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

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2023
OR
o 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 x No o

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 x No o

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	x	Accelerated Filer	o
Non-accelerated Filer	o	Smaller Reporting Company	o
		Emerging Growth Company	o

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. o

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

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 July 28, 2023
Common Stock, $0.01 par value	41,039,761

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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 June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Products	$ 66,003	$ 58,936	$ 128,294	$ 116,478
Preservation services	23,248	21,404	44,186	41,075
Total revenues	**89,251**	**80,340**	**172,480**	**157,553**
Cost of products and preservation services:				
Products	20,977	18,230	40,510	35,638
Preservation services	10,190	9,938	20,159	19,024
Total cost of products and preservation services	**31,167**	**28,168**	**60,669**	**54,662**
Gross margin	**58,084**	**52,172**	**111,811**	**102,891**
Operating expenses:				
General, administrative, and marketing	57,241	38,983	107,606	77,938
Research and development	7,418	8,648	14,641	18,776
Total operating expenses	**64,659**	**47,631**	**122,247**	**96,714**
Gain from sale of non-financial assets	(14,250)	—	(14,250)	—
Operating income	**7,675**	**4,541**	**3,814**	**6,177**
Interest expense	6,356	4,101	12,452	8,049
Interest income	(265)	(30)	(340)	(46)
Other expense, net	4,241	3,770	3,278	3,903
Loss before income taxes	**(2,657)**	**(3,300)**	**(11,576)**	**(5,729)**
Income tax expense	725	959	5,338	1,919
Net loss	**$ (3,382)**	**$ (4,259)**	**$ (16,914)**	**$ (7,648)**
Loss per share:				
Basic	**$ (0.08)**	**$ (0.11)**	**$ (0.41)**	**$ (0.19)**
Diluted	**$ (0.08)**	**$ (0.11)**	**$ (0.41)**	**$ (0.19)**
Weighted-average common shares outstanding:				
Basic	40,755	40,031	40,595	39,941
Diluted	40,755	40,031	40,595	39,941
Net loss	**$ (3,382)**	**$ (4,259)**	**$ (16,914)**	**$ (7,648)**
Other comprehensive loss:				
Foreign currency translation adjustments	1,826	(14,796)	5,442	(18,571)
Comprehensive loss	**$ (1,556)**	**$ (19,055)**	**$ (11,472)**	**$ (26,219)**

See accompanying Notes to Condensed Consolidated Financial Statements

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

	June 30, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 48,775	$ 39,351
Trade receivables, net	64,806	61,820
Other receivables	4,450	7,764
Inventories, net	78,458	74,478
Deferred preservation costs, net	48,302	46,371
Prepaid expenses and other	19,107	17,550
Total current assets	**263,898**	**247,334**
Goodwill	245,561	243,631
Acquired technology, net	147,029	151,263
Operating lease right-of-use assets, net	40,825	41,859
Property and equipment, net	38,389	38,674
Other intangibles, net	29,966	31,384
Deferred income taxes	3,951	1,314
Other assets	8,242	7,339
Total assets	**$ 777,861**	**$ 762,798**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 10,455	$ 12,004
Accrued compensation	12,792	13,810
Taxes payable	10,641	2,635
Accrued expenses	10,365	12,374
Current maturities of operating leases	4,037	3,308
Accrued procurement fees	1,744	2,111
Current portion of long-term debt	1,561	1,608
Other liabilities	4,635	1,825
Total current liabilities	**56,230**	**49,675**
Long-term debt	306,109	306,499
Contingent consideration	56,100	40,400
Non-current maturities of operating leases	39,989	41,257
Deferred income taxes	19,469	24,499
Deferred compensation liability	6,541	5,468
Non-current finance lease obligation	3,446	3,644
Other liabilities	7,469	7,027
Total liabilities	**$ 495,353**	**$ 478,469**
Commitments and contingencies		
Shareholders' equity:		
Preferred stock	—	—
Common stock (75,000 shares authorized, 42,443 and 41,830 shares issued and outstanding in 2023 and 2022, respectively)	424	418
Additional paid-in capital	347,030	337,385
Retained deficit	(34,131)	(17,217)
Accumulated other comprehensive loss	(16,167)	(21,609)
Treasury stock, at cost, 1,487 shares as of June 30, 2023 and December 31, 2022	(14,648)	(14,648)
Total shareholders' equity	**282,508**	**284,329**
Total liabilities and shareholders' equity	**$ 777,861**	**$ 762,798**

See accompanying Notes to Condensed Consolidated Financial Statements

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

	Six Months Ended June 30,	
	2023	**2022**
Net cash flows from operating activities:		
Net loss	$ (16,914)	$ (7,648)
Adjustments to reconcile net loss to net cash from operating activities:		
Change in fair value of contingent consideration	15,700	(5,000)
Depreciation and amortization	11,501	11,497
Non-cash compensation	7,279	6,100
Fair value adjustment of long-term loan	5,000	—
Non-cash lease expense	3,631	3,803
Write-down of inventories and deferred preservation costs	2,021	2,177
Deferred income taxes	(8,073)	(1,611)
Gain from sale of non-financial assets	(14,250)	—
Other	1,836	940
Changes in operating assets and liabilities:		
Accounts payable, accrued expenses, and other liabilities	1,607	(5,677)
Receivables	655	(9,635)
Prepaid expenses and other assets	(2,317)	(205)
Inventories and deferred preservation costs	(6,921)	(3,653)
Net cash flows provided by (used in) operating activities	**755**	**(8,912)**
Net cash flows from investing activities:		
Proceeds from sale of non-financial assets, net	14,250	—
Capital expenditures	(4,029)	(4,055)
Payments for Endospan Agreement	(5,000)	—
Other	(986)	(939)
Net cash flows provided by (used in) investing activities	**4,235**	**(4,994)**
Net cash flows from financing activities:		
Proceeds from financing insurance premiums	3,558	—
Proceeds from exercise of stock options and issuance of common stock	2,581	2,318
Principal payments on short-term notes payable	(529)	—
Redemption and repurchase of stock to cover tax withholdings	(563)	(1,739)
Repayment of term loan	(1,381)	(1,370)
Other	(262)	(241)
Net cash flows provided by (used in) financing activities	**3,404**	**(1,032)**
Effect of exchange rate changes on cash and cash equivalents	1,030	310
Increase (decrease) in cash and cash equivalents	**9,424**	**(14,628)**
Cash and cash equivalents beginning of period	39,351	55,010
Cash and cash equivalents end of period	**$ 48,775**	**$ 40,382**

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 March 31, 2023	**42,366**	**$ 424**	**$ 342,883**	**$(30,749)**	**$ (17,993)**	**(1,487)**	**$(14,648)**	**$ 279,917**
Net loss	—	—	—	(3,382)	—	—	—	(3,382)
Other comprehensive income	—	—	—	—	1,826	—	—	1,826
Equity compensation	75	—	4,119	—	—	—	—	4,119
Redemption and repurchase of stock to cover tax withholdings	2	—	28	—	—	—	—	28
Balance at June 30, 2023	**42,443**	**$ 424**	**$ 347,030**	**$(34,131)**	**$ (16,167)**	**(1,487)**	**$(14,648)**	**$ 282,508**

	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	—	—	—	(16,914)	—	—	—	(16,914)
Other comprehensive income	—	—	—	—	5,442	—	—	5,442
Equity compensation	401	4	7,629	—	—	—	—	7,633
Exercise of options	196	2	2,004	—	—	—	—	2,006
Employee stock purchase plan	56	1	574	—	—	—	—	575
Redemption and repurchase of stock to cover tax withholdings	(40)	(1)	(562)	—	—	—	—	(563)
Balance at June 30, 2023	**42,443**	**$ 424**	**$ 347,030**	**$(34,131)**	**$ (16,167)**	**(1,487)**	**$(14,648)**	**$ 282,508**

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 March 31, 2022	**41,688**	**$ 417**	**$ 326,799**	**$ (1,414)**	**$ (13,662)**	**(1,487)**	**$(14,648)**	**$ 297,492**
Net loss	—	—	—	(4,259)	—	—	—	(4,259)
Other comprehensive loss	—	—	—	—	(14,796)	—	—	(14,796)
Equity compensation	57	—	3,081	—	—	—	—	3,081
Redemption and repurchase of stock to cover tax withholdings	(1)	—	(9)	—	—	—	—	(9)
Balance at June 30, 2022	**41,744**	**$ 417**	**$ 329,871**	**$ (5,673)**	**$ (28,458)**	**(1,487)**	**$(14,648)**	**$ 281,509**

	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	—	—	—	(7,648)	—	—	—	(7,648)
Other comprehensive loss	—	—	—	—	(18,571)	—	—	(18,571)
Equity compensation	262	2	6,419	—	—	—	—	6,421
Exercise of options	140	2	1,678	—	—	—	—	1,680
Employee stock purchase plan	37	—	638	—	—	—	—	638
Redemption and repurchase of stock to cover tax withholdings	(92)	(1)	(1,738)	—	—	—	—	(1,739)
Balance at June 30, 2022	**41,744**	**$ 417**	**$ 329,871**	**$ (5,673)**	**$ (28,458)**	**(1,487)**	**$(14,648)**	**$ 281,509**

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 six months ended, June 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 six months ended June 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 six months ended June 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 three and six months ended June 30, 2023.

Following receipt of the PMA, under the terms of the TMSA, we began manufacturing and supplying PerClot for Baxter.

The Company accounted for this TMSA in accordance with the provision of ASC 842 by bifurcating the lease and non-lease components and recognizing each component based on ASC 842 and ASC 606, 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 June 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 three and six months ended June 30, 2023.

4. Financial Instruments

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

June 30, 2023	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 22,297	$ —	$ —	$ 22,297
Certificates of deposit	948	—	—	948
Total assets	**$ 23,245**	**$ —**	**$ —**	**$ 23,245**
Long-term liabilities:				
Contingent consideration	—	—	(56,100)	(56,100)
Total liabilities	**$ —**	**$ —**	**$ (56,100)**	**$ (56,100)**

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 six months ended June 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 8% and estimated future achievement of milestone dates between 2025 and 2026 to calculate the fair value of contingent consideration as of June 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 $10.9 million and $15.7 million for the three and six months ended June 30, 2023, respectively, and income of $3.2 million and $5.0 million for the three and six months ended June 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	(15,700)
Balance as of June 30, 2023	**$ (56,100)**

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 indicative of net realizable value or reflective of future fair values.

5. Inventories, net and Deferred Preservation Costs

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

	June 30, 2023	December 31, 2022
Raw materials and supplies	$ 36,514	$ 36,715
Work-in-process	12,425	10,476
Finished goods	29,519	27,287
Total inventories, net	**$ 78,458**	**$ 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 June 30, 2023 we had $11.9 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 $48.3 million and $46.4 million as of June 30, 2023 and December 31, 2022, respectively.

Inventory and deferred preservation costs obsolescence reserves were $2.1 million and $2.2 million as of June 30, 2023 and December 31, 2022, respectively.

6. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

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

	June 30, 2023	December 31, 2022
Goodwill	$ 245,561	$ 243,631
In-process R&D	2,119	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 six months ended June 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 June 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 June 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 June 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	1,930
Balance as of June 30, 2023	**$ 245,561**

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 June 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):

June 30, 2023	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Weighted Average Useful Life (Years)
Acquired technology	$ 200,231	$ 53,202	$ 147,029	18.2
Other intangibles:				
Customer lists and relationships	28,696	9,657	19,039	21.6
Distribution and manufacturing rights and know-how	9,448	6,791	2,657	5.0
Patents	4,322	3,201	1,121	17.0
Other	6,181	3,164	3,017	5.0
Total other intangibles	**$ 48,647**	**$ 22,813**	**$ 25,834**	**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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Amortization expense	$ 3,805	$ 3,905	$ 7,687	$ 7,989

As of June 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	$ 7,495	$ 14,815	$ 12,915	$ 12,687	$ 12,586	$ 12,420	$ 72,918

7. Income Taxes

Income Tax Expense

Our effective income tax rate was an expense of 27% and 46% for the three and six months ended June 30, 2023, respectively, as compared to an expense of 29% and 34% for the three and six months ended June 30, 2022, respectively.

Our income tax rate for the three and six months ended June 30, 2023 and 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.

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 $15.5 million and $23.2 million as of June 30, 2023 and December 31, 2022, respectively. Our valuation allowance against our deferred tax assets was $22.7 million and $17.9 million as of June 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:	**June 30, 2023**	**December 31, 2022**
Operating lease right-of-use assets	$ 56,773	$ 56,061
Accumulated amortization	(15,948)	(14,202)
Operating lease right-of-use assets, net	**$ 40,825**	**$ 41,859**
Current maturities of operating leases	$ 4,037	$ 3,308
Non-current maturities of operating leases	39,989	41,257
Total operating lease liabilities	**$ 44,026**	**$ 44,565**
Finance leases:		
Property and equipment, at cost	$ 6,527	$ 6,408
Accumulated amortization	(2,809)	(2,498)
Property and equipment, net	**$ 3,718**	**$ 3,910**
Current maturities of finance leases	$ 528	$ 513
Non-current maturities of finance leases	3,446	3,644
Total finance lease liabilities	**$ 3,974**	**$ 4,157**
Weighted average remaining lease term (in years):		
Operating leases	11.3	11.9
Finance leases	7.4	7.8
Weighted average discount rate:		
Operating leases	5.9%	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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Amortization of property and equipment	$ 133	$ 131	$ 264	$ 268
Interest expense on finance leases	21	22	42	47
Total finance lease expense	**154**	**153**	**306**	**315**
Operating lease expense	1,829	1,883	3,631	3,803
Sublease income	—	(91)	—	(183)
Total lease expense	**$ 1,983**	**$ 1,945**	**$ 3,937**	**$ 3,935**

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

	Six Months Ended June 30,	
Cash paid for amounts included in the measurement of lease liabilities:	2023	2022
Operating cash flows for operating leases	$ 3,627	$ 3,210
Financing cash flows for finance leases	264	244
Operating cash flows for finance leases	42	44

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

	Finance Leases	Operating Leases
Remainder of 2023	$ 290	$ 3,055
2024	606	6,001
2025	584	5,800
2026	566	5,057
2027	561	4,868
Thereafter	1,668	37,109
Total minimum lease payments	**$ 4,275**	**$ 61,890**
Less amount representing interest	(301)	(17,864)
Present value of net minimum lease payments	3,974	44,026
Less current maturities	(528)	(4,037)
Lease liabilities, less current maturities	**$ 3,446**	**$ 39,989**

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. We are in compliance with our debt covenants as of June 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 June 30, 2023 the aggregate interest rate of the Credit Agreement was 9.00% 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 June 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 June 30, 2023 was approximately $104.6 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 $2.5 million for the three and six months ended June 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 $1.5 million and $1.9 million of unamortized debt issuance costs related to Convertible Senior Notes as of June 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 cannot redeem the Convertible Senior Notes before July 5, 2023. Following the expiration of their non-redemption period, ending on July 5, 2023, 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):

	June 30, 2023	December 31, 2022
Term Loan balance	$ 212,625	$ 213,750
Convertible Senior Notes	100,000	100,000
2.45% Sparkasse Zollernalb (KFW Loan 1)	181	296
1.40% Sparkasse Zollernalb (KFW Loan 2)	611	733
Total loan balance	**313,417**	**314,779**
Less unamortized loan origination costs	(5,747)	(6,672)
Net borrowings	307,670	308,107
Less short-term loan balance	(1,561)	(1,608)
Long-term loan balance	**$ 306,109**	**$ 306,499**

Interest Expense

Interest expense was $6.4 million and $12.5 million for the three and six months ended June 30, 2023, respectively, as compared to $4.1 million and $8.0 million for the three and six months ended June 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 June 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 six months ended June 30, 2023 and 2022 the sources of revenue were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Domestic hospitals	$ 42,603	$ 39,279	$ 82,970	$ 75,801
International hospitals	27,558	26,927	56,059	54,714
International distributors	16,614	12,152	29,553	23,216
Other	2,476	1,982	3,898	3,822
Total sources of revenue	**$ 89,251**	**$ 80,340**	**$ 172,480**	**$ 157,553**

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 three and six months ended June 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 June 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 June 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 six months ended June 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 585,000 shares and had an aggregate grant date fair value of $8.0 million.

During the six months ended June 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 509,000 shares and had an aggregate grant date fair value of $9.4 million.

During the six months ended June 30, 2023 and 2022 the Committee authorized, from approved stock incentive plans, grants of stock options to purchase a total of 11,000 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 56,000 and 37,000 shares in the six months ended June 30, 2023 and 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 June 30, 2023		Six Months Ended June 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	0.66	0.45	0.66
Risk-free interest rate	3.94%	4.77%	3.94%	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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
RSA, RSU, and PSU expense	$ 3,396	$ 2,470	$ 6,038	$ 5,238
Stock option and ESPP expense	723	611	1,595	1,183
Total stock compensation expense	**$ 4,119**	**$ 3,081**	**$ 7,633**	**$ 6,421**

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 $182,000 and $354,000 for the three and six months ended June 30, 2023, respectively, and $147,000 and $321,000 for the three and six months ended June 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 June 30,		Six Months Ended June 30,	
Basic loss per common share	**2023**	**2022**	**2023**	**2022**
Net loss	$ (3,382)	$ (4,259)	$ (16,914)	$ (7,648)
Net loss allocated to participating securities	12	21	68	39
Net loss allocated to common shareholders	**$ (3,370)**	**$ (4,238)**	**$ (16,846)**	**$ (7,609)**
Basic weighted-average common shares outstanding	**40,755**	**40,031**	**40,595**	**39,941**
Basic loss per common share	**$ (0.08)**	**$ (0.11)**	**$ (0.41)**	**$ (0.19)**

	Three Months Ended June 30,		Six Months Ended June 30,	
Diluted loss per common share	**2023**	**2022**	**2023**	**2022**
Net loss	$ (3,382)	$ (4,259)	$ (16,914)	$ (7,648)
Net loss allocated to participating securities	12	21	68	39
Net loss allocated to common shareholders	**$ (3,370)**	**$ (4,238)**	**$ (16,846)**	**$ (7,609)**
Diluted weighted-average common shares outstanding	**40,755**	**40,031**	**40,595**	**39,941**
Diluted loss per common share	**$ (0.08)**	**$ (0.11)**	**$ (0.41)**	**$ (0.19)**

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 six months ended June 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, 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 June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Medical devices	$ 66,003	$ 58,936	$ 128,294	$ 116,478
Preservation services	23,248	21,404	44,186	41,075
Total revenues	**89,251**	**80,340**	**172,480**	**157,553**
Cost of products and preservation services:				
Medical devices	20,977	18,230	40,510	35,638
Preservation services	10,190	9,938	20,159	19,024
Total cost of products and preservation services	**31,167**	**28,168**	**60,669**	**54,662**
Gross margin:				
Medical devices	45,026	40,706	87,784	80,840
Preservation services	13,058	11,466	24,027	22,051
Total gross margin	**$ 58,084**	**$ 52,172**	**$ 111,811**	**$ 102,891**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Products:				
Aortic stent grafts	$ 28,359	$ 23,833	$ 54,509	$ 49,339
On-X	17,946	16,255	35,602	30,626
Surgical sealants	16,566	15,967	33,269	31,648
Other	3,132	2,881	4,914	4,865
Total products	**66,003**	**58,936**	**128,294**	**116,478**
Preservation services	23,248	21,404	44,186	41,075
Total revenues	**$ 89,251**	**$ 80,340**	**$ 172,480**	**$ 157,553**

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 war in Ukraine 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, 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, “Risks 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, 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 three months ended June 30, 2023 (as part of the Transitional Manufacturing and Supply Agreement ("TMSA") of the Baxter Transaction, described below).

We reported quarterly revenues of $89.3 million for the three months ended June 30, 2023, an 11% increase from the three months ended June 30, 2022. The increase in revenues for the three months ended June 30, 2023 was due to an increase in revenues from aortic stent grafts, preservation services, On-X products, surgical sealants, and other products. Constant currency revenues, as defined below, increased 11% for the three months ended June 30, 2023, as compared to the three months ended June 30, 2022.

See the "Results of Operations" section below for additional analysis of the three and six months ended June 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 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 observe impacts 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 an increasing 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 conflict between Russia and Ukraine, and 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, 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 June 30,		Percent Change From Prior Year	Revenues as a Percentage of Total Revenues for the Three Months Ended June 30,	
	2023	**2022**		**2023**	**2022**
Products:					
Aortic stent grafts	$ 28,359	$ 23,833	19%	32%	30%
On-X	17,946	16,255	10%	20%	20%
Surgical sealants	16,566	15,967	4%	19%	20%
Other	3,132	2,881	9%	3%	3%
Total products	**66,003**	**58,936**	**12%**	**74%**	**73%**
Preservation services	23,248	21,404	9%	26%	27%
Total	**$ 89,251**	**$ 80,340**	**11%**	**100%**	**100%**

	Revenues for the Six Months Ended June 30,		Percent Change From Prior Year	Revenues as a Percentage of Total Revenues for the Six Months Ended June 30,	
	2023	**2022**		**2023**	**2022**
Products:					
Aortic stent grafts	$ 54,509	$ 49,339	10%	31%	31%
On-X	35,602	30,626	16%	21%	20%
Surgical sealants	33,269	31,648	5%	19%	20%
Other	4,914	4,865	1%	3%	3%
Total products	**128,294**	**116,478**	**10%**	**74%**	**74%**
Preservation services	44,186	41,075	8%	26%	26%
Total	**$ 172,480**	**$ 157,553**	**9%**	**100%**	**100%**

Revenues increased 11% and 9% for the three and six months ended June 30, 2023, respectively, as compared to the three and six months ended June 30, 2022. The increase in revenues for the three months ended June 30, 2023 was due to an increase in revenues from aortic stent grafts, preservation services, On-X products, surgical sealants, and other products. The increase in revenues for the six months ended June 30, 2023 was due to an increase in revenues from aortic stent grafts, On-X products, preservation services, surgical sealants, and other products. Revenues for the three and six months ended June 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 June 30,				Percent Change From Prior Year
	2023	2022			
	US GAAP	US GAAP	Exchange rate effect	Constant Currency	Constant Currency
Products:					
Aortic stent grafts	$ 28,359	$ 23,833	$ 29	$ 23,862	19%
On-X	17,946	16,255	(72)	16,183	11%
Surgical sealants	16,566	15,967	(69)	15,898	4%
Other	3,132	2,881	(4)	2,877	9%
Total products	**66,003**	**58,936**	**(116)**	**58,820**	**12%**
Preservation services	23,248	21,404	(34)	21,370	9%
Total	**$ 89,251**	**$ 80,340**	**$ (150)**	**$ 80,190**	**11%**

	Revenues for the Six Months Ended June 30,				Percent Change From Prior Year
	2023	2022			
	US GAAP	US GAAP	Exchange rate effect	Constant Currency	Constant Currency
Products:					
Aortic stent grafts	$ 54,509	$ 49,339	$ (1,209)	$ 48,130	13%
On-X	35,602	30,626	(219)	30,407	17%
Surgical sealants	33,269	31,648	(354)	31,294	6%
Other	4,914	4,865	(19)	4,846	1%
Total products	**128,294**	**116,478**	**(1,801)**	**114,677**	**12%**
Preservation services	44,186	41,075	(69)	41,006	8%
Total	**$ 172,480**	**$ 157,553**	**$ (1,870)**	**$ 155,683**	**11%**

Constant currency revenues increased 11% for both the three and six months ended June 30, 2023, as compared to the three and six months ended June 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 six months ended June 30, 2023 is presented below.

Product

Revenues from products increased 12% and 10% for the three and six months ended June 30, 2023, respectively, as compared to the three and six months ended June 30, 2022. The increase for the three and six months ended June 30, 2023 was due to an increase in revenues from aortic stent grafts, On-X products, surgical sealants, and other products. Constant currency revenues from products increased 12% for both the three and six months ended June 30, 2023, as compared to the three and six months ended June 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 and six months ended June 30, 2023, as compared to the three and six months ended June 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, 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 aortic stent grafts increased 19% for the three months ended June 30, 2023, as compared to the three months ended June 30, 2022. This increase was primarily due to a change in the mix and an increase in units sold, which increased revenues by 16%, and an increase in average sales prices, which increased revenues by 3%.

Revenues from aortic stent grafts increased 10% for the six months ended June 30, 2023, as compared to the six months ended June 30, 2022. This increase was primarily due to a change in the mix and an increase in units sold, which increased revenues by 9%, and an increase in average sales prices, which increased revenues by 4%, partially offset by the effect of foreign exchange rates, which decreased revenues by 3%.

Constant currency revenues from aortic stent grafts increased 19% and 13% for the three and six months ended June 30, 2023, respectively, as compared to the three and six months ended June 30, 2022. The increase in revenues was partially due to improved conditions from the COVID-19 pandemic for the three and six months ended June 30, 2023, as compared to the three and six months ended June 30, 2022. Revenues for the three and six months ended June 30, 2023 increased in all geographies, primarily in Europe, the Middle East, and Africa (collectively, “EMEA”).

The revenue increase in EMEA for the three and six months ended June 30, 2023 was primarily due to buying patterns in direct (to hospitals) markets. OEM sales of aortic stent grafts accounted for approximately 1% of product revenues for the three and six months ended June 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. On-X product revenues 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.

On-X product revenues increased 10% for the three months ended June 30, 2023, as compared to the three months ended June 30, 2022. This increase was primarily due to an increase in volume of units sold, which increased revenues by 8%, and an increase in average sales prices in certain regions, which increased revenues by 3%, partially offset by the effect of foreign exchange rates, which decreased revenues by 1%.

On-X product revenues increased 16% for the six months ended June 30, 2023, as compared to the six months ended June 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 11%, and an increase in average sales prices, which increased revenues by 6%, partially offset by the effect of foreign exchange rates, which decreased revenues by 1%.

Constant currency On-X product revenues increased 11% and 17% for the three and six months ended June 30, 2023, respectively, as compared to the three and six months ended June 30, 2022. The increase in revenues for the three and six months ended June 30, 2023 was due to revenue increases in all geographies, primarily in North America and Asia Pacific ("APAC"). The revenue increases in these markets were partially due to improved conditions from the COVID-19 pandemic for the three and six months ended June 30, 2023, as compared to the three and six months ended June 30, 2022. The increase in revenues in North America for the three and six months ended June 30, 2023 was also impacted by customer buying patterns. The increase in revenues in APAC for the three and six months ended June 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 six months ended June 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 increased 4% for the three months ended June 30, 2023, as compared to the three months ended June 30, 2022. This increase was primarily due to an increase in average sales prices in certain regions, which increased revenues by 10%, partially offset by a change in the mix of milliliters sold, which decreased revenues by 6%.

Revenues from the sales of surgical sealants increased 5% for the six months ended June 30, 2023, as compared to the six months ended June 30, 2022. This increase was primarily due to an increase in volume of milliliters sold, which increased revenues by 4%, and an increase in average sales prices in certain regions, which increased revenues by 2%, partially offset by the effect of foreign exchange rates, which decreased revenues by 1%.

Constant currency revenues from sales of surgical sealants increased 4% and 6% for the three and six months ended June 30, 2023, respectively, as compared to the three and six months ended June 30, 2022. The increase in revenues for the three months ended June 30, 2023 was primarily due to revenue increases in EMEA. The increase in revenues for the six months ended June 30, 2023 was primarily due to revenue increases in APAC and North America.

Revenue from the sales of surgical sealants increased in EMEA during the three months ended June 30, 2023, as compared to the three months ended June 30, 2022, primarily due to changes in direct and indirect (through distributor) buying patterns in certain markets.

Revenues from the sales of surgical sealants increased in APAC for the six months ended June 30, 2023, as compared to the six months ended June 30, 2022, primarily due to distributor buying patterns. Revenues from the sales of surgical sealants increased in North America during the six months ended June 30, 2023, as compared to the six months ended June 30, 2022, primarily due to hospitals resuming more normal operations resulting from reduction of the COVID-19 pandemic restrictions. Revenues were negatively impacted during the first half of fiscal year 2022 due to delays and cancellations of some surgical procedures due to hospital staffing challenges as a result of a new COVID-19 variant.

Domestic revenues from surgical sealants accounted for 48% and 50% of total surgical sealant revenues for the three and six months ended June 30, 2023, respectively, and 51% and 50% of total surgical sealant revenues for the three and six months ended June 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 30, 2023).

Other revenues increased 9% and 1% for the three and six months ended June 30, 2023, respectively, as compared to the three and six months ended June 30, 2022. The increase in other revenues for the three and six months ended June 30, 2023, as compared to the three and six months ended June 30, 2022, was primarily due to an increase in PerClot and PhotoFix product revenues, partially offset by decreased CardioGenesis revenues as a result of our abandonment of the CardioGenesis cardiac laser therapy business.

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 three and six months ended June 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 9% for the three months ended June 30, 2023, as compared to the three months ended June 30, 2022. The increase in revenues for the three months ended June 30, 2023 was primarily due to an increase in average sales prices, which increased revenues by 9%.

Revenues from tissue processing increased 8% for the six months ended June 30, 2023, as compared to the six months ended June 30, 2022. The increase in revenues for the six months ended June 30, 2023 was primarily due to an increase in average sales prices, which increased revenues by 7%, and a change in the mix of tissues shipped, which increased revenues by 1%.

The increase in revenues from tissue processing for the three and six months ended June 30, 2023 was primarily due to an increase in pricing for certain tissues and, to a lesser extent, an increase in medical procedures that utilize our cardiac tissues.

Cost of Products and Preservation Services

Cost of Products

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Cost of products	$ 20,977	$ 18,230	$ 40,510	$ 35,638

Cost of products increased 15% and 14% for the three and six months ended June 30, 2023, respectively, as compared to the three and six months ended June 30, 2022. Cost of products for the three and six months ended June 30, 2023 and 2022 included costs related to aortic stent grafts, On-X products, surgical sealants, and other products.

The increase in cost of products for the three months ended June 30, 2023 was primarily due to an increase in the cost of aortic stent grafts as well as an increase in shipments of all product lines, particularly On-X products, as compared to the three months ended June 30, 2022.

The increase in cost of products for the six months ended June 30, 2023 was primarily due to an increase in shipments of On-X products as well as an increase in the cost of aortic stent grafts, and, to a lesser extent, On-X products, as compared to the six months ended June 30, 2022.

Cost of Preservation Services

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Cost of preservation services	$ 10,190	$ 9,938	$ 20,159	$ 19,024

Cost of preservation services increased 3% and 6% for the three and six months ended June 30, 2023, respectively, as compared to the three and six months ended June 30, 2022. Cost of preservation services included costs for cardiac and vascular tissue preservation services.

The increase in cost of preservation services for the three months ended June 30, 2023 was primarily due to an increase in the processing cost of vascular tissues, and, to a lesser extent, due to an increase in the shipments of cardiac tissues, as compared to the three months ended June 30, 2022.

The increase in cost of preservation services for the six months ended June 30, 2023 was primarily due to an increase in shipments of cardiac tissues as well as an increase in the processing cost of vascular tissues, as compared to the six months ended June 30, 2022.

Gross Margin

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Gross margin	$ 58,084	$ 52,172	$ 111,811	$ 102,891
Gross margin as a percentage of total revenues	65%	65%	65%	65%

Gross margin increased 11% and 9% for the three and six months ended June 30, 2023, respectively, as compared to the three and six months ended June 30, 2022.

Gross margin for the three and six months ended June 30, 2023 was positively impacted by shipments of PerClot as part of the Baxter Transaction described above. PerClot shipped during the three and six months ended June 30, 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 June 30, 2023, as compared to the three months ended June 30, 2022, was also due to an increase in shipments of certain aortic stent grafts and On-X products, as well as an increase in average sales prices of cardiac tissues, and a mix of aortic stent grafts shipped. The increase in gross margin was partially offset by an increase in product costs of aortic stent grafts and surgical sealants. Gross margin as a percentage of total revenues was flat for the three months ended June 30, 2023, as compared to the three months ended June 30, 2022. Gross margin as a percentage of total revenues was positively impacted by a favorable mix and price of certain products, offset by an increased cost of certain products shipped during the three months ended June 30, 2023.

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

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
General, administrative, and marketing expenses	$ 57,241	$ 38,983	$ 107,606	$ 77,938
General, administrative, and marketing expenses as a percentage of total revenues	64%	49%	62%	49%

General, administrative, and marketing expenses increased 47% and 38% for the three and six months ended June 30, 2023, respectively, as compared to the three and six months ended June 30, 2022. The increase in General, administrative, and marketing expenses for the three and six months ended June 30, 2023 was primarily due to an increase in business development expense and personnel-related costs.

General, administrative, and marketing expenses included $11.1 million and $16.1 million of business development expense for the three and six months ended June 30, 2023, respectively, as compared to $3.1 million and $4.7 million of income for the three and six months ended June 30, 2022, respectively. We incurred $10.9 million and $15.7 million of business development expense during the three and six months ended June 30, 2023, respectively, related to the fair value adjustments for the Ascyrus contingent consideration, as compared to $3.2 million and $5.0 million of business development income during the three and six months ended June 30, 2022, respectively.

Research and Development Expenses

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Research and development expenses	$ 7,418	$ 8,648	$ 14,641	$ 18,776
Research and development expenses as a percentage of total revenues	8%	11%	8%	12%

Research and development expenses decreased 14% and 22% for the three and six months ended June 30, 2023, respectively, as compared to the three and six months ended June 30, 2022. Research and development spending for the three and six months ended June 30, 2023 was primarily focused on clinical work to gain regulatory approvals for certain aortic stent grafts, On-X, and PerClot products.

Gain from Sale of Non-Financial Assets

Gain from sale of non-financial assets for the three and six months ended June 30, 2023 consisted of the net $14.3 million received as part of the Baxter Transaction upon receipt of the PerClot PMA in May 2023.

Interest Expense

Interest expense was $6.4 million and $12.5 million for the three and six months ended June 30, 2023, respectively, as compared to $4.1 million and $8.0 million for the three and six months ended June 30, 2022, respectively. Interest expense for the three and six months ended June 30, 2023 and 2022 relates to interest on debt and uncertain tax positions. The increase in interest expense for the three and six months ended June 30, 2023, as compared to the three and six months ended June 30, 2022, was primarily due to an increase in the interest rate on our term loan.

Other Expense, Net

Other expense, net was $4.2 million and $3.3 million for the three and six months ended June 30, 2023, respectively, as compared to $3.8 million and $3.9 million for the three and six months ended June 30, 2022, respectively. Other expense, net for the three and six months ended June 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 six months ended June 30, 2022 primarily included the realized and unrealized effects of foreign currency gains and losses.

Earnings

(Table in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Loss before income taxes	$ (2,657)	$ (3,300)	$ (11,576)	$ (5,729)
Income tax expense	725	959	5,338	1,919
Net loss	**$ (3,382)**	**$ (4,259)**	**$ (16,914)**	**$ (7,648)**
Diluted loss per common share	**$ (0.08)**	**$ (0.11)**	**$ (0.41)**	**$ (0.19)**
Diluted weighted-average common shares outstanding	**40,755**	**40,031**	**40,595**	**39,941**

We incurred a loss before income taxes for the three and six months ended June 30, 2023 and 2022. The loss before income taxes for the three and six months ended June 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 six months ended June 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, partially offset by the change in fair value of our financial instruments. Revenues for the three and six months ended June 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 27% and 46% for the three and six months ended June 30, 2023, respectively, as compared to an expense of 29% and 34% for the three and six months ended June 30, 2022, respectively. The change in the tax rate for the three and six months ended June 30, 2023 was primarily due to changes in pre-tax book income, a decrease in the excess tax benefit related to stock compensation, and an increase in the estimated current year valuation allowance, as compared to the three and six months ended June 30, 2022.

Our income tax rate for the three and six months ended June 30, 2023 and 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 six months ended June 30, 2023 and 2022. Net loss and diluted loss per common share for the three and six months ended June 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 June 30, 2023 net working capital (current assets of $263.9 million less current liabilities of $56.2 million) was $207.7 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 six months ended June 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, and repurchases of stock to cover tax withholdings. 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 Endospan and 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 June 30, 2023 the aggregate interest rate of the Credit Agreement was 9.00% 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 June 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 June 30, 2023 was approximately $104.6 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 $2.5 million for the three and six months ended June 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 $1.5 million and $1.9 million of unamortized debt issuance costs related to Convertible Senior Notes as of June 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 cannot redeem the Convertible Senior Notes before July 5, 2023. We can redeem them on or after July 5, 2023, 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 June 30, 2023 approximately 34% 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):

	Six Months Ended June 30,	
	2023	**2022**
Cash flows provided by (used in):		
Operating activities	$ 755	$ (8,912)
Investing activities	4,235	(4,994)
Financing activities	3,404	(1,032)
Effect of exchange rate changes on cash and cash equivalents	1,030	310
Increase (decrease) in cash and cash equivalents	**$ 9,424**	**$ (14,628)**

Net Cash Flows from Operating Activities

Net cash provided by operating activities was $755,000 for the six months ended June 30, 2023, as compared to net cash used in operating activities of $8.9 million for the six months ended June 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 six months ended June 30, 2023 these non-cash items primarily included $15.7 million of fair value adjustments of financial instruments, $14.3 million of gain from sale of non-financial assets, $11.5 million of depreciation and amortization expenses, $8.1 million of deferred income tax changes, $7.3 million of non-cash compensation, 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 six months ended June 30, 2023 these included $1.6 million due to timing differences between the recording of accounts payable, accrued expenses, and other liabilities and the payment of cash, and the favorable effect of $655,000 due to the timing differences between recording receivables and the receipt of cash, partially offset by $6.9 million due to an increase in inventory balances and deferred preservation costs and $2.3 million due to an increase in prepaid expenses and other assets.

Net Cash Flows from Investing Activities

Net cash provided by investing activities was $4.2 million for the six months ended June 30, 2023, as compared to net cash used in investing activities of $5.0 million for the six months ended June 30, 2022. During the six months ended June 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 a $5.0 million payment related to our agreement with Endospan and $4.0 million of cash used for capital expenditures.

Net Cash Flows from Financing Activities

Net cash provided by financing activities was $3.4 million for the six months ended June 30, 2023, as compared to net cash used in financing activities of $1.0 million for the six months ended June 30, 2022. The current year cash provided by financing activities was primarily due to $3.6 million of proceeds from financing insurance premiums and $2.6 million of proceeds from the exercise of stock options and issuances of common stock, partially offset by $1.4 million for the repayment of debt and $563,000 for repurchases of common stock to cover tax withholdings.

Scheduled Contractual Obligations and Future Payments

Our long-term debt obligations and interest payments include $313.4 million of scheduled principal payments and $84.1 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 $4.0 million and $4.1 million for the six months ended June 30, 2023 and 2022, respectively. Capital expenditures for the six months ended June 30, 2023 were primarily related to routine purchases of manufacturing and tissue processing equipment, leasehold improvements, computer software needed to support our business, 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 $48.8 million as of June 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 six months ended June 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 June 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 six months ended June 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 June 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 June 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; 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 an increasing 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 inflationary pressures in Latin America;
- Potential adverse financial impact and negative erosion of our operating profit margin over time due to increasing inflationary pressures, particularly impacting our Latin American business as well as 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. The war has also 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 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 war or increased export controls or additional sanctions imposed on or by Russia, its allies, or related entities could adversely affect our financial performance. Although we do not have any direct operations in Russia or Ukraine, it is difficult to predict the ultimate course of the war and we may face business operations and supply chain disruptions as a result, including disruptions related to shortages of materials, 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. 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;
- Achieve necessary price increases to be able to reliably process and supply high-demand tissues;
- 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 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, in the fourth quarter of 2021, 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 war in Ukraine, 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 war in Ukraine 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 war in Ukraine 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 three and six months ended June 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 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 December 1, 2017 we acquired JOTEC AG, a Swiss entity that we converted to JOTEC GmbH and subsequently merged with our Swiss acquisition entity, Jolly Buyer Acquisition GmbH and its subsidiaries;
- 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 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 in the fourth quarter of 2021, 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 voted to extend the MDR transition period and amend other related provisions but it is still unclear whether this extension will be able to mitigate the challenges posed by the transition to the MDR.

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 we cannot obtain upon review of the updated submission, or the costs to do so are prohibitive, we ultimately may be unable to sell BioGlue in China.

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 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 war in Ukraine 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 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. 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 following table provides information about purchases by us during the three months ended June 30, 2023 of equity securities that are registered by us pursuant to Section 12 of the Securities Exchange Act of 1934:

Period	Total Number of Common Shares and Common Stock Units Purchased	Average Price Paid per Common Share	Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs	Dollar Value of Common Shares That May Yet Be Purchased Under the Plans or Programs
04/01/23 - 04/30/23	—	$ —	—	$ —
05/01/23 - 05/31/23	44	14.73	—	—
06/01/23 - 06/30/23	—	—	—	—
Total	**44**	**$ 14.73**	**—**	**$ —**

The common shares purchased during the three months ended June 30, 2023 were tendered to us in payment of taxes on stock compensation and were not part of a publicly announced plan or program.

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.

During the three months ended June 30, 2023, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted, terminated, or modified a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

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., a Delaware Corporation (Incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed January 20, 2022).
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).
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.

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
J. PATRICK MACKIN
Chairman, President, and
Chief Executive Officer
(Principal Executive Officer)

/s/ D. ASHLEY LEE
D. ASHLEY LEE
Executive Vice President, and
Chief Financial Officer
(Principal Financial and
Accounting Officer)

August 4, 2023
DATE

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: August 4, 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: August 4, 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 June 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
August 4, 2023

/s/ D. ASHLEY LEE
D. ASHLEY LEE
Executive Vice President, and
Chief Financial Officer
August 4, 2023