control a majority of our outstanding Class A common stock. As a result, we qualify as a "controlled company" within the meaning of Nasdaq's corporate governance standards. A company of which more than 50% of the voting power for the election of directors is held by an individual, a group or another company is a "controlled company" within the meaning of Nasdaq's rules and may elect not to comply with certain corporate governance requirements of Nasdaq, including, among others:

- the requirement that a majority of our board of directors consist of independent directors;
- the requirement that we have a nominating and corporate governance committee that is comprised entirely of independent directors with a written charter addressing the committee's purpose and responsibilities;
- the requirement that we have a compensation committee that is comprised entirely of independent directors with a written charter addressing the committee's purpose and responsibilities;
- the requirement for an annual performance evaluation of the nominating and corporate governance and compensation committees.

For so long as we remain a controlled company, we may at any time and from time to time, utilize any or all of these exemptions. As a result, our board of directors and those committees may have more directors who do not meet Nasdaq's independence standards than they would if those standards were to apply. The independence standards are intended to ensure that directors who meet those standards are free of any conflicting interest that could influence their actions as directors. Accordingly, you may not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq.

**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.**

<b>Exhibit Number</b>	<b>Description</b>	<b>Form</b>	<b>File No.</b>	<b>Exhibit</b>	<b>Filing Date</b>	<b>Filed/ Furnished Herewith</b>
3.1	<a href="#">Restated Certificate of Incorporation of Aziyo Biologics, Inc.</a>	8-K	001-39577	3.1	10/13/2020	
3.2	<a href="#">Amended and Restated Bylaws of Aziyo Biologics, Inc.</a>	8-K	001-39577	3.2	10/13/2020	
4.1	<a href="#">Second Amended and Restated Investor Rights Agreement, dated as of September 14, 2020, among the Registrant and the investors named therein</a>	S-1	333-248788	4.1	09/14/2020	
4.2	<a href="#">Specimen stock certificate evidencing the shares of Class A common stock</a>	S-1	333-248788	4.2	09/14/2020	
4.3	<a href="#">Specimen stock certificate evidencing the shares of Class B common stock</a>	S-1/A	333-248788	4.3	09/30/2020	
31.1	<a href="#">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.</a>					*
31.2	<a href="#">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.</a>					*
32.1	<a href="#">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.</a>					**
32.2	<a href="#">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.</a>					**
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					*

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101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	*

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\* 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: November 10, 2021

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

Date: November 10, 2021

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







