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

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2023
or

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

Commission file number: 001-39577

Aziyo Biologics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**47-4790334**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

As of August 9, 2023, there were 11,936,441 shares of the registrant's Class A common stock and 4,313,406 shares of the registrant's Class B common stock outstanding.

FORWARD-LOOKING STATEMENTS

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

Without limiting the foregoing, the words "aim," "believe," "may," "will," "should," "expect," "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, are intended to identify forward-looking statements, although not all forward-looking statements contain these words. These forward-looking statements are not a guarantee of future results, performance, or achievements, and one should avoid placing undue reliance on such statements.

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

- our ability to continue as a going concern;
- our ability to achieve or sustain profitability;
- 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 enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings;
- our dependence on our commercial partners and independent sales agents to generate a substantial portion of our net sales;
- our ability to maintain our relationships with our existing contract manufacturing customers and enter into agreements with new contract manufacturing customers, or if existing contract manufacturing customers reduce purchases of our products;
- our ability to successfully execute or realize the anticipated benefits under our distribution arrangements with LeMaitre Vascular and Sientra;

- 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 dependence on a limited number of third-party suppliers;
- our ability to defend against the various lawsuits related to our recall of a single lot of FiberCel and avoid a material adverse financial consequence; and
- our ability to regain compliance with the listing standards of the Nasdaq Capital Market.

These and other important factors discussed in Part I, Item 2. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Part II, Item 1A. “Risk Factors” in this Quarterly Report, and 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, 2022 (the “Annual Report”) and in our other filings with the Securities and Exchange Commission (the “SEC”), each of which filings are accessible on the SEC’s website at www.sec.gov and the Investor Relations page of our website at https://investors.aziyo.com/financials/sec-filings, could cause actual results to differ materially from those indicated by the forward-looking statements made in this Quarterly Report.

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

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

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

WEBSITE DISCLOSURE

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

TRADEMARKS, TRADE NAMES AND SERVICE MARKS

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

INDUSTRY AND OTHER DATA

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

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

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

(UNAUDITED)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash	$ 9,296	$ 16,989
Accounts receivable, net of credit loss reserve of $921 and $87, respectively	6,317	6,830
Inventory	9,274	10,052
Receivables of FiberCel litigation costs	8,876	13,813
Prepaid expenses and other current assets	2,363	3,015
Total current assets	36,126	50,699
Property and equipment, net	1,467	1,403
Intangible assets, net	13,370	15,069
Operating lease right-of-use assets and other	1,366	1,670
Total assets	**$ 52,329**	**$ 68,841**
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 3,227	$ 2,328
Accrued expenses and other current liabilities	11,724	10,103
Payables to tissue suppliers	2,460	3,152
Current portion of revenue interest obligation	10,366	8,990
Contingent liability for FiberCel litigation	14,470	17,360
Current operating lease liabilities	620	682
Total current liabilities	42,867	42,615
Long-term debt	24,927	24,260
Long-term revenue interest obligation	5,601	5,916
Long-term operating lease liabilities	711	956
Other long-term liabilities	351	127
Total liabilities	74,457	73,874
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Class A Common stock, $0.001 par value, 200,000,000 shares authorized as of June 30, 2023 and December 31, 2022, and 11,936,441 and 11,823,445 shares issued and outstanding, as of June 30, 2023 and December 31, 2022, respectively	12	12
Class B Common stock, $0.001 par value, 20,000,000 shares authorized, as of June 30, 2023 and December 31, 2022 and 4,313,406 issued and outstanding as of June 30, 2023 and December 31, 2022	4	4
Additional paid-in capital	134,439	132,939
Accumulated deficit	(156,583)	(137,988)
Total stockholders' deficit	(22,128)	(5,033)
Total liabilities and stockholders' deficit	**$ 52,329**	**$ 68,841**

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net sales	$ 10,296	$ 12,638	$ 23,346	$ 24,133
Cost of goods sold	9,316	7,740	16,035	14,954
Gross profit	980	4,898	7,311	9,179
Sales and marketing	3,618	5,406	8,974	10,224
General and administrative	4,005	4,711	7,684	8,736
Research and development	1,171	2,617	2,974	4,889
FiberCel litigation costs, net	1,271	346	3,182	434
Total operating expenses	10,065	13,080	22,814	24,283
Loss from operations	(9,085)	(8,182)	(15,503)	(15,104)
Interest expense	1,524	1,204	3,068	2,419
Loss before provision for income taxes	(10,609)	(9,386)	(18,571)	(17,523)
Income tax expense	12	12	24	24
Net loss	**$ (10,621)**	**$ (9,398)**	**$ (18,595)**	**$ (17,547)**
Net loss per share - basic and diluted	**$ (0.65)**	**$ (0.69)**	**$ (1.15)**	**$ (1.29)**
Weighted average common shares outstanding - basic and diluted	16,223,919	13,620,196	16,208,905	13,597,243

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

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

(UNAUDITED)

	Class A Common Stock		Class B Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, March 31, 2023	**11,876,792**	**$ 12**	**4,313,406**	**$ 4**	**$ 133,771**	**$ (145,962)**	**$ (12,175)**
Vesting of restricted stock units, net of shares withheld and taxes paid	59,649	—	—	—	(19)	—	(19)
Stock-based compensation	—	—	—	—	687	—	687
Net loss	—	—	—	—	—	(10,621)	(10,621)
Balance, June 30, 2023	**11,936,441**	**$ 12**	**4,313,406**	**$ 4**	**$ 134,439**	**$ (156,583)**	**$ (22,128)**
Balance, March 31, 2022	**9,306,738**	**$ 9**	**4,313,406**	**$ 4**	**$ 119,786**	**$ (113,240)**	**$ 6,559**
Vesting of restricted stock units	100	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	1,470	—	1,470
Net loss	—	—	—	—	—	(9,398)	(9,398)
Balance, June 30, 2022	**9,306,838**	**$ 9**	**4,313,406**	**$ 4**	**$ 121,256**	**$ (122,638)**	**$ (1,369)**

	Class A Common Stock		Class B Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, December 31, 2022	**11,823,445**	**$ 12**	**4,313,406**	**$ 4**	**$ 132,939**	**$ (137,988)**	**$ (5,033)**
Proceeds from sale of common stock through Employee Stock Purchase Plan	41,277	—	—	—	148	—	148
Vesting of restricted stock units, net of shares withheld and taxes paid	71,719	—	—	—	(19)	—	(19)
Stock-based compensation	—	—	—	—	1,371	—	1,371
Net loss	—	—	—	—	—	(18,595)	(18,595)
Balance, June 30, 2023	**11,936,441**	**$ 12**	**4,313,406**	**$ 4**	**$ 134,439**	**$ (156,583)**	**$ (22,128)**
Balance, December 31, 2021	**9,245,146**	**$ 9**	**4,313,406**	**$ 4**	**$ 118,599**	**$ (105,091)**	**$ 13,521**
Additional issuance costs in connection with Private Placement	—	—	—	—	(110)	—	(110)
Proceeds from sale of common stock through Employee Stock Purchase Plan	42,345	—	—	—	192	—	192
Vesting of restricted stock units	19,347	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	2,575	—	2,575
Net loss	—	—	—	—	—	(17,547)	(17,547)
Balance, June 30, 2022	**9,306,838**	**$ 9**	**4,313,406**	**$ 4**	**$ 121,256**	**$ (122,638)**	**$ (1,369)**

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)

	Six Months Ended June 30,	
	2023	2022
Net loss	$ (18,595)	$ (17,547)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,901	1,863
Amortization of deferred financing costs and debt discount	107	29
Interest expense recorded as additional revenue interest obligation or long-term debt	1,619	1,319
Stock-based compensation	1,371	2,575
Bad debt expense	834	—
Losses associated with viable bone matrix recall and market withdrawal	1,984	—
Changes in operating assets and liabilities:		
Accounts receivable	(321)	(650)
Inventory	(1,206)	(145)
Receivables of FiberCel litigation costs	4,937	—
Prepaid expenses and other	652	(378)
Accounts payable and accrued expenses and other current liabilities	2,520	1,324
Obligations to tissue suppliers	(692)	732
Contingent liability for FiberCel litigation	(2,890)	—
Deferred revenue and other liabilities	224	204
Net cash used in operating activities	**(7,555)**	**(10,674)**
INVESTING ACTIVITIES:		
Expenditures for property, plant and equipment	(267)	(289)
Net cash used in investing activities	**(267)**	**(289)**
FINANCING ACTIVITIES:		
Additional issuance costs in connection with Private Placement	—	(110)
Net borrowings (repayments) under revolving line of credit	—	1,689
Repayments of long-term debt	—	(3,333)
Payments on revenue interest obligation	—	(1,392)
Payments for taxes upon vesting of restricted stock units	(19)	—
Proceeds from sales of common stock through Employee Stock Purchase Plan	148	192
Net cash provided by (used in) financing activities	**129**	**(2,954)**
Net decrease in cash and restricted cash	**(7,693)**	**(13,917)**
Cash and restricted cash, beginning of period	**16,989**	**30,428**
Cash and restricted cash, end of period	**$ 9,296**	**$ 16,511**
Supplemental Cash Flow and Non-Cash Financing Activities Disclosures:		
Cash paid for interest	$ 1,100	$ 1,162

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 products span the device protection, women's health, orthobiologics and cardiovascular markets. 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 with corporate customers.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation and Liquidity

The unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's consolidated financial statements and accompanying notes included in the Company's annual report on Form 10-K ("Annual Report") for the fiscal year ended December 31, 2022. The financial information as of June 30, 2023 and for the three and six months ended June 30, 2023 and 2022 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, 2022 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 consolidaton.

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 six months ended June 30, 2023, the Company incurred a net loss of $18.6 million, and as of June 30, 2023, the Company had an accumulated deficit of $156.6 million. In addition, during the six months ended June 30, 2023, the Company used $7.6 million of cash in operating activities, and expects to continue to incur cash outflows during the remainder of 2023. Because of the numerous risks and uncertainties associated with the Company's commercialization and development efforts, the Company is unable to predict when it will become profitable, and it may never become profitable. The Company's inability to achieve and then maintain profitability would negatively affect its business, financial condition, results of operations and cash flows.

In order to mitigate the current and potential future liquidity issues caused by the matters noted above, the Company may seek to raise capital through the issuance of common stock or debt, restructure its Revenue Interest Obligation (as such term is defined, and further described, in Note 7), or pursue asset sale or other transactions. However, such transactions may not be successful and the Company may not be able to raise additional equity or debt, restructure its Revenue Interest Obligation, or sell or license assets on acceptable terms, or at all. As such, based on its current operating plans, the Company believes there is uncertainty as to whether its future cash flows along with its existing cash, issuances of additional equity and cash generated from expected future sales will be sufficient to meet the Company's anticipated operating needs through twelve months from the financial statement issuance date. Due to these factors, there

is substantial doubt about the Company's ability to continue as a going concern within one year after the issuance of the financial statements.

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

Reclassifications

Certain reclassifications have been made to prior year amounts to conform to current year financial statement presentation. The reclassifications relate to the separate presentation of prior year costs related to the FiberCel Litigation. Such costs were formerly shown as a component of general and administrative expenses in the accompanying consolidated statements of operations. Additionally, the Company determined in its fourth quarter of 2022 that its operating and reportable segments are consistent with its major product groupings – Device Protection, Women's Health, Orthobiologics and Cardiovascular. Segment results for the three and six months ended June 30, 2022, have been recasted to conform to the new segment presentation. Refer to the Segment Information in Note 10.

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 inventories, receivables, long-lived assets, the valuation of stock-based awards, the valuation of the revenue interest obligation, the contingent liability for the FiberCel Litigation 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.

Net Loss per Share Attributable to Common Stockholders

Our common stock has a dual class structure, consisting of Class A common stock, $0.001 par value per share (the "Class A common stock") and Class B common stock, $0.001 par value per share (the "Class B common stock"). Other than voting rights, the Class B common stock has the same rights as the Class A common stock, and therefore both are treated as the same class of stock for purposes of the earnings per share calculation. Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average shares outstanding during the period. For purposes of the diluted net income (loss) per share attributable to common stockholders calculation, stock options, restricted stock units ("RSUs") and 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

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.

Accounts Receivable and Allowances

Accounts receivable in the accompanying balance sheets are presented net of allowances for credit losses. 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 credit losses is recorded based on factors including the length of time the receivables are past due, the current business environment and the Company's historical experience. Provisions to the allowance for doubtful accounts are recorded to general and administrative expenses. Account balances are charged off against the allowance when it is probable that the receivable will not be recovered.

Inventory

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

Property and Equipment

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

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

Leasehold improvements are amortized on the straight-line method over the shorter of the lease term or the estimated useful life of the asset. Repairs and maintenance costs are expensed as incurred.

Leases

In February 2016, the FASB issued ASU No 2016-02 “Leases” to increase the transparency and comparability about leases among entities. ASU 2016-02 and certain additional ASUs are now codified as Accounting Standards Codification Standard 842 - “Leases” (“ASC 842”). ASC 842 supersedes the lease accounting guidance in Accounting Standards Codification 840 “Leases” (“ASC 840”) and requires lessees to recognize a lease liability and a corresponding lease asset for virtually all lease contracts. The Company determines if an arrangement contains a lease at inception. Right-of-use (“ROU”) assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent the Company’s obligation to make lease payments arising from that lease. For leases with a term greater than 12 months, ROU assets and liabilities are recognized at the lease commencement date based on the estimated present value of lease payments over the lease term. The lease term includes the option to extend the lease when it is reasonably certain the Company will exercise that option. When available, the Company uses the rate implicit in the lease to discount lease payments to present value. In the case the implicit rate is not available, the Company uses its incremental borrowing rate based on information available at the lease commencement date, including publicly available data for instruments with similar characteristics, to determine the present value of lease payments. The Company combines lease and non-lease elements for office leases.

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 six months ended June 30, 2023 or 2022.

Revenue Recognition

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

As noted above, the Company enters into contracts to primarily (i) sell and distribute products to healthcare providers or commercial partners, or (ii) produce and sell products 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 distributors and 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.

Stock-Based Compensation Plans

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

Research and Development Costs

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

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash. At June 30, 2023, the Company maintained $9.3 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. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash, the Company could lose its deposits in excess of the federally insured or protected amounts and there can be no assurance that we will be able to access uninsured funds in a timely manner or at all. The Company has not experienced any losses in such accounts.

On June 19, 2023, Surgalign Holdings, Inc. ("Surgalign") and certain of its direct and indirect subsidiaries commenced voluntary proceedings under chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of Texas. The percentage of the Company's total revenues derived from Surgalign was 10% during the three and six months ended June 30, 2023 and 2022. As of June 30, 2023, the Company's gross accounts receivable from Surgalign totaled $1.1 million, of which $0.8 million has been reserved at June 30, 2023 due to the uncertainty of collection.

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 six months ended June 30, 2023 and 2022, 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 June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326): Disclosure Framework – Measurement of Credit Losses on Financial Instruments, which requires financial assets measured at amortized cost, including trade receivables, be presented net of the amount expected to be collected. The measurement of all expected credit losses is based on relevant information about the credit quality of customers, past events, including historical experience, and reasonable and supportable forecasts that affect the collectability of the reported amount. In October 2019, the FASB voted to approve a proposal to defer the effective date of ASC 2016-13 for certain entities, including emerging growth companies that take advantage of the extended transition period, to fiscal years beginning after December 15, 2022. This ASU was effective for the Company beginning on January 1, 2023 and did not have a material impact on our condensed consolidated Financial Statements. The Company adopted this ASU using the modified retrospective transition method. Under this transition method, the new standard is applied from January 1, 2023 without restatement of comparative period amounts. The impact of transitioning to the new standard was immaterial and no adjustment was recorded to retained earnings for the cumulative effect of adopting this ASU on January 1, 2023. Results for reporting periods beginning after January 1, 2023 are presented under Topic 326 while prior period amounts continue to be reported in accordance with previously applicable GAAP.

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, the Company adopted the Aziyo Biologics, Inc. 2020 Incentive Award Plan, which was amended and restated on June 8, 2023 (the "2020 Plan"). The 2020 Plan 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 3,636,000 have been reserved for issuance under the 2020 Plan. In addition, the shares reserved for issuance under the 2020 Plan 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 June 30, 2023, the Company had 3,308,997 shares of Class A common stock available for issuance under the 2020 Plan.

On June 21, 2022, C. Randal Mills, Ph.D., a member of the Board of Directors (the "Board") of the Company, was appointed as the Company's Interim President and Chief Executive Officer, succeeding Ronald Lloyd, who stepped down as the Company's President and Chief Executive Officer and as a member of the Board. In connection with his appointment as the Interim President and Chief Executive Officer, Dr. Mills and the Company entered into an employment agreement for an initial term of 90 days (such period, the "Interim Period"). On August 9, 2022, Dr. Mills was appointed to the role of President and Chief Executive Officer of the Company, thereby ending the Interim Period, and his employment agreement was extended pursuant to the terms thereof. In accordance with the terms of his employment agreement, Dr. Mills (1) received a stock option award to purchase 456,278 shares of Class A common stock of the Company (the "Option Grant") on June 21, 2022; three-fifths of such Option Grant is subject to time-based vesting (the

"Time-Based Options") and two-fifths of such Option Grant is subject to performance-based vesting (the "Performance Based Options") and (2) is eligible to receive 224,734 restricted stock units (the "RSU Grant"); three-fifths of such RSU Grant is subject to time-based vesting (the "Time-Based RSUs") and two-fifths of such RSU Grant is subject to performance-based vesting (the "Performance-Based RSUs"). One-third of the Time-Based Options vested on August 9, 2022 (end of the Interim Period), and two-thirds of the Time-Based Options vest over a four-year vesting schedule with 25% vesting on the first anniversary of June 21, 2022 and the remaining portion vesting in twelve equal quarterly installments. One-third of the Time-Based RSUs vest on the grant date, and two-thirds of the Time-Based RSUs vest over a four-year vesting schedule in equal annual installments. The Performance-Based Options and Performance-Based RSUs each vest in equal installments upon the achievement of certain share price thresholds for twenty consecutive days of trading at each respective threshold. Pursuant to the terms of the employment agreement, all of these awards were deemed granted on June 21, 2022, for purposes of and in accordance with ASC 718, *Accounting for Stock Based Compensation*; however, the RSUs were not legally granted until April 2023 and the vested shares underlying the award were not deemed outstanding until such time.

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 generally have contractual terms of 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 six months ended June 30, 2023 is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2022	1,864,739	$ 9.41	7.5	$ 8
Granted	157,500	$ 2.64		
Exercised	—	$ —		
Forfeited	(355,690)	$ 10.00		
Outstanding, June 30, 2023	1,666,549	$ 8.64	8.3	$ -
Vested and exercisable, June 30, 2023	704,485	$ 9.85	7.6	$ -

The weighted average grant date fair value of options granted during the six months ended June 30, 2023 was $1.63. As of June 30, 2023, there was approximately $3.1 million of total unrecognized compensation expense related to unvested stock options. These costs are expected to be recognized over a weighted-average period of 2.2 years.

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

The following weighted-average assumptions were used to determine the fair value of options granted during the six months ended June 30, 2023 and 2022:

	Six Months Ended June 30,	
	2023	2022
Expected term (years)	6.0	6.2
Risk-free interest rate	3.9 %	2.0 %
Volatility factor	63.8 %	53.0 %
Dividend yield	—	—

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

Restricted Stock Units

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

A summary of the RSU activity under the Company's 2020 Plan for the six months ended June 30, 2023 is as follows:

	Number of Shares Underlying RSUs	Weighted-Average Grant Date Fair Value
Unvested, December 31, 2022	372,307	$ 5.90
Granted	—	$ —
Vested	(34,994)	$ 9.23
Forfeited	(33,378)	$ 4.45
Unvested, June 30, 2023	303,935	$ 5.60

For the Performance-Based RSUs, including those granted to Dr. Mills as described above, the Company accounted for the awards as market condition awards and used an option pricing model, the Monte Carlo model, to determine the fair value of the respective equity instruments and an expense recognition term of two to three years using the graded vesting method.

As of June 30, 2023, $0.9 million of unrecognized compensation costs related to RSUs is expected to be recognized over a weighted average period of approximately two years.

Employee Stock Purchase Plan

The Company makes shares of its Class A common stock available for purchase under the Aziyo Biologics, Inc. 2020 Employee Stock Purchase Plan (the "ESPP"). The ESPP provides for separate six-month offering periods that begin in March and September of each year. Under the ESPP, employees may purchase a limited number of shares of Aziyo Class A common stock at 85% of the fair market value on either the first day of the offering period or the purchase date, whichever is lower. The ESPP is considered compensatory for purposes of stock-based compensation expense. The number of shares reserved under the ESPP will automatically increase on the first day of each fiscal year through January 1, 2030, in an amount as set forth in the ESPP. As of June 30, 2023, the total shares of Class A common stock authorized for issuance under the ESPP was 542,365, of which 399,436 remained available for future issuance. During the three and six months ended June 30, 2023, 41,277 shares of Class A common stock were issued under the ESPP.

Stock-Based Compensation Expense

Stock-based compensation expense recognized during the three and six months ended June 30, 2023 and 2022 was comprised of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Sales and marketing	$ 159	$ 302	$ 303	$ 498
General and administrative	441	903	895	1,585
Research and development	45	247	91	424
Cost of goods sold	42	18	82	68
Total stock-based compensation expense	$ 687	$ 1,470	$ 1,371	$ 2,575

Note 5. Inventory

Inventory was comprised of the following (in thousands):

	June 30, 2023	December 31, 2022
Raw materials	$ 1,489	$ 1,716
Work in process	937	623
Finished goods	6,848	7,713
Total	$ 9,274	$ 10,052

Note 6. Long-Term Debt

On August 10, 2022 (the “Closing Date”), the Company entered into a senior secured term loan facility with SWK Funding LLC (“SWK”), as agent, and other lenders party thereto (the “SWK Loan Facility”) for an aggregate principal amount of $25 million. An initial draw of $21 million drawn was made on the Closing Date with the additional $4 million drawn on December 14, 2022 upon satisfaction of the amended terms enabling such receipt. The SWK Loan Facility also allows for the establishment of a separate, new asset-based revolving loan facility of up to $8 million, which had not been entered into as of June 30, 2023. The SWK Loan Facility matures on August 10, 2027 and accrues interest, payable quarterly in arrears. Principal amortization of the SWK Loan Facility starts on November 15, 2024, which amortization may be extended to November 17, 2025 if certain conditions have been satisfied. Principal payments during the amortization period will be limited based on revenue-based caps. As of June 30, 2023, quarterly principal payments are scheduled to begin on November 15, 2024, in an amount equal to 5% of the outstanding principal on such principal payment commencement date with the balance paid at maturity. The SWK Loan Facility also includes both revenue and minimum liquidity covenants, restrictions as to payment of dividends, and is secured by all assets of the Company, subject to certain customary exceptions. On May 12, 2023, the Company entered into that certain First Amendment to the SWK Loan Facility Agreement with SWK, as agent, and the other lenders party thereto (the “Amendment”). The Amendment modified the minimum liquidity covenant applicable to the Company under the SWK Loan Facility Agreement, such that the Company must maintain a minimum liquidity of at least $5.0 million until August 15, 2023 (which date may be extended by SWK in its commercially-reasonable discretion, to November 15, 2023), and after such date, a minimum liquidity of at least the greater of (i) $5.0 million, and (ii) the sum of the operating cash burn (as defined in the SWK Loan Facility Agreement) for the two prior consecutive fiscal quarters then ended. As of June 30, 2023, Aziyo was in compliance with its financial covenants under the agreement governing the SWK Loan Facility (the “SWK Loan Facility Agreement”).

All of the SWK Loan Facility borrowings take the form of Secured Overnight Financing Rate (“SOFR”) loans and bear interest at a rate per annum equal to the sum of an applicable margin of (i) 7.75% and the “Term SOFR Rate” (based upon an interest period of 3 months), or (ii) if the Company has elected the PIK Interest option (as defined below), 3.75% and the “Term SOFR Rate.” The Company may elect a portion of the interest due, to be paid in-kind at a rate per annum of 4.5% (“PIK Interest”), and such election may be made (x) until November 15, 2024 if the conditions to draw the Additional Term Loan have not been met, or (y) if such conditions to draw the Additional Term Loan have been satisfied, until November 17, 2025. The “Term SOFR Rate” is subject to a floor of 2.75%. The agreement, as amended, governing

the SWK Loan Facility also includes an exit fee equal to 6.5% of the aggregate principal amount funded prior to termination plus $62,500 and prepayment penalties equal to: (i) if such prepayment occurs prior to the first anniversary of the Closing Date, 2% of the aggregate principal amount funded prior to the termination plus remaining unpaid interest payments scheduled to be paid during the first year of the loan or (ii) if such prepayment occurs after the first anniversary of the Closing Date but prior to the second anniversary of the Closing Date, 2% of the aggregate principal amount funded prior to the termination. The weighted average interest rate on the SWK Loan Facility was 13.0% and 12.9% for the three and six months ended June 30, 2023, respectively.

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

The SWK Loan Facility Agreement requires certain mandatory prepayments, subject to certain exceptions, with: (1) 100% of any net casualty proceeds in excess of $250,000 and (2) for non-ordinary course asset sales, an amount equal to the difference between (x) the proportion of divested gross profit (as defined in the SWK Loan Facility Agreement) to the Company's total gross profit (as defined in the SWK Loan Facility Agreement) multiplied by the outstanding loans under the SWK Loan Facility and (y) the difference between $1,000,000 and the aggregate sale proceeds of any assets previously sold during the fiscal year. No such mandatory prepayments were required during the three and six months ended June 30, 2023.

In connection with the August 2022 debt refinancing, the Company used $16 million of the proceeds of the SWK Loan Facility to repay all outstanding obligations on its former MidCap term loan ("MidCap Loan Facility") and former asset-backed revolving line of credit ("MidCap Credit Facility"). Borrowings under the MidCap Loan Facility bore interest at a rate per annum equal to the sum of (x) the greater of (i) 2.25% and (ii) the applicable London Interbank Offered Rate for U.S. dollar deposits divided by 1.00 minus the maximum effective reserve percentage for Eurocurrency funding ("LIBOR") plus (y) 7.25%. The weighted average interest rate on MidCap Loan Facility was 9.5% for the three and six months ended June 30, 2022. Borrowings under the MidCap Credit Facility bore interest at a rate per annum equal to the sum of (x) the greater of (i) 2.25% and (ii) LIBOR plus (y) 4.95%. The weighted average interest rate on MidCap Credit Facility was 7.2% for the three and six months ended June 30, 2022.

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

	June 30, 2023	December 31, 2022
Term Loan Facility, net of unamortized discount and deferred financing costs	$ 24,927	$ 24,260
Current Portion	—	—
Long-Term Debt	$ 24,927	$ 24,260

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 June 30, 2023 and December 31, 2022.

Note 7. Revenue Interest Obligation

On May 31, 2017, the Company completed an asset purchase agreement with CorMatrix Cardiovascular, Inc. ("CorMatrix") and acquired all CorMatrix commercial assets and related intellectual property (the "CorMatrix Acquisition"). As part of the CorMatrix Acquisition, the Company assumed a restructured, long-term obligation (the

"Revenue Interest Obligation") to Ligand Pharmaceuticals ("Ligand") with an estimated present value on the acquisition date of $27.7 million. Subject to annual minimum payments of $2.75 million per year, the terms of the Revenue Interest Obligation require Aziyo to pay Ligand, 5% of future sales of the products Aziyo acquired from CorMatrix, including CanGaroo, ProxiCor, Tyke and VasCure, as well as products substantially similar to those products, such as the version of CanGaroo Aziyo is currently developing that is designed to include antibiotics.

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

The Company recorded the present value of the estimated total future payments under the Revenue Interest Obligation as a long-term obligation, with the annual minimum payments, along with the expected payment timing of the first $5.0 million sales milestone payment noted above, serving to establish the short-term portion. At each reporting period, the value of the Revenue Interest Obligation is re-measured based on current estimates of future payments, with changes to be recorded in the condensed consolidated statements of operations using the catch-up method. There was no change to estimated future payments during the three and six months ended June 30, 2023 and 2022, and thus, no re-measurement gain or loss was recognized. Interest expense related to the Revenue Interest Obligation of approximately $0.5 million and $0.7 million was recorded for the three months ended June 30, 2023 and 2022, respectively and approximately $1.1 million and $1.3 million was recorded for the six months ended June 30, 2023 and 2022, respectively.

Note 8. Commitments and Contingencies

Cook Biotech License and Supply Agreements

Aziyo has entered into a license agreement with Cook Biotech ("Cook") for an exclusive, worldwide license to the porcine tissue for use in the Company's Cardiac Patch and CanGaroo products, subject to certain co-exclusive rights retained by Cook (the "Cook License Agreement"). The term of such license is through the date of the last to expire of the licensed Cook patents, which is anticipated to be July 2031. Along with this license agreement, Aziyo entered into a supply agreement whereby Cook would be the exclusive supplier to Aziyo of the licensed porcine tissue. Under certain limited circumstances, Aziyo has the right to manufacture the licensed product and pay Cook a royalty of 3% of sales of the Aziyo-manufactured tissue. The supply agreement expires on the same date as the related license agreement. No royalties were paid to Cook during the three and six months ended June 30, 2023 or 2022. Aziyo has also entered into an amendment to the Cook License Agreement (the "Cook Amendment") in order to add fields of exclusive use. Specifically, the Cook Amendment provides for a worldwide exclusive license to the porcine tissue for use with neuromodulation devices in addition to cardiovascular devices. The Cook Amendment includes license fee payments of $0.1 million per year in each of the years 2021 through 2026. Such license payments would accelerate if a change in control, as defined in the Cook Amendment, occurs within Aziyo. The Company, in its sole discretion, can terminate the Cook License Agreement at any time.

Legal Proceedings

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

FiberCel Litigation

In June 2021, the Company announced a voluntary recall of a single lot of FiberCel fiber viable bone matrix. Since September 2021, 76 lawsuits (78 plaintiffs) in Indiana, Delaware, Florida, Maryland, Colorado, Michigan, Ohio, Kentucky, Oregon, North Carolina, Louisiana, Illinois, Virginia, California, Pennsylvania, and Arizona have been filed against Aziyo Biologics Inc., certain Medtronic entities, and others alleging that the plaintiffs were exposed to and/or contracted tuberculosis and/or suffered substantial symptoms and complications following the implantation of FiberCel during spinal fusion operations. Such lawsuits were filed in Indiana state court (collectively, the "Indiana State Complaints"); the Superior Court of the State of Delaware (collectively, the "Delaware State Complaints"); the Circuit Court of Maryland (collectively, the "Maryland State Complaints"); the Court of Common Pleas of Ohio and the U.S. District Court of the Southern District of Ohio (collectively, the "Ohio Complaints"); the U.S. District Court for the Western District of North Carolina ("North Carolina Federal Complaint"); the U.S. District Court for the Northern District of Florida and the U.S. District Court for the Southern District of Florida (collectively, the "Florida Federal Complaints"); the U.S. District Court for the Eastern District of Michigan (collectively "the Michigan Federal Complaints."); the U.S. District Court for the District of Colorado ("Colorado Federal Complaint"); the U.S. District Court for the District of Oregon ("Oregon Federal Complaint"); the Fayette, Kentucky Circuit Court and the U.S. District Court for the Eastern District of Kentucky (collectively, the "Kentucky Complaints."); the U.S. District Court for the Western District of Louisiana ("Louisiana Federal Complaint"); the Illinois Circuit Court (collectively, the "Illinois State Complaints"); the U.S. District Court for the Eastern District of Virginia ("Virginia Federal Complaint"); the U.S. District Court for the Eastern District of Pennsylvania ("Pennsylvania Federal Complaint"); Philadelphia County Court of Common Pleas ("Pennsylvania State Complaint"); the U.S. District Court for the Central District of California ("California Federal Complaint") and the U.S. District Court for the District of Arizona ("Arizona Federal Complaint.")

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

(defective design and manufacture), negligence and breach of implied warranty and seeks compensatory damages and recovery for medical monitoring. The Arizona Federal Complaint asserts strict product liability claims for defective design, manufacture and failure to warn, negligence, breach of implied warranty and breach of express warranty and seeks recovery for medical monitoring, loss of consortium, compensatory damages, and punitive damages. Plaintiff in the Pennsylvania State Complaint asserts claims for strict liability, negligence, breach of implied warranty, and breach of express warranty, as well as claims under the Wrongful Death Act and the Survival Act and seeks compensatory and punitive damages.

In addition to the above, there are 31 claims related to the FiberCel recall that have not yet resulted in a lawsuit. The Company refers to all of the aforementioned litigation, or claim notices, collectively as the "FiberCel Litigation."

Since August 2022, the Company has engaged in a process to negotiate and attempt to resolve many of the cases in the FiberCel Litigation. In total, Aziyo's liability in 27 of the cases was settled for a total of approximately $7.5 million. Of these settled matters, 26 cases were both settled and paid as of June 30, 2023 for a total cash outlay of $7.3 million. For the remaining 82 cases for which settlements have not been reached, the Company estimated a probable loss related to each case and has recorded a liability at an estimated amount of $14.3 million bringing the total estimated liability at June 30, 2023 to $14.5 million, which is recorded as Contingent Liability for FiberCel Litigation in the accompanying consolidated balance sheets. Although the Company believes there is a possibility that a loss in excess of the amount recognized exists, the Company is unable to estimate the possible loss or range of loss in excess of the amount recognized at this time. In order to reasonably estimate the liability for the unsettled FiberCel Litigation cases, the Company, along with outside legal counsel, has assessed a variety of factors, including (i) the extent of the injuries incurred, (ii) recent experience on the settled claims, (iii) settlement offers made to the other parties to the litigation and (iv) any other factors that may have a material effect on the FiberCel Litigation. While the Company believes its estimated liability to be reasonable, the actual loss amounts are highly variable and turn on a case-by-case analysis of the relevant facts. As more information is learned about asserted claims and potential future trends, adjustments may be made to this Contingent Liability for FiberCel Litigation as appropriate.

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

The Company has purchased insurance coverage that, subject to common contract exclusions, provided coverage for the FiberCel Litigation product liability losses as well as legal defense costs. Additionally, the Company has various potential indemnity and/or contribution rights against third party sources with respect to certain product liability losses. When settlements are reached and/or amounts are recorded in the related Contingent Liability for FiberCel Litigation, the Company calculates amounts due to be reimbursed pursuant to the terms of the coverage and related agreements, and pursuant to other indemnity or contribution claims, in respect of product liability losses and related defense costs. The amounts probable of reimbursement or recovery from this calculation are recorded as receivables. The determination that the recorded receivables are probable of collection is based on the terms of agreements reached in respect of indemnity and contribution claims as well as the advice of the Company's outside legal counsel. These receivables at June 30, 2023 totaled $8.9 million and are recorded as Receivables of FiberCel Litigation Costs in the accompanying consolidated balance sheets.

The indemnity and contribution receivables amount at June 30, 2023 represents amounts that are not believed to be subject to any current dispute. At June 30, 2023, the Company continues to pursue up to $3.8 million or more in additional amounts in respect of such indemnity and contribution claims and as such, has not been reflected as part of this receivable. The Company will vigorously pursue its position with respect to this amount.

Viable Bone Matrix Recall

In July 2023, the Company announced a voluntary recall of a single lot of a certain viable bone matrix ("VBM") product and the market withdrawal of all of its VBM products produced after a specified date (the "VBM Matter"). Such VBM products are within the Company's Orthobiologics business. Notice of the voluntary recall was issued to centers after the Company learned of post-surgical Mycobacterium tuberculosis (MTB) infections in two patients treated with a VBM product from a single donor lot. Prior to release, samples from this specific lot had tested negative for MTB by an independent laboratory using a nucleic acid test that is designed to specifically detect the MTB organism.

The VBM recall and market withdrawal necessitated the establishment of a product returns reserve and reversal of revenue totaling $3.0 million, which is included in accrued expenses and other current liabilities in the condensed consolidated balance sheet as of June 30, 2023. Furthermore, the Company has written off the full value of its VBM inventory on-hand at June 30, 2023 resulting in a $2.0 million charge to cost of goods sold in the condensed consolidated income statement for the three and six months ended June 30, 2023. Such writedown was deemed necessary due to the limited shelf-life of the inventory and the inability to sell the VBM inventory until a valid MTB test can be identified or developed, both of which are uncertain at this time.

At present, no lawsuits have been filed or claims asserted as a result of the VBM Matter. Management has determined that there is a reasonably possible likelihood of material claims due to the recall and market withdrawal but does not believe that the claims are probable or estimable. Consequently, management has determined that no liability for such possible claims would be recognized for the VBM recall and market withdrawal as of June 30, 2023. While unknown at this time, possible losses in connection with the VBM Matter could have a material effect on the Company's financial position and results of operations. Consistent with the FiberCel Litigation above, the Company has purchased insurance coverage that, subject to common contract exclusions, provide coverage for the possible claims associated with the VBM Matter as well as legal defense costs.

As of both June 30, 2023 and 2022, the Company was not a party to, or aware of, any legal matters or claims with material financial exposure, except for the FiberCel Litigation.

Note 9. Net Loss Per Share Attributable to Common Stockholders

(in thousands, except share and per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Numerator:				
Net loss	$ (10,621)	$ (9,398)	$ (18,595)	$ (17,547)
Denominator:				
Weighted average number of common shares - basic and diluted	16,223,919	13,620,196	16,208,905	13,597,243
Net loss per share - basic and diluted	$ (0.65)	$ (0.69)	$ (1.15)	$ (1.29)

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:

	June 30,	
	2023	2022
Options to purchase common stock	1,666,549	2,370,226
Restricted stock units	303,935	773,285
Class A common stock warrants	187,969	—
Total	2,158,453	3,143,511

Note 10. Segment Information

The Company operates in four segments. These segments are based on financial information that is utilized by the Company's CODM to assess performance and allocate resources. The Company determined its operating and reportable segments to be consistent with its major product groupings – Device Protection, Women's Health, Orthobiologics and Cardiovascular.

The Company’s net sales disaggregated by segment were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net sales:				
Device protection	$ 2,221	2,244	$ 4,571	$ 4,296
Women's health	2,400	1,824	4,695	3,458
Orthobiologics	3,945	6,476	10,603	12,720
Cardiovascular	1,730	2,094	3,477	3,659
Total Net Sales	$ 10,296	$ 12,638	$ 23,346	$ 24,133

The Company’s gross profit disaggregated by segment were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Gross profit:				
Device protection	$ 1,498	$ 1,430	$ 3,294	$ 2,749
Women's health	907	1,004	1,959	1,678
Orthobiologics	(1,733)	1,642	1,225	3,545
Cardiovascular	1,157	1,671	2,532	2,906
Gross profit, excluding intangible asset amortization	$ 1,829	5,747	9,010	10,878
Intangible asset amortization expense	849	849	1,699	1,699
Gross profit	$ 980	$ 4,898	$ 7,311	$ 9,179

The following table is a reconciliation of segment gross profit to the consolidated loss before provision for income taxes (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Gross profit, excluding intangible asset amortization	$ 1,829	$ 5,747	$ 9,010	$ 10,878
Adjustments:				
Intangible asset amortization expense	(849)	(849)	(1,699)	(1,699)
Sales and marketing	(3,618)	(5,406)	(8,974)	(10,224)
General and administrative	(4,005)	(4,711)	(7,684)	(8,736)
Research and development	(1,171)	(2,617)	(2,974)	(4,889)
FiberCel litigation costs	(1,271)	(346)	(3,182)	(434)
Loss from operations	(9,085)	(8,182)	(15,503)	(15,104)
Interest expense	1,524	1204	3,068	2,419
Loss before provision for income taxes	$ (10,609)	$ (9,386)	$ (18,571)	$ (17,523)

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

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

Overview

We are a commercial-stage regenerative medicine company focused on creating the next generation of differentiated products and improving outcomes in patients undergoing surgery. We seek to leverage our unique understanding of biologics to improve the interaction between medical devices and patients, with the goal of reducing complications and improving healing. From our proprietary tissue processing platforms, we have developed a portfolio of advanced regenerative medical products that are designed to mimic the healing response of natural biological material. Our proprietary products are designed to address the device protection, women's health, orthobiologics and cardiovascular markets, which represented a combined $3 billion market opportunity in the United States in 2019. To expand our commercial reach, we have commercial relationships with major medical device companies, such as Boston Scientific, Biotronik, Sientra and LeMaitre Vascular, to promote and sell some of our products. We believe our focus on our unique regenerative medicine platforms 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 were 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 has been driven by advances in medical device technologies, reimbursement models focused on patient outcomes, 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 contribute to other complications upon device implant.

Our 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 infection, scar-tissue formation, capsular contraction, erosion, migration, non-union of implants and implant rejection. We have leading products in each of our four priority markets: device protection, cardiovascular, orthobiologics and women's health. In device protection, we sell the only biological envelope, protected by a global patent portfolio, that forms a natural, systemically vascularized pocket for holding implanted electronic devices. In cardiovascular, we sell our SIS ECM for use as an intracardiac and vascular patch. In orthobiologics, we have a proprietary processing technology for manufacturing a comprehensive portfolio of bone regenerative products designed to promote the body's ability to regenerate healthy bone, osteogenesis, while decreasing cell apoptosis, or programmed cell death. In women's health, we have a patented cell removal technology that produces undamaged extracellular dermal matrices with superior handling, designed to promote faster healing and reduce inflammation. In pre-clinical and clinical studies, our products have supported and, in some cases, accelerated tissue healing, and thereby improved patient outcomes.

We process all of our products at our two manufacturing facilities in Roswell, Georgia and Richmond, California, and stock inventory of raw materials, supplies and finished goods at those locations. We rely on a single or limited number of suppliers for certain raw materials and supplies. 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. Our products are shipped either directly to hospital customers or through distribution partners.

Since inception, we have financed our operations primarily through private placements of our convertible preferred stock, amounts borrowed under our credit facilities, sales of our products and, more recently, with proceeds from our initial public offering ("IPO") and a private placement of our common stock. We have devoted the majority of our resources to acquisitions and integration, manufacturing and administrative costs, general and administrative, research and development, clinical activity, purchase of property and equipment used in the production activities of our Richmond, California facility and investing in our commercial infrastructure through our direct sales force and our commercial partners in order to expand our presence and to promote awareness and adoption of our products. As of June 30, 2023, we had 151 employees.

We have incurred significant operating losses since our inception. We incurred a net loss of $18.6 million for the six months ended June 30, 2023. Our accumulated deficit as of June 30, 2023 was $156.6 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, including risks relating to our ability to obtain FDA clearance for the next generation of our flagship CanGaroo product, CanGaroo RM, and our ability to successfully commercialize this product, we are unable to predict when we will become profitable, and we may never become profitable. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows.

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

Viable Bone Matrix Recall and FiberCel Recall

Viable Bone Matrix Recall

In July 2023, we announced a voluntary recall of a single lot of a certain viable bone matrix product and the market withdrawal of all of our viable bone matrix ("VBM") products produced after a specified date. Notice of the voluntary recall was issued to centers after we learned of post-surgical Mycobacterium tuberculosis (MTB) infections in two patients treated with a VBM product from a single donor lot. Prior to release, samples from this specific lot had tested negative for MTB by an independent laboratory using a nucleic acid test that is designed to specifically detect the MTB organism.

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. We have identified the 115 units comprising the single product lot in question. Based on information from the CDC, 49 units within this product lot were implanted into 36 patients and the remaining units were either never distributed by us or were returned to either us or the CDC. Of these 36 patients, CDC has identified at least five patients who have exhibited clinical or diagnostic findings consistent with tuberculosis infection.

We are continuing to work closely with the FDA and CDC in investigating the circumstances surrounding the event.

FiberCel Recall

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

Recent Strategic Transactions

In March 2023, we entered into an agreement with Sientra, a medical aesthetics company uniquely focused on plastic surgery, to expand the distribution of our women's health segment product line, SimpliDerm. Under the agreement terms, Aziyo will grant Sientra certain non-exclusive rights in the United States to market, sell and distribute SimpliDerm for select use in reconstruction surgery.

In April 2023, we entered into an agreement with LeMaitre Vascular, a provider of vascular devices, implants and services, granting LeMaitre Vascular the exclusive U.S. distribution rights for the products within its cardiovascular segment: ProxiCor® PC, ProxiCor® CTR, Tyke® and VasCure®. The term of the collaboration is three years, and LeMaitre Vascular will have the exclusive option to acquire the product line following the first year or under certain other circumstances.

CanGaroo RM Status

We are currently developing a version of the CanGaroo Envelope, CanGaroo RM, that combines the envelope with antibiotics and is designed to reduce the risk of infection following surgical implantation of an electronic device. Based on feedback from the FDA, CanGaroo RM will require clearance of a 510(k) submission to be marketed in the United States. We submitted the required 510(k) in April 2022 and, in March 2023, received a Not Substantially Equivalent ("NSE") letter from FDA requiring us to address questions relating to drug testing, primarily a request by FDA to modify an *in vitro* drug release assay employed as a manufacturing control. We intend to address the questions raised in the NSE letter and continue to work with FDA for potential clearance via the 510(k) pathway. We anticipate being able to complete our responses to outstanding questions from FDA in the 2023 calendar year.

Impact of Inflation

Inflationary factors, such as increases in our cost of goods sold or other operating expenses, may adversely affect our operating results. While it is difficult to accurately measure the impact of inflation due to the imprecise nature of the estimates required, we do not believe inflation had a material effect on our financial condition or results of operations during the three or six months ended June 30, 2023 and 2022. We cannot assure you, however, that we will be able to increase the selling prices of our products or reduce our operating expenses in an amount sufficient to offset the effects future inflationary pressures may have on our gross margin. Accordingly, we cannot assure you that our financial condition and results of operations will not be materially impacted by inflation in the future.

Components of Our Results of Operations

Net Sales

We recognize revenue on the sale of our products. During the three months ended June 30, 2023, our device protection and cardiovascular products were sold to hospitals and other healthcare facilities primarily through our direct sales force, commercial partners or independent sales agents; however, beginning in April 2023, our cardiovascular products have been sold domestically through our distribution agreement with LeMaitre Vascular and internationally through commercial partners. Our women's health product, SimpliDerm, is sold directly to hospitals and other healthcare facilities through independent sales agents or through our distribution agreement with Sientra. Our orthobiologics products

are sold through commercial partners. Our contract manufacturing products are sold directly to corporate customers. Gross to net sales adjustments include sales returns and prompt payment and volume discounts.

Expenses

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

Cost of Goods Sold

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

Sales and Marketing Expenses

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

General and Administrative Expenses

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

Research and Development Expenses

Research and development (“R&D”) expenses consist primarily of salaries and fringe benefits, laboratory supplies, clinical studies and outside service costs. Our product development efforts primarily relate to new offerings in support of the orthobiologics market and activities associated with the development of CanGaroo RM, our CanGaroo Envelope with antibiotics. Our future R&D expenses may increase as a result of additional work required to address the FDA’s questions in the NSE letter we recently received regarding our CanGaroo RM. We also conduct clinical studies to validate the performance characteristics of our products and to capture patient data necessary to support our commercial efforts.

FiberCel Litigation Costs

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

Results of Operations

Comparison of the Three Months Ended June 30, 2023 and 2022

	Three Months Ended June 30,					
	2023		2022		Change 2022 / 2023	
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Net sales	$ 10,296	100.0 %	$ 12,638	100.0 %	$ (2,342)	(18.5)%
Cost of goods sold	9,316	90.5 %	7,740	61.2 %	1,576	20.4 %
Gross profit	980	9.5 %	4,898	38.8 %	(3,918)	(80.0)%
Sales and marketing	3,618	35.1 %	5,406	42.8 %	(1,788)	(33.1)%
General and administrative	4,005	38.9 %	4,711	37.3 %	(706)	(15.0)%
Research and development	1,171	11.4 %	2,617	20.7 %	(1,446)	(55.3)%
FiberCel litigation costs	1,271	12.3 %	346	2.7 %	925	NM
Total operating expenses	10,065	97.8 %	13,080	103.5 %	(3,015)	(23.1)%
Loss from operations	(9,085)	(88.2)%	(8,182)	(64.7)%	(903)	11.0 %
Interest expense	1,524	14.8 %	1,204	9.5 %	320	26.6 %
Other (income) expense, net	—	— %	—	— %	—	NM
Loss before provision of income taxes	(10,609)	(103.0)%	(9,386)	(74.3)%	(1,223)	13.0 %
Income tax expense	12	0.1 %	12	0.1 %	—	— %
Net loss	**$ (10,621)**	**(103.2)%**	**$ (9,398)**	**(74.4)%**	**$ (1,223)**	**13.0 %**

Net Sales

Net sales information for our products is summarized as follows:

	Three Months Ended June 30,					
	2023		2022		Change 2022 / 2023	
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Products:						
Device protection	$ 2,221	21.6 %	$ 2,244	17.8 %	$ (23)	(1.0)%
Women's health	2,400	23.3 %	1,824	14.4 %	576	31.6 %
Orthobiologics	3,945	38.3 %	6,476	51.2 %	$ (2,531)	(39.1)%
Cardiovascular	1,730	16.8 %	2,094	16.6 %	$ (364)	(17.4)%
Total Net Sales	**$ 10,296**	**100.0 %**	**$ 12,638**	**100.0 %**	**$ (2,342)**	**(18.5)%**

Total net sales decreased $2.3 million, or 18.5%, to $10.3 million in the three months ended June 30, 2023 compared to $12.6 million in the three months ended June 30, 2022, with such decrease primarily attributable to the viable bone matrix recall and market withdrawal in July 2023 described above. Such recall and market withdrawal, which impacted only our Orthobiologics business, necessitated the establishment of a product returns reserve and reversal of revenue totaling $3.0 million. Revenues from Women's Health increased compared to the prior year's second quarter due to volume growth and revenues from Cardiovascular decreased slightly due to the commencement of our distribution agreement with LeMaitre Vascular which provides for sales at a transfer price versus sales prior to such agreement being made at end-user pricing.

On June 19, 2023, Surgalign Holdings, Inc. ("Surgalign") and certain of its direct and indirect subsidiaries commenced voluntary proceedings under chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of Texas. Total revenues generated by us from Surgalign during the three months ended June 30, 2023 and 2022 were $1.1 million and $1.3, respectively. Surgalign is in the process of selling its assets through the chapter 11 process. Our contract with Surgalign is not being assumed by the buyer of the relevant assets. Consequently, future revenues from our Surgalign distribution relationship are highly uncertain.

Cost of Goods Sold

Cost of goods sold and gross margin percentage information for our products is summarized as follows:

	Three Months Ended June 30,					
	2023		2022			
(in thousands, except percentages)	Amount	Gross Margin %	Amount	Gross Margin %	Change 2022 / 2023 $	Change 2022 / 2023 %
Products:						
Device protection	$ 723	67.4 %	$ 814	63.7 %	$ (91)	3.7 %
Women's health	1,493	37.8 %	820	55.0 %	673	(17.3)%
Orthobiologics	5,678	(43.9)%	4,834	25.4 %	844	(69.3)%
Cardiovascular	573	66.9 %	423	79.8 %	150	(12.9)%
Cost of goods sold, excluding intangible asset amortization	8,467	17.8 %	6,891	45.5 %	1,576	(27.7)%
Intangible asset amortization expense	849	(8.2)%	849	(6.7)%	—	(1.5)%
Total Cost of Goods Sold	**$ 9,316**	**9.5 %**	**$ 7,740**	**38.8 %**	**$ 1,576**	**(29.2)%**

Total cost of goods sold increased $1.6 million to $9.3 million in the three months ended June 30, 2023 compared to $7.7 million in the three months ended June 30, 2022. Gross margin was 9.5% in the three months ended June 30, 2023 compared to 38.8% in the three months ended June 30, 2022. Gross margin, excluding intangible asset amortization, was 17.8% in the three months ended June 30, 2023 compared to 45.5% in the three months ended June 30, 2022. The decline in gross margin was due to the gross margin impact of the viable bone matrix recall and market withdrawal in July 2023 which, including both the revenue reversal noted above and inventory writedown described in Note 8 to the condensed consolidated financial statements, totaled $5.0 million causing a decrease in gross margin percentage of 35.4%. With respect to the individual product segments, the gross margin of Device Protection improved in the three months ended June 30, 2023 compared to the three months ended June 30, 2022 due to operational efficiencies in the current year causing lower costs to manufacture the product. The gross margin of Women's Health declined due to non-recurring production issues and the gross margin of the Cardiovascular business declined due to the commencement of the LeMaitre Vascular distribution agreement described above.

Operating Expenses

Sales and Marketing

Sales and marketing expenses increased $1.8 million, or 33.1%, to $3.6 million in the three months ended June 30, 2023 compared to $5.4 million in the three months ended June 30, 2022. As a percentage of sales, sales and marketing expenses decreased to 35.1% in the three months ended June 30, 2023 from 42.8% in the three months ended June 30, 2022. The decrease in expense was largely attributable to the previously announced reduction in force which occurred in the first quarter of 2023 and primarily impacted certain members of sales and marketing management.

General and Administrative

G&A expenses decreased $0.7 million, or 15.0%, to $4.0 million in the three months ended June 30, 2023 compared to $4.7 million in the three months ended June 30, 2022. As a percentage of net sales, G&A expenses increased to 38.9% in the three months ended June 30, 2023 from 37.3% in the three months ended June 30, 2022. The decrease in expense was primarily due to declines in the cost of insurance and lower equity compensation expense.

Research and Development

R&D expenses decreased to $1.2 million in the three months ended June 30, 2023 compared to $2.6 million in the three months ended June 30, 2022. We continue to focus our R&D efforts primarily on the development of our CanGaroo RM Antibacterial Envelope. Such related costs were less in the second quarter of 2023 versus the prior year's

comparable period due to the reduction of efforts needed and expenses incurred as the development progresses toward anticipated completion.

FiberCel Litigation Costs

FiberCel litigation costs increased to $1.3 million in the three months ended June 30, 2023 compared to $0.3 million in the three months ended June 30, 2022. The increase in expense was primarily due to the establishment of the Contingent Liability for FiberCel litigation in the third quarter of 2022 and the legal defense costs incurred as the FiberCel cases progress. FiberCel litigation costs in the three months ended June 30, 2022 were comprised only of legal fees incurred See further discussion in Note 8 to condensed consolidated financial statements included elsewhere in this Quarterly Report.

Interest Expense

Interest expense was approximately $1.5 million in the three months ended June 30, 2023 compared to $1.2 million in the three months ended June 30, 2022. The increase was due to the higher principal outstanding and interest rates incurred by us on our existing debt, the SWK Loan Facility, as compared to the debt outstanding in the three months ending June 30, 2022, which consisted primarily of the MidCap Loan Facility and MidCap Credit Facility. See " - Liquidity and Capital Resources - Credit Facilities" below for a further discussion of these debt agreements and Note 6 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

Comparison of the Six Months Ended June 30, 2023 and 2022

	Six Months Ended June 30,					
	2023		2022		Change 2022 / 2023	
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Net sales	$ 23,346	100.0 %	$ 24,133	100.0 %	$ (787)	(3.3)%
Cost of goods sold	16,035	68.7 %	14,954	62.0 %	1,081	7.2 %
Gross profit	7,311	31.3 %	9,179	38.0 %	(1,868)	(20.4)%
Sales and marketing	8,974	38.4 %	10,224	42.4 %	(1,250)	(12.2)%
General and administrative	7,684	32.9 %	8,736	36.2 %	(1,052)	(12.0)%
Research and development	2,974	12.7 %	4,889	20.3 %	(1,915)	(39.2)%
FiberCel litigation costs	3,182	13.6 %	434	1.8 %	2,748	NM
Total operating expenses	22,814	97.7 %	24,283	100.6 %	(1,469)	(6.0)%
Loss from operations	(15,503)	(66.4)%	(15,104)	(62.6)%	(399)	(2.6)%
Interest expense	3,068	13.1 %	2,419	10.0 %	649	26.8 %
Loss before provision of income taxes	(18,571)	(79.5)%	(17,523)	(72.6)%	(1,048)	(6.0)%
Income tax expense	24	0.1 %	24	0.1 %	—	— %
Net loss	**$ (18,595)**	**(79.6)%**	**$ (17,547)**	**(72.7)%**	**$ (1,048)**	**(6.0)%**

Net Sales

Net sales information for our products is summarized as follows:

	Six Months Ended June 30,					
	2023		2022		Change 2022 / 2023	
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Products:						
Device protection	$ 4,571	19.6 %	$ 4,296	17.8 %	$ 275	6.4 %
Women's health	4,695	20.1 %	3,458	14.3 %	1,237	35.8 %
Orthobiologics	10,603	45.4 %	12,720	52.7 %	$ (2,117)	(16.6)%
Cardiovascular	3,477	14.9 %	3,659	15.2 %	$ (182)	(5.0)%
Total Net Sales	**$ 23,346**	**100.0 %**	**$ 24,133**	**100.0 %**	**$ (787)**	**(3.3)%**

Total net sales decreased $0.8 million, or 3.3%, to $23.3 million in the six months ended June 30, 2023 compared to $24.1 million in the six months ended June 30, 2022, with such decrease primarily attributable to the viable bone matrix recall and market withdrawal in July 2023 described above. Such recall and market withdrawal, which impacted only our Orthobiologics business, necessitated the establishment of a product returns reserve and reversal of revenue totaling $3.0 million. Revenues from Device Protection and Women's Health increased compared to the corresponding period of the prior year due to volume growth and revenues from Cardiovascular decreased slightly due to the commencement of our distribution agreement with LeMaitre Vascular which provides for sales at a transfer price versus sales prior to such agreement being made at end-user pricing.

On June 19, 2023, Surgalign Holdings, Inc. ("Surgalign") and certain of its direct and indirect subsidiaries commenced voluntary proceedings under chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of Texas. Total revenues generated by us from Surgalign during the six months ended June 30, 2023 and 2022 were $2.3 million and $2.5, respectively. Surgalign is in the process of selling its assets through the chapter 11 process. Our contract with Surgalign is not being assumed by the buyer of the relevant assets. Consequently, future revenues from our Surgalign distribution relationship are highly uncertain.

Cost of Goods Sold

Cost of goods sold and gross margin percentage information for our products is summarized as follows:

	Six Months Ended June 30,					
	2023		2022		Change 2022 / 2023	
(in thousands, except percentages)	Amount	Gross Margin %	Amount	Gross Margin %	$	%
Products:						
Device protection	$ 1,277	72.1 %	$ 1,547	64.0 %	$ (270)	8.1 %
Women's health	2,736	41.7 %	1,780	48.5 %	956	(6.8)%
Orthobiologics	9,378	11.6 %	9,175	27.9 %	203	(16.3)%
Cardiovascular	945	72.8 %	753	79.4 %	192	(6.6)%
Cost of goods sold, excluding intangible asset amortization	14,336	38.6 %	13,255	45.1 %	1,081	(6.5)%
Intangible asset amortization expense	1,699	(7.3)%	1,699	(7.0)%	—	(0.2)%
Total Cost of Goods Sold	**$ 16,035**	**31.3 %**	**$ 14,954**	**38.0 %**	**$ 1,081**	**(6.7)%**

Total cost of goods sold increased $1.1 million to $16.0 million in the six months ended June 30, 2023 compared to $15.0 million in the six months ended June 30, 2022. Gross margin was 31.3% in the six months ended June 30, 2023 compared to 38.0% in the six months ended June 30, 2022. Gross margin, excluding intangible asset amortization, was 38.6% in the six months ended June 30, 2023 compared to 45.1% in the six months ended June 30, 2022. The decline in gross margin was due to the gross margin impact of the viable bone matrix recall and market withdrawal in July 2023

which, including both the revenue reversal noted above and inventory writedown described in Note 8 to the condensed consolidated financial statements, totaled $5.0 million causing a decrease in gross margin percentage of 15.4%. With respect to the individual product segments, the gross margin of Device Protection improved in the six months ended June 30, 2023 compared to the six months ended June 30, 2022 due to operational efficiencies in the current year causing lower costs to manufacture the product. The gross margin of Women's Health declined due to non-recurring production issues and the gross margin of the Cardiovascular business declined due to the commencement of the LeMaitre Vascular distribution agreement described above.

Operating Expenses

Sales and Marketing

Sales and marketing expenses decreased $1.2 million, or 12.2%, to $9.0 million in the six months ended June 30, 2023 compared to $10.2 million in the six months ended June 30, 2022. As a percentage of sales, sales and marketing expenses decreased to 38.4% in the six months ended June 30, 2023 from 42.4% in the six months ended June 30, 2022. The decrease in expense was largely attributable to the previously announced reduction in force which occurred in the first quarter of 2023 and primarily impacted certain members of sales and marketing management.

General and Administrative

G&A expenses decreased $1.0 million, or 12.0%, to $7.7 million in the six months ended June 30, 2023 compared to $8.7 million in the six months ended June 30, 2022. As a percentage of net sales, G&A expenses decreased to 32.9% in the six months ended June 30, 2023 from 36.2% in the six months ended June 30, 2022. The decrease in expense was primarily due to declines in the cost of insurance and lower equity compensation expense.

Research and Development

R&D expenses decreased to $3.0 million in the six months ended June 30, 2023 compared to $4.9 million in the six months ended June 30, 2022. We continue to focus our R&D efforts primarily on the development of our CanGaroo RM Antibacterial Envelope. Such related costs were slightly less in the first six months of 2023 versus the prior year's comparable period due to the reduction of efforts needed and expenses incurred as the development progresses toward anticipated completion.

FiberCel Litigation Costs

FiberCel litigation costs increased to $3.2 million in the six months ended June 30, 2023 compared to $0.4 million in the six months ended June 30, 2022. The increase in expense was primarily due to the establishment of the Contingent Liability for FiberCel litigation in the third quarter of 2022 and the continued evaluation of such liability and legal defense costs incurred as the FiberCel cases progress. FiberCel litigation costs in the six months ended June 30, 2022 were comprised only of legal fees incurred. See further discussion in Note 8 to condensed consolidated financial statements included elsewhere in this Quarterly Report.

Interest Expense

Interest expense was approximately $3.1 million in the six months ended June 30, 2023 compared to $2.4 million in the six months ended June 30, 2022. The increase was due to the higher principal outstanding and interest rates incurred by us on our existing debt, the SWK Loan Facility, as compared to the debt outstanding in the six months ending June 30, 2022, which consisted primarily of the MidCap Loan Facility and MidCap Credit Facility. See " - Liquidity and Capital Resources - Credit Facilities" below for a further discussion of these debt agreements and Note 6 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

Non-GAAP Financial Measures

This Quarterly Report presents our gross margin, excluding intangible asset amortization, for the three and six months ended June 30, 2023 and 2022. 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 six months ended June 30, 2023 and 2022 to the most directly comparable GAAP financial measure, which is our GAAP gross margin (in thousands).

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net sales	$ 10,296	$ 12,638	$ 23,346	$ 24,133
Cost of goods sold	9,316	7,740	16,035	14,954
Gross profit	980	4,898	7,311	9,179
Intangible asset amortization expense	849	849	1,698	1,698
Gross profit, excluding intangible asset amortization	$ 1,829	$ 5,747	$ 9,009	$ 10,877
Gross margin	9.5 %	38.8 %	31.3 %	38.0 %
Gross margin, excluding intangible asset amortization	17.8 %	45.5 %	38.6 %	45.1 %

Seasonality

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

Liquidity and Capital Resources

As of June 30, 2023, we had cash of approximately $9.3 million. In August 2022, we refinanced our debt as described below under "— Credit Facilities." Since inception, we have financed our operations primarily through private placements of our convertible preferred stock, amounts borrowed under our credit facilities, sales of our products and more recently, proceeds from our IPO and a private placement of our common stock. Our historical cash outflows have primarily been associated with acquisitions and integration, manufacturing and administrative costs, general and marketing, research and development, clinical activity, purchase of property and equipment used in the production activities of our Richmond, California facility and investing in our commercial infrastructure through our direct sales force and our commercial partners in order to expand our presence and to promote awareness and adoption of our products. As of June 30, 2023, our accumulated deficit was $156.6 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.

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

Cash Flows for the Six Months Ended June 30, 2023 and 2022

	Six Months Ended June 30,	
	2023	2022
	(in thousands)	
Net cash used in:		
Operating activities	$ (7,555)	$ (10,674)
Investing activities	(267)	(289)
Financing activities	129	(2,954)
Net decrease in cash	**$ (7,693)**	**$ (13,917)**

Net Cash Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2023 was $7.6 million compared to $10.7 million for the six months ended June 30, 2022. The year-over-year decrease was primarily due to a higher net loss (after adjustment for non-cash charges and gains) as well as the timing of certain annual insurance prepayments and reduction to receivables offset by inventory builds.

Net Cash Used in Investing Activities

Net cash used in investing activities for the six months ended June 30, 2023 and 2022 was $0.3 million. In both periods, the use of cash related to the purchase of property and equipment, the majority of which were used in the production activities of our Richmond, California facility.

Net Cash Used in Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2023 was $0.1 million compared to net cash used in financing activities of $3.0 million for the six months ended June 30, 2022. The year-over-year net decrease was caused primarily by payments made in the 2022 period related to our Revenue Interest Obligation with no such payments having been made in the 2023 period due to ongoing restructuring discussions with Ligand (as defined below).

Credit Facilities

General

On August 10, 2022 (the "Closing Date"), we entered into a senior secured term loan facility with SWK Funding LLC ("SWK"), as agent, and other lenders party thereto (as amended and modified subsequent to the Closing Date, the "SWK Loan Facility") for an aggregate principal amount of $25 million. An initial draw of $21 million drawn was made on the Closing Date with the additional $4 million drawn on December 14, 2022 upon satisfaction of the amended terms enabling such receipt. The SWK Loan Facility also allows for the establishment of a separate, new asset-based revolving loan facility of up to $8 million, which had not been entered into to date. In connection with the August 2022 debt refinancing, we used $16 million of the proceeds of the SWK Loan Facility to pay all outstanding obligations on the formerly outstanding MidCap Loan Facility and MidCap Credit Facility. Such payment included (i) $12.8 million to repay all outstanding principal and accrued interest on the MidCap Loan Facility, (ii) $1.7 million to pay the prepayment and exit fees on the MidCap Loan Facility and (iii) $1.5 million to repay the outstanding balance, accrued interest and exit fees on the MidCap Credit Facility. As of June 30, 2023, we had $24.9 million of indebtedness outstanding under our SWK Loan Facility, with such balance being net of $0.9 million of unamortized discount and deferred financing costs, but increased by capitalized PIK Interest (as defined below) of $0.9 million since November 2022.

Interest Rates

All of the SWK Loan Facility borrowings take the form of Secured Overnight Financing Rate ("SOFR") loans and will bear interest at a rate per annum equal to the sum of an applicable margin of (i) 7.75% and the "Term SOFR Rate" (based upon an interest period of 3 months), or (ii) if we have elected the PIK Interest option (as defined below), 3.75% and the "Term SOFR Rate." We may elect a portion of the interest due, to be paid in-kind at a rate per annum of 4.5% ("PIK Interest"), and such election may be made (x) until November 15, 2024 if certain profitability and regulatory conditions ("Extension Conditions") have not been met, or until November 17, 2025 if such conditions have been satisfied. The "Term SOFR Rate" is subject to a floor of 2.75%.

Mandatory Prepayments

The SWK Loan Facility Agreement requires certain mandatory prepayments, subject to certain exceptions, with: (1) 100% of any net casualty proceeds in excess of $250,000 and (2) for non-ordinary course asset sales, an amount equal to the difference between (x) the proportion of divested gross profit (as defined in the SWK Loan Facility Agreement) to the Company's total gross profit (as defined in the SWK Loan Facility Agreement) multiplied by the outstanding loans under the SWK Loan Facility, and (y) the difference between $1,000,000 and the aggregate sale proceeds of any assets previously sold during the fiscal year. No such mandatory prepayments were required during the three months ended June 30, 2023.

Optional Prepayment

The SWK Loan Facility Agreement also includes an exit fee equal to 6.5% of the aggregate principal amount funded prior to termination, and prepayment penalties that are equal to: (i) 2% of the aggregate principal amount funded prior to the termination plus remaining unpaid interest payments scheduled to be paid during the first year of the loan if such prepayment occurs prior to the first anniversary of the Closing Date, or (ii) 2% of the aggregate principal amount funded prior to termination if such prepayment occurs after the first anniversary of the Closing Date but prior to the second anniversary of the Closing Date.

Amortization and Final Maturity

The SWK Loan Facility matures on August 10, 2027 and accrues interest, payable quarterly in arrears. Principal amortization of the SWK Loan Facility starts on November 15, 2024, which amortization may be extended to November 17, 2025 if the Extension Conditions (as defined in the SWK Loan Facility Agreement) have been satisfied. Principal payments during the amortization period will be limited based on revenue-based caps. As of June 30, 2023, quarterly

principal payments are scheduled to begin on November 15, 2024, in an amount equal to 5% of the outstanding principal on such principal payment commencement date with the balance paid at maturity.

Security

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

Covenants and Other Matters

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

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

In addition, the SWK Loan Facility Agreement contains two financial covenants. The first covenant, which is measured quarterly, requires us to achieve a specified Minimum Aggregate Revenue (as defined in the SWK Loan Facility Agreement) for the preceding 12-month period. The second covenant requires us to maintain a minimum liquidity (as defined in the SWK Loan Facility Agreement) of $5.0 million until December 16, 2022 and thereafter, the greater of (a) $5.0 million and (b) the sum of the operating cash burn (as defined in the SWK Loan Facility Agreement) for the two prior consecutive fiscal quarters then ended (the “Liquidity Covenant”).

The SWK Loan Facility Agreement contains events of default, including, most significantly, a failure to timely pay interest or principal, insolvency, or an action by the FDA or such other material adverse event impacting the operations of Aziyo. As of June 30, 2023, we were in compliance with the financial covenant and all other covenants.

On May 12, 2023, we entered into a first amendment to the SWK Loan Facility Agreement with SWK and the other lenders party thereto. The amendment is described in further detail in Note 6 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

Supplier Promissory Note

During 2017, we restructured certain of our liabilities with a tissue supplier and entered into an unsecured promissory note bearing interest at 5%. As of June 30, 2022, the balance of this promissory note totaled $1.4 million plus

accrued interest. In connection with the August 2022 debt refinancing, we used $1.4 million of the proceeds from the SWK Loan Facility to repay the remaining balance on the promissory note, and as of June 30, 2023, we had no balance remaining on the promissory note.

Funding Requirements

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

As of June 30, 2023, we had $24.9 million of indebtedness outstanding, consisting of $25.8 million outstanding under our SWK Loan Facility (net of $0.9 million of unamortized discount and deferred financing costs). In addition, as further described in Note 7 to these condensed consolidated financial statements included elsewhere in this Quarterly Report, we are party to a royalty agreement with Ligand Pharmaceuticals Incorporated ("Ligand") pursuant to which we assumed a restructured, long-term obligation to Ligand (the "Revenue Interest Obligation"), that requires us to pay Ligand 5.0% of future sales of the products we acquired from CorMatrix (as well as products substantially similar to those products), subject to annual minimum payments of $2.75 million. Furthermore, a $5.0 million payment will be due to Ligand if cumulative sales of these products exceed $100 million and a second $5.0 million will be due if cumulative sales exceed $300 million during the ten-year term of the agreement which expires on May 31, 2027. The initial $5.0 million milestone payment became due in the second quarter of 2023.

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

- continued patient, physician and market acceptance of our products;
- the scope, rate of progress and cost of our current and future pre-clinical and clinical studies;
- the cost of our research and development activities and the cost and timing of commercializing new products or technologies;
- the cost and timing of expanding our sales and marketing capabilities;
- the cost of filing and prosecuting patent applications and maintaining, defending and enforcing our patent or other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights;
- the costs of defending against or the damages payable in connection with the FiberCel Litigation and any future litigation that we may be subject to (to the extent above the applicable insurance coverage);
- the cost and timing of additional regulatory approvals;
- costs associated with any product recall that may occur;
- the effect of competing technological and market developments;
- the expenses we incur in manufacturing and selling our products;

- the extent to which we acquire or invest in products, technologies and businesses in the future, although we may currently have no commitments or agreements relating to any of these types of transactions;
- the costs of operating as a public company;
- unanticipated general, legal and administrative expenses; and
- the effects on any of the above of the current COVID-19 pandemic or any other pandemic, epidemic or outbreak of infectious disease.

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

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

Critical Accounting Policies and Estimates

The preparation of our unaudited condensed consolidated financial statements in accordance with GAAP requires us to make estimates and assumptions that affect reported amounts and related disclosures. We have discussed the policies and estimates that we believe are critical and require the use of complex judgment in their application in our Annual Report, and, during the three and six months ended June 30, 2023, there were no material changes to those previously disclosed. Refer to Note 2, “Summary of Significant Accounting Policies,” to our condensed consolidated financial statements included elsewhere in this Quarterly Report for information regarding our critical accounting estimates and policies.

Recent Accounting Pronouncements

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

JOBS Act

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

effective dates for new or revised accounting standards that are applicable to public companies. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Interest Rate Risk

Our primary exposure to market risk relates to changes in interest rates. Borrowings under our SWK Loan Facility bear interest at variable rates, subject to an interest rate floor. Interest rate risk is highly sensitive due to many factors, including U.S. monetary and tax policies, U.S. and international economic factors and other factors beyond our control. A hypothetical 10% relative change in interest rates on our variable rate indebtedness outstanding at June 30, 2023 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 June 30, 2023, our cash was maintained with three financial institutions 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 these financial institutions have sufficient assets and liquidity to conduct their operations in the ordinary course of business with little or no credit risk to us.

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.

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, our Chief

Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of June 30, 2023.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended June 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

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

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. For example, we have commercial agreements with major medical device companies, including Boston Scientific, Biotronik, Sientra and LeMaitre Vascular. 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, has and could in the future materially and adversely affect our ability to generate revenue and profits.

One such partner, Surgalign Holdings, Inc. ("Surgalign") and certain of its direct and indirect subsidiaries commenced voluntary proceedings under chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of Texas on June 19, 2023. Total revenues generated by us from Surgalign during the six months ended June 30, 2023 and 2022 were $2.3 million and $2.5 million, respectively. Surgalign is in the process of selling its assets through the chapter 11 process, but our contract with Surgalign is not being assumed by the buyer of the relevant assets. Consequently, future revenues from our Surgalign relationship are highly uncertain.

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 adversely impact sales in that territory or result in harm to the reputation of the 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 believe is underperforming.

In order to increase our sales, 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, which, in turn, could materially and adversely affect our business, financial condition and results of operations.

The loss of one or more significant commercial partners, a material reduction in their purchases of our products, such as what we may experience with Surgalign, or their inability to perform their contractual obligations, including, for example, committed purchase requirements, has affected and could continue to 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.

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, in July 2023, we announced a voluntary recall of a single lot of a certain viable bone matrix product and the market withdrawal of all of our viable bone matrix ("VBM") products produced after a specified date ("VBM Matter"). Notice of the voluntary recall was issued to centers after the Company learned of post-surgical Mycobacterium tuberculosis (MTB) infections in two patients treated with a VBM product from a single donor lot. Prior to release, samples from this specific lot had tested negative for MTB by an independent laboratory using a nucleic acid test that is designed to specifically detect the MTB organism.

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. 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 us in connection with FiberCel. 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.

These product recalls and investigations, 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, and since September 2021, we have received notice of 109 separate lawsuits or claims alleging that the plaintiffs contracted tuberculosis and/or suffered substantial symptoms and complications following the implantation of FiberCel during spinal fusion operations. We have settled 27 of these lawsuits for a total of approximately $7.5 million as of June 30, 2023. Of these settled matters, 26 cases were both settled and paid as of June 30, 2023 for a total cash outlay of $7.3 million. For the remaining 82 cases for which settlements have not been reached, we estimated a probable loss related to each case and have recorded a liability at an estimated amount of $14.3 million for a total estimated liability at June 30, 2023 of $14.5 million, which is recorded as Contingent Liability for FiberCel Litigation in the accompanying condensed consolidated balance sheets included in this Quarterly Report. See Part II, Item 1, "Legal Proceedings" and Note 8 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

We are, and may in the future be, subject to product liability claims and lawsuits, including claims that may result from the VBM Matter noted above, and 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.

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 the Annual Report.

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. As of June 30, 2023, we have recorded insurance receivables of $8.9 million on our balance sheet in respect of our insurance coverage for the FiberCel Litigation product liability losses. However, it is possible that future claims related to the FiberCel Litigation or other product liability claims could exceed the limits of, or be excluded from, coverage under our policies, and claims against us could also increase the cost of maintaining our coverage. If these or other claims are excluded from our coverages, or 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.

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 EU member states and similar foreign agencies. Compliance with these regulatory requirements, including but not limited to the FDA's Quality System Regulation ("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 EU member states 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 or certified 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 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 and resulted in a number of lawsuits filed against us as discussed under the risk factor " *We face significant litigation related to FiberCel*" included in our Annual Report. Furthermore, in July 2023, we announced a voluntary recall of a single lot of a certain viable bone matrix product and the market withdrawal of all of our viable bone matrix ("VBM") products produced after a specified date ("VBM Matter"). Notice of the voluntary recall was issued to centers after we learned of post-surgical Mycobacterium tuberculosis (MTB) infections in two patients treated with a VBM product from a single donor lot. Prior to release, samples from this specific lot had tested negative for MTB by an independent laboratory using a nucleic acid test that is designed to specifically detect the MTB organism. The VBM Matter product recall has had and may continue to have, and any product recall we or a third-party manufacturer may conduct in the future, whether voluntary or required, could also have, a negative impact on 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 recently received a Nasdaq notice for failing to comply with listing requirements and there is no assurance we will regain compliance or maintain our Nasdaq listing.

On May 4, 2023, we received a letter from the Listing Qualifications Department of the Nasdaq Stock Market ("Nasdaq") informing us that, due to our Market Value of Listed Securities ("MVLS") having been below the minimum of $35 million for 30 consecutive business days, we are not in compliance with the MVLS required for continued listing on the Nasdaq Capital Market set forth in Nasdaq Listing Rule 5550(b)(2) (the "Market Value Standard"). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have a period of 180 calendar days from May 4, 2023, or until October 31, 2023, to regain compliance with the Market Value Standard. If we do not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock will be subject to delisting.

We intend to monitor our MVLS during the allotted compliance period, and may, if appropriate, evaluate available options to regain compliance by resolving the deficiency under the Market Value Standard, or under Nasdaq's alternative continued listing requirements. However, there can be no assurance that we will regain compliance with the Market Value Standard during the 180 day compliance period, secure an extension to the 180 calendar day period to regain compliance, or gain or maintain compliance under or with Nasdaq's other applicable listing requirements.

If we cannot regain compliance with the Market Value Standard or under Nasdaq's alternative continued listing requirements, and if our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell-side analysts

and might deter certain institutions and persons from investing in our securities at all. Delisting could also cause a loss of confidence of our collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

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.

During the three months ended June 30, 2023, none of our directors or officers (as defined in Rule 16a-1 under the Exchange Act) adopted or terminated any contract, instruction, or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement" (as defined in Item 408 of Regulation S-K).

Item 6. Exhibits.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
3.1	Restated Certificate of Incorporation of Aziyo Biologics, Inc.	8-K	001-39577	3.1	10/13/2020	
3.2	Amended and Restated Bylaws of Aziyo Biologics, Inc.	8-K	001-39577	3.2	10/13/2020	
4.1	Second Amended and Restated Investor Rights Agreement, dated as of March 14, 2020, among the Registrant and the investors named therein	S-1	333-248788	4.1	09/14/2020	
4.2	Specimen stock certificate evidencing the shares of Class A common stock	S-1	333-248788	4.2	09/14/2020	
4.3	Specimen stock certificate evidencing the shares of Class B common stock	S-1/A	333-248788	4.3	09/30/2020	
4.4	Warrant to Purchase Stock, issued on August 10, 2022, by Aziyo Biologics, Inc.to SWK Funding LLC.	8-K	001-39577	4.1	08/15/2022	
10.1†	Aziyo Biologics, Inc. Amended and Restated 2020 Incentive Award Plan	Proxy Statement	001-39577	Annex A	04/27/2023	
10.2	Distribution Agreement by and between Aziyo Biologics, Inc. and LeMaitre Vascular, Inc.					*
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*

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

* Filed herewith.

** Furnished herewith.

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

† Denotes a management contract or compensation plan or arrangement.

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: August 14, 2023

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

Date: August 14, 2023

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

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (i) NOT MATERIAL AND (ii) THE REGISTRANT CUSTOMARILY AND ACTUALLY TREATS THAT INFORMATION AS PRIVATE OR CONFIDENTIAL.

DISTRIBUTION AGREEMENT

This DISTRIBUTION AGREEMENT is entered into as of April 20, 2023 (the "Effective Date") by and between Aziyo Biologics, Inc., a Delaware corporation having a principal place of business at 12510 Prosperity Drive, Suite 370, Silver Spring, Maryland 20904 ("Supplier"), and LeMaitre Vascular, Inc., a Delaware corporation having a principal place of business at 63 Second Avenue, Burlington, Massachusetts 01803 ("Distributor").

Background

WHEREAS, Supplier has developed and manufactures certain Products (as defined herein); and

WHEREAS, Distributor desires to market, sell, and distribute the Products in the Territory (as defined herein) as an exclusive distributor for a period of time with an option to acquire Supplier's worldwide business of such Products;

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by each of the parties hereto, Supplier and Distributor agree as follows:

1. TERM & OPTION

1.1 Term. This Agreement shall commence on the Effective Date and expire three (3) years thereafter (the "Term"), unless (i) terminated earlier as set forth in Section 7, or (ii) extended by Supplier and Distributer by written agreement.

1.2 Option. Supplier hereby grants to Distributor the exclusive option (the "Option") to acquire the assets of the worldwide business of the Products, on the terms set forth on **Exhibit A** hereto, during the following time periods: (a) the period of time commencing on the first anniversary of the Effective Date and ending on the third anniversary of the Effective Date; and (b) upon and subsequent to Supplier or any successor entity of Suppler (i) failing to maintain the listing of its shares of capital stock on the Nasdaq Capital Market, (ii) being acquired, whether by an acquisition of the assets or a majority of the shares of Supplier by a Nasdaq-, NYSE or other publicly-listed or private entity or (iii) being in material breach of this Agreement, which breach, to the extent curable, is not cured by Supplier within five (5) business days following the date of notice by Distributor of such breach (the "Option Period"). If Distributor elects to exercise the Option, Distributor shall provide to Supplier written notice of Distributor's exercise of the Option during the Option Period and intent

to begin negotiations for entering into a binding acquisition agreement ("Acquisition Agreement"), to be negotiated by the parties in good faith. If Distributor does not exercise the Option during the Option Period, this Agreement and the Option shall expire at the end of the Term. Prior to expiration of the Option Period, Supplier: (i) shall not sell, convey, transfer or assign to any Person other than Distributor or its assignee any of the Purchased Assets as defined in **Exhibit A** or otherwise impair the ability of Distributor to exercise the Option and consummate the Acquisition Agreement and the transaction contemplated thereby, and (ii) shall provide full and prompt response to Distributor's diligence inquiries and requests and otherwise fully cooperate with Distributor in its diligence process.

2. APPOINTMENT OF EXCLUSIVE DISTRIBUTORSHIP

2.1. Exclusive Distributorship. Subject to the provisions of this Agreement, Supplier hereby appoints Distributor as the exclusive distributor to promote, market and sell the Products (set forth on **Exhibit B**) within the United States (the "Territory"). Distributor hereby accepts such appointment.

2.1.1. Distributor shall not (i) distribute Products outside of the Territory, (ii) solicit sales of Products outside of the Territory, or (iii) distribute any Products to any Person that it knows, has reason to know, or reasonably should know will resell, distribute or consume the Products outside of the Territory. All outstanding trunk stock of Products in the possession or control of Supplier's internal sales representatives or Supplier's independent sales agents shall be returned to Supplier by no later than May 15, 2023, and Supplier shall use commercially reasonable efforts to cause all other outstanding trunk stock of Products in the Territory to be returned to Supplier.

2.1.2. Supplier shall not (i) enter into agreements to distribute Products in the Territory, (ii) solicit sales of Products in the Territory, or (iii) enter into any agreements to distribute any Products to any Person that it knows, has reason to know, or reasonably should know will resell, distribute or consume the Products in the Territory. Commencing upon execution of this Agreement, Supplier shall (a) in accordance with the terms of the applicable agreement or authorization, terminate any agreement (or portion thereof) or authorization of its employees, distributors, sales representatives and authorized sales agents with respect to sales of Products in the Territory or where Supplier knows, or has reason to know, or reasonably should know that Products sold by such Person will be resold, distributed of consumed in the Territory, (b) cease to accept orders (other than by Distributor) with respect to sales of Products in the Territory or where Supplier knows, or has reason to know, or reasonably should know that Products sold by such Person will be resold, distributed of consumed in the Territory, (c) refer to Distributor any request for orders with respect to sales of Products in the Territory or where Supplier knows, or has reason to know, or reasonably should know that Products sold by such Person will be resold, distributed of consumed in the Territory, (d) as applicable, either cause Distributor to be admitted as a distributor pursuant to Supplier's existing hospital, group purchasing organization (GPO) agreements (the "GPO Agreements"), government and other customer agreements or transition Supplier's existing agreements with respect to sales of Products to Distributor and not adversely amend or terminate any such agreement to which Distributor is admitted without the prior written consent of Distributor, not

to be unreasonably withheld, conditioned or delayed. Prior to the termination of any such agreement or authorization, Supplier shall take all reasonable measures to ensure that neither it, nor any of its employees, distributors, sales representatives or independent sales agents engage in any practice in the Territory with the intent of increasing the levels of inventory of the Products in the distributor or sales channels outside of the ordinary course of business or in anticipation of entering into this Agreement with respect to the Products. Supplier shall remit to Distributor the gross profit realized by Supplier in accordance with U.S. generally accepted accounting practices consistently applied by Supplier with respect to any income recognized by Supplier subsequent to the date hereof with respect to Products sold or distributed in the Territory, other than to Distributor.

2.1.3. Notwithstanding anything to the contrary, Distributor acknowledges that the appointment granted hereunder does not impose any liability on Supplier if there are any currently ongoing active or passive sales, or marketing activities, relating to Products in the Territory by unauthorized third parties; provided, however, that such third parties are not acting on behalf of Supplier or otherwise authorized (expressly or impliedly) by Supplier, and Supplier has taken reasonable measures to terminate such sales and marketing activities; provided, further, that Supplier deliver a complete and accurate list of all such third parties of which it is aware as of the Effective Date and promptly notify Distributor of any such third parties of which Supplier it becomes aware during the Term of this Agreement.

2.1.4. Supplier reserves all rights not expressly granted herein. Supplier reserves the right to sell Products itself or through agents, distributors or other representatives to any parties for distribution and sale outside of the Territory; provided, however, Supplier shall not, directly or indirectly, (i) appoint as its distributor any Person to, nor shall itself, sell, distribute, market, promote or advertise Products in the Territory, (ii) solicit sales of Products in the Territory, (iii) distribute any Products to any Person that it knows, has reason to know, or reasonably should know will resell, distribute or consume the Products in the Territory, or (iv) authorize or license the use of any Supplier Intellectual Property Rights to a Person to manufacture, sell, distribute or market products that compete with the Products in the Territory.

3. PURCHASE AND SALE OF PRODUCTS

3.1. Purchase of Products. Subject to the terms and conditions set forth herein, Supplier agrees to sell and Distributor agrees to purchase Products in accordance with this Agreement. The purchase price for the Products (the "Product Price") shall be set forth on **Exhibit C**. [***] Supplier shall give Distributor at least ninety (90) days prior written notice of any change in the Product Price.

3.2. Ligand Royalties. Supplier is responsible, and shall remain responsible regardless of whether Distributor chooses to exercise the Option, for all royalty payments due pursuant to the Royalty Agreement dated as of May 31, 2017, by and between Aziyo Med, LLC and Ligand Pharmaceuticals Incorporated (the "Ligand Royalty Agreement"). Supplier represents, warrants, and covenants that there are no, and will not be other royalty or other

payments due to any Person associated with the sale or use of Products or Distributor's rights hereunder.

3.3. Initial Purchase. Distributor shall make an initial purchase of the Products at the volumes and prices set forth on **Exhibit C** (the "Initial Purchase"). The Supplier warrants that the ProxiCor Products and VasCure for Vascular Repair Products provided under the Initial Purchase will, unless otherwise noted by Supplier in the Purchase Order, have a Shelf Life of at least [***] and the Tyke Products will have a Shelf Life of at least [***] from the date each such Product is shipped to the Distributor, and that no Products delivered to Distributor under this Agreement shall be recycled, refurbished or otherwise not original manufactured Products. To the extent the ProxiCor Products and VasCure for Vascular Repair Products provided under the Initial Purchase have a Shelf Life of less than [***] and the Tyke Products have a Shelf Life of less than [***] from the date each such Product is shipped to the Distributor, Distributor shall have the right to cause Supplier to repurchase such Products from Supplier, at the same price paid by Distributor to Supplier for such Products, to the extent Distributor has not sold the Products.

3.4. Orders and Order Acceptance.

3.4.1. All Distributor orders for Products must be made pursuant to the terms and conditions of a signed written purchase order in the form attached hereto as **Exhibit D** (a "Purchase Order") and Supplier shall make each shipment of Product in the quantity and on the shipment date specified for it on the Purchase Order; provided, however, that the quantity of Products on such Purchase Order is within the volume of the rolling Supply Forecast provided in Section 3.7. Supplier will use commercially reasonable efforts to supply Products on a Purchase Order in excess of one hundred fifty percent (150%) of the applicable Supply Forecast. Distributor shall ensure that all ProxiCor Products and VasCure for Vascular Repair Products provided to Distributor subsequent to the Initial Purchase will have a Shelf Life of at least [***] and the Tyke Products will have a Shelf Life of at least [***] from the date each such Product is shipped to the Distributor, and that no Products delivered to Distributor under this Agreement shall be recycled, refurbished or otherwise not original manufactured Products.

3.4.2. Upon receipt of a shipment of Products from Supplier, Distributor will inspect such shipment to determine conformity with the "Supplier Quality Agreement", attached hereto as **Exhibit E** ("Initial Inspection"). The parties agree that such Initial Inspection cannot fully determine the functionality of the Products, the Products' conformance to specifications, or the presence or absence of any defects in material or workmanship. Distributor may reject any Products that do not satisfy the Initial Inspection; provided, however, that if Distributor does not notify Supplier in writing within [***] business days after receipt of a shipment of a problem with the shipment, such shipment will be deemed to conform with the Purchase Order solely as to type and quantity of Products. In the event of a conflict between the terms of this Agreement and any Purchase Order, the terms and conditions of this Agreement shall govern.

3.5. Invoicing. Supplier shall invoice Distributor for Products as of the date shipped by Supplier. Each invoice shall be payable by Distributor net [***] days from the date of receipt by Distributor of the invoice. Supplier may charge interest of [***] from the date of receipt by Distributor of such invoice.

3.6. Title and Risk of Loss. All Products shall be shipped FOB Burlington, Massachusetts, U.S.A.

3.7. Supply Forecasts. During the Term, Distributor shall provide to Supplier, on a calendar quarterly basis, within two (2) weeks after the first day of the current calendar quarter, a twelve-month rolling forecast of expected orders of Products beginning with the month following the month in which the forecast is delivered (the "Supply Forecast"), with the first Supply Forecast to be delivered to Supplier on or before thirty (30) days following the Effective Date. The forecast for the first two (2) months in each Supply Forecast shall be binding on both parties with respect to the Products described therein for such months, and the remainder of the Supply Forecast shall be non-binding on both parties. In the event that the Supply Forecast involves an increase of more than one and one-half (1.5) times the Supply Forecast of the previous calendar quarter, it shall be subject to acceptance by Supplier, which acceptance shall not be unreasonably delayed or withheld.

3.8. Samples. Within thirty (30) days of the Effective Date, Supplier will provide Distributor 84 ProxiCor Product samples and 84 VasCure for Vascular Repair Product samples, free of charge, for use solely in sales demonstrations, internal training and trade shows. Distributor may purchase additional samples of each of the Products at fifty percent (50%) of the prices specified in **Exhibit C**. Samples provided under this Section 3.8 may include trunk stock, expired, or nearly-expired Products.

3.9. Product Changes and Maintaining Value. Supplier shall continue to manufacture, have manufactured, and sell to Distributor pursuant to this Agreement any and all Products and Supplier shall not be entitled to change or discontinue the sale to Distributor pursuant to this Agreement, other than as provided herein, or the manufacture of any and all of Products without prior notice and written approval of Distributor. However, if Supplier's manufacturer experiences an event that would excuse performance under Section 14.12 (Force Majeure) of this Agreement ("Excusable Delay"), Supplier shall (i) promptly notify Distributor of an Excusable Delay upon its knowledge, and (ii) be treated as if Supplier itself experienced the Excusable Delay, and any delay in delivery of the Products shall be excused under Section 14.12. Supplier shall maintain the value of the Products and shall not create any lien, security interest or other adverse interest in or to the Products or that may diminish the value of any Product.

3.10. Training, Advice and Assistance. Within ten (10) days of the Effective Date and, if needed, periodically upon mutual agreement of the parties, Supplier will, at no cost to Distributor unless otherwise agreed by Supplier and Distributor, provide reasonable technical assistance and training regarding the Products for Distributor's representatives and will introduce Distributor's representatives to key customers.

3.11. Marketing. All business decisions concerning the marketing in the Territory of the Products, including the price, other sale terms, and promotion thereof, will be within the discretion of Distributor, provided, that from time to time, upon Supplier's reasonable request, Distributor shall consult with Supplier on material marketing decisions regarding the Products.

3.12. Deliverables. Upon the Effective Date, Supplier shall provide to Distributor (i) a complete customer list with contact information, sales history by date, SKU, units, and price by customer for sales of Products made since January 1, 2018 (preferably in an Excel format or other format to be mutually agreed); (ii) the current price list of Products; (iii) copies of all agreements with current customers in the Territory, including pricing agreements, and summaries of oral agreements, if any; (iv) a mutually agreed letter to customers in the Territory, signed by Supplier; (v) marketing materials in existence as of the Effective Date related to the Products to support Distributor's marketing activities; and (vi) the executed notice to send on the Effective Date to all of Supplier's current independent sales agents who are authorized to sell any Products in the Territory.

3.13. [***]

3.14. Product Support and Complaints. Supplier shall execute the Distributor's "Supplier Quality Agreement", attached hereto as **Exhibit E**. Distributor will forward all complaints regarding Products to Supplier, and Supplier shall be solely responsible for handling all such Product complaints and all associated reporting obligations to any regulatory authority and agency, including but not limited to the FDA, as required by applicable law. Supplier will provide a full report of all Product complaints to Distributor upon Distributor's request.

4. USE OF TRADEMARKS AND OTHER INTELLECTUAL PROPERTY

4.1. Trademark License. Supplier hereby grants to Distributor a fully paid up, royalty-free, non-transferable, non-sublicensable, non-exclusive, right and license to use the trademarks described on **Exhibit F** ("Trademarks") solely in connection with the promotion, marketing, sale, distribution and delivery of the Products in the Territory during the Term. Supplier shall take such actions as are reasonably required to maintain the Trademarks in effect and shall inform Distributor of any changes in or additions to the Trademarks. Except as expressly provided otherwise in this Agreement, nothing herein shall be deemed to grant to Distributor, either directly or by implication, estoppel, or otherwise, any license or rights to the Trademarks. All use of the Trademarks by Distributor and all goodwill developed therefrom will inure to the benefit and be on behalf of Supplier.

4.2. Use of Trademarks. Prior to the first use of any of the Trademarks in the manner permitted herein, Distributor shall submit a sample of such proposed use of Supplier's trademarks to Supplier for its prior written approval, not to be unreasonably withheld, conditioned or delayed. Once Supplier approves a particular use of a Trademark, the approval will remain in effect for such use until withdrawn with reasonable prior written notice. Without

limiting the generality of the foregoing, Distributor must strictly comply with all standards with respect to the Trademarks which may be furnished by Supplier from time to time, and all use of the Trademarks in proximity to the trade name, trademark, service name or service mark of any other Person must be consistent with the standards furnished by Supplier from time to time.

4.3. Patent License and Prosecution. Supplier shall prosecute and maintain, during the Term, any patents required for the Products (the "Patent Rights"), using counsel selected solely by Supplier. Supplier hereby grants to Distributor a fully paid up, royalty-free, non-transferable, non-exclusive, non-sublicensable right and license under the Patent Rights to offer for sale and sell the Products as purchased from Supplier in the Territory during the Term. Supplier and its counsel will be responsible for all decisions made for the prosecution and maintenance of the Patent Rights in Supplier's sole discretion. Payment of all fees and costs relating to the filing, prosecution and maintenance of the Patent Rights shall be the responsibility of Supplier. During the Term, Distributor shall not take any action, directly or indirectly, to invalidate, limit the scope of, or adversely affect the enforceability of the Patent Rights.

4.4. Infringement. Distributor will notify Supplier in writing of any infringement of a Patent Right or Trademark or unauthorized disclosure or use of any Confidential Information within thirty (30) days after it becomes aware of such infringement or unauthorized disclosure. Supplier shall have the exclusive right at its own cost to take all legal action it deems necessary or advisable to eliminate or minimize the consequences of any infringement of a Patent Right or Trademark. Supplier shall be entitled to all proceeds realized upon any judgment or settlement regarding an action undertaken pursuant to this Section 4.4.

4.5. **No Other Licenses**. Except as expressly set forth in this Agreement, Distributor will not acquire any license or other intellectual property right or interest, by implication or otherwise, under or to any Patent Rights, Trademarks or other intellectual property owned or controlled by Supplier. Supplier reserves all right, title and interest in and to the Patent Rights, Trademarks, and all other intellectual property not expressly granted to Distributor under this Agreement, and nothing in this Agreement shall limit Supplier's ability to use, or grant any right or license to any other individual or entity to use, the Patent Rights or manufacture, use, offer for sale, sell or engage in any other activity with respect to any Product or any other good or service, or otherwise practice under the Patent Rights. Distributor will not, and will not permit any of its affiliates to, practice outside the scope of the licenses granted to it under this Agreement.

5. REPORTING REQUIREMENTS

5.1. Reports to Supplier.

5.1.1. With respect to the period commencing on the Effective Date and ending on June 30, 2023 or such later date as may be mutually agreed by the parties, Distributor shall provide Supplier a sales report of Products sold during such period, with detail by quantity of each SKU, corresponding price and customer geography. The quarterly

sales report for the period ended June 30, 2023 must be delivered to Supplier via email no later than July 15, 2023.

5.2. Reports to Distributor.

5.2.1. Supplier shall provide Distributor a quarterly sales report of Products sold other than to Distributor during the such period, providing sufficient detail for Distributor to calculate gross profit realized by Supplier in accordance with U.S. generally accepted accounting practices consistently applied by Supplier with respect to any income recognized by Supplier subsequent to the date hereof with respect to Products sold or distributed in the Territory.

5.2.2. Upon termination of this Agreement and the payment by Supplier to Distributor with respect to all Products to be repurchased by Supplier upon termination of this Agreement, Distributor shall provide Supplier with a then-current customer list with respect to the Products.

5.3. Audit Rights.

5.3.1. Supplier shall have the right to audit Distributor's facilities, books and records to ascertain or confirm the correctness of any reports and the compliance by Distributor with the terms of this Agreement and Applicable Laws (defined below), rules and regulations. Distributor shall permit Supplier or its designee to examine such books and records upon five (5) business days' notice at facilities during normal business hours.

5.3.2. As may be reasonably related to the obligation of Supplier to remit gross profit to Distributor pursuant to Section 2.1.2, Distributor shall have the right to audit Supplier's facilities, books and records to ascertain or confirm the correctness of any reports and the compliance by Supplier with the terms of this Agreement and Applicable Laws (defined below), rules and regulations. Supplier shall permit Distributor or its designee to examine such books and records upon five (5) business days' notice at facilities during normal business hours.

6. COMPLIANCE WITH LAWS AND REGULATIONS; GOVERNMENTAL AUTHORIZATIONS

6.1. Regulatory Compliance. Supplier shall, at its expense, obtain, maintain and comply with at all times all regulatory requirements and approvals, including, without limitation, those issued by the United States Food and Drug Administration ("FDA"), necessary or useful to promote and sell the Products in the Territory. Supplier will manufacture the Products in accordance with (a) the specifications of the Product, and (b) other pertinent rules and regulations of the FDA.

6.2. Recall. If, in the reasonable judgment of Supplier or Distributor, any Product defect or any government action requires a recall of, or the issuance of an advisory letter regarding, any Product, either party may undertake such recall or issue such advisory letter after consultation with the other party. Each party shall notify the other party in a timely manner prior to making any recall or issuing any advisory letter. The parties shall endeavor to reach an agreement prior to making any recall or issuing any advisory letter regarding the manner, text and timing of any publicity to be given such matters in time to comply with

any applicable legal or regulatory requirements, but such agreement will not be a precondition to any action that either party deems necessary to protect users of the Products or to comply with any applicable governmental orders or mandates. The parties agree to provide commercially reasonable assistance to one another in the event of any recall or issuance of any advisory letter. Distributor shall maintain a traceability system that assures that in the event of a recall or field action involving a Product, each Product can be traced to the user of such Product.

6.3. Compliance with Laws. Distributor shall not at any time take any action which violates, and shall at all times comply with, any and all applicable laws, regulations and guidelines of all federal, state or local governmental bodies and agencies in the Territory pertaining to the sale, distribution, use, promotion, marketing, resale and use of the Products or otherwise ("Applicable Laws"). Distributor shall at no time engage in any unfair or deceptive trade practices with respect to the Products. Distributor shall not, by act or omission, misrepresent Supplier or any Product or mislead any Person concerning Supplier or any Product. Distributor shall not make any claims, representations, or warranties in connection with any Product, or any other claims, representations, or warranties, whether on behalf of Distributor or purportedly on behalf of any of Supplier, except if and to the extent expressly authorized in advance in writing by Supplier.

6.4. Anti-Bribery Laws. Distributor will comply at all times with, and shall not cause Supplier to violate, the provisions of the United States Foreign Corrupt Practices Act ("FCPA"), the U.S. Travel Act (to the extent applicable), the U.S. domestic bribery statute contained in USC §201 (to the extent applicable), and all other anti-corruption laws and regulations applicable to Distributor's business or the performance of this Agreement. Without limiting the generality of the foregoing, Distributor represents, warrants and covenants that it has not, and shall not at any time pay, give, or offer, promise, or authorize others to pay or give, any money (such as a bribe or kickback) or any other thing of value (such as an improper gift, hospitality, or favor), directly or indirectly to, or for the benefit of: (i) any employee, official, or agent of a government, a state-owned or affiliated entity or organization, a political party, a public international organization or an instrumentality thereof; (ii) a political party or candidate for political office; or (iii) any other Person, for the purpose of obtaining, retaining, or directing any business, regulatory approval, or other improper advantage, in connection with Distributor's business or the performance of this Agreement. Distributor shall cause its employees and contractors to comply with this provision. Distributor understands and acknowledges that any violation of this paragraph shall constitute a material breach and will Supplier to terminate this Agreement pursuant to Section 7.1.2.2 and/or seek all legal remedies, including, but not limited to, injunctive relief against as well as indemnities from Distributor for all related damages.

7. TERMINATION

7.1. Supplier's Termination Rights. Supplier shall have the right to terminate this Agreement and the Option upon delivery of written notice to Distributor:

7.1.1. Upon the insolvency of Distributor or any action causing Distributor to avail itself of laws for the protection of debtors, including, without limitation, the appointment of a receiver or the like, a complete or partial moratorium on payment of debt, a petition in bankruptcy or the like filed by or against Distributor, or an assignment of all or a portion of Distributor's assets for the benefit of its creditors; or

7.1.2. Upon the occurrence of any one or more of the following events, which event has not been cured within thirty (30) days after the written notice thereof to Distributor specifying the nature of the alleged default and referencing this Section 7.1:

7.1.2.1. Distributor infringes or causes any third party to infringe the Trademarks, Patent Rights or any proprietary rights of Supplier or Supplier's affiliates with respect to the Products;

7.1.2.2. Material breach of the Agreement by Distributor or Breach by Distributor of any of its obligations and/or representations and warranties, as applicable, under Sections 2.1, 3.13, 4.1, 4.3, 6.3, 6.4, 8, 11, 12, or 14.1 of this Agreement; or

7.1.2.3. Subject to Supplier's compliance with its obligations under Section 3.4 hereof, the failure of Distributor to purchase the following volume of Products, based on Product Purchase Price, during the applicable period specified below, or as purchased by Distributor within thirty (30) days after receiving notice from Supplier of such failure and directed by Distributor to be allocated to the applicable preceding period:

Minimum Period	**Minimum Purchase Volume of Licensed Products (by Product Price)**
October 1, 2023 through December 31, 2023	US $[***]
January 1, 2024 through March 31, 2024	US $[***]
Any four (4) quarter period following April 1, 2024	US $[***]

7.2. Distributor's Termination Rights. Distributor shall have the right to terminate this Agreement or the Option upon delivery of written notice to Supplier:

7.2.1. After a period of twelve (12) months following the Effective Date, for convenience upon delivery of sixty (60) days prior written notice to Supplier; or

7.2.2. Upon the insolvency of Supplier or any action causing Supplier to avail itself of laws for the protection of debtors, including, without limitation, the appointment of a receiver or the like, a complete or partial moratorium on payment of debt, a petition in bankruptcy or the like filed by or against Supplier, or an assignment of all or a portion of Supplier's assets for the benefit of its creditors; or

7.2.3. Upon the occurrence of any one or more of the following events, which event has not been cured within thirty (30) days after the written notice thereof to Supplier specifying the nature of the alleged default:

7.2.3.1. Material breach of the Agreement by Supplier or breach by Supplier of any of its obligations and/or representations and warranties, as applicable, under Sections 2.1, 3.1, 3.2, 3.9, 3.12, 3.13, 4.1, 4.3, 6, 8, 11, or 12 of this Agreement.

7.3. Effect of Termination or Expiration.

7.3.1. Upon any expiration of the Term without exercise of the Option or earlier termination of this Agreement for any reason, each Receiving Party shall promptly return to the Disclosing Party or destroy (together with a certification of destruction executed by an officer or director of Distributor) all copies of the Disclosing Party's Confidential Information in the possession or control of the Receiving Party.

7.3.2. Upon expiration of the Term without exercise of the Option or if the parties have failed to enter into a binding Acquisition Agreement and consummate the transactions thereunder within ninety (90) days of exercise of the Option, or upon termination of this Agreement by either Supplier or Distributor, [***]

7.4. Outstanding Liabilities. Notwithstanding expiration or termination of this Agreement, the parties shall each remain liable to the other for any indebtedness or other liability directly arising under this Agreement. If this Agreement is terminated, the due date of all unpaid or partially paid invoices shall be the earlier of the original date of the invoice or the date of the effectiveness of the termination. Invoices not paid within five (5) days after payment is due as set forth in the preceding sentence shall bear interest at the rate of 1.5% per month, or the maximum rate permitted by Applicable Law, whichever is lower.

7.5. Sections 7.4-7.5, and 9-12, 14 and 15 shall survive the termination or expiration of this Agreement.

8. REPRESENTATIONS AND WARRANTIES

8.1. In addition to the representations and warranties by the parties set forth herein, each party represents, warrants and covenants that:

8.1.1. It is a corporation duly formed, validly existing and in good standing;

8.1.2. It has all requisite corporate power and authority to execute, deliver and perform its obligations under this Agreement;

8.1.3. The execution, delivery and performance of this Agreement (i) has been duly authorized, and (ii) shall not conflict with, result in a breach of or constitute a default under any other agreement to which the party is bound; and

8.1.4. It is duly licensed, authorized or qualified to do business and is in good standing in the Territory.

8.2. Supplier hereby represents, warrants and covenants to Distributor that, as of the Effective Date and to Supplier's knowledge, (i) there is no pending or threatened claim, action, suit or proceeding involving a claim that the manufacture, distribution or sale of any Products, or the use of any materials to be provided by Supplier to Distributor hereunder, infringes or violates the intellectual property rights of any third person; (ii) the manufacture, distribution or sale of any Products or the use of any materials to be provided by Supplier to Distributor, does not infringe or violate the intellectual property rights of any third party; (iii) there is no recall or safety issue with regard to any Products which would reasonably be expected to impair the ability of Distributor to successfully market and sell any Products; (iv) it has good and unencumbered title or license to the Products delivered to Distributor hereunder; (v) other than the GPO Agreements and as set forth on Schedule 8.2(v), it is not a party to any agreement with a customer or other third party that includes a most-favored customer, pricing or other favorable consideration obligation with respect to any Product; and (vi) it has provided Distributor with a copy of each of its GPO Agreements, and the aggregate amount of fees paid and payable thereunder with respect to sales in calendar 2022 of Products for use in the Territory is approximately $80,000; and (vii) set forth on Schedule 8.2(vii) is a summary of product liability claims made against Supplier since January 1, 2021 with respect to any Product.

9. LIMITED WARRANTY

9.1. In addition to the express warranties by Supplier hereunder, Supplier warrants that Products supplied to Distributor hereunder shall: (a) conform to the Specifications, any documentation, and any materials published by Supplier with respect to each of the Products, and (b) be manufactured, labeled, packaged and tested (while in the possession or control of Supplier) in accordance with the applicable regulatory authorities, including those set forth in Section 6.1, and (c) be free from material defects in materials and workmanship. SUPPLIER MAKE NO FURTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND, NATURE OR DESCRIPTION, EXPRESS OR IMPLIED, BY STATUTE, COMMON LAW OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, OR FITNESS OF ANY OF THE PRODUCTS FOR ANY PARTICULAR PURPOSE AND HEREBY DISCLAIMS THE SAME.

10. LIMITATION OF LIABILITY; LIMITATION ON ACTIONS

10.1. NOTHING IN THIS AGREEMENT SHALL LIMIT OR EXCLUDE THE LIABILITY OF EITHER PARTY FOR: (A) DEATH, OR PERSONAL INJURY OR PROPERTY DAMAGE; (B) FRAUD OR FRAUDULENT MISREPRESENTATION; (C) GROSS NEGLIGENCE OR WILLFUL MISCONDUCT; (D) ANY OTHER LIABILITY THAT CANNOT BE EXCLUDED UNDER APPLICABLE LAW; AND (E) BREACH OF SECTION 1.2 (THE "EXCLUDED CLAIMS"). NEITHER PARTY'S LIABILITY FOR STRICT PRODUCT LIABILITY CLAIMS SHALL EXCEED TEN MILLION

DOLLARS ($10,000,000). OTHER THAN THE EXCLUDED CLAIMS AND CLAIMS FOR STRICT PRODUCT LIABILITY, IN NO EVENT WILL EITHER PARTY OR ITS RESPECTIVE AFFILIATES, OFFICERS, DIRECTORS, EMPLOYEES OR AGENTS, BE LIABLE FOR LOSS OF PROFITS, USE, BUSINESS, CUSTOMERS, FUTURE BUSINESS, CONTRACTS, ANTICIPATED SAVINGS, GOODWILL, REVENUE OR ANY WASTED EXPENDITURE (REGARDLESS OF WHETHER ANY OF THESE TYPES OF LOSS OR DAMAGE ARE DIRECT, SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL) OR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREUNDER REGARDLESS OF THE FORM OF ACTION (WHETHER FROM BREACH OF CONTRACT, BREACH OF WARRANTY, OR FROM NEGLIGENCE, STRICT LIABILITY, BREACH OF STATUTORY DUTY, LIABILITY UNDER INDEMNITIES, OR ANY OTHER FORM OF ACTION), EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, TO THE EXTENT PERMISSIBLE UNDER APPLICABLE LAW. OTHER THAN THE EXCLUDED CLAIMS, CLAIMS FOR STRICT PRODUCT LIABILITY AND CLAIMS PURSUANT TO SECTION 11.1.2(III), IN NO EVENT WILL EITHER PARTY'S TOTAL AGGREGATE LIABILITY (HOWEVER ARISING) UNDER, OUT OF OR IN CONNECTION WITH, OR TO THIS AGREEMENT, INCLUDING (BUT NOT LIMITED TO) LIABILITY FOR BREACH OF CONTRACT, MISREPRESENTATION (WHETHER TORTIOUS OR STATUTORY), TORT (INCLUDING BUT NOT LIMITED TO NEGLIGENCE), BREACH OF STATUTORY DUTY, LIABILITY UNDER INDEMNITIES, OR OTHERWISE, EXCEED THE SUM OF ALL AMOUNTS ACTUALLY PAID TO SUPPLIER BY DISTRIBUTOR DURING THE TWELVE (12) MONTH PERIOD IMMEDIATELY PRECEDING THE FIRST EVENT GIVING RISE TO LIABILITY. THIS LIMITATION OF LIABILITY IS CUMULATIVE, WITH ALL PAYMENTS BEING AGGREGATED TO DETERMINE SATISFACTION OF THE LIMIT. THE EXISTENCE OF TWO OR MORE CLAIMS OR SUITS WILL NOT ENLARGE THIS LIMIT. THE PARTIES ACKNOWLEDGE THAT THE TERMS AND CONDITIONS, INCLUDING THE PRICES, SPECIFIED IN THIS AGREEMENT REFLECT THE ALLOCATION OF RISK SET FORTH IN THIS AGREEMENT AND THAT NEITHER PARTY WOULD ENTER INTO THIS AGREEMENT WITHOUT THE FOREGOING LIMITATIONS OF LIABILITY AND THE WARRANTY DISCLAIMERS CONTAINED HEREIN. THE FOREGOING LIMITATIONS OF LIABILITY SHALL APPLY NOTWITHSTANDING THE FAILURE OF AN ESSENTIAL PURPOSE OF ANY PROVISION OR LIMITED REMEDY HEREIN.

10.2. No action, regardless of form, arising out of or in connection with the sale of Products under this Agreement (other than an action by Supplier for any amount due to Supplier from Distributor) may be brought more than one (1) year after the cause of action has arisen; provided, that (x) in the case of claims or actions for product liability, actions may also be brought until two (2) years after the product liability event, and (y) in the case of claims or actions relating to Supplier's manufacturers or Ligand related to the Patent Rights or the Ligand Royalty Agreement, no time limit shall apply such claims or actions. Notwithstanding the foregoing, any action asserted in writing by notice from the

applicable non-breaching party or Indemnified Party to the breaching party or Indemnifying Party prior to the expiration date of the applicable survival period (and any subsequent claim or claims based on substantially the same facts) shall not thereafter be barred by the expiration of the relevant period and such claims shall survive until finally resolved.

11. INDEMNIFICATION

11.1. Indemnification.

11.1.1. Distributor agrees to, at its expense, defend, indemnify and hold Supplier harmless from and against any and all claims, demands, liabilities, losses, costs and expenses (including, without limitation, reasonable attorneys' fees), irrespective of the theory upon which based (including, without limitation, negligence and strict liability), Supplier may suffer or incur as a result of any claims, demands or actions by third parties arising out of any acts or omissions of Distributor or any of its officers, directors, employees or agents, relating to: (i) the breach of any material provisions of this Agreement, (ii) Distributor's or any of its officers', directors', employees' or agents' fraud or gross negligence, (iii) representations or statements inconsistent with the Specifications or materials provided by Supplier to Distributor, or (iv) violation by Distributor (or any of its officers, directors, employees or agents) of any Applicable Laws.

11.1.2. Supplier agrees to, at its expense, defend, indemnify and hold Distributor harmless from and against any and all claims, demands, liabilities, losses, costs and expenses (including, without limitation, reasonable attorneys' fees), irrespective of the theory upon which based (including, without limitation, negligence and strict liability), the Distributor may suffer or incur as a result of any claims, demands or actions by third parties arising out of any acts or omissions of Supplier or any of its officers, directors, employees or agents, relating to: (i) the breach of any material provisions of this Agreement; (ii) violation by Supplier (or any of its officers, directors, employees or agents) of any Applicable Laws, or (iii) infringement, misappropriation or other violation of any third party right by the Products in the Territory, provided, with respect to the Trademarks, Distributor has utilized the Trademarks in compliance with the terms of this Agreement or as directed by Supplier.

11.1.3. A party or parties entitled to indemnification hereunder with respect to a third party claim (the "Indemnified Party") will give the party or parties required to provide such indemnification (the "Indemnifying Party") prompt written notice, but not later than thirty (30) days after the Indemnified Party learns of the Claim, of any legal proceeding, claim or demand instituted by any third party (in each case, a "Claim") in respect of which the Indemnified Party is entitled to indemnification hereunder. The Indemnifying Party shall have the right, at the Indemnifying Party's expense, to defend against, negotiate, settle or otherwise deal with such Claim provided that the Indemnifying Party provides written notice to the Indemnified

Party stating that the Indemnifying Party is responsible for the entire Claim within 10 days after the Indemnifying Party's receipt of written notice from the Indemnified Party of such claim, the Claim is not reasonably anticipated to have a material adverse effect on the Indemnified Party, the Claim does not relate to a dispute with a customer or business partner of the Indemnified Party, or the matter relates to any criminal proceeding, indictment or investigation. The Indemnified Party shall reasonably cooperate with the Indemnifying Party to facilitate the defense of any such Claim. The Indemnified Party may, at its option and expense, choose to participate in the defense of the Claim represented by counsel, reasonably satisfactory to the Indemnified Party. The Indemnified Party may take over the defense and prosecution of a Claim from the Indemnifying Party if the Indemnifying Party has failed or is failing to vigorously prosecute or defend such Claim. The Indemnifying Party may not enter into a settlement of any Claim unless such settlement provides solely for monetary damages for which the Indemnified Party is indemnified hereunder for the entirety of such monetary amount. The Indemnified Party may assume control of the settlement of a Claim if the Indemnifying Party fails or refuses to defend the Indemnified Party .

12. CONFIDENTIALITY

12.1. As used in this Agreement:

12.1.1. "Representatives" means a party's employees, officers, directors, affiliates, subcontractors, agents, actual and prospective lenders, investors, attorneys, accountants, successors and assigns; and

12.1.2. "Confidential Information" means any and all information disclosed by or on behalf of a party or any of its Representatives ("Disclosing Party") to the other party or any of its Representatives ("Receiving Party"), including information relating to the matters which are the subject of this Agreement, the terms, existence and nature of this Agreement, and all other information regarding Disclosing Party's past, present or future research, technology, know-how, ideas, concepts, designs, products, markets, computer programs, prototypes, processes, machines, manufacture, compositions of matter, business plans and operations, technical information, drawings, specifications, and the like, except information which is: (a) at the time of disclosure, or thereafter becomes, a part of the public domain through no act or omission by Receiving Party or its Representatives; (b) lawfully in the possession of Receiving Party prior to disclosure by or on behalf of Disclosing Party; (c) lawfully disclosed to Receiving Party by a third party which did not acquire the same under an obligation of confidentiality from or through Disclosing Party; or (d) independently developed by Receiving Party without use of or access to Disclosing Party's Confidential Information.

12.2. Receiving Party shall not: (i) without the prior consent of Disclosing Party, disclose any of Disclosing Party's Confidential Information to anyone for any reason at any time or use any of Disclosing Party's Confidential Information other than in furtherance of its rights and obligations under this Agreement, or (ii) by virtue of this Agreement, obtain any title to, or any interest or license in, any of Disclosing Party's Confidential Information. If

Receiving Party believes in good faith that it is: (y) required by the law or a competent regulatory authority, or (z) necessary to comply with the rules and regulations of any stock exchange, the NASDAQ Stock Market or the Securities and Exchange Commission (the "SEC"); to disclose any of Disclosing Party's Confidential Information, it shall provide notice to Disclosing Party, to the greatest extent possible, prior to making such disclosure so as to allow Disclosing Party time to undertake legal or other action to prevent such disclosure or otherwise obtain confidential treatment of such disclosure. In no event will Receiving Party disclose any of Disclosing Party's Confidential Information that Receiving Party is not compelled to disclose by law or a competent regulatory authority or to comply with the rules and regulations of any stock exchange, the NASDAQ Stock Market or the SEC, and Receiving Party will exercise reasonable efforts to obtain assurance that confidential treatment will be accorded to any of Disclosing Party's Confidential Information so disclosed. Each party acknowledges that the Disclosing Party's disclosure of Disclosing Party's Confidential Information (including that which is a process, machine, manufacture, or composition of matter) is not intended to be an offer for sale or public use.

Neither party shall issue a press release or other public announcement or public disclosure concerning the Agreement (or any term sheets, bids, quotes, proposals, negotiations or other related information), the transactions contemplated herein, or the relationships between the parties without the prior written approval of an authorized representative of the other party, which approval shall not be unreasonably withheld and provided that neither party shall have the right to approve the other parties disclosures that are required to comply with the rules and regulations of any stock exchange or the NASDAQ Stock market or the SEC. Except as set forth above, neither party shall use any word, name, logo, image, symbol, slogan, sample or design of the other party or any quote or statement from an employee, consultant or agent of the other party, in any written or oral advertisement, endorsement or other promotional materials without the prior approval of an authorized representative of the other party or as otherwise contemplated under this Agreement.

12.3. Neither party shall, nor shall it permit any of its Representatives, to: (i) disclose to the other party any confidential or proprietary information belonging to any third party without the consent of such party; or (ii) represent as being unrestricted any designs, plans, models, samples, or other writings or products that it or its Representative knows or has reason to know are covered by valid patent, copyright, or other form of intellectual property protection.

13. INSURANCE

13.1. Within thirty (30) calendar days after the Effective Date, for the remainder of the Term and for two (2) years after the termination or expiration of this Agreement, Distributor shall obtain and continuously maintain, at Distributor's sole cost and expense, comprehensive general liability insurance issued on an occurrence basis with broad form coverage, with limits not below two million dollars ($2,000,000) in the annual aggregate and one million dollars ($1,000,000) per occurrence for bodily injury liability, personal and advertising injury liability, products liability, property damage liability, contractual and incidental

contracts liability, errors and omissions liability and completed operations liability (the "Distributor Required Insurance"). Distributor shall name Supplier as additional insureds under such policy. Distributor shall provide Supplier with a certificate of insurance from the issuing insurance company evidencing the foregoing insurance, naming Supplier as additional insureds and providing that such insurance coverage may not be amended or terminated without thirty (30) days prior notice to and approval of Supplier. Renewal certificates of insurance must be filed prior to policy expiration so that a current certificate is on file at all times during the period specified above. If Distributor fails to provide a certificate of insurance evidencing the Distributor Required Insurance, in addition to other rights available, Supplier will have the right, but not the obligation, to purchase the Distributor Required Insurance at Distributor's expense. Any failure to demand such certificates or identify any deficiency in any of the Distributor Required Insurance coverage by Supplier shall not be deemed to be a waiver of Distributor's obligation to maintain such insurance.

13.2. Within thirty (30) calendar days after the Effective Date, for the remainder of the Term and for two (2) years after the termination or expiration of this Agreement, Supplier shall obtain and continuously maintain, at Supplier's sole cost and expense, comprehensive general liability insurance issued on an occurrence basis with broad form coverage, with limits not below two million dollars ($2,000,000) in the annual aggregate and one million dollars ($1,000,000) per occurrence for bodily injury liability, personal and advertising injury liability, products liability, property damage liability, contractual and incidental contracts liability, errors and omissions liability and completed operations liability (the "Supplier Required Insurance"). Supplier shall name Distributor as additional insureds under such policy. Supplier shall provide Distributor with a certificate of insurance from the issuing insurance company evidencing the foregoing insurance, naming Distributor as additional insureds and providing that such insurance coverage may not be amended or terminated without thirty (30) days prior notice to and approval of Distributor. Renewal certificates of insurance must be filed prior to policy expiration so that a current certificate is on file at all times during the period specified above. If Supplier fails to provide a certificate of insurance evidencing the Supplier Required Insurance, in addition to other rights available, Distributor will have the right, but not the obligation, to purchase the Supplier Required Insurance at Supplier's expense. Any failure to demand such certificates or identify any deficiency in any of the Supplier Required Insurance coverage by Distributor shall not be deemed to be a waiver of Supplier's obligation to maintain such insurance.

14. MISCELLANEOUS

14.1. Assignment. This Agreement, and each party's rights and obligations hereunder, shall not be assigned in whole or in part without the prior written authorization from the other party, and any such attempted assignment shall be void and of no effect. Notwithstanding the foregoing, written consent is not required for assignment of the entirety of either party's rights or delegation of the entirety of its duties to one or more affiliates, or to an acquiring or surviving entity in any merger or acquisition (regardless of the form of transaction including by merger, consolidation, reorganization, acquisition or sale of stock or assets, provided in each case that such assignee acknowledges to the other party its obligations

hereunder), provided that in each case the assigning party shall remain jointly bound by its obligations hereunder. All obligations of the parties herein shall be binding upon their respective successors and permitted assigns.

14.2. Choice of Law. This Agreement shall be governed, interpreted and construed in accordance with the internal substantive laws of the State of New York, United States of America. Any and all claims, controversies, and causes of action arising out of or relating to this Agreement and the relationship created thereby, whether sounding in contract, tort, statute or otherwise, shall be governed by the laws of the State of New York, including its statutes of limitations, without giving effect to any conflict-of-laws or other rule that would result in the application of the laws of any other jurisdiction.

14.3. Dispute Resolution.

14.3.1. The parties agree to attempt to resolve amicably on the basis of good faith negotiations, any dispute, difference or claim between the parties arising under or in connection with this Agreement, its performance, interpretation, application or validity ("Disputes"). In the event of a Dispute, the parties shall each nominate a representative to meet (either in person or telephonically) to engage in good faith negotiations to resolve the Dispute. If the representatives are unable to resolve any Dispute to their mutual satisfaction within thirty (30) days after they commence discussions regarding same, and do not agree to extend the time for resolution of the issue at the end of the thirty (30) day period, then either party may initiate alternative dispute resolution in accordance with subsection 14.3.2 of this Section. Except where the Agreement has been terminated for breach by either party under Section 7, both parties will continue their performance under this Agreement pending resolution of any Dispute.

14.3.2. In the event that Dispute cannot be resolved by good faith negotiations in accordance with subsection 14.3.1 of this Section, such Dispute shall be submitted for mediation under the Fast Track Mediation Rules of the International Institute for Conflict Prevention and Resolution ("CPR"). If such mediation fails, and a dispute still exists between the parties, any dispute arising out of or relating in any way whatsoever to this Agreement, or the interpretation, scope or enforcement of this arbitration provision shall be arbitrated privately and confidentially in New York, New York by three arbitrators mutually agreed to by the parties (or if none, appointed pursuant to the CPR Fast Track Arbitration Rules), and shall be administered by CPR and in accordance with CPR's Fast Track Arbitration Rules in existence at the time of the execution of this Agreement. The presentation of witnesses in the arbitration shall be in accordance with Mode A of Schedule 3 to the CPR Protocol on Disclosure of Documents and Presentation of Witnesses in Commercial Arbitration in existence at the time of the execution of this Agreement ("Mode A"). Should CPR be unavailable or unable to administer the arbitration, the parties shall submit their dispute privately and confidentially to another arbitral body (such as AAA, JAMS, etc.) or to a private arbitrator, provided, however, that the arbitration shall be conducted strictly in accordance with the CPR rules and

witness presentation protocol identified in this paragraph. Unless the parties agree otherwise, they shall be limited in their discovery to directly relevant documents.

14.3.3. The award of the arbitral tribunal shall be final and binding upon the parties and shall be the sole and exclusive remedy between the parties regarding any claims, counterclaims, issues, or requests for declaratory, accounting, or other relief presented to the arbitral tribunal. The costs of arbitration shall be apportioned by the arbitral tribunal in the award. The arbitral tribunal shall have the power to grant any remedy or relief that the arbitrators deem appropriate, including specific performance and penalties in the event of noncompliance of its orders or awards as well as interim, conservatory, or provisional measures, and any such measures may be enforced in a court of competent jurisdiction. The arbitral tribunal shall not decide as amiable compositeur or ex aequo et bono.

14.3.4. By agreeing to arbitration, the parties do not intend to deprive any court of its jurisdiction to issue an injunction, attachment or other interim measure in aid of arbitration prior to the constitution of the arbitral tribunal. A request for such provisional remedy or interim or conservatory measure by a party shall not be deemed a waiver of the agreement to arbitrate.

14.3.5. All arbitration proceedings shall be confidential and shall not be disclosed except as, and only to the extent, necessary to prepare for or conduct the arbitration hearing on the merits, as required by applicable law, or required in connection with any court application for interim relief or post-arbitration confirmation or enforcement proceedings. Any documentary or other evidence given by a party or witness in the arbitration shall be treated as confidential by any party whose access to such evidence arises exclusively as a result of its participation in the arbitration, and, except as may be required by applicable law, shall not be disclosed to any third party (other than a witness or expert, provided that such witness or expert agrees to maintain the confidentiality of the information).

14.4. Waiver. No waiver or breach of any term or condition of this Agreement shall operate as a waiver of any other breach of such term or condition, or of any other term or condition, nor shall any failure to enforce any provisions hereunder operate as a waiver of such provision or any other provision hereunder.

14.5. Severability. In case any one or more of the provisions contained in this Agreement shall for any reason be held to be invalid, illegal or unenforceable in any respect, except in those instances where removal or elimination of such invalid, illegal, or unenforceable provision or provisions would result in a failure of consideration under this Agreement, such invalidity, illegality or unenforceability shall not affect any other provision hereof, and this Agreement shall be construed as if such invalid, illegal or unenforceable provisions had never been contained herein.

14.6. Notices. All notices hereunder shall be in writing and shall be deemed to have been duly given if delivered personally, one day after delivery to a nationally recognized overnight

delivery service, charges prepaid, or three days after being sent by registered or certified mail, postage prepaid, to the parties at their respective addresses set forth above and:

If to Distributor, addressed to:
63 Second Avenue
Burlington, MA 01803
Attn: Legal Department
legal@lemaitre.com

If to Supplier, addressed to:

Attn: Matt Ferguson, Chief Financial Officer
12510 Prosperity Drive, Suite 370
Silver Spring, MD 20904
mferguson@aziyo.com
cc: legal@aziyo.com

or to such other address as any party shall have specified by notice to the other in accordance with this Section. Purchase orders, forecasts and other routine business forms (and any notices not sent in accordance with the foregoing) shall be effective only upon receipt.

14.7. Independent Contractors. Nothing set forth in this Agreement will be deemed to create a partnership, joint venture, or agency relationship between Distributor and Supplier. Distributor is an independent contractor and shall not represent itself as an employee, partner, representative or agent of Supplier.

14.8. No Other Terms and Conditions; Order of Priority. Unless the parties agree to the contrary in writing, the parties acknowledge and agree that any terms and conditions of any purchase order, sales acknowledgement or other document submitted to the other by either party which conflict with the terms and conditions of this Agreement shall be of no force or effect, and the terms and conditions hereof control and supersede such conflicting documents and any course of conduct or usage of the trade inconsistent with any of the terms and conditions hereof.

14.9. Headings. Headings used in this Agreement are for the purpose of reference only and are not to be considered in construction or interpretation of this Agreement.

14.10. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall be deemed one and the same instrument. The parties intend that facsimile signatures shall have the same binding effect as originals.

14.11. Entire Agreement; Amendment. This Agreement, including the Exhibits, contain the entire Agreement between the parties relating to the subject matter hereof. All prior agreements and all prior negotiations, representations and communications relating to the same subject

are superseded by this Agreement. This Agreement may not be modified other than by a written document signed by an authorized representative of each party.

14.12. Force Majeure. Supplier shall not be liable for any delay in the delivery of any Products resulting from any cause or circumstance which is not within the control of Supplier, including but not limited to acts of God, acts of Distributor, acts or orders of governmental authorities having or asserting jurisdiction, fires, floods, transportation delays and interruptions as the result of strikes, lockouts, riots or civil disturbances, war, or manufacturer shortages. Distributor shall not be liable for any delay in the performance of its obligations hereunder resulting from acts of God, breaches of this Agreement by Supplier, acts or orders of governmental authorities having or asserting jurisdiction, fires, floods, unavoidable transportation delays and interruptions as the result of riots or civil disturbances, war, or unavoidable shortages.

15. CERTAIN DEFINITIONS

In addition to defined terms included in other sections of this Agreement, when used here, the following capitalized terms shall have the following definitions:

15.1. "Net Sales" means revenue recognized by Distributor or Supplier, as applicable, in the applicable period in accordance with U.S. generally accepted accounting principles consistently applied by such Person, net of returns, allowances and refunds.

15.2. "Person" means any natural person or any corporation, partnership, limited liability company, business association, joint venture or other entity.

15.3. "Product" means the ProxiCor Products, the Tyke Product and the VasCure for Vascular Repair Products collectively and individually.

15.4. "ProxiCor for Cardiac Tissue Repair Product" shall mean the product currently distributed by Supplier as its "ProxiCor for Cardiac Tissue Repair" product.

15.5. "ProxiCor for Pericardial Closure Product" shall mean the product currently distributed by Supplier as its "ProxiCor for Pericardial Closure" product.

15.6. "ProxiCor Product" shall mean the ProxiCor for Pericardial Closure Product and the ProxiCor for Cardiac Tissue Product, collectively.

15.7. "Shelf Life" means with respect to a Product the time remaining from the date of shipment of such Product by Supplier to Distributor and the expiration date on the corresponding inventory schedule maintained in the ordinary course of business by Supplier.

15.8. "Specifications" means the specifications for applicable Product as approved by the Food and Drug Administration in the 510(k) clearance applicable to the Product.

15.9. "Tyke Product" shall mean the product currently distributed by Supplier as its "Tyke" product.

15.10. "VasCure for Vascular Repair Product" shall mean the product currently distributed by Supplier as its "VasCure for Vascular Repair" product.

[signature page follows]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective duly authorized representatives the day and year first set forth above:

AZIYO BIOLOGICS, INC.

By: /s/ Matt Ferguson
Name:
Title:

LEMAITRE VASCULAR, INC.

By: /s/ Dave Roberts
Name:
Title:

Schedule 8.2

[***]

(vii)

- None

Exhibit A

OPTION TERMS

Parties:	LeMaitre Vascular, Inc. ("Distributor") Aziyo Biologics, Inc. ("Supplier")
Products:	1. ProxiCor for Pericardial Closure Product 2. ProxiCor for Cardiac Tissue Repair Product 3. Tyke Product 4. VasCure for Vascular Repair Product and the ex-US version thereof marketed currently as "VasCure for Carotid Repair"
Structure:	Asset purchase
Purchased Assets:	All right, title and interest of Supplier with respect to the Products and assets used primarily with respect to the Products (collectively, the "Purchased Assets"), including, without limitation: [***] ● Distribution, supplier, manufacture and customer agreements with respect to the Products that Distributor elects to assume (the "Commercial Agreements"); [***] Unless otherwise agreed by Distributor, all Purchased Assets will be delivered by Supplier to Distributor FOB at Distributor's offices in Burlington, Massachusetts on the Closing Date.
Purchase Price and Payment:	"Purchase Price" to equal the greater of (a) $[***] million and (b) [***] times the last 12 months' worldwide Net Sales of the Products (equal to Distributor's Net Sales of the Products in the United States plus Supplier's Net Sales of Products outside the United States during the 12 months immediately prior to the date of the option exercise notice). The Purchase Price would also serve as consideration for transition services, which Supplier would provide pursuant to a mutually agreed transition services agreement (the "Transition Services Agreement"), as described below. [***]
Transition Period:	As a condition to Closing, the parties shall enter into a Transition Services Agreement providing for the following: [***]
Employees:	[***]

Non-Compete:	[***]
Liabilities:	The sole liabilities of Supplier to be assumed are those pursuant to the Commercial Agreements that Distributor elects to assume. Distributor would not assume any other liabilities of Supplier, including any obligation to pay Ligand royalties (collectively, the "Excluded Liabilities"). Supplier would agree to discharge the Excluded Liabilities in accordance with their terms.
Reports:	[***]
Expenses:	Supplier and Distributor will be responsible for the payment of their respective expenses and professional fees incurred in connection with the negotiation and consummation of the acquisition.
Other:	● Representations, warranties, indemnity, confidentiality, and closing conditions customary for a transaction of this nature will be included in the definitive documentation. ● Supplier would agree to indemnify Distributor for losses arising out of breaches of representations, warranties and covenants, pre-closing liabilities of Supplier subject to other customary indemnification terms (such as a basket, cap, and sunset period), all of which will be finalized in connection with the negotiation of the asset purchase agreement.

Exhibit B

PRODUCTS

1. **ProxiCor for Pericardial Closure Product**

2. **ProxiCor for Cardiac Tissue Repair Product**

3. **Tyke Product**

4. **VasCure for Vascular Repair Product**

Exhibit C

PURCHASE PRICE

Product ID	Model #	Description	Transfer Price per unit	Transfer Price per pack
FP-20054-10	CMCV-060-402	ProxiCor for Pericardial Closure, Single Pack, 7 x 15 cm	[***]	[***]
FP-20055-02	CMCV-003-402	ProxiCor for Pericardial Closure, Five Pack, 7 x 15 cm	[***]	[***]
FP-20054-09	CMCV-059-401	ProxiCor for Pericardial Closure, Single Pack, 7 x 10 cm	[***]	[***]
FP-20055-01	CMCV-003-401	ProxiCor for Pericardial Closure, Five Pack, 7 x 10 cm	[***]	[***]
FP-20060-11	CMCV-064-401	ProxiCor for Cardiac Tissue Repair, Single Pack, 7 x 10 cm	[***]	[***]
FP-20061-01	CMCV-004-401	ProxiCor for Cardiac Tissue Repair, Five Pack, 7 x 10 cm	[***]	[***]
FP-20060-12	CMCV-067-404	ProxiCor for Cardiac Tissue Repair, Single Packs, 4 x 7 cm	[***]	[***]
FP-20061-04	CMCV-004-404	ProxiCor for Cardiac Tissue Repair, Five Pack, 4 x 7 cm	[***]	[***]
FP-20436-09	CMCV-013-609	VasCure for Vascular Repair, Single Pack, 1 x 10 cm	[***]	[***]
FP-20437-09	CMCV-014-609	VasCure for Vascular Repair, Five Pack, 1 x 10 cm	[***]	[***]
FP-20436-06	CMCV-011-606	VasCure for Vascular Repair, Single Pack, 2 x 10 cm	[***]	[***]
FP-20437-06	CMCV-012-606	VasCure for Vascular Repair, Five Pack, 2 x 10 cm	[***]	[***]
FP-20513-01	CMCV-098-204	Tyke®, Single Pack, 4 x 7 cm	[***]	[***]
FP-20513-02	CMCV-099-204	Tyke®, Five Pack, 4 x 7 cm	[***]	[***]

INITIAL PURCHASE ORDER QUANTITIES

[***]

Exhibit D

FORM OF PURCHASE ORDER

PO#

Vendor ID:
Company:
Address:

City,
State,
Zip: **Tel:** **Fax:** **Tel: 781-425-1690** **Fax: 781-425-6295**

Date: **Terms:**

Line #	Catalog # /Vendor #	Product Description	Qty	Unit Price	Line Total

Requested by: **Promised by:**

Comments:

Subtotal

Trade Discount
Miscellaneous
Tax

Total

Exhibit E

SUPPLIER QUALITY AGREEMENT

This Supplier Quality Agreement (this "Agreement") is made and entered into this 20th day of April, 2023 (the "Effective Date") by and between **Aziyo Biologics, Inc.**, a company organized and existing under the laws of Maryland with offices located at 12510 Prosperity Drive, Suite 370, Silver Spring, MD 20904 ("**Aziyo**") and **LeMaitre Vascular, Inc.**, a Delaware corporation with offices located at 63 Second Avenue, Burlington, MA 01803 ("**Company**"). Each of Aziyo and Company is a "Party" and together, "Parties" to this Agreement. For issues not addressed in this document, refer to the Distribution Agreement ("DA") between Aziyo and Company dated 20th April 2023. To the extent that the terms of this Quality Agreement conflict with the terms otherwise provided in the DA, the terms of the DA shall supersede those terms in this Quality Agreement.

WHEREAS, Aziyo manufactures, packages and sells **Biological Patches (Product)**, as described in the DA, to Company for sale by Company to third parties; and

WHEREAS, Company desires to purchase such Product from Aziyo under the DA and terms and conditions herein set forth.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. TERM

1.1 This Quality Agreement shall remain in place until the termination of the DA.

2. TECHNICAL SPECIFICATIONS

2.1. **Design Specifications**: Aziyo is responsible for all product design specifications.

2.2. **Product Labeling**: Aziyo is responsible for design and manufacture of all product labeling (product affixed, packaging labeling, IFU's).

3. REGULATIONS

3.1. **Regulatory**: Aziyo shall maintain throughout the term of this Quality Agreement all permits, registrations, approvals, and authorizations as may be required to manufacture, promote, market, distribute, and sell Products in accordance with the terms of the DA. Company shall respond in a timely and efficient manner with all reasonable requests from Aziyo for documentation or other support needed for Aziyo to comply with this Section 3.1. During the term hereof, Aziyo will maintain or cause to be maintained the Product manufacturing facility's registration with the FDA and other regulatory agencies, as applicable, as a medical device manufacturing facility and will maintain such facility registration with all applicable regulatory authorities or cause such facility to be maintained such that the facility would pass a FDA audit for compliance with GMP and QSR.

3.2. **Reporting**: Each Party shall notify the other Party in writing within five (5) business days of

notice of any Product issue or incident involving Product, including those which, according to any applicable regulatory authority, require notification of such issue or incident to said authority. If either Party receives a complaint, oral or written, regarding any of the Products from a third party, Aziyo will make a preliminary evaluation of such a complaint for reportability and (i) Company will be responsible facilitating all customer contact regarding the incident and (ii) Aziyo will be responsible for all regulatory contact regarding the incident. The Parties will communicate and coordinate with each other all known information surrounding the third-party report. Company will be responsible for all final reports to customer(s), arranging for Product returns, and follow-up communication with the customer(s), and Aziyo will be responsible for conducting the complaint investigation and follow-up communication with the applicable regulatory agencies, as well as maintenance of complaint files in accordance with regulatory requirements. Company retains a right to review any final reports.

3.3. **Manufacturing**: Aziyo shall manufacture the Product in accordance with (i) the Specifications, (ii) applicable regulations relating to current Good Manufacturing Practices and similar protocols ("GMP"), quality system regulations of the FDA ("QSR"), including master device and lot history records, ISO 13485 requirements (including appropriate certification),
(iii) other applicable rules and regulations of the FDA, and (iv) Aziyo's standard quality assurance policies. During the term hereof, Aziyo shall maintain all ongoing quality assurance and testing procedures required to comply with applicable regulatory requirements. For a period of the longer of five (5) years after delivery to Company of each Product, or such longer period as may be required by GMP and other applicable rules and regulations of any regulatory authority, Aziyo shall (x) maintain traceability for each Product including the manufacturing date and lot number of each unit of Product and each component and material comprising each Product, (y) provide to Company a copy of such records without charge upon Company's request and (z) maintain records subject to 21 CFR 820 Subpart M, such as the Device Master Record, quality system record, and complaint files. Aziyo shall include in each shipment of Product to Company a Certificate of Conformance (COC). Company shall respond in a timely and efficient manner to all reasonable requests from Aziyo for documentation or other support needed for Aziyo to comply with this Section 3.3.

3.4. **Audits**: Aziyo shall provide to Company, or its third party auditor, access to its manufacturing facilities for the purpose of quality system compliance audits provided reasonable advance notice is given to Aziyo, once per year during the term of this Quality Agreement. Each Company audit may not exceed three business days. Additionally, Aziyo agrees to provide access to regulatory agencies, and notified bodies at Company's request when reasonable notice is provided to the extent practicable. This Section 3.4 shall apply only to the extent related to the Products manufactured and sold to Company hereunder.

3.5. **Provisions for Recall**: Each of the Parties hereto agrees to notify the other in writing within forty-eight (48) hours in the event either identifies a potential need for a Product recall. In the event of a recall or market withdrawal that is determined to be necessary by Aziyo or any regulatory authority, whether voluntary or involuntary, Aziyo shall be responsible for the conduct of any such recall or withdrawal from hospitals, customers and/or end users at Aziyo's sole cost and expense; however, the Parties will discuss and cooperate with each other as to the communications with any customers and regulatory authorities, in order to minimize the risk

to any Party of a failure to follow legal requirements for such recall or withdrawal. Company will maintain complete and accurate records of all Products sold by it, for such period as may be required by applicable law, at least equivalent to the shelf-life of the applicable Product, but not less than two years from the date of expiry. In the event of any recall of any Product (whether voluntary, required by the FDA or any other governmental authority, or resulting from any device notification or safety alert), Aziyo shall, in addition to any other obligations to Company or a user of the Products, accept the return of the Product in accordance with Section 3.5 hereof. Aziyo shall, in addition and to the extent they relate directly to matters for which Aziyo is responsible hereunder, via applicable law or as a result of its negligence, reimburse Company for reasonable costs and expenses incurred by Company directly associated with: (a) the initial shipments of the recalled Products, and (b) customers' return of the recalled Products and shipment of replacement Products to customers, (c) any fines, damages, fees (including reasonable attorney's fees), expenses or other costs incurred by Company in conjunction with the recall directly through Claims brought by customers or government agency. Aziyo shall use its reasonable efforts to correct, as promptly as is practicable, problems or other issues that result in recalls (other than recalls resulting from the acts or omissions of Company).

3.6. **Return of Products**: Under the following circumstances, Company may return a Product purchased hereunder: if the Product fails to comply with the limited warranty set forth in Section 9 of the DA, if shipped in error by Aziyo, or if subject to a recall or field action. In the event of return of a Product purchased hereunder, Aziyo shall (i) replace the Product at its sole expense; or (ii) refund the full Product Price for the returned Product plus the costs of freight borne by Company (if borne by Company) to return the Product; provided, however, that after the expiration or earlier termination of this Agreement, Aziyo will perform option (ii). To return a Product, Company shall notify Aziyo in writing or by email of its rejection with detailed explanation and request a Returned Goods Authorization ("RGA") number. Upon issuance of a Return Goods Authorization (RGA) number by Aziyo, which shall not be unreasonably withheld, Company may then return the applicable Product(s) to Aziyo, freight prepaid by Aziyo, within thirty (30) days of the date of issuance of the RGA. The Product must be returned in its original shipping carton, if unused, with the RGA number included on the outside of the shipping carton to receive credit, refund, or replacement. Credit value at the paid Product Price plus any cost of freight will be issued, or during the term of the Agreement, only replacement Product will be provided, for returns meeting the above conditions after inspection of the returned Product by Aziyo.

4. MISCELLANEOUS

4.1. **Assignment**: A Party's rights and obligations under this Agreement may not be transferred or assigned directly or indirectly without the prior written consent of the other Party. Subject to the foregoing sentence, this Agreement shall be binding upon and inure to the benefit of the Parties hereto and their successors in law (including administrators) and assigns. For purposes of this Section 4.1, the term "assignment" shall include the consolidation or merger of a party with and into a third party or the sale of all or substantially all of the assets or business of a party. Any attempted assignment in violation of this Section 4.1 shall be null and void.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement effective as of the date set forth above.

	LEMAITRE VASCULAR, INC.	**AZIYO BIOLOGICS, INC.**
Signature	/s/ Agustin Turriza	/s/ Erica Elchin
Printed Name	**Agustin Turriza**	**Erica Elchin**
Title	**Director, Quality Affairs**	**VP, Global Operations**

Exhibit F

TRADEMARKS

Aziyo
ProxiCor
Tyke
VasCure

Exhibit 31.1

CERTIFICATIONS

I, C. Randal Mills, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023 of Aziyo Biologics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2023

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

Exhibit 31.2

CERTIFICATIONS

I, Matthew Ferguson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023 of Aziyo Biologics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2023

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

Exhibit 32.1

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

In connection with the Quarterly Report of Aziyo Biologics, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2023

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

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

Exhibit 32.2

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

In connection with the Quarterly Report of Aziyo Biologics, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2023

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

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