UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 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: 1-13165

ARTIVION, INC.

(Exact name of registrant as specified in its charter)

Delaware	**59-2417093**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1655 Roberts Boulevard, NW, Kennesaw, Georgia	**30144**
(Address of principal executive offices)	(Zip Code)

(770) 419-3355
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	AORT	New York Stock Exchange

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 ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at October 27, 2023
Common Stock, $0.01 par value	41,048,608

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Part I – FINANCIAL INFORMATION

Item 1. Financial Statements.

Artivion, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations and Comprehensive Loss
In Thousands, Except Per Share Data
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Products	$ 63,747	$ 55,248	$ 192,041	$ 171,726
Preservation services	24,107	21,590	68,293	62,665
Total revenues	**87,854**	**76,838**	**260,334**	**234,391**
Cost of products and preservation services:				
Products	21,574	17,743	62,084	53,381
Preservation services	10,010	10,351	30,169	29,375
Total cost of products and preservation services	**31,584**	**28,094**	**92,253**	**82,756**
Gross margin	**56,270**	**48,744**	**168,081**	**151,635**
Operating expenses:				
General, administrative, and marketing	51,093	41,051	158,699	118,989
Research and development	6,421	11,799	21,062	30,575
Total operating expenses	**57,514**	**52,850**	**179,761**	**149,564**
Gain from sale of non-financial assets	—	—	(14,250)	—
Operating (loss) income	**(1,244)**	**(4,106)**	**2,570**	**2,071**
Interest expense	6,603	4,805	19,055	12,854
Interest income	(339)	(40)	(679)	(86)
Other expense, net	1,911	3,661	5,189	7,564
Loss before income taxes	**(9,419)**	**(12,532)**	**(20,995)**	**(18,261)**
Income tax expense	382	1,181	5,720	3,100
Net loss	**$ (9,801)**	**$ (13,713)**	**$ (26,715)**	**$ (21,361)**
Loss per share:				
Basic	**$ (0.24)**	**$ (0.34)**	**$ (0.65)**	**$ (0.53)**
Diluted	**$ (0.24)**	**$ (0.34)**	**$ (0.65)**	**$ (0.53)**
Weighted-average common shares outstanding:				
Basic	40,881	40,115	40,691	39,999
Diluted	40,881	40,115	40,691	39,999
Net loss	**$ (9,801)**	**$ (13,713)**	**$ (26,715)**	**$ (21,361)**
Other comprehensive loss:				
Foreign currency translation adjustments	(5,010)	(16,895)	432	(35,466)
Comprehensive loss	**$ (14,811)**	**$ (30,608)**	**$ (26,283)**	**$ (56,827)**

See accompanying Notes to Condensed Consolidated Financial Statements

Artivion, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
In Thousands

	September 30, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 53,481	$ 39,351
Trade receivables, net	64,277	61,820
Other receivables	3,993	7,764
Inventories, net	78,792	74,478
Deferred preservation costs, net	49,391	46,371
Prepaid expenses and other	17,175	17,550
Total current assets	**267,109**	**247,334**
Goodwill	242,936	243,631
Acquired technology, net	142,675	151,263
Operating lease right-of-use assets, net	43,345	41,859
Property and equipment, net	37,428	38,674
Other intangibles, net	29,398	31,384
Deferred income taxes	3,705	1,314
Other assets	8,191	7,339
Total assets	**$ 774,787**	**$ 762,798**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 10,819	$ 12,004
Accrued compensation	13,861	13,810
Accrued expenses	9,930	12,374
Taxes payable	9,390	2,635
Current maturities of operating leases	3,940	3,308
Accrued procurement fees	1,860	2,111
Current portion of long-term debt	1,552	1,608
Other liabilities	3,607	1,825
Total current liabilities	**54,959**	**49,675**
Long-term debt	305,877	306,499
Contingent consideration	62,300	40,400
Non-current maturities of operating leases	42,862	41,257
Deferred income taxes	19,514	24,499
Deferred compensation liability	6,460	5,468
Non-current finance lease obligation	3,272	3,644
Other liabilities	7,568	7,027
Total liabilities	**$ 502,812**	**$ 478,469**
Commitments and contingencies		
Shareholders' equity:		
Preferred stock	—	—
Common stock (75,000 shares authorized, 42,537 and 41,830 shares issued and outstanding in 2023 and 2022, respectively)	425	418
Additional paid-in capital	351,307	337,385
Retained deficit	(43,932)	(17,217)
Accumulated other comprehensive loss	(21,177)	(21,609)
Treasury stock, at cost, 1,487 shares as of September 30, 2023 and December 31, 2022	(14,648)	(14,648)
Total shareholders' equity	**271,975**	**284,329**
Total liabilities and shareholders' equity	**$ 774,787**	**$ 762,798**

See accompanying Notes to Condensed Consolidated Financial Statements

Artivion, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
In Thousands
(Unaudited)

	Nine Months Ended September 30,	
	2023	**2022**
Net cash flows from operating activities:		
Net loss	$ (26,715)	$ (21,361)
Adjustments to reconcile net loss to net cash from operating activities:		
Change in fair value of contingent consideration	21,900	(4,600)
Depreciation and amortization	17,260	17,016
Non-cash compensation	10,466	9,189
Non-cash lease expense	5,467	5,656
Fair value adjustment of long-term loan	5,000	—
Write-down of inventories and deferred preservation costs	3,726	3,116
Deferred income taxes	(7,250)	5,097
Gain from sale of non-financial assets	(14,250)	—
Other	2,325	1,523
Changes in operating assets and liabilities:		
Receivables	765	(10,900)
Accounts payable, accrued expenses, and other liabilities	412	(2,103)
Prepaid expenses and other assets	(527)	(1,788)
Inventories and deferred preservation costs	(10,592)	(5,781)
Net cash flows provided by (used in) operating activities	**7,987**	**(4,936)**
Net cash flows from investing activities:		
Proceeds from sale of non-financial assets, net	14,250	—
Payments for Endospan Agreement	(5,000)	—
Capital expenditures	(5,503)	(6,924)
Other	(1,580)	(1,123)
Net cash flows provided by (used in) investing activities	**2,167**	**(8,047)**
Net cash flows from financing activities:		
Proceeds from financing insurance premiums	3,558	—
Proceeds from exercise of stock options and issuance of common stock	3,467	3,344
Redemption and repurchase of stock to cover tax withholdings	(563)	(1,791)
Principal payments on short-term notes payable	(1,522)	—
Repayment of term loan	(2,063)	(2,033)
Other	(382)	(300)
Net cash flows provided by (used in) financing activities	**2,495**	**(780)**
Effect of exchange rate changes on cash and cash equivalents	1,481	(3,675)
Increase (decrease) in cash and cash equivalents	**14,130**	**(17,438)**
Cash and cash equivalents beginning of period	39,351	55,010
Cash and cash equivalents end of period	**$ 53,481**	**$ 37,572**

See accompanying Notes to Condensed Consolidated Financial Statements

Artivion, Inc. and Subsidiaries
Condensed Consolidated Statements of Shareholders' Equity
In Thousands
(Unaudited)

	Common Stock		Additional Paid-In Capital	Retained Deficit	Accumulated Other Comprehensive Loss	Treasury Stock		Total Shareholders' Equity
	Shares	Amount				Shares	Amount	
Balance at June 30, 2023	**42,443**	**$ 424**	**$ 347,030**	**$ (34,131)**	**$ (16,167)**	**(1,487)**	**$ (14,648)**	**$ 282,508**
Net loss	—	—	—	(9,801)	—	—	—	(9,801)
Other comprehensive loss	—	—	—	—	(5,010)	—	—	(5,010)
Equity compensation	8	—	3,392	—	—	—	—	3,392
Employee stock purchase plan	86	1	885	—	—	—	—	886
Balance at September 30, 2023	**42,537**	**$ 425**	**$ 351,307**	**$ (43,932)**	**$ (21,177)**	**(1,487)**	**$ (14,648)**	**$ 271,975**

	Common Stock		Additional Paid-In Capital	Retained Deficit	Accumulated Other Comprehensive Loss	Treasury Stock		Total Shareholders' Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2022	**41,830**	**$ 418**	**$ 337,385**	**$ (17,217)**	**$ (21,609)**	**(1,487)**	**$ (14,648)**	**$ 284,329**
Net loss	—	—	—	(26,715)	—	—	—	(26,715)
Other comprehensive income	—	—	—	—	432	—	—	432
Equity compensation	409	4	11,021	—	—	—	—	11,025
Exercise of options	196	2	2,004	—	—	—	—	2,006
Employee stock purchase plan	142	2	1,459	—	—	—	—	1,461
Redemption and repurchase of stock to cover tax withholdings	(40)	(1)	(562)	—	—	—	—	(563)
Balance at September 30, 2023	**42,537**	**$ 425**	**$ 351,307**	**$ (43,932)**	**$ (21,177)**	**(1,487)**	**$ (14,648)**	**$ 271,975**

See accompanying Notes to Condensed Consolidated Financial Statements

Artivion, Inc. and Subsidiaries
Condensed Consolidated Statements of Shareholders' Equity (continued)
In Thousands
(Unaudited)

	Common Stock		Additional Paid-In Capital	Retained Deficit	Accumulated Other Comprehensive Loss	Treasury Stock		Total Shareholders' Equity
	Shares	Amount				Shares	Amount	
Balance at June 30, 2022	**41,744**	**$ 417**	**$ 329,871**	**$ (5,673)**	**$ (28,458)**	**(1,487)**	**$ (14,648)**	**$ 281,509**
Net loss	—	—	—	(13,713)	—	—	—	(13,713)
Other comprehensive loss	—	—	—	—	(16,895)	—	—	(16,895)
Equity compensation	7	—	3,233	—	—	—	—	3,233
Exercise of options	9	—	85	—	—	—	—	85
Employee stock purchase plan	58	1	940	—	—	—	—	941
Redemption and repurchase of stock to cover tax withholdings	(2)	—	(52)	—	—	—	—	(52)
Balance at September 30, 2022	**41,816**	**$ 418**	**$ 334,077**	**$ (19,386)**	**$ (45,353)**	**(1,487)**	**$ (14,648)**	**$ 255,108**

	Common Stock		Additional Paid-In Capital	Retained Earnings (Deficit)	Accumulated Other Comprehensive Loss	Treasury Stock		Total Shareholders' Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2021	**41,397**	**$ 414**	**$ 322,874**	**$ 1,975**	**$ (9,887)**	**(1,487)**	**$ (14,648)**	**$ 300,728**
Net loss	—	—	—	(21,361)	—	—	—	(21,361)
Other comprehensive loss	—	—	—	—	(35,466)	—	—	(35,466)
Equity compensation	269	2	9,652	—	—	—	—	9,654
Exercise of options	149	2	1,763	—	—	—	—	1,765
Employee stock purchase plan	95	1	1,578	—	—	—	—	1,579
Redemption and repurchase of stock to cover tax withholdings	(94)	(1)	(1,790)	—	—	—	—	(1,791)
Balance at September 30, 2022	**41,816**	**$ 418**	**$ 334,077**	**$ (19,386)**	**$ (45,353)**	**(1,487)**	**$ (14,648)**	**$ 255,108**

Artivion, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Basis of Presentation and Summary of Significant Accounting Policies

Overview

The accompanying Condensed Consolidated Financial Statements include the accounts of Artivion, Inc. and its subsidiaries ("Artivion," the "Company," "we," or "us"). All significant intercompany accounts and transactions have been eliminated in consolidation. The accompanying Consolidated Balance Sheet as of December 31, 2022 has been derived from audited financial statements. The accompanying unaudited Condensed Consolidated Financial Statements as of, and for the three and nine months ended, September 30, 2023 and 2022 have been prepared in accordance with (i) accounting principles generally accepted in the United States of America ("US GAAP") for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the US Securities and Exchange Commission (the "SEC"). Accordingly, such statements do not include all the information and disclosures that are required by US GAAP for a complete presentation of financial statements. In the opinion of management, all adjustments (including those of a normal, recurring nature) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023. These Condensed Consolidated Financial Statements should be read in conjunction with the Consolidated Financial Statements and Notes included in Artivion's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on February 23, 2023.

Significant Accounting Policies

A summary of our significant accounting policies is included in Note 1 of the "Notes to Consolidated Financial Statements" contained in our Form 10-K for the year ended December 31, 2022. Management believes that the consistent application of these policies enables us to provide users of the financial statements with useful and reliable information about our operating results and financial condition. The Condensed Consolidated Financial Statements are prepared in accordance with US GAAP, which require us to make estimates and assumptions. We did not experience any significant changes during the three and nine months ended September 30, 2023 in any of our Significant Accounting Policies from those contained in our Form 10-K for the year ended December 31, 2022.

New Accounting Standards

Recently Adopted

In March 2020 the Financial Accounting Standards Board (the "FASB") issued Accounting Standard Update ("ASU") 2020-04, *Reference Rate Reform Topic 848* ("ASC 848"). The amendments in this ASU were put forth in response to the market transition from the LIBOR and other interbank offered rates to alternative reference rates. US GAAP requires entities to evaluate whether a contract modification, such as the replacement or change of a reference rate, results in the establishment of a new contract or continuation of an existing contract. ASC 848 allows an entity to elect not to apply certain modification accounting requirements to contracts affected by reference rate reform. The standard provides this temporary election through December 31, 2022 and cannot be applied to contract modifications that occur after December 31, 2022. In January 2021 the FASB issued ASU 2021-01, *Reference Rate Reform (Topic 848)*. The objective of the new reference rate reform standard is to clarify the scope of Topic 848 and provide explicit guidance to help companies applying optional expedients and exceptions. We adopted ASU 2020-04 and ASU 2021-01 on a prospective basis in fiscal year 2022. The adoption of ASU 2020-04 and ASU 2021-01 did not have a material impact on our financial condition or results of operations.

2. Sale of PerClot

Overview

On July 28, 2021 we entered into an asset purchase agreement, Transitional Manufacturing and Supply Agreement ("TMSA"), and other ancillary agreements related to the sale of PerClot®, a polysaccharide hemostatic agent used in surgery ("PerClot"), to a subsidiary of Baxter International, Inc. ("Baxter") and an agreement to terminate all of our material agreements with Starch Medical, Inc. ("SMI") related to PerClot (collectively the "Baxter Transaction"). Under the terms of the Baxter Transaction, Baxter will pay an aggregate of up to $54.5 million in consideration (we will receive up to $41.0 million and SMI will receive up to $13.5 million), consisting of (i) $25.0 million at closing, of which $6.0 million was paid to SMI; (ii) $18.8 million upon our receipt of Premarket Approval ("PMA") from the US Food and Drug Administration (the "FDA") for PerClot and our transfer of the PMA to Baxter, of which $4.5 million was paid to SMI; and (iii) up to $10.0 million upon Baxter's achievement of certain cumulative worldwide net sales of PerClot prior to December 31, 2026 and December 31, 2027, of which up to $3.0 million is payable to SMI. In addition, at the conclusion of our manufacturing and supply services for Baxter, Baxter will pay $780,000 upon transfer of our PerClot manufacturing equipment. Under the terms of the Baxter Transaction, we will continue to provide to Baxter certain transition services relating to the sale of SMI PerClot outside of the US. Within the terms of the TMSA, we will manufacture and supply PerClot for Baxter post PMA for a contractual period of 21 months, subject to short-term renewal provisions.

PerClot PMA

On May 23, 2023 the FDA granted PMA of PerClot for use to control bleeding in certain open and laparoscopic surgical procedures. Pursuant to the terms of the TMSA of the Baxter Transaction, we transferred the ownership of the PMA to Baxter following approval. In May 2023 we received a payment of $18.8 million from Baxter, of which $4.5 million was paid to SMI. As a result, we recorded a pre-tax gain of $14.3 million as the assets were derecognized upon closing of the Baxter Transaction in fiscal year 2021, included as Gain from sale of non-financial assets within the Condensed Consolidated Statements of Operations and Comprehensive Loss for the nine months ended September 30, 2023.

Following receipt of the PMA, under the terms of the TMSA, we began manufacturing and supplying PerClot for Baxter and recorded $2.0 million and $3.6 million of PerClot revenues on the Condensed Consolidated Statements of Operations and Comprehensive Loss during the three and nine months ended September 30, 2023, respectively.

The Company accounted for this TMSA in accordance with the provision of ASU 2016-02,*Leases Topic 842* ("ASC 842") by bifurcating the lease and non-lease components and recognizing each component based on ASC 842 and ASU 2014-09, *Revenue from Contracts with Customers Topic 606*. The amount of lease revenue was $87,000 and $101,000 for the three and nine months ended September 30, 2023, respectively.

3. Agreements with Endospan

Exclusive Distribution Agreement and Securities Purchase Option Agreement

On September 11, 2019 Artivion's wholly owned subsidiary, JOTEC GmbH ("JOTEC"), entered into an exclusive distribution agreement with Endospan Ltd. ("Endospan"), an Israeli corporation, pursuant to which JOTEC obtained exclusive distribution rights for NEXUS and accessories in certain countries in Europe in exchange for a fixed distribution fee of $9.0 million paid in September 2019.

We also entered into a securities purchase option agreement ("Endospan Option") with Endospan for $1.0 million paid in September 2019. The Endospan Option provides Artivion the option to purchase all the outstanding securities of Endospan from Endospan's securityholders at the time of acquisition, or the option to acquire all of Endospan's assets, in each case, for a price between $350.0 and $450.0 million before, or within a certain period of time after FDA approval of NEXUS, with such option expiring if not exercised within 90 days after receiving notice that Endospan has received approval from the FDA for NEXUS.

Loan Agreement

Artivion and Endospan also entered into a loan agreement ("Endospan Loan"), dated September 11, 2019, in which Artivion agreed to provide Endospan a secured loan of up to $15.0 million to be funded in three tranches of $5.0 million each.

The first tranche of the Endospan Loan was funded upon execution of the agreement in September 2019. In September 2020 we funded the second tranche payment of $5.0 million upon the certification of the NEXUS IDE from the FDA. In May 2023 we funded the third tranche payment of $5.0 million upon the certification of enrollment of 50% of the required number of patients in the primary arm of the FDA approved clinical trial for NEXUS.

We elected the fair value option for recording the Endospan Loan. We assess the fair value of the Endospan Loan based on quantitative and qualitative characteristics and adjust the amount recorded to its current fair market value at each reporting period. We performed an assessment of the fair value of the Endospan Loan, including the funding of the third tranche payment in May 2023. We determined that the loan had no fair value as of September 30, 2023 and recorded a $5.0 million expense included in Other expense, net within the Condensed Consolidated Statements of Operations and Comprehensive Loss for the nine months ended September 30, 2023.

4. Financial Instruments

The following is a summary of our financial instruments measured at fair value on a recurring basis (in thousands):

September 30, 2023	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 22,548	$ —	$ —	$ 22,548
Certificates of deposit	2,059	—	—	2,059
Total assets	**$ 24,607**	**$ —**	**$ —**	**$ 24,607**
Long-term liabilities:				
Contingent consideration	—	—	(62,300)	(62,300)
Total liabilities	**$ —**	**$ —**	**$ (62,300)**	**$ (62,300)**

December 31, 2022	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 10,098	$ —	$ —	$ 10,098
Total assets	**$ 10,098**	**$ —**	**$ —**	**$ 10,098**
Long-term liabilities:				
Contingent consideration	—	—	(40,400)	(40,400)
Total liabilities	**$ —**	**$ —**	**$ (40,400)**	**$ (40,400)**

We used prices quoted from our investment advisors to determine the Level 1 valuation of our investments in money market funds and certificates of deposit. The estimated market value of all cash equivalents is equal to cost basis as there were no gross realized gains or losses on cash equivalents for the three and nine months ended September 30, 2023 and 2022.

On September 2, 2020 we entered into a Securities Purchase Agreement to acquire 100% of the outstanding equity interests of Ascyrus Medical LLC (“Ascyrus”). Ascyrus developed the AMDS, the world’s first aortic arch remodeling device for use in the treatment of acute Type A aortic dissections. As part of the acquisition, we may be required to pay additional consideration in cash of up to $100.0 million to the former shareholders of Ascyrus upon the achievement of certain milestones and the sales-based additional earn-out.

The contingent consideration represents the estimated fair value of future potential payments. The fair value of the contingent consideration liability was estimated by discounting to present value the contingent payments expected to be made based on a probability-weighted scenario approach. We applied a discount rate based on our unsecured credit spread and the term commensurate risk-free rate to the additional consideration to be paid, and then applied a risk-based estimate of the probability of achieving each scenario to calculate the fair value of the contingent consideration. This fair value measurement was based on unobservable inputs, including management estimates and assumptions about the future achievement of milestones and future estimate of revenues, and is, therefore, classified as Level 3 within the fair value hierarchy. We used a discount rate of approximately 7% and estimated future achievement of milestone dates between 2025 and 2026 to calculate the fair value of contingent consideration as of September 30, 2023. We will remeasure this liability at each reporting date and will record changes in the fair value of the contingent consideration in General, administrative, and marketing expenses on the Condensed Consolidated Statements of Operations and Comprehensive Loss. Increases or decreases in the fair value of the contingent consideration liability can result from changes in passage of time, discount rates, the timing and amount of our revenue estimates, and the timing and expectation of regulatory approvals.

We performed an assessment of the fair value of the contingent consideration and recorded an expense of $6.2 million and $21.9 million for the three and nine months ended September 30, 2023, respectively, and an expense of $400,000 and income of $4.6 million for the three and nine months ended September 30, 2022, respectively, in General, administrative, and marketing expenses on the Condensed Consolidated Statements of Operations and Comprehensive Loss, as a result of this assessment.

The fair value of the contingent consideration component of the Ascyrus acquisition was updated using Level 3 inputs. Changes in fair value of Level 3 assets and liabilities are listed in the tables below (in thousands):

	Contingent Consideration
Balance as of December 31, 2022	$ (40,400)
Change in valuation	(21,900)
Balance as of September 30, 2023	**$ (62,300)**

The determination of fair value and the assessment of a measurement's placement within the hierarchy requires judgment. Level 3 valuations often involve a higher degree of judgment and complexity. Although we believe that the recorded fair values of our financial instruments are appropriate, these fair values may not be reflective of future fair values.

5. Inventories, net and Deferred Preservation Costs

Inventories, net at September 30, 2023 and December 31, 2022 were comprised of the following (in thousands):

	September 30, 2023	December 31, 2022
Raw materials and supplies	$ 35,639	$ 36,715
Work-in-process	13,042	10,476
Finished goods	30,111	27,287
Total inventories, net	**$ 78,792**	**$ 74,478**

To facilitate product usage, we maintain consignment inventory of our On-X heart valves at domestic hospital locations and On-X heart valves and aortic stent grafts at international hospital locations. We retain title and control over this consignment inventory until the device is implanted, at which time we invoice the hospital and recognize revenue. As of September 30, 2023 we had $11.1 million in consignment inventory, with approximately 43% in domestic locations and 57% in international locations. As of December 31, 2022 we had $12.7 million in consignment inventory, with approximately 41% in domestic locations and 59% in international locations.

Total deferred preservation costs were $49.4 million and $46.4 million as of September 30, 2023 and December 31, 2022, respectively.

Inventory and deferred preservation costs obsolescence reserves were $2.7 million and $2.2 million as of September 30, 2023 and December 31, 2022, respectively.

6. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

As of September 30, 2023 and December 31, 2022 the carrying values of our indefinite lived intangible assets were as follows (in thousands):

	September 30, 2023	December 31, 2022
Goodwill	$ 242,936	$ 243,631
In-process R&D	2,066	2,080
Procurement contracts and agreements	2,013	2,013

We monitor the phases of development of our acquired in-process research and development projects, including the risks associated with further development and the amount and timing of benefits expected to be derived from the completed projects. Incremental costs associated with development are charged to expense as incurred. Capitalized costs are amortized over the estimated useful life of the developed asset once completed. Our in-process research and development projects are reviewed for impairment annually, or more frequently, if events or changes in circumstances indicate that the asset might be impaired. We did not record any impairment of indefinite lived intangible assets during the three and nine months ended September 30, 2023. In-process research and development, procurement contracts and agreements are included in Other intangibles, net on the Condensed Consolidated Balance Sheets as of September 30, 2023 and December 31, 2022.

Based on our experience with similar agreements, we believe that our acquired procurement contracts and agreements have indefinite useful lives, as we expect to continue to renew these contracts for the foreseeable future.

We evaluate our goodwill and non-amortizing intangible assets for impairment on an annual basis during the fourth quarter of the year, and, if necessary, during interim periods if factors indicate that an impairment review is warranted. As of September 30, 2023 we concluded that our assessment of current factors did not indicate that goodwill or non-amortizing intangible assets are more likely than not to be impaired. We will continue to evaluate the recoverability of these non-amortizing intangible assets in future periods as necessary.

As of September 30, 2023 and December 31, 2022 the carrying value of goodwill, all of which is related to our Medical Devices segment, was as follows (in thousands):

	Medical Devices Segment
Balance as of December 31, 2022	$ 243,631
Foreign currency translation	(695)
Balance as of September 30, 2023	**$ 242,936**

Definite Lived Intangible Assets

The definite lived intangible assets balance includes balances related to acquired technology, customer relationships, distribution and manufacturing rights and know-how, patents, and other definite lived intangible assets. As of September 30, 2023 and December 31, 2022 the gross carrying values, accumulated amortization, and approximate amortization period of our definite lived intangible assets were as follows (in thousands, except weighted average useful life):

September 30, 2023	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Weighted Average Useful Life (Years)
Acquired technology	$ 197,768	$ 55,093	$ 142,675	18.2
Other intangibles:				
Customer lists and relationships	28,648	9,973	18,675	21.6
Distribution and manufacturing rights and know-how	9,211	7,052	2,159	5.0
Patents	4,322	3,210	1,112	17.0
Other	6,684	3,311	3,373	5.0
Total other intangibles	**$ 48,865**	**$ 23,546**	**$ 25,319**	**10.3**

December 31, 2022	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Weighted Average Useful Life (Years)
Acquired technology	$ 198,420	$ 47,157	$ 151,263	18.2
Other intangibles:				
Customer lists and relationships	31,030	11,100	19,930	20.5
Distribution and manufacturing rights and know-how	9,274	5,796	3,478	5.0
Patents	4,246	3,180	1,066	17.0
Other	5,360	2,543	2,817	4.4
Total other intangibles	**$ 49,910**	**$ 22,619**	**$ 27,291**	**10.3**

Amortization Expense

The following is a summary of amortization expense as recorded in General, administrative, and marketing expenses on our Condensed Consolidated Statement of Operations and Comprehensive Loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Amortization expense	$ 3,766	$ 3,686	$ 11,453	$ 11,675

As of September 30, 2023 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	Remainder of 2023	2024	2025	2026	2027	2028	Total
Amortization expense	$ 3,720	$ 14,700	$ 12,848	$ 12,617	$ 12,511	$ 12,313	$ 68,709

7. Income Taxes

Income Tax Expense

Our effective income tax rate was an expense of 4% and 27% for the three and nine months ended September 30, 2023, respectively, as compared to an expense of 9% and 17% for the three and nine months ended September 30, 2022, respectively. Our income tax rate for the three and nine months ended September 30, 2023 was primarily impacted by changes in pre-tax book loss, valuation allowance against our net deferred tax assets, non-deductible executive compensation, the foreign derived intangible income deduction, the research and development tax credit, return to provision adjustments in foreign jurisdictions, and changes in our uncertain tax position liabilities. Our income tax rate for the three and nine months ended September 30, 2022 was primarily impacted by changes in valuation allowance against our net deferred tax assets, non-deductible executive compensation, the foreign derived intangible income deduction, the research and development tax credit, changes in our uncertain tax position liabilities, and tax shortfalls on stock compensation.

Deferred Income Taxes

We generate deferred tax assets primarily as a result of finance and operating leases, net operating losses, excess interest carryforward, accrued compensation, and stock compensation. Our deferred tax liabilities are primarily comprised of intangible assets acquired in previous years, finance and operating leases, and unrealized gains and losses.

We maintained a net deferred tax liability of $15.8 million and $23.2 million as of September 30, 2023 and December 31, 2022, respectively. Our valuation allowance against our deferred tax assets was $25.2 million and $17.9 million as of September 30, 2023 and December 31, 2022, respectively, primarily related to net operating loss carryforwards, disallowed excess interest carryforwards, and capitalized research and development expenses.

8. Leases

We have operating and finance lease obligations resulting from the lease of land and buildings that comprise our corporate headquarters and various manufacturing facilities; leases related to additional manufacturing, office, and warehouse space; leases on company vehicles; and leases on a variety of office and other equipment.

Information related to leases included in the Condensed Consolidated Balance Sheets was as follows (in thousands, except lease term and discount rate):

Operating leases:	**September 30, 2023**	**December 31, 2022**
Operating lease right-of-use assets	$ 59,975	$ 56,061
Accumulated amortization	(16,630)	(14,202)
Operating lease right-of-use assets, net	**$ 43,345**	**$ 41,859**
Current maturities of operating leases	$ 3,940	$ 3,308
Non-current maturities of operating leases	42,862	41,257
Total operating lease liabilities	**$ 46,802**	**$ 44,565**
Finance leases:		
Property and equipment, at cost	$ 6,421	$ 6,408
Accumulated amortization	(2,869)	(2,498)
Property and equipment, net	**$ 3,552**	**$ 3,910**
Current maturities of finance leases	$ 529	$ 513
Non-current maturities of finance leases	3,272	3,644
Total finance lease liabilities	**$ 3,801**	**$ 4,157**
Weighted average remaining lease term (in years):		
Operating leases	10.7	11.9
Finance leases	7.1	7.8
Weighted average discount rate:		
Operating leases	6.3%	5.9%
Finance leases	2.1%	2.1%

Current maturities of finance leases are included as a component of Other current liabilities on our Condensed Consolidated Balance Sheets. A summary of lease expenses for our finance and operating leases included in General, administrative, and marketing expenses on our Condensed Consolidated Statements of Operations and Comprehensive Loss was as follows (in thousands):

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2023	**2022**	**2023**	**2022**
Amortization of property and equipment	$ 136	$ 127	$ 400	$ 395
Interest expense on finance leases	20	22	62	69
Total finance lease expense	**156**	**149**	**462**	**464**
Operating lease expense	1,836	1,853	5,467	5,656
Sublease income	(87)	(92)	(101)	(275)
Total lease expense	**$ 1,905**	**$ 1,910**	**$ 5,828**	**$ 5,845**

A summary of our cash flow information related to leases was as follows (in thousands):

	Nine Months Ended September 30,	
Cash paid for amounts included in the measurement of lease liabilities:	**2023**	**2022**
Operating cash flows for operating leases	$ 5,422	$ 4,939
Financing cash flows for finance leases	396	346
Operating cash flows for finance leases	62	62

Future minimum lease payments and sublease rental income are as follows (in thousands):

	Finance Leases	Operating Leases
Remainder of 2023	$ 139	$ 1,460
2024	606	6,119
2025	585	6,652
2026	567	6,162
2027	557	5,865
Thereafter	1,626	39,441
Total minimum lease payments	**$ 4,080**	**$ 65,699**
Less amount representing interest	(279)	(18,897)
Present value of net minimum lease payments	3,801	46,802
Less current maturities	(529)	(3,940)
Lease liabilities, less current maturities	**$ 3,272**	**$ 42,862**

9. Debt

Credit Agreement

On December 1, 2017 we entered into a credit and guaranty agreement for a $255.0 million senior secured credit facility, consisting of a $225.0 million secured term loan facility (the "Term Loan Facility") and a $30.0 million secured revolving credit facility (the "Revolving Credit Facility" and, together with the Term Loan Facility, the "Credit Agreement"). We and each of our existing domestic subsidiaries (subject to certain exceptions and exclusions) guarantee the obligations under the Credit Agreement (the "Guarantors"). The Credit Agreement is secured by a security interest in substantially all existing and after-acquired real and personal property (subject to certain exceptions and exclusions) of us and the Guarantors.

On June 2, 2021 we entered into an amendment to our Credit Agreement to extend the maturity dates of both our Term Loan and Revolving Credit Facility. As part of the amendment, the maturity dates of both our Term Loan and Revolving Credit Facility were each extended by two and one-half years, until June 1, 2027 and June 1, 2025, respectively, subject to earlier springing maturities triggered if our 4.25% Convertible Senior Notes, described below, remain outstanding on April 1, 2025 and December 31, 2024, respectively. With respect to the Term Loan, if the Convertible Senior Notes remain outstanding on April 1, 2025, the Term Loan's maturity date will be April 1, 2025, or, if the Convertible Senior Notes' own maturity date has been extended, the earlier of (i) 91 days prior to the Convertible Senior Notes' new maturity date and (ii) June 1, 2027. In the case of the Revolving Credit Facility, if the Convertible Senior Notes are still outstanding on December 31, 2024, the Revolving Credit Facility's maturity date will be either December 31, 2024 or, if the Convertible Senior Notes' own maturity date has been extended, the earlier of (i) 182 days prior to the Convertible Senior Notes' new maturity date and (ii) June 1, 2025. Under the amendment, the Term Loan Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of 2.50%, or LIBOR, plus a margin of 3.50%. Prior to the amendment, the optional floating annual rate was equal to either the base rate plus a margin of 2.25%, or LIBOR, plus a margin of 3.25%. We paid debt issuance costs of $2.1 million, of which $1.8 million will be amortized over the life of the Term Loan Facility and included in current and long-term debt on the Condensed Consolidated Balance Sheets. The remaining $361,000 of debt issuance costs and $474,000 of non-cash debt extinguishment costs were recorded in Interest expense on the Condensed Consolidated Statements of Operations and Comprehensive Loss.

As discussed in our Annual Report on Form 10-K for the year ended December 31, 2022 the Credit Agreement contains certain customary affirmative and negative covenants, including covenants that limit our ability and the ability of our subsidiaries to, among other things, grant liens, incur debt, dispose of assets, make loans and investments, make acquisitions, make certain restricted payments (including cash dividends), merge or consolidate, change business or accounting or reporting practices, in each case subject to customary exceptions for a credit facility of this size and type. Beginning in 2021 if we repay borrowings under our Revolving Credit Facility to 25% or less, no financial maintenance covenants, including the minimum liquidity covenant and the maximum first lien net leverage ratio covenant, are applicable. No amounts are outstanding on the Revolving Credit Facility as of September 30, 2023. We are in compliance with our debt covenants as of September 30, 2023.

On December 19, 2022 in accordance with adopting ASU 2020-04 and 2021-01, we entered into an amendment to our Credit Agreement to replace the LIBOR based benchmark interest rate with the Secured Overnight Financing Rate ("SOFR") based benchmark interest rate for our Term Loan Facility and our Revolving Credit Facility. Based on historical analysis of the differences between the benchmark rates, SOFR is adjusted to arrive at a Term SOFR rate that serves as the replacement base rate for LIBOR under our amended credit facilities. Under this amendment, at the maturity of our existing LIBOR-based loan on December 30, 2022, the interest rate at the repricing of our Term Loan Facility was calculated as Term SOFR plus a fixed percentage credit spread of 3.50%. The loan under the Revolving Credit Facility bears interest at Term SOFR plus a margin of between 4.00% and 4.25%, depending on our consolidated leverage ratio. As of September 30, 2023 the aggregate interest rate of the Credit Agreement was 8.93% per annum.

Convertible Senior Notes

On June 18, 2020 we issued $100.0 million aggregate principal amount of 4.25% Convertible Senior Notes with a maturity date of July 1, 2025 (the "Convertible Senior Notes"). The net proceeds from this offering, after deducting initial purchasers' discounts and costs directly related to this offering, were approximately $96.5 million. On January 1, 2021 we adopted ASU 2020-06 and adjusted the carrying balance of the Convertible Senior Notes to notional. The Convertible Senior Notes balance was $100.0 million recorded in Long-term debt on the Condensed Consolidated Balance Sheets as of September 30, 2023 and December 31, 2022. The Convertible Senior Notes may be settled in cash, stock, or a combination thereof, solely at our discretion. The initial conversion rate of the Convertible Senior Notes is 42.6203 shares per $1,000 principal amount, which is equivalent to a conversion price of approximately $23.46 per share, subject to adjustments. We use the if-converted method for assumed conversion of the Convertible Senior Notes for the diluted earnings per share calculation. The fair value and the effective interest rate of the Convertible Senior Notes as of September 30, 2023 was approximately $101.6 million and 5.05%, respectively. The fair value was based on market prices observable for similar instruments and is considered Level 2 in the fair value hierarchy.

The interest expense recognized on the Convertible Senior Notes includes $1.2 million and $3.7 million for thethree and nine months ended September 30, 2023 and 2022, respectively, related to the aggregate of the contractual coupon interest and the amortization of the debt issuance costs Interest on the Convertible Senior Notes began accruing upon issuance and is payable semi-annually. There were $1.3 million and $1.9 million of unamortized debt issuance costs related to Convertible Senior Notes as of September 30, 2023 and December 31, 2022, respectively.

Holders of the Convertible Senior Notes may convert their notes at their option at any time prior to January 1, 2025, but only under the following circumstances: (i) during any calendar quarter commencing after the calendar quarter ending on September 30, 2020 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (ii) during the five business day period after any five consecutive trading day period in which the trading price per $1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; (iii) we give a notice of redemption with respect to any or all of the notes, at any time prior to the close of business on the second scheduled trading day immediately preceding the redemption date; or (iv) upon the occurrence of specified corporate events. On or after January 1, 2025 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their notes at any time, regardless of the foregoing circumstances.

We became eligible to redeem the Convertible Senior Notes beginning on July 5, 2023, following the expiration of their non-redemption period. We are able to redeem the Convertible Senior Notes in whole or in part, at our option, if the last reported sale price per share of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption. We may redeem for cash all or part of the Convertible Senior Notes at a redemption price equal to 100% of the principal amount of the redeemable Convertible Senior Notes, plus accrued and unpaid interest to, but excluding, the redemption date. No principal payments are due on the Convertible Senior Notes prior to maturity. Other than restrictions relating to certain fundamental changes and consolidations, mergers or asset sales and customary anti-dilution adjustments, the Convertible Senior Notes do not contain any financial covenants and do not restrict us from conducting significant restructuring transactions or issuing or repurchasing any of its other securities.

Loan Balances

The short-term and long-term balances of our Term Loan and other long-term borrowings were as follows (in thousands):

	September 30, 2023	December 31, 2022
Term Loan balance	$ 212,063	$ 213,750
Convertible Senior Notes	100,000	100,000
2.45% Sparkasse Zollernalb (KFW Loan 1)	117	296
1.40% Sparkasse Zollernalb (KFW Loan 2)	530	733
Total loan balance	**312,710**	**314,779**
Less unamortized loan origination costs	(5,281)	(6,672)
Net borrowings	307,429	308,107
Less short-term loan balance	(1,552)	(1,608)
Long-term loan balance	**$ 305,877**	**$ 306,499**

Interest Expense

Interest expense was $6.6 million and $19.1 million for the three and nine months ended September 30, 2023, respectively, as compared to $4.8 million and $12.9 million for the three and nine months ended September 30, 2022, respectively. Interest expense includes interest on debt and uncertain tax positions in all periods.

10. Commitments and Contingencies

Liability Claims

In the normal course of business, we are made aware of adverse events involving our products and tissues. Future adverse events could ultimately give rise to a lawsuit against us, and liability claims may be asserted against us in the future based on past events that we are not aware of at the present time. We maintain claims-made insurance policies to mitigate our financial exposure to product and tissue processing liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. The amounts recorded in these Condensed Consolidated Financial Statements as of September 30, 2023 and the Consolidated Financial Statements as of December 31, 2022 represent our estimate of the probable losses and anticipated recoveries for incurred but not reported claims related to products sold and services performed prior to the balance sheet date.

11. Revenue Recognition

Sources of Revenue

We have identified the following revenues disaggregated by revenue source:

- Domestic hospitals – direct sales of products and preservation services.
- International hospitals – direct sales of products and preservation services.

- International distributors – generally these contracts specify a geographic area that the distributor will service, terms and conditions of the relationship, and purchase targets for the next calendar year.
- Other – PerClot manufacturing and supply agreement with Baxter, sales of CardioGenesis cardiac laser therapy prior to business abandonment in June 2023 described below, and original equipment manufacturing sales of aortic stent grafts and On-X products.

For the three and nine months ended September 30, 2023 and 2022 the sources of revenue were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Domestic hospitals	$ 43,794	$ 40,710	$ 126,764	$ 116,512
International hospitals	24,481	23,655	80,543	78,368
International distributors	16,616	11,469	46,166	34,685
Other	2,963	1,004	6,861	4,826
Total sources of revenue	**$ 87,854**	**$ 76,838**	**$ 260,334**	**$ 234,391**

Also see segment disaggregation information in Note 14 below.

In February 2023 our supplier of CardioGenesis cardiac laser therapy handpieces informed us that it was exiting the business and will no longer be supplying handpieces effective immediately because the sole-source manufacturer of tubing used in the handpiece assembly had gone out of business and a new supplier had yet to be identified and qualified. We evaluated the impact of this disruption on our CardioGenesis cardiac laser therapy business and possible avenues for resumption of supply including the evaluation of alternate suppliers and handpiece manufacturers. As of June 30, 2023 we were unable to identify an alternative source of supply or handpiece manufacturer and do not foresee a resumption of this business in the future. As a result, we wrote-off all of our CardioGenesis cardiac laser therapy assets and recorded an expense of $390,000 during the nine months ended September 30, 2023 on our Condensed Consolidated Statements of Operations and Comprehensive Loss.

Contract Balances

We may generate contract assets during the pre-delivery design and manufacturing stage of E-xtra Design Engineering product order fulfillment. We assess the balance related to any arrangements in process and determine if the enforceable right to payment creates a material contract asset requiring disclosure. No material arrangements in process existed as of September 30, 2023 and 2022.

We also incur contract obligations on general customer purchase orders that have been accepted but unfulfilled. Due to the short duration of time between order acceptance and delivery of the related product or service, we have determined that the balance related to these contract obligations is generally immaterial at any point in time. We monitor the value of orders accepted but unfulfilled at the close of each reporting period to determine if disclosure is appropriate. The value of orders accepted but unfulfilled as of September 30, 2023 and 2022 was not material.

12. Stock Compensation

Overview

We have stock option and stock incentive plans for employees and non-employee directors that provide for grants of restricted stock awards (“RSAs”), restricted stock units (“RSUs”), performance stock units (“PSUs”), and options to purchase shares of our common stock at exercise prices generally equal to the fair value of such stock at the dates of grant. We also maintain a shareholder-approved Employee Stock Purchase Plan (“ESPP”) for the benefit of our employees. The ESPP allows eligible employees to purchase common stock on a regular basis at the lower of 85% of the market price at the beginning or end of each offering period.

Equity Grants

During the nine months ended September 30, 2023 the Compensation Committee of our Board of Directors (the "Committee") authorized awards from approved stock incentive plans of RSAs to non-employee directors and RSUs and PSUs to certain employees and company officers, which, assuming that performance under the PSUs will be achieved at target levels, together totaled 616,000 shares and had an aggregate grant date fair value of $8.5 million.

During the nine months ended September 30, 2022 the Committee authorized awards from approved stock incentive plans of RSAs to non-employee directors and RSUs and PSUs to certain employees and company officers, which, assuming that performance under the PSUs were to be achieved at target levels, together totaled 520,000 shares and had an aggregate grant date fair value of $9.7 million.

During the nine months ended September 30, 2023 and 2022 the Committee authorized, from approved stock incentive plans, grants of stock options to purchase a total of 16,000 and 314,000 shares, respectively, to certain company officers. The exercise prices of the options were equal to the closing stock prices on their respective grant dates.

Employees purchased common stock totaling 86,000 and 142,000 shares in the three and nine months ended September 30, 2023, respectively, as compared to 58,000 and 95,000 shares in the three and nine months ended September 30, 2022, respectively, through the ESPP.

Stock Compensation Expense

The following weighted-average assumptions were used to determine the fair value of options and shares purchased under the ESPP:

	Three Months Ended September 30, 2023		Nine Months Ended September 30, 2023	
	Stock Options	**ESPP**	**Stock Options**	**ESPP**
Expected life	5.0 Years	0.5 Years	5.0 Years	0.5 Years
Expected stock price volatility	0.45	0.42	0.45	0.66
Risk-free interest rate	4.11%	5.47%	3.99%	4.77%

The following table summarizes total stock compensation expenses prior to the capitalization of amounts into Deferred preservation and Inventory costs (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
RSA, RSU, and PSU expense	$ 2,647	$ 2,622	$ 8,685	$ 7,860
Stock option and ESPP expense	745	611	2,340	1,794
Total stock compensation expense	**$ 3,392**	**$ 3,233**	**$ 11,025**	**$ 9,654**

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, RSUs, PSUs, and stock options issued in each respective year, as well as those issued in prior periods that continue to vest during the period, and compensation related to the ESPP. These amounts were recorded as stock compensation expense and were subject to our normal allocation of expenses to inventory costs and deferred preservation costs. We capitalized $205,000 and $559,000 for the three and nine months ended September 30, 2023, respectively, and $144,000 and $465,000 for the three and nine months ended September 30, 2022, respectively, of the stock compensation expense into our inventory costs and deferred preservation costs.

13. Loss Per Common Share

The following table sets forth the computation of basic and diluted loss per common share (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Basic loss per common share	**2023**	**2022**	**2023**	**2022**
Net loss	$ (9,801)	$ (13,713)	$ (26,715)	$ (21,361)
Net loss allocated to participating securities	39	70	108	109
Net loss allocated to common shareholders	**$ (9,762)**	**$ (13,643)**	**$ (26,607)**	**$ (21,252)**
Basic weighted-average common shares outstanding	**40,881**	**40,115**	**40,691**	**39,999**
Basic loss per common share	**$ (0.24)**	**$ (0.34)**	**$ (0.65)**	**$ (0.53)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
Diluted loss per common share	**2023**	**2022**	**2023**	**2022**
Net loss	$ (9,801)	$ (13,713)	$ (26,715)	$ (21,361)
Net loss allocated to participating securities	39	70	108	109
Net loss allocated to common shareholders	**$ (9,762)**	**$ (13,643)**	**$ (26,607)**	**$ (21,252)**
Diluted weighted-average common shares outstanding	**40,881**	**40,115**	**40,691**	**39,999**
Diluted loss per common share	**$ (0.24)**	**$ (0.34)**	**$ (0.65)**	**$ (0.53)**

We excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares because the inclusion of these stock options would be antidilutive to loss per common share. For the three and nine months ended September 30, 2023 and 2022 all stock options and awards were excluded from the calculation of diluted weighted-average common shares outstanding as these would be antidilutive due to the net loss.

14. Segment Information

We have two reportable segments organized according to our products and services: Medical Devices and Preservation Services. The Medical Devices segment includes external revenues from product sales of aortic stent grafts, On-X, surgical sealants, and other product revenues. Aortic stent grafts include aortic arch stent grafts, abdominal stent grafts, and synthetic vascular grafts. Aortic arch stent grafts include our E-vita Open NEO, E-vita Open Plus, AMDS, NEXUS, NEXUS DUO, and E-vita Thoracic 3G. Abdominal stent grafts include our E-xtra Design Engineering, E-nside, E-tegra, E-ventus BX, and E-liac products. Surgical sealants include BioGlue Surgical Adhesive products. The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues. There are no intersegment revenues.

The primary measure of segment performance, as viewed by our management, is segment gross margin or net external revenues less cost of products and preservation services. We do not segregate assets by segment; therefore, asset information is excluded from the segment disclosures below.

The following table summarizes revenues, cost of products and preservation services, and gross margins for our operating segments (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Medical devices	$ 63,747	$ 55,248	$ 192,041	$ 171,726
Preservation services	24,107	21,590	68,293	62,665
Total revenues	**87,854**	**76,838**	**260,334**	**234,391**
Cost of products and preservation services:				
Medical devices	21,574	17,743	62,084	53,381
Preservation services	10,010	10,351	30,169	29,375
Total cost of products and preservation services	**31,584**	**28,094**	**92,253**	**82,756**
Gross margin:				
Medical devices	42,173	37,505	129,957	118,345
Preservation services	14,097	11,239	38,124	33,290
Total gross margin	**$ 56,270**	**$ 48,744**	**$ 168,081**	**$ 151,635**

The following table summarizes net revenues by product and service (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Products:				
Aortic stent grafts	$ 25,523	$ 19,674	$ 80,032	$ 69,013
On-X	18,744	16,456	54,346	47,082
Surgical sealants	16,234	17,374	49,503	49,022
Other	3,246	1,744	8,160	6,609
Total products	**63,747**	**55,248**	**192,041**	**171,726**
Preservation services	24,107	21,590	68,293	62,665
Total revenues	**$ 87,854**	**$ 76,838**	**$ 260,334**	**$ 234,391**

Forward-Looking Statements

This Form 10-Q includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). Forward-looking statements give our expectations or forecasts of future events as of the date of this Form 10-Q. In some cases, words such as "could," "may," "might," "will," "would," "shall," "should," "pro forma," "potential," "pending," "intend," "believe," "expect," "anticipate," "estimate," "plan," "future," "assume," and variations of these types of words or other similar expressions identify forward-looking statements. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements, which are made as of the date of this Form 10-Q.

All statements included herein, other than statements of historical facts, that address activities, events, or developments that we expect or anticipate will or may occur in the future, or that reflect our beliefs about the future and/or expectations, are forward-looking statements, including statements about the following:

- Our belief that new products, new indications, global expansion, and business development are the four growth areas that will drive our business in the future;
- The potential impact the COVID-19 pandemic and the wars in Ukraine and the Gaza Strip may have on demand for and sales of our products and services, business operations, manufacturing operations, supply chain, cash flow, workforce, clinical and regulatory timelines, and our research and development projects;
- The potential impact general global, regional, or national economic downturns and macroeconomic trends, including heightened inflation, interest rate and currency fluctuations, as well as general or localized economic slowdowns or recessions may have on demand for and sales of our products and services, including ordering trends for international distributors based on currency fluctuation against the US dollar, and our business operations, manufacturing operations, supply chain, and workforce;
- Our beliefs about the robustness of our global supply chain in light of current global and macroeconomic conditions and about the potential impact of supply chain disruptions, particularly disruptions to single and sole source suppliers and third-party manufacturing partners;
- Our beliefs about our R&D and product pipeline, including our beliefs about the timing of our clinical trials and product launches;
- Our beliefs and anticipation regarding the favorable attributes, benefits, and clinical advantages of our products and services, the basis on which our products and services compete, the benefits of our physician education activities, and the advantages of our relationships with organ and tissue procurement organizations and tissue banks;
- Our beliefs about the future regulatory status of our medical devices, our compliance with applicable laws and regulations, and our ability to make timely transitions to our Notified Bodies and obtain renewals for our Conformité Européene Mark product certification impacted by Brexit and the transition to the Medical Device Regulation in Europe, and the impact these transitions, renewals, and related processes may have on our business, including any impact on our customers' ordering patterns and our ability to supply products;
- Our beliefs regarding our global expansion efforts, including the international growth opportunity that would be provided by obtaining regulatory approval for BioGlue in China;
- Our beliefs regarding the impact lower INR anticoagulation therapy and transcatheter heart valve replacement may have on the number of patients choosing On-X mechanical heart valves;
- Our beliefs about the advantages of our intellectual property and its significance to our segments and our business as a whole, and our beliefs about the present value and potential impairment of our intangible assets and leases;
- Our beliefs about our workforce, including our ability to attract and retain talent at all levels, and about our relationship with our workforce, including our works council in Germany and union in Brazil;
- Our beliefs about potential information security vulnerabilities, and the associated potential adverse effects on our business;
- The dependencies affecting our ability to realize the anticipated business opportunities, growth prospects, synergies, and other benefits of the agreements with Endospan and Baxter and our acquisition of Ascyrus, and our beliefs about the costs and timelines for certain regulatory approvals and clinical trial milestones;
- Our beliefs regarding the fair value of our acquisitions, divestitures, and other business development activities and the estimates and assumptions about the future achievements of milestones and future revenues and cash flows related to those business development activities, including our ability to achieve the milestones in the Baxter Transaction;
- Our beliefs about the anticipated benefits from our corporate reincorporation and rebranding and the risks posed by the same;

- Our belief that revenues for preservation services, particularly revenues for certain high-demand cardiac tissues, can vary from quarter-to-quarter and year-to-year due to a variety of factors including: quantity and type of incoming tissues, yields of tissue through the preservation process, timing of receipt of donor information, staffing levels, timing of the release of tissues to an implantable status, demand for certain tissue types due to the number and type of procedures being performed, and pressures from competing products or services;
- Our beliefs regarding the seasonal nature of the demand for some of our products and services and the reasons for such seasonality, if any, and regarding the impact of consignment inventory on product sales, if any;
- Our belief that our cash from operations and existing cash and cash equivalents will enable us to meet our current operational liquidity needs for at least the next twelve months, our expectations regarding future cash requirements, and the impact that our cash requirements might have on our cash flows for the next twelve months;
- Our expectation regarding the impact on cash flows of undertaking significant business development activities and the potential need to obtain additional debt financing or equity financing;
- Our belief that we will incur expenses for research and development projects, including for clinical research projects to gain regulatory approvals for products or indications, including On-X, aortic stent grafts, and BioGlue products, and for new products and technologies which will likely require additional investment, research, and new clinical studies or data;
- Our beliefs about pending and potential legal or other governmental or regulatory proceedings;
- Our expectations regarding the timing and impact of clinical research work and regulatory approvals for certain products or indications, including On-X, aortic stent grafts, and BioGlue products, and CryoValve SG pulmonary heart valve if the US Food and Drug Administration reclassifies allograft heart valves as Class III medical devices;
- Our beliefs and expectations regarding the utilization of net operating loss carryforwards from our acquisitions of JOTEC, On-X, Hemosphere, Inc., and Cardiogenesis Corporation;
- Our beliefs about our operating results which may fluctuate significantly on a periodic basis as a result of internal and external factors, including reduced demand for our products, the potential impact of GLP-1 drugs, healthcare workforce trends and labor disputes, availability of products, materials, and supplies, strategic actions we take such as acquisitions or divestitures, unanticipated costs and expenses, market reception of our new or improved product offerings, and interest rate and currency fluctuations; and
- Other statements regarding projections of future financial and business performance; anticipated growth and trends in our business and the markets relevant to our business, including as our growth relates to our competitors; the robustness and reliability of our workforce and supply chain; future production capacity and product supply; the availability and benefits of our products in the future; and the expected timing and impact of our strategic initiatives.

These and other forward-looking statements reflect the views of management at the time and such statements are originally made based on certain assumptions and analyses made by us in light of our experience and our perception of historical trends, current conditions, and expected future developments as well as other factors we believe are appropriate in the circumstances and are subject to a number of risks, uncertainties, estimates, and assumptions. Whether actual results and developments will conform with our expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially and adversely from our expectations, including, without limitation, in addition to those specified in the text surrounding such statements, the risks described in Part II, Item 1A, “Risk Factors” in this Form 10-Q and elsewhere throughout this report, the risks described in our other filings with the Securities and Exchange Commission including the risks described in Part I, Item 1A, “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022 and elsewhere throughout that report, and other risks which we may not be able to identify in advance, many of which are beyond our control. Consequently, all of the forward-looking statements made in this Form 10-Q are qualified by these cautionary statements, and there can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us or our business or operations. We assume no obligation, and expressly disclaim any duty, to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

Part I – FINANCIAL INFORMATION

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

Overview

Artivion, Inc. ("Artivion," the "Company," "we," or "us"), is a leader in the manufacturing, processing, and distribution of medical devices and implantable human tissues used in cardiac and vascular surgical procedures for patients with aortic disease. We have four major product families: aortic stent grafts, surgical sealants, On-X® mechanical heart valves and related surgical products, and implantable cardiac and vascular human tissues. Aortic stent grafts include aortic arch stent grafts, abdominal stent grafts, and synthetic vascular grafts. Aortic arch stent grafts include our E-vita Open NEO, E-vita Open Plus, AMDS, NEXUS, NEXUS DUO, and E-vita Thoracic 3G products. Abdominal stent grafts include our E-xtra Design Engineering, E-nside, E-tegra, E-ventus BX, and E-liac products. Surgical sealants include BioGlue® Surgical Adhesive ("BioGlue") products. In addition to these four major product families, we sell or distribute PhotoFix® bovine surgical patches and CardioGenesis® cardiac laser therapy (prior to our abandonment of the business as of June 30, 2023). We began to manufacture and supply PerClot® hemostatic powder during the second quarter of 2023 (as part of the Transitional Manufacturing and Supply Agreement ("TMSA") of the Baxter Transaction, described below).

We reported quarterly revenues of $87.9 million for the three months ended September 30, 2023, a 14% increase from the three months ended September 30, 2022. The increase in revenues for the three months ended September 30, 2023 was due to an increase in revenues from aortic stent grafts, preservation services, On-X products, and other products, partially offset by a decrease in revenues from surgical sealants. Constant currency revenues, as defined below, increased 12% for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022.

See the "Results of Operations" section below for additional analysis of the three and nine months ended September 30, 2023.

Presentation

In addition to the corresponding measures under generally accepted accounting principles ("US GAAP"), management uses non-GAAP measures in reviewing and disclosing our financial results. The foreign exchange neutral revenues ("constant currency revenues") discussed below are non-GAAP financial measures and are not in accordance with, or an alternative to, measures prepared in accordance with US GAAP. Accordingly, the constant currency information appearing in the following discussion of our results of operations should be read in conjunction with the information provided in "Non-GAAP Measures of Financial Performance" below, which includes a reconciliation of constant currency financial measures to the most directly comparable US GAAP measure.

Effects of COVID-19 and Macroeconomic Uncertainties

The COVID-19 pandemic had wide-ranging and unpredictable impacts on global economic conditions, our operations, and our financial results. The effects of the pandemic may continue to or again adversely impact aspects of our business and the global markets, including our workforce, supply chain, and operations, and the workforce and operations of our customers, suppliers, and business partners.

Although the global healthcare system continues to recover from challenges resulting from the COVID-19 pandemic, we continue to be at risk for impact on procedural volumes from staffing shortages due to workforce trends, worker availability, and more recently, shortages related to healthcare labor disputes in some markets.

The COVID-19 pandemic has also impacted certain aspects of the global supply chain and resulted in supply chain inflation. Although we have yet to experience material effects on our supply chain or operations, we face a continued risk that upstream disruptions may occur or worsen.

As global economies continue to recover from the COVID-19 downturn, increased opportunities for remote work and competitive labor markets at all levels have resulted in turnover and retention challenges that have impacted our workforce and the workforces of our customers and business partners.

Macroeconomic factors, both originating from the pandemic and otherwise, continue to have an impact on our business and operations. Global geopolitical conditions, including the war between Russia and Ukraine, and more recently, declaration of war in the Gaza Strip, as well as global economic challenges and inflationary pressures have increased prices, placed pressure on worldwide financial and credit markets, and strained the global supply chain.

The extent to which our operations and financial performance will be impacted by the pandemic and macroeconomic uncertainties during fiscal year 2023 and beyond will depend largely on future developments, including changes in hospital utilization rates and staffing, the resilience of the global supply chain, geopolitical stability, and macroeconomic trends. The significant uncertainty related to the pandemic and macroeconomic conditions could have a material impact on our financial condition, profitability, cash flows, and results and operations.

New Accounting Pronouncements

See Note 1 of "Notes to Condensed Consolidated Financial Statements" identified in Part I, Item I of this Form 10-Q for further discussion of new accounting standards that have been adopted.

Results of Operations
(Tables in thousands, except percentages)

Revenues

	Revenues for the Three Months Ended September 30,		Percent Change From Prior Year	Revenues as a Percentage of Total Revenues for the Three Months Ended September 30,	
	2023	**2022**		**2023**	**2022**
Products:					
Aortic stent grafts	$ 25,523	$ 19,674	30%	29%	26%
On-X	18,744	16,456	14%	21%	21%
Surgical sealants	16,234	17,374	-7%	19%	23%
Other	3,246	1,744	86%	4%	2%
Total products	**63,747**	**55,248**	**15%**	**73%**	**72%**
Preservation services	24,107	21,590	12%	27%	28%
Total	**$ 87,854**	**$ 76,838**	**14%**	**100%**	**100%**

	Revenues for the Nine Months Ended September 30,		Percent Change From Prior Year	Revenues as a Percentage of Total Revenues for the Nine Months Ended September 30,	
	2023	**2022**		**2023**	**2022**
Products:					
Aortic stent grafts	$ 80,032	$ 69,013	16%	31%	29%
On-X	54,346	47,082	15%	21%	20%
Surgical sealants	49,503	49,022	1%	19%	21%
Other	8,160	6,609	23%	3%	3%
Total products	**192,041**	**171,726**	**12%**	**74%**	**73%**
Preservation services	68,293	62,665	9%	26%	27%
Total	**$ 260,334**	**$ 234,391**	**11%**	**100%**	**100%**

Revenues increased 14% and 11% for the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022. The increase in revenues for the three months ended September 30, 2023 was due to an increase in revenues from aortic stent grafts, preservation services, On-X products, and other products, partially offset by a decrease in revenues from surgical sealants. The increase in revenues for the nine months ended September 30, 2023 was due to an increase in revenues from aortic stent grafts, On-X products, preservation services, other products, and surgical sealants. Revenues for the three and nine months ended September 30, 2022 were negatively impacted in certain regions by delays or cancellations of some surgical procedures as a result of reduced hospital capacity and staffing and hospital restrictions due to the COVID-19 pandemic and local labor disputes.

The following table reconciles revenues to constant currency revenues for the periods presented:

	Revenues for the Three Months Ended September 30,				Percent Change From Prior Year
	2023	2022			
	US GAAP	US GAAP	Exchange Rate Effect	Constant Currency	Constant Currency
Products:					
Aortic stent grafts	$ 25,523	$ 19,674	$ 1,193	$ 20,867	22%
On-X	18,744	16,456	90	16,546	13%
Surgical sealants	16,234	17,374	318	17,692	-8%
Other	3,246	1,744	8	1,752	85%
Total products	**63,747**	**55,248**	**1,609**	**56,857**	**12%**
Preservation services	24,107	21,590	(12)	21,578	12%
Total	**$ 87,854**	**$ 76,838**	**$ 1,597**	**$ 78,435**	**12%**

	Revenues for the Nine Months Ended September 30,				Percent Change From Prior Year
	2023	2022			
	US GAAP	US GAAP	Exchange Rate Effect	Constant Currency	Constant Currency
Products:					
Aortic stent grafts	$ 80,032	$ 69,013	$ (17)	$ 68,996	16%
On-X	54,346	47,082	(129)	46,953	16%
Surgical sealants	49,503	49,022	(36)	48,986	1%
Other	8,160	6,609	(10)	6,599	24%
Total products	**192,041**	**171,726**	**(192)**	**171,534**	**12%**
Preservation services	68,293	62,665	(81)	62,584	9%
Total	**$ 260,334**	**$ 234,391**	**$ (273)**	**$ 234,118**	**11%**

Constant currency revenues increased 12% and 11% for the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022. See "Non-GAAP Measures of Financial Performance" below for further background on our non-GAAP measures.

A detailed discussion of the changes in product revenues and preservation services revenues for the three and nine months ended September 30, 2023 is presented below.

Products

Revenues from products increased 15% and 12% for the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022. The increase for the three months ended September 30, 2023 was due to an increase in revenues from aortic stent grafts, On-X products, and other products, partially offset by a decrease in revenues from surgical sealants. The increase for the nine months ended September 30, 2023 was due to an increase in revenues from all products. Constant currency revenues from products increased 12% for both the three and nine months ended September 30, 2023, as compared to the three and nine months ended September 30, 2022. A discussion of the changes in product revenues for aortic stent grafts, On-X products, surgical sealants, and other product revenues is presented below.

Sales of certain products through our direct sales force and distributors across Europe and various other countries are denominated in a variety of currencies including Euros, British Pounds, Polish Zlotys, Swiss Francs, Brazilian Reals, and Canadian Dollars, with a concentration denominated in Euros. Each currency is subject to exchange rate fluctuations. For the three months ended September 30, 2023, as compared to the three months ended September 30, 2022, the US Dollar weakened in comparison to major currencies, resulting in revenue increases when these foreign currency denominated transactions were translated into US Dollars. For the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, the US Dollar strengthened in comparison to major currencies, resulting in revenue decreases when these foreign currency denominated transactions were translated into US Dollars. Future changes in these exchange rates could have a material, adverse effect on our revenues denominated in these currencies. Additionally, our sales to many distributors around the world are denominated in US Dollars, and although these sales are not directly impacted by currency exchange rates, we believe that some of our distributors may delay or reduce purchases of products in US Dollars depending on the relative price of these goods in their local currencies.

Aortic Stent Grafts

Aortic stent grafts include aortic arch stent grafts, abdominal stent grafts, synthetic vascular grafts, and original equipment manufacturing ("OEM") aortic stent graft products. Aortic arch stent grafts include E-vita Open NEO, E-vita Open Plus, AMDS, NEXUS, NEXUS DUO, and E-vita Thoracic 3G products. Abdominal stent grafts include E-xtra Design Engineering, E-nside, E-tegra, E-ventus BX, and E-liac products. Aortic stent grafts are used in endovascular and open vascular surgery for the treatment of complex aortic arch, thoracic, and abdominal aortic diseases. Our aortic stent grafts are primarily distributed in international markets.

Revenues from the sales of aortic stent grafts increased 30% for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. This increase was primarily due to an increase in the volume and a change in the mix of units sold, which increased revenues by 23%, and the effect of foreign exchange rates, which increased revenues by 7%.

Revenues from the sales of aortic stent grafts increased 16% for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. This increase was primarily due to an increase in the volume and a change in the mix of units sold, which increased revenues by 12%, and an increase in average sales prices, which increased revenues by 4%.

Constant currency revenues from the sales of aortic stent grafts increased 22% and 16% for the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022. The increase in revenues was partially due to improved conditions from the COVID-19 pandemic for the three and nine months ended September 30, 2023, as compared to the three and nine months ended September 30, 2022. Revenues for the three months ended September 30, 2023 increased primarily in Europe, the Middle East, and Africa (collectively, "EMEA") and Asia Pacific ("APAC"). Revenues for the nine months ended September 30, 2023 increased in all geographies, with the most significant increase in EMEA.

The revenue increase in EMEA for the three and nine months ended September 30, 2023 was primarily due to an increase in buying patterns in direct (to hospitals) markets. The revenue increase in APAC for the three and nine months ended September 30, 2023 was primarily due to an increase in distributor buying patterns in certain markets. OEM sales of aortic stent grafts accounted for approximately 1% of product revenues for both the three and nine months ended September 30, 2023 and 2022.

On-X

The On-X products include the On-X prosthetic aortic and mitral heart valves and the On-X ascending aortic prosthesis ("AAP") for heart valve replacement. Revenues from the sales of On-X products also include revenues from the distribution of CarbonAid® CO_2 diffusion catheters and from the sale of Chord-X® ePTFE sutures for mitral chordal replacement. On-X also generates revenue from pyrolytic carbon coating services for OEM customers.

Revenues from the sales of On-X products increased 14% for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. This increase was primarily due to an increase in volume of units sold, which increased revenues by 8%, an increase in average sales prices in certain regions, which increased revenues by 5%, and the effect of foreign exchange rates, which increased revenues by 1%.

Revenues from the sales of On-X products increased 15% for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. This increase was primarily due to an increase in the volume and change in the mix of units sold, which increased revenues by 9%, and an increase in average sales prices, which increased revenues by 6%.

Constant currency revenues from the sales of On-X products increased 13% and 16% for the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022. The increase in revenues was partially due to improved conditions from the COVID-19 pandemic for the three and nine months ended September 30, 2023, as compared to the three and nine months ended September 30, 2022. Revenues for the three months ended September 30, 2023 increased in all geographies, with the most significant increases in North America and Latin America ("LATAM"). Revenues for the nine months ended September 30, 2023 increased in all geographies, with the most significant increases in North America and APAC. The increase in revenues in North America for the three and nine months ended September 30, 2023 was also impacted by customer buying patterns. The increase in revenues in LATAM for the three and nine months ended September 30, 2023 was also impacted by market penetration in certain regions. The increase in revenues in APAC for the three and nine months ended September 30, 2023 was also impacted by distributor buying patterns. On-X OEM sales accounted for less than 1% of product revenues for both the three and nine months ended September 30, 2023 and 2022.

Surgical Sealants

Surgical sealants include BioGlue products used as an adjunct to standard methods of achieving hemostasis (such as sutures and staples) in adult patients in open surgical repair of large vessels (such as aorta, femoral, and carotid arteries).

Revenues from the sales of surgical sealants decreased 7% for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. This decrease was primarily due to a change in the mix and a decrease in volume of milliliters sold, which decreased revenues by 10%, partially offset by an increase in average sales prices in certain regions, which increased revenues by 2%, and the effect of foreign exchange rates, which increased revenues by 1%.

Revenues from the sales of surgical sealants increased 1% for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. This increase was primarily due to an increase in average sales prices in certain regions, which increased revenues by 2%, partially offset by a change in the mix of milliliters sold, which decreased revenues by 1%.

Constant currency revenues from the sales of surgical sealants decreased 8% for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. Constant currency revenues from sales of surgical sealants increased 1% for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. The decrease in revenues for the three months ended September 30, 2023 was primarily due to revenue decreases in EMEA. The increase in revenues for the nine months ended September 30, 2023 was primarily due to revenue increases in all geographies, except for revenue decreases in EMEA.

Revenues from the sales of surgical sealants decreased in EMEA during the three and nine months ended September 30, 2023, as compared to the three and nine months ended September 30, 2022. During the three months ended September 30, 2022 customers accelerated orders in certain countries in anticipation of temporary commercialization restrictions resulting from the expiration of our BioGlue CE Mark during our transition to a new Notified Body. We received renewal of our BioGlue CE Mark and completed our Notified Body transition late in the fourth quarter of 2022.

Domestic revenues from the sales of surgical sealants accounted for 48% and 49% of total surgical sealant revenues for the three and nine months ended September 30, 2023, respectively, and 46% and 48% of total surgical sealant revenues for the three and nine months ended September 30, 2022, respectively.

Other

Other revenues are comprised of PhotoFix, PerClot (as part of the TMSA of the Baxter Transaction described below), and CardioGenesis cardiac laser therapy product revenues (prior to our abandonment of that business as of June 2023).

Other revenues increased 86% and 23% for the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022. The increase in other revenues for the three and nine months ended September 30, 2023, as compared to the three and nine months ended September 30, 2022, was primarily due to an increase in PerClot product revenues, partially offset by decreased CardioGenesis revenues as a result of our abandonment of the CardioGenesis cardiac laser therapy business as of June 30, 2023.

Revenues from our CardioGenesis cardiac laser therapy product line historically consisted primarily of sales of handpieces and, in certain periods, the sale of laser consoles. In February 2023 our supplier of handpieces informed us that it was exiting the business and will no longer be supplying handpieces effective immediately because the sole-source manufacturer of tubing used in the handpiece assembly had gone out of business and a new supplier had yet to be identified and qualified. We evaluated the impact of this disruption on our CardioGenesis cardiac laser therapy business and possible avenues for resumption of supply including the evaluation of alternate suppliers and handpiece manufacturers. As of June 30, 2023 we were unable to identify an alternative source of supply or handpiece manufacturer and do not foresee a resumption of this business in the future. As a result, we wrote-off all of our CardioGenesis cardiac laser therapy assets and recorded an expense of $390,000 during the nine months ended September 30, 2023 on our Condensed Consolidated Statements of Operations and Comprehensive Loss.

On July 28, 2021 we entered into an asset purchase agreement, TMSA, and other ancillary agreements related to the sale of PerClot, a polysaccharide hemostatic agent used in surgery, to a subsidiary of Baxter International, Inc. (“Baxter”), and an agreement to terminate all of our material agreements with Starch Medical, Inc. (“SMI”) related to PerClot (collectively the “Baxter Transaction”). On May 23, 2023 the US Food and Drug Administration granted Premarket Approval (“PMA”) of PerClot for use to control bleeding in certain open and laparoscopic surgical procedures. Pursuant to the terms of the TMSA of the Baxter Transaction, we transferred the ownership of the PMA to Baxter following approval and began manufacturing and supplying PerClot for Baxter for a period of 21 months, subject to short-term renewal provisions.

Preservation Services

Preservation services include external service revenues from processing cardiac and vascular tissues. Our cardiac valves are primarily used in cardiac replacement and reconstruction surgeries, including the Ross procedure, for patients with endocarditis or congenital heart defects. The majority of our vascular preservation services revenues are related to shipments of saphenous veins, which are mainly used in peripheral vascular reconstruction surgeries to avoid limb amputations. Competition with synthetic product alternatives and the availability of tissues for processing are key factors affecting revenue volume that can fluctuate from quarter to quarter. Our cardiac and vascular tissues are primarily distributed in domestic markets.

We continue to evaluate modifications to our tissue processing procedures in an effort to improve tissue processing throughput, reduce costs, and maintain quality across our tissue processing business. Preservation services revenues, particularly revenues for certain high-demand cardiac tissues, can vary from quarter-to-quarter and year-to-year due to a variety of factors, including quantity and type of incoming tissues, yields of tissue through the preservation process, timing of receipt of donor information, timing of the release of tissues for implant, demand for certain tissue types due to the number and type of procedures being performed, and pressures from competing products or services.

Revenues from tissue processing increased 12% for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. The increase in revenues for the three months ended September 30, 2023 was primarily due to an increase in average sales prices, which increased revenues by 15%, partially offset by a decrease in tissues shipped, which decreased revenues by 3%.

Revenues from tissue processing increased 9% for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. The increase in revenues for the nine months ended September 30, 2023 was primarily due to an increase in average sales prices, which increased revenues by 10%, partially offset by a decrease in tissues shipped, which decreased revenues by 1%.

The increase in revenues from tissue processing for the three and nine months ended September 30, 2023 was primarily due to an increase in pricing for certain tissues.

Cost of Products and Preservation Services

Cost of Products

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Cost of products	$ 21,574	$ 17,743	$ 62,084	$ 53,381

Cost of products increased 22% and 16% for the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022. Cost of products for the three and nine months ended September 30, 2023 and 2022 included costs related to aortic stent grafts, On-X products, surgical sealants, and other products.

The increase in the cost of products for the three months ended September 30, 2023 was primarily due to an increase in the cost of surgical sealants and On-X products, as well as an increase in the volume of all products shipped except for surgical sealants, as compared to the three months ended September 30, 2022.

The increase in the cost of products for the nine months ended September 30, 2023 was primarily due to an increase in the volume of On-X products and aortic stent grafts shipped, and an increase in the cost of On-X products, surgical sealants, and aortic stent grafts shipped, as compared to the nine months ended September 30, 2022.

Cost of Preservation Services

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Cost of preservation services	$ 10,010	$ 10,351	$ 30,169	$ 29,375

Cost of preservation services decreased 3% for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. Cost of preservation services increased 3% for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. Cost of preservation services included costs for cardiac and vascular tissue preservation services.

The decrease in the cost of preservation services for the three months ended September 30, 2023 was primarily due to a decrease in the tissues shipped, as compared to the three months ended September 30, 2022.

The increase in the cost of preservation services for the nine months ended September 30, 2023 was primarily due to an increase in shipments and processing cost of tissues shipped, as compared to the nine months ended September 30, 2022.

Gross Margin

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Gross margin	$ 56,270	$ 48,744	$ 168,081	$ 151,635
Gross margin as a percentage of total revenues	64%	63%	65%	65%

Gross margin increased 15% and 11% for the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022.

Gross margin for the three and nine months ended September 30, 2023 was positively impacted by shipments of PerClot as part of the Baxter Transaction described above. PerClot shipped during the second quarter and a portion of the third quarter of 2023 represented PerClot pre-launch inventory manufactured prior to PMA and previously recorded as research and development expense on the Condensed Consolidated Statements of Operations and Comprehensive Loss.

The increase in gross margin for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022, was also due to an increase in average sales prices of certain tissues and a mix of aortic stent grafts and On-X products shipped, partially offset by an increase in the cost of surgical sealants and On-X products shipped. Gross margin as a percentage of total revenues increased for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022. Gross margin as a percentage of total revenues was positively impacted by favorable prices of certain tissues shipped, a mix of certain aortic stent grafts and On-X products shipped, partially offset by an increase in the cost of On-X products and a mix of surgical sealants shipped during the three months ended September 30, 2023.

The increase in gross margin for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, was also due to an increase in average sales prices of certain tissues, On-X products, and aortic stent grafts shipped, and a mix of certain aortic stent grafts and On-X products shipped, partially offset by an increase in the cost of all products shipped. The increase in gross margin was partially offset by an increase in product costs of surgical sealants, On-X products, aortic stent grafts, and cardiac tissues. Gross margin as a percentage of total revenues was flat for the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. Gross margin as a percentage of total revenues was positively impacted by favorable prices of certain tissues shipped, a mix of On-X products and certain aortic stent grafts shipped, offset by an increase in product costs of surgical sealants and On-X products shipped during the nine months ended September 30, 2023.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
General, administrative, and marketing expenses	$ 51,093	$ 41,051	$ 158,699	$ 118,989
General, administrative, and marketing expenses as a percentage of total revenues	58%	53%	61%	51%

General, administrative, and marketing expenses increased 24% and 33% for the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022. The increase in General, administrative, and marketing expenses for the three and nine months ended September 30, 2023 was primarily due to an increase in business development expense and personnel-related costs.

General, administrative, and marketing expenses included $6.4 million and $22.5 million of business development expense for the three and nine months ended September 30, 2023, respectively, as compared to $864,000 of expense and $3.8 million of income for the three and nine months ended September 30, 2022, respectively. We incurred $6.2 million and $21.9 million of business development expense during the three and nine months ended September 30, 2023, respectively, related to the fair value adjustments for the Ascyrus contingent consideration, as compared to $400,000 of business development expense and $4.6 million of business development income during the three and nine months ended September 30, 2022, respectively.

Research and Development Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Research and development expenses	$ 6,421	$ 11,799	$ 21,062	$ 30,575
Research and development expenses as a percentage of total revenues	7%	15%	8%	13%

Research and development expenses decreased 46% and 31% for the three and nine months ended September 30, 2023, respectively, as compared to the three and nine months ended September 30, 2022. Research and development spending for the three and nine months ended September 30, 2023 was primarily focused on clinical work to gain regulatory approvals for certain aortic stent grafts, and to a lesser extent, On-X and PerClot products. Research and development spending for the three and nine months ended September 30, 2022 was primarily focused on clinical work to gain regulatory approvals for On-X, certain aortic stent grafts, and PerClot products.

Interest Expense

Interest expense was $6.6 million and $19.1 million for the three and nine months ended September 30, 2023, respectively, as compared to $4.8 million and $12.9 million for the three and nine months ended September 30, 2022, respectively. Interest expense for the three and nine months ended September 30, 2023 and 2022 relates to interest on debt. The increase in interest expense for the three and nine months ended September 30, 2023, as compared to the three and nine months ended September 30, 2022, was primarily due to an increase in the interest rate on our term loan.

Other Expense, Net

Other expense, net was $1.9 million and $5.2 million for the three and nine months ended September 30, 2023, respectively, as compared to $3.7 million and $7.6 million for the three and nine months ended September 30, 2022, respectively. Other expense, net for the nine months ended September 30, 2023 primarily included a $5.0 million expense related to a payment to Endospan for achievement of certain milestones related to the NEXUS products. See Part I, Item 1, Note 3 - “Agreements with Endospan” of the “Notes to Condensed Consolidated Financial Statements” for further information on our agreements with Endospan. Other expense, net for the three and nine months ended September 30, 2023 and 2022 included the realized and unrealized effects of foreign currency gains and losses.

Earnings

(Table in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Loss before income taxes	$ (9,419)	$ (12,532)	$ (20,995)	$ (18,261)
Income tax expense	382	1,181	5,720	3,100
Net loss	**$ (9,801)**	**$ (13,713)**	**$ (26,715)**	**$ (21,361)**
Diluted loss per common share	**$ (0.24)**	**$ (0.34)**	**$ (0.65)**	**$ (0.53)**
Diluted weighted-average common shares outstanding	**40,881**	**40,115**	**40,691**	**39,999**

We incurred a loss before income taxes for the three and nine months ended September 30, 2023 and 2022. The loss before income taxes for the three and nine months ended September 30, 2023 was impacted by the change in fair value of our financial instruments, an increase in certain operating expenses to support revenue expansion, and an increase in interest expense. The loss before income taxes for the three and nine months ended September 30, 2022 was impacted by an increase in operating expenses to support revenue expansion, an increase in investments in the research and development pipeline, and an unfavorable impact of foreign currency gains and losses. The loss before income taxes was partially offset by the change in fair value of our financial instruments for the nine months ended September 30, 2022. Revenues for the three and nine months ended September 30, 2022 were also unfavorably impacted by delays or cancellations of some surgical procedures as a result of reduced hospital capacity and staffing and hospital restrictions due in part to the COVID-19 pandemic in certain regions.

Our effective income tax rate was an expense of 4% and 27% for the three and nine months ended September 30, 2023, respectively, as compared to an expense of 9% and 17% for the three and nine months ended September 30, 2022, respectively. The change in the tax rate for the three and nine months ended September 30, 2023 was primarily due to changes in pre-tax book loss, valuation allowance against our net deferred tax assets, non-deductible executive compensation, the foreign derived intangible income deduction, the research and development tax credit, return to provision adjustments in foreign jurisdictions, and changes in our certain tax position liabilities, as compared to the three and nine months ended September 30, 2022.

Our income tax rate for the three and nine months ended September 30, 2023 was primarily impacted by changes in pre-tax book loss, valuation allowance against our net deferred tax assets, non-deductible executive compensation, the foreign derived intangible income deduction, the research and development tax credit, return to provision adjustments in foreign jurisdictions, and changes in our certain tax position liabilities. Our income tax rate for the three and nine months ended September 30, 2022 was primarily impacted by changes in our valuation allowance against our net deferred tax assets, non-deductible executive compensation, the foreign derived intangible income deduction, the research and development tax credit, changes in our uncertain tax position liabilities, and tax shortfalls on stock compensation.

We incurred net loss and diluted loss per common share for the three and nine months ended September 30, 2023 and 2022. Net loss and diluted loss per common share for the three and nine months ended September 30, 2023 was primarily due to loss before income taxes, as discussed above.

Non-GAAP Measures of Financial Performance

To supplement our Condensed Consolidated Financial Statements presented in accordance with US GAAP, we use constant currency revenues, which is a non-GAAP financial measure. We define constant currency revenues as revenues minus the exchange rate effect. We define exchange rate effect as the year-over-year impact of foreign currency movements using current period foreign currency rates applied to prior period transactional currency amounts.

We have provided non-GAAP financial measures in this report as we believe that these figures are helpful in allowing management and investors to more accurately assess the ongoing nature of our operations and measure our performance more consistently across periods. Management uses constant currency revenues internally to assess the operational performance of the Company, as a component in compensation metrics, and as a basis for strategic planning.

We believe the provided non-GAAP measures are meaningful in addition to the information contained in the US GAAP presentation of financial performance. Investors should consider this non-GAAP information in addition to, and not as a substitute for, financial measures prepared in accordance with US GAAP. In addition, this non-GAAP financial information may not be the same as similar measures presented by other companies.

Seasonality

As a result of the uncertainty and other impacts of the COVID-19 pandemic and the resulting shifts of timing in some revenue, our historically observable seasonality of revenues has been impacted or obscured in 2022 and 2023 and potentially beyond.

Historically, we believe the demand for most of our aortic stent grafts is seasonal, with a decline in demand generally occurring in the third quarter due to the summer holiday season in Europe. We are uncertain whether the demand for AMDS and NEXUS products is seasonal, as these products have not fully penetrated many markets and, therefore, the nature of any seasonal trends may not yet be obvious.

Historically, we believe the demand for BioGlue and On-X products is seasonal, with a decline in demand generally occurring in the third quarter followed by stronger demand in the fourth quarter. We believe that this trend may be due to the summer holiday season in Europe and the US.

We do not believe the demand for our other products is seasonal.

Demand for our cardiac preservation services has traditionally been seasonal, with peak demand generally occurring in the third quarter. We believe this trend for cardiac preservation services is primarily due to the high number of surgeries scheduled during the summer months for school-aged patients. Based on experience in recent years, we believe that this trend is lessening as we are distributing a higher percentage of our tissues for use in adult populations.

Demand for our vascular preservation services has also traditionally been seasonal, with lowest demand generally occurring in the fourth quarter. We believe this trend for vascular preservation services was primarily due to fewer vascular surgeries being scheduled during the winter holiday months.

Liquidity and Capital Resources

Net Working Capital

As of September 30, 2023 net working capital (current assets of $267.1 million less current liabilities of $55.0 million) was $212.1 million, with a current ratio (current assets divided by current liabilities) of 5 to 1, as compared to net working capital of $197.6 million and a current ratio of 5 to 1 at December 31, 2022.

Overall Liquidity and Capital Resources

Our primary cash requirements for the nine months ended September 30, 2023 were for general working capital needs, interest and principal payments under our Credit Agreement (defined below), interest payments under our Convertible Senior Notes (defined below), capital expenditures for facilities and equipment, repurchases of stock to cover tax withholdings, and payment to Endospan for achievement of certain milestones related to the NEXUS products. We funded our cash requirements through our existing cash reserves and proceeds from stock option exercises.

We believe our cash from operations and existing cash and cash equivalents will enable us to meet our current operational liquidity needs for at least the next twelve months. Our future cash requirements are expected to include interest and principal payments under our Credit Agreement and Convertible Senior Notes (described in "Significant Sources and Uses of Liquidity" section below), expenditures for clinical trials, research and development expenditures, general working capital needs, capital expenditures, and other corporate purposes and may include cash to fund business development activities including obligations in the agreements related to the Ascyrus transactions. These items may have a significant effect on our future cash flows during the next twelve months. Subject to the terms of our Credit Agreement, we may seek additional borrowing capacity or financing, pursuant to our current or any future shelf registration statement, for general corporate purposes or to fund other future cash requirements. If we undertake any further significant business development activity, we may need to finance such activities by obtaining additional debt financing or using a registration statement to sell equity securities. There can be no assurance that we will be able to obtain any additional debt or equity financing at the time needed or that such financing will be available on terms that are favorable or acceptable to us.

Significant Sources and Uses of Liquidity

On December 1, 2017 we entered into a credit and guaranty agreement for a $255.0 million senior secured credit facility, consisting of a $225.0 million secured term loan facility (the "Term Loan Facility") and a $30.0 million secured revolving credit facility (the "Revolving Credit Facility" and, together with the Term Loan Facility, the "Credit Agreement"). We and each of our existing domestic subsidiaries (subject to certain exceptions and exclusions) guarantee the obligations under the Credit Agreement (the "Guarantors"). The Credit Agreement is secured by a security interest in substantially all existing and after-acquired real and personal property (subject to certain exceptions and exclusions) of us and the Guarantors.

On June 2, 2021 we entered into an amendment to our Credit Agreement to extend the maturity dates of both our Term Loan and Revolving Credit Facility. As part of the amendment, the maturity dates of both our Term Loan and Revolving Credit Facility were each extended by two and one-half years, until June 1, 2027 and June 1, 2025, respectively, subject to earlier springing maturities triggered if our 4.25% Convertible Senior Notes, described below, remain outstanding on April 1, 2025 and December 31, 2024, respectively. With respect to the Term Loan, if the Convertible Senior Notes remain outstanding on April 1, 2025, the Term Loan's maturity date will be April 1, 2025, or, if the Convertible Senior Notes' own maturity date has been extended, the earlier of (i) 91 days prior to the Convertible Senior Notes' new maturity date and (ii) June 1, 2027. In the case of the Revolving Credit Facility, if the Convertible Senior Notes are still outstanding on December 31, 2024, the Revolving Credit Facility's maturity date will be either December 31, 2024 or, if the Convertible Senior Notes' own maturity date has been extended, the earlier of (i) 182 days prior to the Convertible Senior Notes' new maturity date and (ii) June 1, 2025. Under the amendment, the Term Loan Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of 2.50%, or LIBOR, plus a margin of 3.50%. Prior to the amendment, the optional floating annual rate was equal to either the base rate plus a margin of 2.25%, or LIBOR, plus a margin of 3.25%.

On December 19, 2022 in accordance with adopting ASU 2020-04 and 2021-01, we entered into an amendment to our Credit Agreement to replace the LIBOR based benchmark interest rate with the Secured Overnight Financing Rate ("SOFR") based benchmark interest rate for our Term Loan Facility and our Revolving Credit Facility. Based on historical analysis of the differences between the benchmark rates, SOFR is adjusted to arrive at a Term SOFR rate that serves as the replacement base rate for LIBOR under our amended credit facilities. Under this amendment, at the maturity of our existing LIBOR-based loan on December 30, 2022, the interest rate at the repricing of our Term Loan Facility was calculated as Term SOFR plus a fixed percentage credit spread of 3.50%. The loan under the Revolving Credit Facility bears interest at Term SOFR plus a margin of between 4.00% and 4.25%, depending on our consolidated leverage ratio. As of September 30, 2023 the aggregate interest rate of the Credit Agreement was 8.93% per annum.

On June 18, 2020 we issued $100.0 million aggregate principal amount of 4.25% Convertible Senior Notes with a maturity date of July 1, 2025 (the "Convertible Senior Notes"). The net proceeds from this offering, after deducting initial purchasers' discounts and costs directly related to this offering, were approximately $96.5 million. On January 1, 2021 we adopted ASU 2020-06 and adjusted the carrying balance of the Convertible Senior Notes to notional. The Convertible Senior Notes balance was $100.0 million recorded in Long-term debt on the Condensed Consolidated Balance Sheets as of September 30, 2023 and December 31, 2022. The Convertible Senior Notes may be settled in cash, stock, or a combination thereof, solely at our discretion. The initial conversion rate of the Convertible Senior Notes is 42.6203 shares per $1,000 principal amount, which is equivalent to a conversion price of approximately $23.46 per share, subject to adjustments. We use the if-converted method for assumed conversion of the Convertible Senior Notes for the diluted earnings per share calculation. The fair value and the effective interest rate of the Convertible Senior Notes as of September 30, 2023 was approximately $101.6 million and 5.05%, respectively. The fair value was based on market prices observable for similar instruments and is considered Level 2 in the fair value hierarchy.

The interest expense recognized on the Convertible Senior Notes includes $1.2 million and $3.7 million for thethree and nine months ended September 30, 2023 and 2022, respectively, related to the aggregate of the contractual coupon interest and the amortization of the debt issuance costs Interest on the Convertible Senior Notes began accruing upon issuance and is payable semi-annually. There were $1.3 million and $1.9 million of unamortized debt issuance costs related to Convertible Senior Notes as of September 30, 2023 and December 31, 2022, respectively.

Holders of the Convertible Senior Notes may convert their notes at their option at any time prior to January 1, 2025 but only under the following circumstances: (i) during any calendar quarter commencing after the calendar quarter ending on September 30, 2020 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (ii) during the five business day period after any five consecutive trading day period in which the trading price per $1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; (iii) we give a notice of redemption with respect to any or all of the notes, at any time prior to the close of business on the second scheduled trading day immediately preceding the redemption date; or (iv) upon the occurrence of specified corporate events. On or after January 1, 2025 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their notes at any time, regardless of the foregoing circumstances.

We became eligible to redeem the Convertible Senior Notes beginning on July 5, 2023, following the expiration of their non-redemption period. We are able to redeem the Convertible Senior Notes in whole or in part, at our option, if the last reported sale price per share of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption. We may redeem for cash all or part of the Convertible Senior Notes at a redemption price equal to 100% of the principal amount of the redeemable Convertible Senior Notes, plus accrued and unpaid interest to, but excluding, the redemption date. No principal payments are due on the Convertible Senior Notes prior to maturity. Other than restrictions relating to certain fundamental changes and consolidations, mergers or asset sales and customary anti-dilution adjustments, the Convertible Senior Notes do not contain any financial covenants and do not restrict us from conducting significant restructuring transactions or issuing or repurchasing any of its other securities.

As of September 30, 2023 approximately 32% of our cash and cash equivalents were held in foreign jurisdictions.

The following table summarizes cash flows from operating activities, investing activities, and financing activities for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Cash flows provided by (used in):		
Operating activities	$ 7,987	$ (4,936)
Investing activities	2,167	(8,047)
Financing activities	2,495	(780)
Effect of exchange rate changes on cash and cash equivalents	1,481	(3,675)
Increase (decrease) in cash and cash equivalents	**$ 14,130**	**$ (17,438)**

Net Cash Flows from Operating Activities

Net cash provided by operating activities was $8.0 million for the nine months ended September 30, 2023, as compared to net cash used in operating activities of $4.9 million for the nine months ended September 30, 2022.

We use the indirect method to prepare our cash flow statement and, accordingly, the operating cash flows are based on our net income, which is then adjusted to remove non-cash items, items classified as investing and financing cash flows, and changes in operating assets and liabilities from the prior year end. For the nine months ended September 30, 2023 these non-cash items primarily included $21.9 million of fair value adjustments of financial instruments, $17.3 million of depreciation and amortization expenses, $14.3 million of gain from sale of non-financial assets, $10.5 million of non-cash compensation, $7.3 million of deferred income tax changes, $5.5 million of lease expenses, and $5.0 million of fair value adjustment of long-term loan.

Our working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the nine months ended September 30, 2023 these included the favorable effect of $765,000 due to the timing differences between recording receivables and the receipt of cash, $412,000 due to timing differences between the recording of accounts payable, accrued expenses, and other liabilities and the payment of cash, partially offset by $10.6 million due to an increase in inventory balances and deferred preservation costs and $527,000 due to an increase in prepaid expenses and other assets.

Net Cash Flows from Investing Activities

Net cash provided by investing activities was $2.2 million for the nine months ended September 30, 2023, as compared to net cash used in investing activities of $8.0 million for the nine months ended September 30, 2022. During the nine months ended September 30, 2023 cash flows provided by investing activities primarily included $14.3 million of proceeds from the sale of non-financial assets, partially offset by $5.5 million of cash used for capital expenditures and $5.0 million payment related to our agreement with Endospan.

Net Cash Flows from Financing Activities

Net cash provided by financing activities was $2.5 million for the nine months ended September 30, 2023, as compared to net cash used in financing activities of $780,000 for the nine months ended September 30, 2022. The current year cash provided by financing activities was primarily due to $3.6 million of proceeds from financing insurance premiums and $3.5 million of proceeds from the exercise of stock options and issuances of common stock, partially offset by $2.1 million for the repayment of debt and $1.5 million for the payments of short-term notes payable.

Scheduled Contractual Obligations and Future Payments

Our long-term debt obligations and interest payments include $312.7 million of scheduled principal payments and $76.6 million in anticipated interest payments related to our Credit Agreement, Convertible Senior Notes, and other governmental loans.

We have contingent payment obligations that include up to $100.0 million to be paid to the former shareholders of Ascyrus upon the achievement of certain milestones. As part of the transaction with Baxter, we may be required to pay up to $3.0 million if certain milestones are met.

Our operating and finance lease obligations result from the lease of land and buildings that comprise our corporate headquarters and our various manufacturing facilities; leases related to additional manufacturing, office, and warehouse space; leases on company vehicles; and leases on a variety of office and other equipment.

Capital Expenditures

Capital expenditures were $5.5 million and $6.9 million for the nine months ended September 30, 2023 and 2022, respectively. Capital expenditures for the nine months ended September 30, 2023 were primarily related to routine purchases of manufacturing and tissue processing equipment, computer software needed to support our business, leasehold improvements, and computer equipment.

Risks and Uncertainties

See the “Risk Factors” identified in Part II, Item 1A of this Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our interest income and interest expense are sensitive to changes in the general level of US interest rates. In this regard, changes in US interest rates affect the interest earned on our cash and cash equivalents of $53.5 million as of September 30, 2023 and interest paid on the outstanding balances, if any, of our variable rate Revolving Credit Facility, Term Loan Facility, and Convertible Senior Notes. A 10% adverse change in interest rates, as compared to the rates experienced by us for the nine months ended September 30, 2023, affecting our cash and cash equivalents, Term Loan Facility, Revolving Credit Facility, and Convertible Senior Notes would not have a material effect on our financial position, results of operations, or cash flows.

Foreign Currency Exchange Rate Risk

We have balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency denominated balances are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the US Dollar equivalent of cash or funds that we will receive in payment for assets or that we would have to pay to settle liabilities. As a result, we could be required to record these changes as gains or losses on foreign currency translation.

We have revenues and expenses that are denominated in foreign currencies. Specifically, a portion of our international revenues from aortic stent grafts, surgical sealants, On-X, and other products are denominated in Euros, British Pounds, Swiss Francs, Polish Zlotys, Canadian Dollars, and Brazilian Reals and a portion of our General, administrative, and marketing expenses are denominated in Euros, British Pounds, Swiss Francs, Polish Zlotys, Canadian Dollars, Brazilian Reals, and Singapore Dollars. These foreign currency transactions are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the US Dollar equivalent of net income from transactions conducted in other currencies. As a result, we could recognize a reduction in revenues or an increase in expenses related to a change in exchange rates.

An additional 10% adverse change in exchange rates from the exchange rates in effect on September 30, 2023 affecting our balances denominated in foreign currencies could impact our financial position or cash flows by approximately $7.0 million. An additional 10% adverse change in exchange rates from the weighted-average exchange rates experienced by us for the nine months ended September 30, 2023 affecting our revenue and expense transactions denominated in foreign currencies would not have had a material impact on our financial position, profitability, or cash flows.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures ("Disclosure Controls") as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act. These Disclosure Controls are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to management, including to the Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), as appropriate, to allow timely decisions regarding required disclosures.

Our management, including our President and CEO and our Executive Vice President of Finance and CFO, does not expect that our Disclosure Controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Artivion have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Our Disclosure Controls have been designed to provide reasonable assurance of achieving their objectives.

Our management utilizes the criteria set forth in "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our Disclosure Controls over financial reporting. Based upon the most recent Disclosure Controls evaluation conducted by management with the participation of the CEO and CFO, as of September 30, 2023 the CEO and CFO have concluded that our Disclosure Controls were effective at a reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by us in our periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the US Securities and Exchange Commission's rules and forms.

Changes to Disclosure Controls and Procedures

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

Part II – OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we are involved in legal proceedings concerning matters arising from the conduct of our business activities. We regularly evaluate the status of legal proceedings in which we are involved in order to assess whether a loss is probable or whether there is a reasonable possibility that a loss or additional loss may have been incurred and to determine if accruals are appropriate. We further evaluate each legal proceeding to assess whether an estimate of possible loss or range of loss can be made.

Based on current knowledge, we do not believe that there are any pending matters that could potentially have a material, adverse effect on our business, financial condition, results of operations, or cash flows. We are, however, engaged in various legal actions in the normal course of business. There can be no assurances in light of the inherent uncertainties involved in any potential legal proceedings, some of which are beyond our control, and an adverse outcome in any legal proceeding could be material to our results of operations or cash flows for any particular reporting period.

Item 1A. Risk Factors.

Risks Relating to Our Business

Our business involves a variety of risks and uncertainties, known and unknown, including, among others, the risks discussed below. These risks should be carefully considered together with the other information provided in this Quarterly Report on Form 10-Q and in our other filings with the US Securities and Exchange Commission (the "SEC"). Our failure to adequately anticipate or address these risks and uncertainties may have a material, adverse impact on our business, reputation, revenues, financial condition, profitability, and cash flows. Additional risks and uncertainties not presently known or knowable to us, or that we currently believe to be immaterial, may also adversely affect our business.

Business and Economic Risks

Public health crises have, may continue to have, and could have a material, adverse impact on us.

Beginning in early 2020, businesses, communities, and governments worldwide began taking a wide range of actions to mitigate the spread and impact of COVID-19, leading to an unprecedented impact on the global economy. We continue to be subject to risks relating to the COVID-19 pandemic and its impact on broader macroeconomic trends, and risks that may result from future pandemics, epidemics, or other public health crises. The nature and extent of these risks are uncertain and may vary greatly by region, but COVID-19 and similar public health crises have impacted and can impact our workforce, business and manufacturing operations, and our R&D pipeline.

COVID-19 resulted in unprecedented disruptions to and restrictions on global business and personal activities. Because of our role in the healthcare industry, we are particularly susceptible to the impact public health crises have on healthcare systems globally, including impacts on system capacity and procedure volumes, shortages in healthcare staffing, and restrictions on travel and non-critical hospital access, all of which have had, may continue to have, and could have an impact on our business operations and sales, particularly through reductions in demand for certain products and services due to reduced procedure volumes, or through downstream financial impact from delays or difficulty collecting outstanding receivables. This impact on healthcare system capacity may also impact our R&D pipeline by impacting timelines for R&D and clinical research projects and timelines associated with regulatory reviews for new and updated devices.

The COVID-19 pandemic and the related macroeconomic fallout have continued to impact the global supply chain; and the impact on workforces, material availability, demand, and costs has reportedly continued or worsened in many cases. Although we have yet to experience any material effects on our supply chain, we have faced increasing costs and face a continued risk that upstream disruptions may occur. Risks relating to the lingering effects of global supply chain disruptions may continue even after COVID-19's risk as a global pandemic has subsided.

The extent to which COVID-19, its variants, or any future public health crises impact our operations, and extent to which our operations are impacted by the recovery from COVID-19 and its fallout on broader macroeconomic conditions, will depend largely on future developments that are highly uncertain and unpredictable and may vary greatly by region. This impact and any such adverse developments or prolonged periods of uncertainty could adversely affect our financial performance.

We are subject to a variety of risks due to our international operations and continued global expansion.

Our international operations subject us to a number of risks, which may vary significantly from the risks we face in our US operations, including:

- Greater difficulties and costs associated with staffing at all levels, establishing and maintaining internal controls, managing foreign operations and distributor relationships, and selling directly to customers;
- Broader exposure to corruption and expanded compliance obligations, including under the Foreign Corrupt Practices Act, the UK Bribery Law, local anti-corruption laws, Office of Foreign Asset Control administered sanction programs, the European Union's General Data Protection Regulation, and other emerging corruption and data privacy regulations;
- Overlapping and potentially conflicting, or unexpected changes in, international legal and regulatory requirements or reimbursement policies and programs;
- Longer and more expensive collection cycles in certain countries, particularly those in which our primary customers are government-funded hospitals;
- Changes in currency exchange rates, particularly fluctuations in the Euro as compared to the US Dollar and other inflationary pressures;
- Potential adverse financial impact and negative erosion of our operating profit margin over time due to increasing inflationary pressures, including impact felt through our supply chain; our exposure may be increased through our limited ability to raise prices and through global expansion where business occurs with, or pricing is set directly by, government entities, or we are party to long term pricing agreements with governments or local distributors, impacting our ability to pass on rising costs;
- Potential adverse tax consequences of overlapping tax structures or potential changes in domestic and international tax policy, laws, and treaties; and
- Potential adverse financial and regulatory consequences resulting from Brexit.

As an example of this risk, via a Ministerial Decree of July 6, 2022, published September 15, 2022, the Italian government stated that the spending ceiling for medical devices at the national and regional levels had been exceeded, requiring medical device companies to pay back overpayments the government claims companies received between 2015 and 2018. Currently, Artivion's repayment exposure for this period is estimated at approximately €400,000, which is subject to change as judicial challenges and negotiations between the Company, industry and US government representatives, and the Italian government are ongoing.

Our operations and performance have been, and may continue to be, impacted by regional and global geopolitical conditions, domestic and foreign trade and monetary policies, and other factors beyond our control. As an example of these risks, Russia's military attacks on Ukraine have triggered significant sanctions from the US and foreign governments and retaliatory actions from Russia, resulting in significant banking and trade disruptions. More recently, war has been declared in the Gaza Strip resulting in an expanding regional crisis. These wars have resulted in significant devastation to the people and infrastructure in the region, significantly impacting trade and transportation which may impact our global supply chain, increase prices, and limit our ability to continue to do business in affected regions.

To date, sanctions and other disruptions in the Eastern European region have not materially impacted our business or ability to supply products to Russia, Belarus, Ukraine, and the region generally; however, continuation or escalation of the wars in Ukraine or the Middle East, or increased export controls or additional sanctions imposed on or by impacted countries, their allies, or related entities could adversely affect our financial performance. Although we do not have any direct operations in Russia, Ukraine, Israel, or Gaza, the NEXUS products are solely manufactured by Endospan in Herzliya, Israel. Although we have not experienced any disruption of supply from Endospan, the conflict in and around Israel is rapidly evolving. Ultimately, it is difficult to predict the ultimate course of these wars and we may face business operations and supply chain disruptions as a result, including disruptions related to shortages of materials and finished goods, higher costs of materials and freight, freight delays, increased energy costs or energy shortages, travel disruptions, currency fluctuation, and disruptions to banking systems or capital markets.

We operate in highly competitive market segments, face competition from large, well-established medical device companies and tissue service providers with greater resources and we may not be able to compete effectively.

The market for our products and services is competitive and affected by new product introductions and activities of other industry participants, including the introduction of novel products and therapies aimed at unrelated disease states or even overall patient health. In addition, such products and therapies like the recently introduced GLP-1 drugs, which we believe have or will have little to no actual impact on demand for our products, can lead to investor and customer confusion and impact the perceived demand for our products. We face intense competition in virtually all of our product lines. A significant percentage of market revenues from competitive products are generated by Baxter, Ethicon (a Johnson & Johnson Company), Medtronic, plc, Abbott Laboratories, Edwards Lifesciences Corp., C.R. Bard, Inc. (a subsidiary of Becton, Dickinson and Company), Integra Life Sciences Holdings, LifeNet, Corcym, Anteris Technologies, Inc., Aziyo Biologics, Cook Medical, Gore & Associates, Terumo, LeMaitre Vascular, Inc., Maquet, Inc., Pfizer, Inc., and BioCer Entwicklungs-GmbH. Several of our competitors enjoy competitive advantages over us, including:

- Greater financial and other resources for research and development, commercialization, acquisitions, and litigation and to weather the impacts of COVID-19 and increased workforce competition;
- Greater name recognition as well as more recognizable trademarks for products similar to products that we sell;
- More established record of obtaining and maintaining regulatory product clearances or approvals;
- More established relationships with healthcare providers and payors;
- Lower cost of goods sold or preservation costs; and
- Larger direct sales forces and more established distribution networks.

We are significantly dependent on our revenues from tissue preservation services and are subject to a variety of risks affecting them.

Tissue preservation services are a significant source of our revenues, and as such, we face risks if we are unable to:

- Source sufficient quantities of some human tissue or address potential excess supply of others. We rely primarily upon the efforts of third parties to educate the public and foster a willingness to donate tissue. Factors beyond our control such as supply, regulatory changes, negative publicity concerning methods of tissue recovery or disease transmission from donated tissue, or public opinion of the donor process as well as our own reputation in the industry can negatively impact the supply of tissue;
- Compete effectively, as we may be unable to capitalize on our clinical advantages or our competitors may have advantages over us in terms of cost structure, pricing, back-office automation, marketing, and sourcing; or
- Mitigate sufficiently the risk that tissue can become contaminated during processing; that processed tissue cannot be end-sterilized and hence carries an inherent risk of infection or disease transmission or that our quality controls can eliminate that risk.

As an example of these risks, in the fourth quarter of 2020 we became aware that a supplier shipped to us a lot of saline solution that we use in our tissue processing that contained some contamination. The contamination was identified by our routine quality controls. While we were able to mitigate the impact of this contamination through our own efforts and additional testing that was reviewed with the US Food and Drug Administration (the “FDA”), the contaminated solution impacted a small percentage of the tissue processed with this lot of solution, requiring us to write-off approximately $826,000 in contaminated tissues in the fourth quarter of 2020. The written off and temporarily quarantined tissue impacted our ability to fully meet demand for certain tissues and sizes in the fourth quarter of 2020, the first quarter of 2021, and to a lesser extent the second quarter of 2021. See also, Part I, Item 1A, “Risk Factors—Operational Risks— We are heavily dependent on our suppliers and contract manufacturers to provide quality products.”

In addition, US and foreign governmental authorities have adopted laws and regulations that restrict tissue preservation services. Any of these laws or regulations could change, including becoming more restrictive, or our interpretation of them could be challenged by governmental authorities.

We are significantly dependent on our revenues from BioGlue and are subject to a variety of related risks.

BioGlue is a significant source of our revenues, and as such, any risk adversely affecting our BioGlue products or business would likely be material to our financial results. We face the following risks relating to BioGlue:

- Competing effectively with our major and start up competitors, as they may have advantages over us in terms of cost structure, supply chain, pricing, sales force footprint, and brand recognition;
- We may be unable to obtain approval to commercialize BioGlue in certain non-US countries as fast as our competitors do or at all. We also may not be able to capitalize on new BioGlue approvals, including for new indications, in non-US countries; and
- BioGlue contains a bovine blood protein. Animal-based products are subject to increased scrutiny from the public and regulators, who may seek to impose additional regulations, regulatory hurdles or product bans in certain countries on such products; BioGlue is a mature product and other companies may use the inventions disclosed in expired BioGlue patents to develop and make competing products.

As an example of this risk, our BioGlue CE Mark expired in December 2021. Delays in renewing the CE Mark and challenges securing certain related derogations ultimately impacted the availability of BioGlue in certain European markets and other markets reliant on the CE Mark, impacting our revenue from BioGlue in those markets. See also, Part I, Item 1A, "Risk Factors—Industry Risks— Our products and tissues are highly regulated and subject to significant quality and regulatory risks." (further discussing the impact of and risks relating to the BioGlue CE Mark).

We are significantly dependent on our revenues from aortic stent grafts and are subject to a variety of related risks.

Aortic stent grafts are a significant source of our revenues, and as such, any risk adversely affecting aortic stent grafts would likely be material to our financial results. We face risks relating to aortic stent grafts based on our ability to:

- Compete effectively with some of our major competitors, as they may have advantages over us in terms of cost structure, supply chain, pricing, sales force footprint, and brand recognition;
- Develop innovative, high quality, and in-demand aortic repair products;
- Respond adequately to enhanced regulatory requirements and enforcement activities, and particularly, our ability to obtain regulatory approvals and renewals globally;
- Meet demand and manage inventory for aortic stent grafts as we seek to expand our business globally; and
- Maintain a productive working relationship with our Works Council in Germany.

We are significantly dependent on our revenues from On-X products and are subject to a variety of related risks.

On-X products are a significant source of our revenues, and as such, any risk adversely affecting our On-X products or business would likely be material to our financial results. We face risks based on our ability to:

- Compete effectively with some of our major competitors, as they may have advantages over us in terms of cost structure, supply chain, pricing, sales force footprint, and brand recognition;
- Take further market share in the mechanical heart valve market based on the FDA's approved lower INR indication for the On-X aortic heart valve or complete the associated FDA mandated post-approval studies;
- Address clinical trial data or changes in technology that may reduce the demand for mechanical heart valves, such as data regarding transcatheter aortic valve replacement, or "TAVR" devices;
- Manage risks associated with less favorable contract terms for On-X products on consignment at hospitals; and
- Respond adequately to enhanced international regulatory requirements or enforcement activities.

Continued fluctuation of foreign currencies relative to the US Dollar could materially, adversely affect our business.

The majority of our foreign product revenues are denominated in Euros and, as such, are sensitive to changes in exchange rates. In addition, a portion of our dollar-denominated and euro-denominated product sales are made to customers in other countries who must convert local currencies into US Dollars or Euros in order to purchase these products. We also have balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency transactions and balances are sensitive to changes in exchange rates. Additionally, as a result of global inflationary pressures, and in some cases, currency crises, it is possible that foreign currency controls, the development of parallel exchange rates, or highly inflationary economies could arise in certain countries. Fluctuations in exchange rates of Euros or other local currencies in relation to the US Dollar could materially reduce our future revenues as compared to the comparable prior periods. Should this occur, it could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

Our charges resulting from acquisitions, restructurings, and integrations may materially, adversely affect the market value of our common stock.

We account for the completion of acquisitions using the purchase method of accounting. Our financial results could be adversely affected by a number of financial adjustments required by purchase accounting such as:

- We may incur added amortization expense over the estimated useful lives of some acquired intangible assets;
- We may incur additional depreciation expense as a result of recording purchased tangible assets;
- We may be required to incur material charges relating to any impairment of goodwill and intangible assets;
- Cost of sales may increase temporarily if acquired inventory is recorded at fair market value;
- If acquisition consideration consists of earn-outs, our earnings may be affected by changes in estimates of future contingent consideration; or
- Earnings may be affected by transaction and integration costs, which are expensed immediately.

As an example of this risk, we fully impaired the value of a securities purchase option agreement with Endospan ("Endospan Option") and fully wrote-down the value of an agreement for a secured loan from Artivion to Endospan ("Endospan Loan"), primarily driven by a decrease in forecasted operating results. This impairment, and other potential risks like those mentioned above, may adversely affect the market value of our common stock.

Operational Risks

We are heavily dependent on our suppliers and contract manufacturers to provide quality products.

The materials and supplies used in our product manufacturing and tissue processing are subject to regulatory requirements and oversight. If materials or supplies used in our processes fail to meet these requirements or are subject to regulatory enforcement action, they may have to be scrapped, or our products or tissues could be rejected during or after processing, recalled, or rejected by customers. In these cases, we may have to immediately scrap raw or in-process materials, or expense the costs of manufacturing or preservation.

As an example of this risk, in the fourth quarter of 2020 we became aware that a supplier shipped to us a lot of saline solution that we use in our tissue processing that contained some contamination. The contamination was identified by our routine quality controls. While we were able to mitigate the impact of this contamination through our own efforts and additional testing that was reviewed with the FDA, the contaminated solution impacted a small percentage of the tissue processed with this lot of solution, requiring us to write-off those contaminated tissues in the fourth quarter of 2020 and impacting our ability to fully meet demand for certain tissues and sizes in the fourth quarter of 2020, the first quarter of 2021, and to a lesser extent the second quarter of 2021.

In addition, if these materials or supplies, or changes to them, do not receive regulatory approval or are recalled, if the related suppliers and/or their facilities are shut down temporarily or permanently, for any reason, or if the related suppliers are otherwise unable or unwilling to supply us, we may not have sufficient materials or supplies to manufacture our products or process tissues. In addition, we rely on contract manufacturers to manufacture some of our products or to provide additional manufacturing capacity for some products. If these contract manufacturers fail to meet our quality standards or other requirements or if they are unable or unwilling to supply the products, we may not be able to meet demand for these products. Our ability to fully recover all possible losses from these suppliers and contract manufacturers may have practical limitations imposed by factors like industry standard contractual terms or the financial resources of the adverse party.

Finally, the COVID-19 pandemic, the wars in Ukraine and the Gaza Strip, work force shortages, exchange rates, and inflation continue to impact the global supply chain; their impact on workforces, global mobility, material availability, demand, and shipping and reorder times and reliability has reportedly continued or worsened in many cases. The ongoing wars may add to or exacerbate challenges faced by the global supply chain. See Part I, Item 1A, "Risk Factors – Business and Economic Risks – We are subject to a variety of risks due to our international operations and continued global expansion." Although we have yet to experience any material effects of this impact on our supply chain or operations, we face an increasing risk that upstream disruptions may occur. Risks relating to the lingering effects of global supply chain disruptions may even continue after COVID-19's risk as a global pandemic and the wars in Ukraine and Gaza have subsided.

We are dependent on single and sole-source suppliers and single facilities.

Some of the materials, supplies, and services used in our product manufacturing and tissue processing, as well as some of our products, are sourced from single- or sole-source suppliers. As a result, our ability to negotiate favorable terms with those suppliers may be limited, and if those suppliers experience operational, financial, quality, or regulatory difficulties, or if those suppliers and/or their facilities refuse to supply us or cease operations temporarily or permanently, or if those suppliers take unreasonable business positions, we could be forced to cease product manufacturing or tissue processing until the suppliers resume operations, until alternative suppliers could be identified and qualified, or permanently if the suppliers do not resume operations and no alternative suppliers could be identified and qualified. We could also be forced to purchase alternative materials, supplies, or services with unfavorable terms due to diminished bargaining power.

As an example of these risks, in 2019 we lost our supply of handpieces for cardiac laser therapy resulting from a manufacturing location change at our supplier that ultimately required a Premarket Approval ("PMA") supplement and FDA approval before handpiece manufacturing and distribution could resume. Even though the FDA approved the PMA-S, our supplier was unable to fully resume production due to factors outside of our control. Due to these and other supplier issues, we had virtually no supply of handpieces during the first three quarters of 2021. In the fourth quarter of 2021 our supplier was notified that their sole-source manufacturer of tubing used in the handpiece assembly had gone out of business, requiring us to work with our supplier to identify and qualify a new supplier before a disruption in handpiece availability occurred. In February 2023 we were notified by our supplier that, because the sole-source manufacturer had gone out of business, and because a new supplier had yet to be identified and qualified, our supplier would cease to supply handpieces, effective immediately. As of June 30, 2023 we were unable to identify an alternative source of supply or handpiece manufacturer and do not foresee a resumption of this business in the future. As a result, we wrote-off all of our CardioGenesis cardiac laser therapy assets and recorded an expense of $390,000 during the nine months ended September 30, 2023 on our Condensed Consolidated Statements of Operations and Comprehensive Loss.

By way of additional non-limiting examples, our BioGlue product has three main product components: bovine protein, a cross linker, and a molded plastic resin delivery device. The bovine protein and cross linker are obtained from a small number of qualified suppliers. The delivery devices are manufactured by a single supplier, using resin supplied by a single supplier. We purchase grafts for our On-X AAP from a single supplier and various other components for our On-X valves come from single-source suppliers.

Our preservation services business and our ability to supply needed tissues is dependent upon donation of tissues from human donors by donor families. Donated human tissue is procured from deceased human donors by organ and tissue procurement organizations ("OPOs") and tissue banks. We must rely on the OPOs and tissue banks that we work with to educate the public on the need for donation, to foster a willingness to donate tissue, to follow our donor screening and procurement procedures, and to send donated tissue to us. We have active relationships with approximately 60 OPOs and tissue banks throughout the US. As with any vendor, we believe these relationships with our OPOs are critical in the preservation services industry and that the breadth of these existing relationships provides us with a significant advantage over potential new entrants to this market. We also use various raw materials, including medicines and solutions, in our tissue processing. Some of these raw materials are manufactured by single suppliers or by a small group of suppliers.

Our aortic stent graft systems consist of two main product components: the stent graft and the delivery system. The stent graft is manufactured from several different raw materials that are manufactured internally or at various external suppliers, including single suppliers. The delivery systems we manufacture are comprised of several different raw materials and subassemblies. Our internal manufacturing processes include injection molding and machining of plastic parts, suturing of stent grafts, processing of Nitinol, and weaving of textiles. Our conventional polyester grafts consist of two main product components: polyester fabric and collagen coating. The polyester fabric is woven from a few different yarns that are supplied by an external supplier. The collagen suspension we manufacture is comprised of a collagenous tissue that is supplied by a single supplier. The conventional ePTFE grafts we manufacture are comprised of various raw materials supplied by several suppliers. For some products the ePTFE grafts are heparin coated. For these products, the heparin suspension we manufacture is comprised of a heparin solution that is also supplied by an external supplier.

We have three internal manufacturing facilities: Austin, Texas for On-X products, Hechingen, Germany for internally manufactured aortic stent grafts, and Kennesaw, Georgia for all other products and services. Certain aortic stent graft assemblies are manufactured for us by a contract manufacturer in Slovakia. The AMDS product is solely manufactured by a supplier in Charlotte, North Carolina, and the NEXUS products are solely manufactured by Endospan in Herzliya, Israel. If one of these suppliers or facilities ceases operations temporarily or permanently, for any reason including a pandemic, war, or climate change related event, our business could be substantially disrupted.

Although we work diligently to maintain adequate inventories of raw materials, components, supplies, subassemblies, and finished goods, there can be no assurance that we will be able to avoid all disruptions to our global supply chain, or disruptions to our sterilization or distribution networks. Any of these disruptions could have a material, adverse effect on our revenues, reputation, or profitability.

We are dependent on our specialized workforce.

Our business and future operating results depend in significant part upon the continued contributions of our specialized workforce, including key personnel, qualified personnel with medical device and tissue processing experience, and senior management with experience in the medical device or tissue processing space, some of whom would be difficult to replace. Our business and future operating results, including production at our manufacturing and tissue processing facilities, also depend in significant part on our ability to attract and retain qualified management, operations, processing, marketing, sales, and support personnel. Our primary facilities are in Kennesaw, Georgia; Austin, Texas; and Hechingen, Germany, where the supply of qualified medical device and tissue processing and other personnel is limited, competition for such personnel is significant, and we cannot ensure that we will be successful in attracting or retaining them. We face risks if we lose any key employees to other employers or due to severe illness, death, or retirement, if any of our key employees fail to perform adequately, or if we are unable to attract and retain skilled employees. This risk was exacerbated by the pandemic and continues to be impacted by changes in macroeconomic conditions. Competition for talent and worker shortages at all levels have impacted supply chains and distribution channels and our ability to attract and retain the specialized workforce necessary for our business and operations.

We continue to evaluate expansion through acquisitions of, or licenses with, investments in, and distribution arrangements with, other companies or technologies, which may carry significant risks.

One of our growth strategies is to pursue select acquisitions, licensing, or distribution rights with companies or technologies that complement our existing products, services, and infrastructure. In connection with one or more of these transactions, we may:

- Issue additional equity securities that would dilute our stockholders' ownership interest;
- Use cash we may need in the future to operate our business;
- Incur debt, including on terms that could be unfavorable to us or debt we might be unable to repay;
- Structure the transaction resulting in unfavorable tax consequences, such as a stock purchase that does not permit a step-up in basis for the assets acquired;
- Be unable to realize the anticipated benefits of the transaction; or
- Assume material unknown liabilities associated with the acquired business.

We may not realize all the anticipated benefits of our business development activities.

As part of our efforts to drive growth by pursuing select acquisition, license, and distribution opportunities that are aligned to our objectives and complement our existing products, services, and infrastructure or to divest non-core product lines, we have completed several transactions in recent years and may pursue similar additional transactions in the future. Examples of these activities include the following:

- On September 11, 2019 we entered into various agreements with Endospan, an Israeli medical device manufacturer (the "Endospan Transaction"). The Endospan Transaction included an exclusive distribution agreement for NEXUS in Europe, the Endospan Loan, and a security purchase option agreement for Artivion to purchase all the outstanding Endospan securities from Endospan's existing security holders upon FDA approval of the NEXUS products;
- On September 2, 2020 we acquired 100% of the outstanding shares of Ascyrus, the developer of AMDS; and
- On July 28, 2021 we entered into various agreements with Baxter and SMI related to the sale of our PerClot assets to Baxter and the termination of our existing material agreements with SMI.

Our ability to realize the anticipated business opportunities, growth prospects, cost savings, synergies, and other benefits of these and other transactions depends on a number of factors including our ability to:

- Leverage our global infrastructure to sell and cross-market the acquired products;
- Drive adoption of NEXUS, NEXUS DUO, and AMDS in the European and other markets, including our ability to manage the substantial product training, implant support, and proctoring requirements for NEXUS procedures;

- Bring acquired products to the US market, including our acquired aortic stent grafts;
- Harness the aortic stent graft product pipeline and our research and development capabilities;
- Obtain regulatory approvals in relevant markets, including our ability to timely obtain or maintain CE Mark product certifications for pipeline and current products;
- Execute on development and clinical trial timelines for acquired products;
- Manage global inventories, including our ability to manage inventories for product lines with large numbers of product configurations and manage manufacturing and demand cycles to avoid excess inventory obsolescence due to shelf life expiration, particularly for processed tissues and aortic stent grafts;
- Carry, service, and manage significant debt and repayment obligations; and
- Manage the unforeseen risks and uncertainties related to these transactions, including any related to intellectual property rights.

Additionally, our ability to realize the anticipated business opportunities, growth prospects, synergies, and other benefits of the Endospan Transaction depends on a number of additional factors including Endospan's ability to: (a) comply with the Endospan Loan and other debt obligations, and avoid an event of default; (b) successfully commercialize NEXUS and NEXUS DUO, raise capital and drive adoption in markets in and outside of Europe; (c) meet demand for NEXUS and NEXUS DUO; (d) meet quality and regulatory requirements for NEXUS and NEXUS DUO; (e) manage any intellectual property risks and uncertainties associated with NEXUS and NEXUS DUO; (f) obtain FDA approval of NEXUS and NEXUS DUO; (g) remain a going concern; and (h) develop NEXUS, NEXUS DUO, and other product improvements to meet competitive threats and physician demand. As an example of this risk, the forecasted operating results related to NEXUS decreased, resulting in an impairment to the carrying value of the Endospan Option, and a full write-down of the value of the Endospan Loan, reflecting decreased expectations with respect to the anticipated benefits of the Endospan Transaction.

Many of these factors are outside of our control and any one of them could result in increased costs, decreased revenues, and diversion of management's time and energy. The benefits of these transactions may not be achieved within the anticipated time frame or at all. Any of these factors could negatively impact our earnings per share, decrease or delay the expected accretive effect of the transaction, and negatively impact the price of our common stock. In addition, if we fail to realize the anticipated benefits of a transaction, we could experience an interruption or loss of momentum in our existing business activities.

We may not realize all the anticipated benefits of our corporate rebranding and it may result in unanticipated disruptions to our on-going business.

In order to reflect our evolution to focus on providing innovative technologies to surgeons who treat patients with aortic disease, we changed our name to Artivion, Inc., effective January 18, 2022 (the "Corporate Rebrand"). The Corporate Rebrand also involved the adoption of a new ticker symbol on the New York Stock Exchange, "AORT". We may face unanticipated disruptions to our business arising from the Corporate Rebrand, and it may expose us to additional risks, including:

- Disruptions or unanticipated delays accessing certain markets or segments due to delays or other issues with regulatory approvals, clinical trials, or other updates arising from or related to the Corporate Rebrand;
- Confusion within the marketplace, particularly with multiple points of contact in our downstream product flow involving purchasing and accounts payable departments and end users;
- Intellectual property risks associated with the adoption of a new corporate identity and trade dress; and
- Loss of brand equity associated with our legacy brands, including our CryoLife and JOTEC brands that will become less prominent over time.

The Corporate Rebrand involved significant financial and resource investment and will continue to do so as we complete our global brand transitions over the coming years. The anticipated benefits of the Corporate Rebrand may not be achieved within the anticipated timeframe, without additional near or long-term investment, or at all. Any of these factors could negatively impact our revenues, earnings per share, decrease or delay the expected accretive effect of the Corporate Rebrand, and negatively impact the price of our common stock.

Significant disruptions of information technology systems or breaches of information security systems could adversely affect our business.

We rely upon a combination of sophisticated information technology systems as well as traditional recordkeeping to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information (including, but not limited to, information about our business, financial information, personnel data, intellectual property, and, in some instances, patient data). Our information technology and information security systems and records are potentially vulnerable to security breaches, service interruptions, data loss, or malicious attacks resulting from inadvertent or intentional actions by our employees, vendors, or other third parties. In addition, due to the COVID-19 pandemic, we have implemented remote work arrangements for some employees, and those employees may use outside technology and systems that are vulnerable to security breaches, service interruptions, data loss or malicious attacks, including by third parties.

While we have invested, and continue to invest, in our information technology and information security systems and employee information security training, there can be no assurance that our efforts will prevent all security breaches, service interruptions, or data losses, particularly in light of rapid improvements in information processing technology accompanying developments in, among other areas, artificial intelligence platforms. We have limited cyber-insurance coverage that may not cover all possible events, and this insurance is subject to deductibles and coverage limitations. Any security breaches, service interruptions, or data losses could adversely affect our business operations or result in the loss of critical or sensitive confidential information or intellectual property, or in financial, legal, business, and reputational harm to us or allow third parties to gain material, inside information that they may use to trade in our securities.

Industry Risks

Our products and tissues are highly regulated and subject to significant quality and regulatory risks.

The commercialization of medical devices and processing and distribution of human tissues are highly complex and subject to significant global quality and regulatory risks and as such, we face the following risks:

- Our products and tissues allegedly have caused, and may in the future cause, patient injury, which has exposed, and could in the future expose, us to liability claims that could lead to additional regulatory scrutiny;
- Our manufacturing and tissue processing operations are subject to regulatory scrutiny, inspections and enforcement actions, and regulatory agencies could require us to change or modify our operations or take other action, such as issuing product recalls or holds;
- Regulatory agencies could reclassify, re-evaluate, or suspend our clearances or approvals, or fail, or decline to, issue or reissue our clearances or approvals that are necessary to sell our products and distribute tissues;
- Regulatory and quality requirements are subject to change, which could adversely affect our ability to sell our products or distribute tissues; and
- Adverse publicity associated with our products, processed tissues, or our industry could lead to a decreased use of our products or tissues, increased regulatory scrutiny, or product or tissue processing liability claims.

As an example of these risks, on May 25, 2017, the European Union adopted new regulations governing medical devices (the MDR), which were fully implemented on May 26, 2021. The MDR places stricter requirements on manufacturers and European Notified Bodies regarding, among other things, product classifications and pre- and post-market clinical studies for product clearances and approvals which could result in product reclassifications or the imposition of other regulatory requirements that could delay, impede, or prevent our ability to commercialize existing, improved, or new products in the European Economic Area and other markets that require CE Marking. Additionally, to the extent the MDR places stricter requirements on manufacturers of custom-made devices, those new requirements could delay, impede, or otherwise impact the availability of our E-xtra Design Engineering products. COVID-19 has impacted the predictability and timelines associated with the MDR transition. Most recently, the European Parliament extended the MDR transition period under Regulation (EU) 2023/607 but it is still unclear whether this extension will be able to mitigate the challenges posed by the transition to the MDR. In order for devices to qualify for the extended MDR transition period, manufacturers must submit a formal application to the relevant notified body by May 26, 2024, and the applicant and notified body must enter into a signed written agreement no later than September 26, 2024. If we are unable to obtain agreements covering our products by that time, the presently applicable extensions will expire and impact our ability to market those devices.

Since the implementation of the MDR, Notified Bodies must review any proposed changes to determine if they require evaluation under the MDR or if they can still be evaluated under the currently held Medical Device Directive ("MDD") certifications. Our inability to obtain certifications for changes under the transitional provisions of the MDR's Article 120 or successfully submit proposed changes requiring MDR evaluation will delay implementation of those changes which could adversely impact our ability to obtain or renew certifications, clearances, or approvals for our products.

Additionally, as MDD-based CE Marks expire, recertification must be obtained under the MDR. Industry-wide, companies are experiencing delays in obtaining new and updated certifications under the MDR as Notified Bodies struggle to recover from COVID-19, deal with depleted workforces, and handle the volume of work required to transition tens of thousands of currently-marketed devices from the MDD to the MDR. As one such example, our MDD-based CE Mark for Chord-X expired in September 2022, which will impact our ability to supply certain territories once our saleable inventory is depleted. If Notified Bodies continue to struggle to meet demand and timely process submissions and recertifications, we may face additional disruptions associated with the MDR transition.

As another example of this risk, our CE Mark for BioGlue expired in December 2021. Due to delays renewing this CE Mark and transitioning BioGlue to a new Notified Body, our ability to supply certain markets with BioGlue was impacted. Although we were able to mitigate most of the impact by obtaining derogations in the majority of relevant territories, we may face similar risks and market disruptions related to the MDR transition which continues to be in a state of change.

Finally, we anticipate additional regulatory impact as a result of Brexit. The UK Medicines and Healthcare Products Regulatory Agency has announced that CE Marking will continue to be recognized in the UK and certificates issued by EU-recognized Notified Bodies will continue to be valid in the UK market until the certificates expire or the applicable transition period expires (currently June 30, 2028 at the earliest). Upon expiration, all devices marketed in the UK will require UK Conformity Assessed Marks certified by a UK Approved Body (the re-designation of the UK Notified Body).

In 2019 our Notified Body in the UK, LRQA, informed us that it would no longer provide Notified Body services for medical devices effective September 2019. The governing German competent authority, the Regierungspraesidium-Tubingen, granted us an extended grace period until December 31, 2021 to transfer LRQA-issued certifications for BioGlue and PhotoFix to a new Notified Body. Although our BioGlue CE Mark has been successfully transferred to our new Notified Body, DEKRA, we are still in the process of transferring PhotoFix to DEKRA. While progress has been made, failure to timely complete the transfer or any other delays in the MDR transition, may have a material, adverse effect on our ability to supply PhotoFix in affected jurisdictions, have a material, adverse impact on our business, and may also impact our Medical Device Single Audit Program ("MDSAP") certifications. Failure to timely obtain new MDSAP certifications following their expiration may impact our ability to distribute covered products in Australia, Brazil, Canada, and Japan.

Reclassification by the FDA of CryoValve SG pulmonary heart valve ("CryoValve SGPV") may make it commercially infeasible to continue processing the CryoValve SGPV.

In December 2019 we learned that the FDA is preparing to issue a proposed rule for reclassification of more than minimally manipulated ("MMM") allograft heart valves to Class III medical devices, which could include our CryoValve SGPV. Following a comment period and subsequent publication of any final rule, should the CryoValve SGPV be determined to be MMM, we expect to have approximately thirty months to submit an FDA PMA application, after which the FDA will determine if, and for how long, we may continue to provide these tissues to customers during review of the PMA application. To date, the FDA has not issued such a proposed final rule.

If the FDA ultimately classifies our CryoValve SGPV as a Class III medical device, and if there are delays in obtaining the PMA, if we are unsuccessful in obtaining the PMA, or if the costs associated with these activities are significant, we could decide that the requirements for continued processing of the CryoValve SGPV are too onerous, leading us to discontinue distribution of these tissues.

We may not be successful in obtaining clinical results or regulatory clearances/approvals for new and existing products and services, and our approved products and services may not achieve market acceptance.

Our growth and profitability depends in part upon our ability to develop, and successfully introduce, new products and services, or expand upon existing indications, clearances, and approvals, requiring that we invest significant time and resources to obtain new regulatory clearances/approvals, including investment into pre- and post-market clinical studies. Although we believe certain products and services in our portfolio or under development may be effective in a particular application, we cannot be certain until we successfully execute on relevant clinical trials, and the results we obtain from pre- and post-market clinical studies may be insufficient for us to obtain or maintain any required regulatory approvals or clearances.

We are currently seeking regulatory approval for BioGlue in China, where the Chinese regulatory body has made additional requests, and expressed several concerns, related to the application. We have obtained an extension of time until February 2024 in which to file an updated submission for BioGlue in China. If the costs to file an updated submission are prohibitive, or we cannot obtain approval following the review of the updated submission or the costs to do so are prohibitive, we ultimately may be unable to sell BioGlue in China. Similarly, in November 2023 we announced that we were no longer pursuing a labeling change for our On-X mitral valve in connection with our PROACT Mitral trial due to additional investments that would be required to do so.

As another example of this risk, we obtained a CE Mark for E-nya in the fourth quarter of 2019 and began limited distribution of E-nya in the second quarter of 2020. In the fourth quarter of 2021 we suspended the limited release to evaluate modifications in response to customer feedback. We ultimately concluded the E-nya device would not achieve our market acceptance targets without additional design changes and ended the limited market release.

As a further example of this risk, in September 2022 we halted the PROACT Xa clinical trial based on the recommendation of the trial's Data and Safety Monitoring Board ("DSMB") due to insufficient evidence to support non-inferiority of apixaban to warfarin for valve thrombosis and thromboembolism. The DSMB found that continuing the trial was unlikely to achieve the primary endpoint while possibly exposing patients to increased risk.

Each of our trials, studies, and approvals is subject to the risks outlined herein.

We cannot give assurance that regulatory agencies will clear or approve these products and services or indications, or any new products and services or new indications, on a timely basis, if ever, or that the products and services or new indications will adequately meet the requirements of the market or achieve market acceptance. Pre- and post-market clinical studies may also be delayed or halted due to many factors beyond our control.

If we are unable to successfully complete the development of a product, service, or application, or if we determine for any reason not to complete development or obtain regulatory approval or clearance of any product, service, or application, particularly in instances when we have expended significant capital, this could materially, adversely affect our financial performance. Research and development efforts are time consuming and expensive, and we cannot be certain that these efforts will lead to commercially successful products or services. Halting R&D efforts and clinical trials prematurely may lead to accelerated or unanticipated wind down costs. Even the successful commercialization of a new product or service in the medical industry can be characterized by slow growth and high costs associated with marketing, under-utilized production capacity, and continuing research and development and education costs, among other things. The introduction of new products or services may require significant physician training or years of clinical evidence in order to gain acceptance in the medical community.

Regulatory enforcement activities or private litigation regarding the use of ethylene oxide ("EtO"), which is used to sterilize some of our products and components, could have a material, adverse impact on us.

Some of our products, including our On-X products, are sterilized using EtO. Although we have a small-scale EtO facility in Austin, Texas, we rely primarily on third-party large-scale EtO facilities to sterilize our products. In addition, some of our suppliers use, or rely upon third parties to use, EtO to sterilize some of our product components. Concerns about the release of EtO into the environment at unsafe levels have led to increased activism and lobbying as well as various regulatory enforcement activities against EtO facilities, including closures and temporary closures, lawsuits against EtO service providers, and proposals increasing regulations related to EtO. The number of EtO facilities in the US is limited, and any permanent or temporary closures or disruption to their operations for any reason could delay, impede, or prevent our ability to commercialize our products. In addition, any litigation, regulatory enforcement, or government regulation regarding the use of EtO could result in financial, legal, business, and reputational harm to us.

We may be subject to fines, penalties, and other sanctions if we are deemed to be promoting the use of our products for unapproved, or off-label, uses.

Our business and future growth depend on the continued use of our products for approved uses. Generally, regulators contend that, unless our products are approved or cleared by a regulatory body for alternative uses, we may not make claims about the safety or effectiveness of our products or promote them for such uses. Such limitations present a risk that law enforcement could allege that the nature and scope of our sales, marketing, or support activities, though designed to comply with all regulatory requirements, constitute unlawful promotion of our products for an unapproved use. We also face the risk that such authorities might pursue enforcement based on past activities that we discontinued or changed. Investigations concerning the promotion of unapproved uses and related issues are typically expensive, disruptive, and burdensome and generate negative publicity. If our promotional activities are found to be in violation of the law, we may face significant fines and penalties and may be required to substantially change our sales, promotion, grant, and educational activities. In addition, we or our officers could be excluded from participation in government healthcare programs such as Medicare and Medicaid.

Healthcare policy changes may have a material, adverse effect on us.

In response to perceived increases in healthcare costs in recent years, there have been, and continue to be, proposals by the governmental authorities, third-party payors, and elected office holders and candidates to impact public health, control healthcare costs and, more generally, to reform the healthcare systems. Additional uncertainty is anticipated as debates about healthcare and public health continue in light of the COVID-19 pandemic which may have an impact on US law relating to the healthcare industry. Many US healthcare laws, such as the Affordable Care Act, are complex, subject to change, and dependent on interpretation and enforcement decisions from government agencies with broad discretion. The application of these laws to us, our customers, or the specific services and relationships we have with our customers is not always clear. Our failure to anticipate accurately any changes to, or the repeal or invalidation of all or part of the Affordable Care Act and similar or future laws and regulations, or our failure to comply with them, could create liability for us, result in adverse publicity and negatively affect our business, results of operations, and financial condition.

Further, the growth of our business, results of operations and financial condition rely, in part, on customers in the healthcare industry that receive substantial revenues from governmental and other third-party payer programs. A reduction or less than expected increase in government funding for these programs or a change in reimbursement or allocation methodologies, or a change in reimbursement related to products designated as “breakthrough devices” by the FDA, could negatively affect our customers’ businesses and, in turn, negatively impact our business, results of operations and financial condition. Any changes that lower reimbursement for our products or reduce medical procedure volumes, could adversely affect our business and profitability.

Legal, Quality, and Regulatory Risks

As a medical device manufacturer and tissue services provider we are exposed to risk of product liability claims and our existing insurance coverage may be insufficient, or we may be unable to obtain insurance in the future, to cover any resulting liability.

Our products and processed tissues allegedly have caused, and may in the future cause, injury or result in other serious complications that may result in product or other liability claims from our customers or their patients. If our products are defectively designed, manufactured, or labeled, or contain inadequate warnings, defective components, or are misused, or are used contrary to our warnings, instructions, and approved indications, we may become subject to costly litigation that can have unpredictable and sometimes extreme outcomes.

We maintain claims-made insurance policies to mitigate our financial exposure to product and tissue processing liability and securities, claims, among others, that are reported to the insurance carrier while the policy is in effect. These policies do not include coverage for punitive damages. Although we have insurance for product and tissue processing liabilities, securities, property, and general liabilities, if we are unsuccessful in arranging cost-effective acceptable resolutions of claims, it is possible that our insurance program may not be adequate to cover any or all possible claims or losses, including losses arising out of natural disasters or catastrophic circumstances. Any significant claim could result in an increase in our insurance rates or jeopardize our ability to secure coverage on reasonable terms, if at all.

Any securities or product liability/tissue processing claim, even a meritless or unsuccessful one, could be costly to defend, and result in diversion of our management's attention from our business, adverse publicity, withdrawal of clinical trial participants, injury to our reputation, or loss of revenue.

We are subject to various US and international bribery, anti-kickback, false claims, privacy, transparency, and similar laws, any breach of which could cause a material, adverse effect on our business, financial condition, and profitability.

Our relationships with physicians, hospitals, and other healthcare providers are subject to scrutiny under various US and international bribery, anti-kickback, false claims, privacy, transparency, and similar laws, often referred to collectively as "healthcare compliance laws." Healthcare compliance laws are broad, sometimes ambiguous, complex, and subject to change and changing interpretations. The ongoing wars in Ukraine and Gaza, and the current and future sanctions imposed on Russia and others as a result may exacerbate these risks. See also Part I, Item 1A, "Risk Factors – Business and Economic Risks - We are subject to a variety of risks due to our international operations and continued global expansion." Possible sanctions for violation of these healthcare compliance laws include fines, civil and criminal penalties, exclusion from government healthcare programs, and despite our compliance efforts, we face the risk of an enforcement activity or a finding of a violation of these laws.

We have entered into consulting and product development agreements with healthcare professionals and healthcare organizations, including some who may order our products or make decisions to use them. We have also adopted the AdvaMed Code of Conduct, the MedTech Europe Code of Ethical Business Practice, and the APACMed Code of Ethical Conduct which govern our relationships with healthcare professionals to bolster our compliance with healthcare compliance laws. While our relationships with healthcare professionals and organizations are structured to comply with such laws and we conduct training sessions on these laws and codes, it is possible that enforcement authorities may view our relationships as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties or debarment. In any event, any enforcement review of or action against us as a result of such review, regardless of outcome, could be costly and time consuming. Additionally, we cannot predict the impact of any changes in or interpretations of these laws, whether these changes will be retroactive or will have effect on a going-forward basis only.

The proliferation of new and expanded data privacy laws, including the General Data Protection Regulation in the European Union, could adversely affect our business.

An increasing number of federal, state, and foreign data privacy laws and regulations, which can be enforced by private parties or governmental entities, have been or are being promulgated and are constantly evolving. These laws and regulations may include new requirements for companies that receive or process an individual's personal data (including employees), which increases our operating costs and requires significant management time and energy. Many of these laws and regulations, including the European Union's General Data Protection Regulation ("GDPR") also include significant penalties for noncompliance. Although our personal data practices, policies, and procedures are intended to comply with GDPR and other data privacy laws and regulations, there can be no assurance that regulatory or enforcement authorities will view our arrangements as being in compliance with applicable laws, or that one or more of our employees or agents will not disregard the rules we have established. Any privacy related government enforcement activities may be costly, result in negative publicity, or subject us to significant penalties.

Some of our products and technologies are subject to significant intellectual property risks and uncertainty.

We own trade secrets, patents, patent applications, and licenses relating to our technologies and trademarks and goodwill related to our products and services, which we believe provide us with important competitive advantages. We cannot be certain that we will be able to maintain our trade secrets, that our pending patent applications will issue as patents, or that no one will challenge the validity or enforceability of any intellectual property that we adopt, own, or license. Competitors may independently develop our proprietary technologies or design non-infringing alternatives to patented inventions. We do not control the maintenance, prosecution, enforcement, or strategy for in-licensed intellectual property and as such are dependent in part on the owners of these rights to maintain their viability. Their failure to do so could significantly impair our ability to exploit those technologies. Additionally, our technologies, products, or services could infringe intellectual property rights owned by others, or others could infringe our intellectual property rights.

If we become involved in intellectual property disputes, the costs could be expensive, and if we were to lose or decide to settle, the amounts or effects of the settlement or award by a tribunal could be costly.

Risks Relating to Our Indebtedness

The agreements governing our indebtedness contain restrictions that limit our flexibility in operating our business.

The agreements currently governing our indebtedness contain, and any instruments governing future indebtedness of ours may contain, covenants that impose significant operating and financial restrictions on us and certain of our subsidiaries, including (subject in each case to certain exceptions) restrictions or prohibitions on our and certain of our subsidiaries' ability to, among other things:

- Incur or guarantee additional debt or create liens on certain assets;
- Pay dividends on or make distributions of our share capital, including repurchasing or redeeming capital stock, or make other restricted payments, including restricted junior payments;
- Enter into agreements that restrict our subsidiaries' ability to pay dividends to us, repay debt owed to us or our subsidiaries, or make loans or advances to us or our other subsidiaries;
- Enter into certain transactions with our affiliates including any transaction or merger or consolidation, liquidation, winding-up, or dissolution; convey, sell, lease, exchange, transfer or otherwise dispose of all or any part of our business, assets or property; or sell, assign, or otherwise dispose of any capital stock of any subsidiary;
- Enter into certain rate swap transactions, basis swaps, credit derivative transactions, and other similar transactions, whether relating to interest rates, commodities, investments, securities, currencies, or any other relevant measure, or transactions of any kind subject to any form of master purchase agreement governed by the International Swaps and Derivatives Association, Inc., any International Foreign Exchange Master Agreement, or any other master agreement;
- Amend, supplement, waive, or otherwise modify our or our subsidiaries' organizational documents in a manner that would be materially adverse to the interests of the lenders, or change or amend the terms of documentation regarding junior financing in a manner that would be materially adverse to the interests of the lenders;
- Make changes to our and our subsidiaries' fiscal year without notice to the administrative agent;
- Enter into agreements which restrict our ability to incur liens;
- Engage in any line of business substantially different from that in which we are currently engaged; and
- Make certain investments, including strategic acquisitions or joint ventures.

Additionally, because of the terms governing our indebtedness, including springing maturities in our Credit Agreement and Convertible Senior Notes, we may be forced to refinance or take other measures related to our capital structure earlier than we may otherwise desire.

Our indebtedness could adversely affect our ability to raise additional capital to fund operations and limit our ability to react to changes in the economy or our industry.

Our current and future levels of indebtedness could adversely affect our ability to raise additional capital, limit our operational flexibility, and hinder our ability to react to changes in the economy or our industry. It may also limit our ability to borrow money, require us to dedicate substantial portions of our cash flow to repayment, and restrict our ability to invest in business opportunities. Because most of our borrowings are at a variable rate of interest, we are exposed to interest rate fluctuations.

We have pledged substantially all of our US assets as collateral under our existing Credit Agreement. If we default on the terms of such credit agreements and the holders of our indebtedness accelerate the repayment of such indebtedness, there can be no assurance that we will have sufficient assets to repay our indebtedness.

A failure to comply with the covenants in our existing Credit Agreement could result in an event of default, which, if not cured or waived, could have a material, adverse effect on our business, financial condition, and profitability. In the event of any such default, the holders of our indebtedness:

- Will not be required to lend any additional amounts to us; and
- Could elect to declare all indebtedness outstanding, together with accrued and unpaid interest and fees, to be due and payable and terminate all commitments to extend further credit, if applicable.

If we are unable to repay those amounts, the holders of our secured indebtedness could proceed against their secured collateral to seek repayment out of proceeds from the sale or liquidation of our assets. If our indebtedness were to be accelerated, there can be no assurance that our assets would be sufficient to repay such indebtedness in full.

Risks Relating to Ownership of our Common Stock

Our business could be negatively impacted as a result of shareholder activism.

In recent years, shareholder activists have become involved in the governance, strategic direction, and operations of companies. Such involvement with us may disrupt our business and divert the attention of our management, and any perceived uncertainties as to our future direction resulting from such involvement could result in the loss of business opportunities, be exploited by our competitors, cause concern for our current or potential customers, cause significant fluctuations in stock price, or make it more difficult to attract and retain qualified personnel and business partners.

Our business could be impacted by increased shareholder emphasis on environmental, social, and governance matters or efforts by certain governmental authorities to reduce such emphasis.

Investors and other key stakeholders are increasingly focusing on areas of corporate responsibility, and particularly matters related to environmental, social, and governance ("ESG") factors. Institutional investors have expressed expectations with respect to ESG matters that they use to guide their investment strategies and may, in some cases, choose not to invest in us if they believe our ESG policies are lagging or inadequate. Other stakeholders also have expectations regarding ESG factors, such as employees or potential employees who desire to work for a company that reflects their personal values. These areas of focus are continuing to evolve, as are the criteria that investors assess companies' performance in these areas. Investors are increasingly looking to companies that demonstrate strong ESG and sustainability practices as an indicator of long-term resilience, especially in light of events such as the COVID-19 pandemic. Additionally, some governmental entities, regulators, and industry activist groups, particularly in Europe, are placing an increased emphasis on sustainability including through initiatives like the German Sustainability Code (the ("Deutscher Nachhaltigkeitskodex"), the Global Reporting Initiative, and guidance from agencies like the European Federation of Financial Analyst Societies. Conversely, certain governmental authorities are challenging investors' reliance on ESG factors as, among other things, inconsistent with certain fiduciary duties. Keeping up with and meeting these expectations, sometimes contradictory, may disrupt our business and divert the attention of our management, and we may be unable to make the investments in ESG programs that our competitors with greater financial resources are able to make or we may be challenged by governmental authorities if we choose to make such investments. Failure to meet the expectations of investors, other stakeholders, or certain governmental authorities in these areas may damage our reputation, impact employee retention, impact the willingness of our customers to do business with us, or otherwise impact our financial results and stock price.

We do not anticipate paying any dividends on our common stock for the foreseeable future.

In December 2015 our Board of Directors discontinued dividend payments on our common stock for the foreseeable future. If we do not pay cash dividends, our shareholders may receive a return on their investment in our common stock only through appreciation of shares of our common stock that they own. In addition, restrictions in our credit facility limit our ability to pay future dividends.

Provisions of Delaware law and anti-takeover provisions in our organizational documents may discourage or prevent a change of control, even if an acquisition would be beneficial to shareholders, which could affect our share price adversely and prevent attempts by shareholders to remove current management.

Effective January 1, 2022 we reincorporated in Delaware. Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay, or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, the organizational documents adopted in connection with our reincorporation contain provisions that restrict persons who may call shareholder meetings, allow the issuance of blank-check preferred stock without the vote of shareholders, and allow the Board of Directors to fill vacancies and fix the number of directors. These provisions of Delaware law and our articles of incorporation and bylaws could prevent attempts by shareholders to remove current management, prohibit or delay mergers or other changes of control transactions, and discourage attempts by other companies to acquire us, even if such a transaction would be beneficial to our shareholders. The effects of reincorporation in Delaware are detailed in our 2021 Special Proxy Statement and Notice of Special Meeting filed with the SEC on October 7, 2021.

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

(c) The Company did not repurchase any of its equity security during the three months ended September 30, 2023.

Under our Credit Agreement, we are prohibited from repurchasing our common stock, except for the repurchase of stock from our employees or directors when tendered in payment of taxes or the exercise price of stock options, upon the satisfaction of certain requirements.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

On September 11, 2023 J. Patrick Mackin, our Chairman, President, and Chief Executive Officer, adopted a Rule 10b5-1 trading arrangement, pursuant to which he may sell up to 59,225 shares of the Company's common stock. The trading arrangement is intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The duration of the trading arrangement is from December 14, 2023 to February 21, 2024.

No other directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated the contracts, instructions or written plans for the purchase or sale of the Company’s securities during the quarter ended September 30, 2023.

Item 6. Exhibits.

The exhibit index can be found below.

Exhibit Number	Description
3.1	Delaware Certificate of Incorporation, effective January 1, 2022. (Incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed January 4, 2022).
3.2	Delaware Certificate of Amendment of Certificate of Incorporation, effective January 18, 2022. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed January 20, 2022).
3.3	Amended and Restated Bylaws of Artivion, Inc. (Incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed August 8, 2023).
10.1	Artivion, Inc. 2020 Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed May 19, 2023).
10.2*	Form of Indemnification Agreement for Non-Employee Directors and Executive Officers.
10.3+	Lease Agreement between On-X Life Technologies, Inc. and 1300 E. Anderson Lane, Ltd., dated March 2, 2009. (Incorporated herein by reference to Exhibit 10.14 to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018).
10.3(a)+	First Amendment to Lease Agreement between On-X Life Technologies, Inc. and 1300 E. Anderson Lane, Ltd., dated November 15, 2012. (Incorporated herein by reference to Exhibit 10.14(a) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018).
10.3(b)+	Second Amendment to Lease Agreement between On-X Life Technologies, Inc. and 1300 E. Anderson Lane, Ltd., dated January 29, 2015. (Incorporated herein by reference to Exhibit 10.14(b) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018).
10.3(c)+	Third Amendment to Lease Agreement between On-X Life Technologies, Inc. and 1300 E. Anderson Lane, Ltd., dated January 29, 2015. (Incorporated herein by reference to Exhibit 10.14(c) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018).
10.3(d)*+	Fourth Amendment to Lease Agreement between CryoLife, Inc. and 1300 E. Anderson Lane, Ltd., dated March 8, 2019.
10.3(e)*+	Fifth Amendment to Lease Agreement between CryoLife, Inc. and 1300 E. Anderson Lane, Ltd., dated September 1, 2023.
31.1*	Certification by J. Patrick Mackin pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32**	Certification pursuant to 18 USC. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	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.

\+ The Registrant has redacted exhibit provisions or terms that are both not material and would likely cause competitive harm to the Registrant if publicly disclosed.

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.

ARTIVION, INC.
(Registrant)

/s/ J. PATRICK MACKIN	/s/ D. ASHLEY LEE
J. PATRICK MACKIN	D. ASHLEY LEE
Chairman, President, and Chief Executive Officer (Principal Executive Officer)	Executive Vice President, and Chief Financial Officer (Principal Financial and Accounting Officer)
November 3, 2023	
DATE	

Exhibit 10.2

INDEMNIFICATION AGREEMENT

THIS INDEMNIFICATION AGREEMENT (this "Agreement") is made and entered into as of _____, between ARTIVION, INC., a Delaware corporation (the "Corporation"), and _____, a resident of _____ (the "Indemnitee").

W I T N E S S E T H

WHEREAS, at the request of the Corporation, Indemnitee is an executive officer and/or a member of the board of directors of the Corporation (the "Board of Directors") and in such capacity is performing a valuable service for the Corporation;

WHEREAS, both the Corporation and Indemnitee recognize the increased risk of litigation and other claims being asserted against directors and officers of public companies;

WHEREAS, in addition to the indemnification to which Indemnitee is entitled pursuant to the Certificate of Incorporation and Bylaws of the Corporation (as amended, the "Governing Documents") and as additional consideration for Indemnitee's service, the Corporation has obtained or may in the future obtain, at its expense, directors' and officers' liability insurance protecting Indemnitee in connection with such service; and

WHEREAS, Indemnitee and the Corporation acknowledge that the indemnities available under the Governing Documents and such insurance may not, in all situations, be adequate to protect Indemnitee against the risks associated with service to the Corporation.

NOW, THEREFORE, in consideration of the premises and the covenants in this Agreement, the parties hereto, intending to be legally bound hereby, agree as follows:

1. **Indemnification**.

(a) Subject to Sections 3 and 5 of this Agreement, the Corporation shall indemnify Indemnitee to the fullest extent permitted by the Delaware General Corporation Law and any other applicable law. This obligation includes the obligation to indemnify Indemnitee whenever Indemnitee is or was a party or witness or is threatened to be made a party or witness to any Proceeding (capitalized terms not otherwise defined are defined in Section 13) because (or arising in part because) Indemnitee is or was (or is alleged to be or have been) a director, officer, employee, partner, fiduciary or agent of the Corporation or is or was (or is alleged to be or have been) serving at the request of the Corporation as a director, officer, employee, partner, fiduciary or agent of another corporation, partnership, joint venture, limited liability company, limited liability partnership, limited partnership, employee benefit plan, trust or other enterprise, or because of anything done or not done by Indemnitee in such capacity (any such event or occurrence, an "Indemnifiable Event"), against Expenses and Liabilities as defined below (including the costs of any investigation, defense, service as a witness, settlement or appeal), actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding. The foregoing indemnification, including the conditions thereto, shall also apply to any such Proceeding brought by or in the right of the Corporation.

(b) To the extent that Indemnitee has been successful on the merits or otherwise in defense of any Proceeding, including dismissal without prejudice, Indemnitee shall be indemnified against Expenses and Liabilities actually and reasonably incurred by Indemnitee in connection therewith.

(c) If the indemnification provided for in Section 1(a) above for any reason is held by a court of competent jurisdiction to be unavailable to Indemnitee in respect of any losses, claims, damages, expenses or liabilities referred to therein due to public policy related to applicable federal or state securities laws, then the Corporation, in lieu of indemnifying Indemnitee thereunder, shall contribute to the amount paid or payable by Indemnitee as a result of such losses, claims, damages, expenses or liabilities (i) in such proportion as is appropriate to reflect the relative benefits received by the Corporation and Indemnitee, or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Corporation and Indemnitee in connection with the action or inaction which resulted in such losses, claims, damages, expenses or liabilities, as well as any other relevant equitable considerations. In connection with the registration of the Corporation's securities, the relative benefits received by the Corporation and Indemnitee shall be deemed to be in the same respective proportions that the net proceeds from the offering (before deducting expenses) received by the Corporation and Indemnitee, in each case as set forth in the table on the cover page of the applicable prospectus, bear to the aggregate public offering price of the securities so offered. The relative fault of the Corporation and Indemnitee shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Corporation or Indemnitee and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The Corporation and Indemnitee agree that it would not be just and equitable if contribution pursuant to this Section 1(c) were determined by pro rata or per capita allocation or by any other method of allocation which does not take account of the equitable considerations referred to in the immediately preceding paragraph. In connection with the registration of the Corporation's securities, in no event shall Indemnitee be required to contribute any amount under this Section 1(c) in excess of the *lesser of* (i) that proportion of the total of such losses, claims, damages or liabilities indemnified against equal to the proportion of the total securities sold under such registration statement which was sold by Indemnitee or (ii) the proceeds received by Indemnitee from sale of securities under such registration statement. No person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not found guilty of such fraudulent misrepresentation.

2. **Mandatory Advancement of Expenses**.

(a) *General*. Unless a determination has been made pursuant to Section 5 (and remains in effect) that Indemnitee is not entitled to indemnification pursuant to Section 1, all reasonable Expenses incurred by or on behalf of Indemnitee shall be advanced from time to time by the Corporation to Indemnitee within twenty (20) days after the Corporation's receipt of a written request for an advance of Expenses by Indemnitee, whether prior to or after final disposition of a Proceeding. For the sake of clarity, the Corporation shall not be obligated to make an affirmative determination under Section 5 in order to advance expenses prior to final disposition of a Proceeding. Furthermore, any Section 5 determination that Indemnitee is not entitled to advancement of expenses, if made prior to the final disposition of the relevant Proceeding, must be reasonable and must be based on facts that, in the reasonable opinion of the decision-making party, at the time such determination is made, demonstrate by clear and convincing evidence, sufficient to overcome the presumption of entitlement set forth in Section 5, that Indemnitee did not meet the applicable standard of conduct under Delaware law.

The written request for an advancement of any and all Expenses under this Section shall contain reasonable detail of the Expenses incurred by Indemnitee, provided that Indemnitee shall not be required to provide any documentation or information to the extent that the provision thereof would undermine or otherwise jeopardize attorney-client privilege. Indemnitee shall agree, at the time of such written request for an advance, to repay the amounts advanced if it is ultimately determined that Indemnitee is not entitled to be indemnified pursuant to the terms of this Agreement. Any advances made shall be unsecured and no interest shall be charged thereon.

(b) *Indemnification for Expenses in Enforcing Rights*. To the fullest extent allowable under applicable law, the Corporation shall also indemnify against, and, if requested by Indemnitee, shall advance to Indemnitee subject to and in accordance with the terms of Section 2(a), any Expenses actually and reasonably paid or incurred by Indemnitee in connection with any action or proceeding by Indemnitee for (a) indemnification or reimbursement or advance payment of Expenses by the Corporation under any provision of this Agreement, or under any other agreement or provision of the Governing Documents now or hereafter in effect relating to Proceedings regarding Indemnifiable Events, and/or (b) recovery under any directors' and officers' liability insurance policies maintained by the Corporation, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification or insurance recovery, as the case may be. However, in the event that Indemnitee is ultimately determined not to be entitled to such indemnification or insurance recovery, as the case may be, then all amounts advanced under this Section 2(b) shall be repaid. Indemnitee shall be required to reimburse the Corporation in the event that a final judicial determination is made that such action brought by Indemnitee was frivolous or not made in good faith.

3. **Limitations**. The foregoing indemnity and advancement of Expenses shall apply only to the extent that Indemnitee has not been indemnified and reimbursed pursuant to such insurance as the Corporation may maintain for Indemnitee's benefit or pursuant to the Governing Documents or otherwise; provided, however, that notwithstanding the availability of such other indemnification and reimbursement pursuant to such Corporation-maintained policies, Indemnitee may, with the Corporation's consent, claim indemnification and advancement of Expenses pursuant to this Agreement by assigning Indemnitee's claims under such insurance to the Corporation to the extent Indemnitee is paid by the Corporation.

Furthermore, any other provision herein to the contrary notwithstanding, the Corporation shall not be obligated pursuant to the terms of this Agreement to (a) indemnify or advance Expenses to Indemnitee with respect to any Proceeding initiated or brought voluntarily by such Indemnitee and not by way of defense, except (i) with respect to actions or proceedings to establish or enforce a right to indemnity under this Agreement or any other agreement or insurance policy or under the Governing Documents now or hereafter in effect relating to a Proceeding and (ii) in specific cases in which the Board of Directors has approved the initiation or bringing of such Proceeding, (b) indemnify Indemnitee for expenses and/or the payment of profits with respect to any short swing profit liability owed to the Corporation by Indemnitee pursuant to Section 16(b) of the Securities Exchange Act of 1934, as amended, or any similar successor statute, and the regulations promulgated thereunder (the "Exchange Act"), (c) indemnify or advance funds to Indemnitee for Indemnitee's reimbursement to the Corporation of any bonus or other incentive-based or equity-based compensation previously received by Indemnitee, or payment of any profits realized by Indemnitee from the sale of securities of the Corporation, as required in each case under the Exchange Act (including any such reimbursements under Section 304 of the Sarbanes-Oxley Act of 2002) in connection with an accounting restatement of the Corporation or under the Artivion, Inc. Clawback Policy, as it may be amended from time to time, under Rule 10D-1 under the Exchange Act, or (d) indemnify Indemnitee with respect to any proceeding instituted by Indemnitee to enforce or interpret this Agreement, if a court of competent jurisdiction determines that each of the material assertions made by the Indemnitee in such proceeding was not made in good faith or was frivolous.

4. **Insurance**. The Corporation may, but is not obligated to, maintain insurance to protect itself and/or Indemnitee against Expenses and Liabilities in connection with Proceedings to the fullest extent permitted by applicable laws or its Governing Documents. The Corporation may, but is not obligated to, create a trust fund, grant a security interest or use other means (including, without limitation, a letter of credit) to ensure the payment of such amounts as may be necessary to effect indemnification or advancement of Expenses as provided in this Agreement. If, at the time of the receipt by the Corporation of a notice of a claim by Indemnitee pursuant to Section 5 hereof (or upon the Corporation otherwise becoming aware of such a claim), the Corporation has liability insurance in effect which may cover such claim, then the Corporation shall give timely notice of the commencement of such claim to the insurers in accordance with the procedures set forth in the respective policies. The Corporation shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of Indemnitee, all amounts payable as a result of such action, suit, proceeding, inquiry or investigation in accordance with the terms of such policies.

5. **Procedures and Presumptions for Determination of Entitlement to Indemnification**.

(a) *Mandatory Indemnification; Indemnification as a Witness.*

(i) To the extent that Indemnitee shall have been successful on the merits or otherwise in defense of any Proceeding relating to an Indemnifiable Event or any portion thereof or in defense of any issue or matter therein, including without limitation dismissal without prejudice, Indemnitee shall be indemnified against all Liabilities relating to such Proceeding in accordance with Section 1 to the fullest extent allowable by law, and no Standard of Conduct Determination (as defined in Section 5(b)) shall be required.

(ii) To the extent that Indemnitee's involvement in a Proceeding relating to an Indemnifiable Event is to prepare to serve and serve as a witness, and not as a party, the Indemnitee shall be indemnified against all Liabilities and Expenses incurred in connection therewith to the fullest extent allowable by law and no Standard of Conduct Determination shall be required.

(b) *Standard of Conduct.* To the extent that the provisions of Section 5(a) are inapplicable to a Proceeding related to an Indemnifiable Event that shall have been finally disposed of, any determination of whether Indemnitee has satisfied any applicable standard of conduct under Delaware law that is a legally required condition to indemnification of Indemnitee hereunder against Liabilities relating to such Proceeding and any determination that an advancement of Expenses must be repaid to the Corporation (a "Standard of Conduct Determination") shall be made as follows:

(i) if no Change in Control has occurred, (A) by a majority vote of the Disinterested Directors, even if less than a quorum of the Board of Directors, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum or (C) if there are no such Disinterested Directors, by Independent Counsel in a written opinion addressed to the Board of Directors, a copy of which shall be delivered to Indemnitee; and

(ii) if a Change in Control shall have occurred, (A) if the Indemnitee so requests in writing, by a majority vote of the Disinterested Directors, even if less than a quorum of the Board of Directors, or (B) otherwise, by Independent Counsel in a written opinion addressed to the Board of Directors, a copy of which shall be delivered to Indemnitee.

The Corporation shall indemnify and hold harmless Indemnitee against and, if requested by Indemnitee, shall reimburse Indemnitee for, or advance to Indemnitee, within fifteen (15) days of such request, any and all Expenses incurred by Indemnitee in cooperating with the person or persons making such Standard of Conduct Determination.

(c) *Making the Standard of Conduct Determination.* The Corporation shall use its reasonable best efforts to cause any Standard of Conduct Determination required under Section 5(b) to be made as promptly as practicable. If the person or persons designated to make the Standard of Conduct Determination under Section 5(b) shall not have made a determination within thirty (30) days after the later of (A) receipt by the Corporation of a written request from Indemnitee for indemnification pursuant to Section 1 (the date of such receipt being the "Notification Date") and (B) the selection of an Independent Counsel, if such determination is to be made by Independent Counsel, then Indemnitee shall be deemed to have satisfied the applicable standard of conduct; provided that such 30-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person or persons making such determination in good faith requires such additional time to obtain or evaluate information relating thereto. Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement of Indemnitee to indemnification under this Agreement shall be required to be made prior to the final disposition of any Proceeding.

(d) *Payment of Indemnification.* If, in regard to any Liabilities:

(i) Indemnitee shall be entitled to indemnification pursuant to Section 5(a),

(ii) No Standard of Conduct Determination is legally required as a condition to indemnification of Indemnitee hereunder, or

(iii) Indemnitee has been determined or deemed pursuance to Section 5(b) or 5(c) to have satisfied the Standard of Conduct Determination,

then the Corporation shall pay to Indemnitee, within fifteen (15) days after the later of (A) the Notification Date or (B) the earliest date on which the applicable criterion specified in clause (i), (ii) or (iii) is satisfied, an amount equal to such Liabilities.

(e) *Selection of Independent Counsel for Standard of Conduct Determination.* If a Standard of Conduct Determination is to be made by Independent Counsel pursuant to Section 5(b)(i), the Independent Counsel shall be selected by the Board of Directors, and the Corporation shall give written notice to Indemnitee advising Indemnitee of the identity of the Independent Counsel so selected. If a Standard of Conduct Determination is to be made by Independent Counsel pursuant to Section 5(b)(ii), the Independent Counsel shall be selected by Indemnitee, and Indemnitee shall give written notice to the Corporation advising it of the identity of the Independent Counsel so selected. In either case, Indemnitee or the Corporation, as applicable, may, within five (5) days after receiving written notice of selection from the other, deliver to the other a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not satisfy the criteria set forth in the definition of "Independent Counsel" in Section 13(f), and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person or firm so selected shall act as Independent Counsel. If such written objection is properly and timely made and substantiated, (i) the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or a court has determined that such objection is without merit; and (ii) the non-objecting party may, at its option, select an alternative Independent Counsel and give written notice to the other party advising such other party of the identity of the alternative Independent Counsel so selected, in which case the provisions of the two immediately preceding sentences, the introductory clause of this sentence and numbered clause (i) of this sentence shall apply to such subsequent selection and notice. If applicable, the provisions of clause (ii) of the immediately preceding sentence shall apply to successive alternative selections. If no Independent Counsel that is permitted under the foregoing provisions of this Section 5(e) to make the Standard of Conduct Determination shall have been selected within twenty (20) days after the Corporation gives its initial notice pursuant to the first sentence of this Section 5(e) or Indemnitee gives its initial notice pursuant to the second sentence of this Section 5(e), as the case may be, either the Corporation or Indemnitee may petition the Court of Chancery of the State of Delaware (the "Delaware Court") to resolve any objection which shall have been made by the Corporation or Indemnitee to the other's selection of Independent Counsel and/or to appoint as Independent Counsel a person to be selected by the Court or such other person as the Court shall designate, and the person or firm with respect to whom all objections are so resolved or the person or firm so appointed will act as Independent Counsel. In all events, the Corporation shall pay all of the reasonable fees and expenses of the Independent Counsel incurred in connection with the Independent Counsel's determination pursuant to Section 5(b).

(f) *Presumptions and Defenses.*

(i) Indemnitee's Entitlement to Indemnification. In making any Standard of Conduct Determination, the person or persons making such determination shall presume that Indemnitee has satisfied the applicable standard of conduct and is entitled to indemnification, and the Corporation shall have the burden of proof to overcome that presumption and establish that Indemnitee is not so entitled. Any Standard of Conduct Determination that is adverse to Indemnitee may be challenged by the Indemnitee in the Delaware Court. No determination by the Corporation (including by its directors or any Independent Counsel) that Indemnitee has not satisfied any applicable standard of conduct may be used as a defense to any legal proceedings brought by Indemnitee to secure indemnification or reimbursement or advance payment of Expenses by the Corporation hereunder or create a presumption that Indemnitee has not met any applicable standard of conduct.

(ii) Reliance as a Safe Harbor. For purposes of this Agreement, and without creating any presumption as to a lack of good faith if the following circumstances do not exist, Indemnitee shall be deemed to have acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Corporation if Indemnitee's actions or omissions to act are taken in good faith reliance upon the records of the Corporation, including its financial statements, or upon information, opinions, reports or statements furnished to Indemnitee by the officers or employees of the Corporation or any of its subsidiaries in the course of their duties, or by committees of the Board of Directors or by any other Person (including legal counsel, accountants and financial advisors) as to matters Indemnitee reasonably believes are within such other Person's professional or expert competence and who has been selected with reasonable care by or on behalf of the Corporation. In addition, the knowledge and/or actions, or failures to act, of any other director, officer, agent or employee of the Corporation shall not be imputed to Indemnitee for purposes of determining the right to indemnity hereunder.

(iii) No Other Presumptions. For purposes of this Agreement, the termination of any Proceeding by judgment, order, settlement (whether with or without court approval) or conviction, or upon a plea of nolo contendere or its equivalent, will not create a presumption that Indemnitee did not meet any applicable standard of conduct or have any particular belief, or that indemnification hereunder is otherwise not permitted.

(iv) Defense to Indemnification and Burden of Proof. It shall be a defense to any action brought by Indemnitee against the Corporation to enforce this Agreement (other than an action brought to enforce a claim for Liabilities incurred in defending against a Proceeding related to an Indemnifiable Event in advance of its final disposition) that it is not permissible under applicable law for the Corporation to indemnify Indemnitee for the amount claimed. In connection with any such action or any related Standard of Conduct Determination, the burden of proving such a defense or that the Indemnitee did not satisfy the applicable standard of conduct shall be on the Corporation.

6. **Fees and Expenses of Counsel**. The Corporation agrees to pay the reasonable fees and expenses of independent legal counsel (including appropriate retainers) should such counsel be retained to make a determination of Indemnitee's entitlement to indemnification pursuant to Section 5 of this Agreement.

7. **Remedies of Indemnitee**.

(a) In the event that (i) a determination pursuant to Section 5 hereof is made that Indemnitee is not entitled to indemnification, (ii) advances of Expenses are not made pursuant to this Agreement for any reason, (iii) payment has not been timely made following a determination of entitlement to indemnification pursuant to this Agreement, or (iv) Indemnitee otherwise seeks enforcement of this Agreement, Indemnitee shall be entitled to a final adjudication of Indemnitee's rights in an appropriate court. The Corporation shall not oppose Indemnitee's right to seek any such adjudication.

(b) In the event that a determination that Indemnitee is not entitled to indemnification, in whole or in part, has been made pursuant to Section 5 hereof, the decision in the judicial proceeding provided in paragraph (a) of this Section 7 shall be made de novo and Indemnitee shall not be prejudiced by reason of a determination that Indemnitee is not entitled to indemnification.

(c) If a determination that Indemnitee is entitled to indemnification has been made pursuant to Section 5 hereof or otherwise pursuant to the terms of this Agreement, the Corporation shall be bound by such determination in the absence of (i) misrepresentation of a material fact by Indemnitee or (ii) a specific finding (which has become final) by an appropriate court that all or any part of such indemnification is expressly prohibited by law.

(d) In any court proceeding pursuant to this Section 7, the Corporation shall be precluded from asserting that the procedures and presumptions of this Agreement are not valid, binding and enforceable. The Corporation shall stipulate in any such court that the Corporation is bound by all the provisions of this Agreement (including the rebuttable presumptions specified in Section 5(f)(i)) and is precluded from making any assertion to the contrary.

8. **Modification. Waiver, Termination and Cancellation**. No supplement, modification, termination, cancellation or amendment of this Agreement shall be binding unless executed in writing by both of the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions hereof (whether or not similar), nor shall any such waiver constitute a continuing waiver.

9. **Notice by Indemnitee and Defense of Claim**. Indemnitee shall promptly notify the Corporation in writing upon being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any matter, whether civil, criminal, administrative or investigative, but the omission to so notify the Corporation will not relieve it from any liability which it may have to Indemnitee if such omission does not prejudice the Corporation's rights. If such omission does prejudice the Corporation's rights, the Corporation will be relieved from liability only to the extent of such prejudice. With respect to any Proceeding as to which Indemnitee notifies the Corporation of the commencement thereof:

(a) The Corporation will be entitled to participate therein at its own expense; and

(b) The Corporation jointly with any other indemnifying party similarly notified will be entitled to assume the defense thereof, with counsel reasonably satisfactory to Indemnitee; provided, however, that the Corporation shall not be entitled to assume the defense of any Proceeding if Indemnitee shall have reasonably concluded that there may be a conflict of interest between the Corporation and Indemnitee with respect to such Proceeding. After notice from the Corporation to Indemnitee of its election to assume the defense thereof, the Corporation will not be liable to Indemnitee under this Agreement for any Expenses subsequently incurred by Indemnitee in connection with the defense thereof, other than reasonable costs of investigation or as otherwise provided below. Indemnitee shall have the right to employ Indemnitee's own counsel in such Proceeding but the fees and expenses of such counsel incurred after notice from the Corporation of its assumption of the defense thereof shall be at the expense of Indemnitee unless:

(i) The employment of counsel by Indemnitee has been authorized in writing by the Corporation;

(ii) Indemnitee shall have reasonably concluded that counsel engaged by the Corporation may not adequately represent Indemnitee; or

(iii) The Corporation shall not in fact have employed counsel to assume the defense in such Proceeding or shall not in fact have assumed such defense and be acting in connection therewith with reasonable diligence;

in each of which cases the fees and expenses of such counsel shall be at the expense of the Corporation.

(c) The Corporation shall not settle any Proceeding in any manner which would impose any penalty or limitation on Indemnitee, other than monetary penalties paid by the Corporation, without Indemnitee's written consent; provided, however, that Indemnitee will not unreasonably withhold Indemnitee's consent to any such proposed settlement. In addition, the Corporation shall not enter into any settlement of any Proceeding unless such settlement provides for a full and final release of all claims asserted against Indemnitee.

10. **Deposit of Funds in Trust**. If the Corporation voluntarily decides to dissolve or to file a petition for relief under any applicable bankruptcy, moratorium or similar laws, then not later than 10 days prior to such dissolution or filing, the Corporation shall deposit in trust for the sole and exclusive benefit of Indemnitee a cash amount equal to all amounts previously authorized to be paid to Indemnitee hereunder, such amounts to be used to discharge the Corporation's obligations to Indemnitee hereunder. Any amounts in such trust not required for such purpose shall be returned to the Corporation. This Section 10 shall not apply to the dissolution of the Corporation in connection with a transaction as to which Section 13(b)(iii) applies.

11. **Notices**. All notices, requests, consents and other communications hereunder shall be in writing and shall be sent by Federal Express or other nationally recognized overnight or same day courier service providing a return receipt (and shall be effective when received, when refused or when the same cannot be delivered, as evidenced on the return receipt) to the following addresses (or to such other address as a party may subsequently provide written notification of to the other party):

To Corporation:
Artivion, Inc.
1655 Roberts Blvd., NW
Kennesaw, GA 30144
Attn: General Counsel

To Indemnitee:
_____
1655 Roberts Blvd., NW
Kennesaw, GA 30144

12. **Nonexclusivity**. The rights of Indemnitee hereunder shall not be deemed exclusive of any other rights to which Indemnitee may now or in the future be entitled under the Delaware General Corporation Law, the Governing Documents, or any agreements, insurance policies, vote of stockholders, resolution of the Board of Directors or Disinterested Directors, or otherwise. The provisions of this Agreement are hereby deemed to be a contract right between the Corporation and the Indemnitee and any repeal of the relevant provisions of the Delaware General Corporation Law, or other applicable law, shall not affect this Agreement or its enforceability.

13. **Certain Definitions**.

(a) References to the "Corporation" shall include, in addition to the resulting corporation, any constituent corporation or other enterprise (including any constituent of a constituent or other enterprise) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, and employees, partners, fiduciaries or agents, so that any person who is or was a director, officer, employee, partner, fiduciary or agent of such constituent corporation or other enterprise, or is or was serving at the request of such constituent corporation or other enterprise as a director, officer, employee, partner, fiduciary or agent of another corporation, partnership, joint venture, limited liability company, limited liability partnership, limited partnership, employee benefit plan, trust or other enterprise, shall stand in the same position under this Agreement with respect to the resulting or surviving corporation as Indemnitee would have with respect to such constituent corporation or other enterprise if its separate existence had continued.

(b) A "Change in Control" shall be deemed to have occurred if

(i) any "Person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act), other than a trustee or other fiduciary holding securities under an employee benefit plan of the Corporation or a corporation owned directly or indirectly by the stockholders of the Corporation in substantially the same proportions as their ownership of stock of the Corporation,

(A) who is or becomes the beneficial owner, directly or indirectly, of securities of the Corporation representing 20% or more of the combined voting power of the Corporation's then outstanding voting securities, increases his beneficial ownership of such securities by 5% or more over the percentage so owned by such person, or

(B) becomes the "beneficial owner" (as defined in rule 13d-3 under said Act), directly or indirectly, of securities of the Corporation representing more than 30% of the total voting power represented by the Corporation's then outstanding voting securities,

(ii) during any period of two consecutive years, individuals who at the beginning of such period constitute the Board of Directors of the Corporation and any new director whose election by the Board of Directors or nomination for election by the Corporation's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof, or

(iii) the stockholders of the Corporation approve a merger or consolidation of the Corporation with any other corporation, other than a merger or consolidation which would result in the voting securities of the Corporation outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) at least 80% of the total voting power represented by the voting securities of the Corporation or such surviving entity outstanding immediately after such merger or consolidation, or the stockholders of the Corporation approve a plan of complete liquidation of the Corporation or an agreement for the sale or disposition by the Corporation of (in one transaction or a series of transactions) all or substantially all of the Corporation's assets.

(c) "Disinterested Director" shall mean a director of the Corporation who is not and was not a party to the Proceeding in respect of which indemnification is being sought by Indemnitee. If there has been a Change in Control since the date hereof, to qualify as a Disinterested Director, such director must also have been a director of the Corporation prior to such Change in Control.

(d) "Expenses" shall mean all direct and indirect costs (including, without limitation, attorneys' fees, retainers, court costs, transcripts, costs of investigation, costs of defense, costs of defending witnesses or preparing to be a witness, costs of negotiating settlements, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, costs of attachment, appeal or similar bonds, and all other disbursements or out-of-pocket expenses) actually and reasonably incurred in connection with a Proceeding or establishing or enforcing a right to indemnification or advances under this Agreement, applicable law or otherwise; provided, however, that "Expenses" shall not include any Liabilities.

(e) "Indemnification Period" shall mean the period of time during which Indemnitee shall continue to serve as a director or executive officer of the Corporation, and thereafter so long as Indemnitee shall be subject to any possible Proceeding arising out of acts or omissions of Indemnitee as a director or executive officer, which may include serving as a fiduciary or agent of the Corporation or otherwise acting or omitting at the request of or on behalf of the Corporation. For non-directors, status as an executive officer is required for this Agreement to provide indemnification related to a person's actions or omissions. Should a non-director Indemnitee cease to be an executive officer, his or her actions and omissions, performed as a non-officer employee, are not entitled to indemnification under this Agreement. Furthermore, only those executive officers who hold a validly executed Indemnification Agreement are entitled to the rights and privileges herein.

(f) "Independent Counsel" means a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently performs, nor in the past five (5) years has performed, services for either: (i) the Corporation (including any affiliate of the Corporation) or Indemnitee (other than in connection with matters concerning Indemnitee under this Agreement or of other indemnitees under similar agreements) or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Corporation or Indemnitee in an action to determine Indemnitee's rights under this Agreement.

(g) "Liabilities" shall mean liabilities of any type whatsoever including, but not limited to, any damages, judgments, fines, ERISA excise taxes and penalties, penalties and amounts paid in settlement (including all interest assessments and other charges paid or payable in connection with or in respect of such judgments, fines, penalties or amounts paid in settlement) related to any Proceeding, as well as any federal, state, local or foreign taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement.

(h) "Person" shall mean any individual, corporation, firm, partnership, joint venture, limited liability company, estate, trust, business association, organization, governmental entity or other entity.

(i) "Proceeding" shall mean any threatened, asserted, pending or completed action, claim, suit, arbitration, alternate dispute resolution mechanism, investigation, administrative hearing or any other proceeding whether civil, criminal, administrative or investigative, including any appeal therefrom.

(j) For purposes of this Agreement, references to an "other enterprise" shall include employee benefit plans; references to "fines" shall include any excise taxes assessed on a person with respect to any employee benefit plan; and references to "serving at the request of the corporation" shall include any service as a director, officer, employee, partner, fiduciary or agent of the corporation which imposes duties on, or involves services by, such director, officer, employee, partner, fiduciary or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner Indemnitee reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the Corporation" as referred to in this Agreement.

14. **Binding Effect, Duration and Scope of Agreement**. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the parties hereto and their respective successors and assigns (including the executors, administrators and heirs of Indemnitee's estate (including without limitation, spouses), and any direct or indirect successor by purchase, merger, consolidation or otherwise, to all or substantially all of the business or assets of the Corporation), heirs, and personal and legal representatives. This Agreement shall continue in effect during the Indemnification Period, regardless of whether Indemnitee continues to serve as a director, officer, employee, fiduciary or agent.

15. **Severability**. If any provision or provisions of this Agreement (or any portion thereof) shall be held to be invalid, illegal or unenforceable for any reason whatsoever:

(a) the validity, legality and enforceability of the remaining provisions of this Agreement shall not in any way be affected or impaired thereby; and

(b) to the fullest extent legally possible, the provisions of this Agreement shall be construed so as to give effect to the intent of any provision held invalid, illegal or unenforceable.

16. **Governing Law, Interpretation of Agreement, and Jurisdiction**. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of Delaware (without regard to its conflict of laws rules, other than the internal affairs doctrine). It is the intent of this agreement to indemnify Indemnitee to the fullest extent permitted by the Delaware General Corporation Law and other applicable law as in effect on the date hereof or as they may be amended from time to time, to the extent such amendments may broaden the scope of indemnification permitted. For the sake of clarity, no change in the Delaware General Corporation Law shall have the effect of reducing the benefits available to Indemnitee except to the extent expressly so required by law. However, if the Governing Documents or the Delaware General Corporation Law are amended to provide for greater indemnification rights or privileges, this Agreement shall not be construed so as to limit Indemnitee's rights and privileges to the terms hereof and Indemnitee shall be entitled to the full benefits of any such additional rights and privileges. The Corporation and Indemnitee each hereby irrevocably consent to the jurisdiction of the courts of the State of Georgia for all purposes in connection with any action or proceeding which arises out of or relates to this Agreement and agree that any action instituted under this Agreement shall be commenced, prosecuted and continued only in the federal and state courts of the State of Georgia in and for Fulton County, which shall be the exclusive and only proper forum for adjudicating such a claim.

17. **Entire Agreement**. This Agreement represents the entire agreement between the parties hereto, and there are no other agreements, contracts or understandings between the parties hereto with respect to the subject matter of this Agreement, except as specifically referred to herein or as provided in Section 12 hereof. In furtherance and not in limitation of the foregoing, and notwithstanding the provisions of Section 12 hereof, the indemnification agreement between the Corporation and the Indemnitee dated _____ is hereby terminated in its entirety, shall have no further force and effect, and is superseded by this Agreement.

18. **Partial Indemnification**. If Indemnitee is entitled under any provision of this Agreement to indemnification by the Corporation for some or a portion of any Expenses or Liabilities, but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify Indemnitee for the portion of such Expenses or Liabilities to which Indemnitee is entitled.

19. **Counterparts**. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement.

[signatures on following page(s)]

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the date first written above.

CORPORATION:

ARTIVION, INC.

By: _____
Name: D. Ashley Lee
Title: Executive Vice President and Chief Financial Officer

INDEMNITEE:

_____
_____

Exhibit 10.3(d)

CERTAIN INFORMATION HAS BEEN OMITTED OR REDACTED FROM VERSION OF THIS EXHIBIT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION BECAUSE IT BOTH (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

FOURTH AMENDMENT TO LEASE AGREEMENT

This FOURTH AMENDMENT TO LEASE AGREEMENT (FOURTH AMENDMENT) is made between **1300 E. ANDERSON LANE, LTD.,** (LANDLORD), and **CRYOLIFE, INC.,** successor in interest to ON-X LIFE TECHNOLOGIES, INC., (TENANT).

LANDLORD and TENANT are parties to the Lease Agreement (Original Lease) dated March 2, 2009, for premises described as Building B (Premises) In the 1300 East Anderson Lane Business Park located at 1300 East Anderson Lane, Austin, Texas.

The Original Lease was amended by First Amendment dated November 15, 2012 In order to add [redacted] square feet of office space located In Building C; by Second Amendment dated January 29, 2015 to add and renovate all of Building A, and by Third Amendment also dated January 29, 2015 to renovate building B (collectively, the Lease). By mutual agreement and Tenant's proper notice to Landlord, Building C expansion was terminated as of June 30, 2015. Consequently, Premises now totals [redacted] square feet and Includes only Building A and B.

The Lease expires on April 30, 2020. LANDLORD and TENANT wish to extend this Lease for five (5) years under the following terms:

PREMISES
1300 E. Anderson Lane, Building A and B, Austin, Texas 78752

TERM PERIOD
May 1, 2020 through April 30, 2025.

BASE RENT
$[redacted] PSF with two and a half percent (2.5%) annual Increases per the rent table below.

PERIOD	PSF	Monthly	Annual
05/01/2020 - 04/30/2021	$ [redacted]	$ [redacted]	$ [redacted]
05/01/2021- 04/30/2022	$ [redacted]	$ [redacted]	$ [redacted]
05/01/2022 - 04/30/2023	$ [redacted]	$ [redacted]	$ [redacted]
05/01/2023 - 04/30/2024	$ [redacted]	$ [redacted]	$ [redacted]
05/01/2024 - 04/30/2025	$ [redacted]	$ [redacted]	$ [redacted]

ADDITIONAL RENT
Rent table above does not include additional rent, which will continue as established In the Lease.

ADDITIONAL WORK
Landlord agrees to participate in fifty percent (50%) of gate security camera installation costs and fiber connections for buildings A and B.

[redacted]INSTALLATION
Landlord and Tenant **agree** that, per article 9 in the Original Lease, an exception is hereby made should Tenant, at Tenant's sole cost, elect to [redacted]

[redacted]. Landlord does not waive any of Landlord's remedies, particularly as defined In article 21 (Lessor's Remedies), and as referenced in article 22 (Surrender and Holdover). and 23 (Sale of Abandoned Property) of the Original Lease. [redacted] must be approved by Landlord in writing prior to installation, whose approval will not be unreasonably withheld.

FIRST RIGHT OF REFUSAL TO PURCHASE
Tenant's existing Right of First Refusal to Purchase as defined in the Original Lease, Addendum #11, is hereby amended to [redacted].

Landlord agrees to pay Tenant's representative, Cushman & Wakefield under separate agreement.

Executed this 8th day of March ,2019.

LANDLORD:
1300 E. ANDERSON LANE, LTD.

/s/ Tony Juarez

Tony Juarez
Vice President
Of Its General Partner

TENANT:
CRYOLIFE, INC.

/s/ D. Ashley Lee
Signature

D. Ashley Lee Exec. VP COO & CFO
PRINT NAME TITLE

Exhibit 10.3(e)

CERTAIN INFORMATION HAS BEEN OMITTED OR REDACTED FROM VERSION OF THIS EXHIBIT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION BECAUSE IT BOTH (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

FIFTH AMENDMENT TO LEASE AGREEMENT

This FIFTH AMENDMENT TO LEASE AGREEMENT (FIFTH AMENDMENT) is made and entered into on this 11th day of September 2023 by and between **1300 E. ANDERSON LANE, LTD.,** (LANDLORD), and **ARTIVION, INC.,** successor in interest to CRYOLIFE, INC., successor in interest to ON-X LIFE TECHNOLOGIES, INC. (TENANT).

LANDLORD and TENANT are parties to the original lease agreement (the ORIGINAL LEASE) dated March 2, 2009, for premises described as Building B (Premises) in the 1300 East Anderson Lane Business Park located at 1300 East Anderson Lane, Austin, Texas 78752.

The Lease was amended by First Amendment dated November 15, 2012 in order to add [redacted] square feet of office space located in Building C; by Second Amendment dated January 29, 2015 to add and renovate all of Building A, by Third Amendment also dated January 29, 2015 to renovate building B, and renewed by Fourth Amendment dated March 8, 2019 (collectively, the LEASE). By mutual agreement and Tenant's proper notice to Landlord, Building C expansion, was terminated as of June 30, 2015. Consequently, Premises now totals [redacted] square feet and includes only Building A and B.

The Lease expires on April 30, 2025. Landlord and Tenant wish to amend the Lease prior to term expiration in the following way:

1. **RIGHT OF FIRST REFUSAL TO PURCHASE**. The Lease contains a Right of First Refusal to Purchase as defined in the Original Lease Addendum #11, which was further amended by the Fourth Amendment to [redacted]. Landlord and Tenant agree to remove the Right of First Refusal to Purchase in its entirety in exchange for a one-time, single payment from Landlord to Tenant of [redacted] ($[redacted]) on or before [redacted].

2. **LEASE EXTENSION**. Tenant is currently in year four (4) of the existing Lease Term. The Lease is extended for an additional five (5) years with annual base rent increases of 2.5%.

~ Year four (4) of the current term expires on April 30, 2024, as outlined below.

YR	TERM	PSF	MONTHLY	YEARLY
4	5/1/2023 – 4/30/2024	$[redacted]	$[redacted]	$[redacted]
5	5/1/2024 – 4/30/2025	$[redacted]	$[redacted]	$[redacted]

~ The additional five (5) year period will begin on May 1, 2025, and expire on April 30, 2030.

YR	TERM	PSF	MONTHLY	YEARLY
1	5/1/2025 – 4/30/2026	$[redacted]	$[redacted]	$[redacted]
2	5/1/2026 – 4/30/2027	$[redacted]	$[redacted]	$[redacted]
3	5/1/2027 – 4/30/2028	$[redacted]	$[redacted]	$[redacted]
4	5/1/2028 – 4/30/2029	$[redacted]	$[redacted]	$[redacted]
5	5/1/2029 – 4/30/2030	$[redacted]	$[redacted]	$[redacted]

3. **OPTION TO RENEW**. Tenant now has an Option to Renew for an additional three (3) years with annual base rent increases of 2.5%. Tenant must exercise this Option to Renew by giving Landlord written notice on or before [redacted].

YR	TERM	PSF	MONTHLY	YEARLY
1	5/1/2030 – 4/30/2031	$[redacted]	$[redacted]	$[redacted]
2	5/1/2031 – 4/30/2032	$[redacted]	$[redacted]	$[redacted]
3	5/1/2032 – 4/30/2033	$[redacted]	$[redacted]	$[redacted]

4. **MISCELLANEOUS**.

a. Except as expressly provided in this Fifth Amendment, all of the terms and provisions of the Lease shall remain in full force and effect.

b. Landlord shall provide Tenant with sixty (60) days prior written notice of any proposed transfer, assignment, or sale, in whole or in part, of the Lease and/or the Premises, Building, Land, or Business Park (as defined in the Lease), whether by merger, reorganization, acquisition, stock sale, asset sale, or otherwise (each, a SALE). For the avoidance of doubt, upon such Sale, the Lease shall remain in full force and effect, and the transferee shall be obligated to assume all of the obligations of Landlord under the Lease arising from and after the date of such Sale.

c. This Fifth Amendment is governed by and construed in accordance with the laws of the State of Texas, without regard to the conflict of laws provisions of such State.

d. This Fifth Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Fifth Amendment delivered by means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy.

LANDLORD:
1300 E. ANDERSON LANE, LTD.

/s/ Kat Sparks September 11, 2023

Kat Sparks Date
Vice President
Sales & Leasing

TENANT:
ARTIVION, INC.

/s/ D. Ashley Lee September 7, 2023

Signature Date

D. Ashley Lee EVP & Chief Financial Officer

PRINT NAME TITLE

Exhibit 31.1

CERTIFICATIONS

I, James Patrick Mackin, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Artivion, 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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 3, 2023

/s/ J. PATRICK MACKIN

Chairman, President, and
Chief Executive Officer

Exhibit 31.2

I, David Ashley Lee, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Artivion, 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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 3, 2023

/s/ D. ASHLEY LEE

Executive Vice President, and
Chief Financial Officer

Exhibit 32

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 Artivion, Inc. (the "Company") on Form 10-Q for the quarter ending September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of James Patrick Mackin, the Chairman, President, and Chief Executive Officer of the Company, and David Ashley Lee, the Executive Vice President, and Chief Financial Officer of the Company, hereby certifies, pursuant to and for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, in his capacity as an officer of the Company and to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

/s/ J. PATRICK MACKIN
J. PATRICK MACKIN
Chairman, President, and
Chief Executive Officer
November 3, 2023

/s/ D. ASHLEY LEE
D. ASHLEY LEE
Executive Vice President, and
Chief Financial Officer
November 3, 2023