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

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2025
OR
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission file number: 1-13165

ARTIVION, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

Large Accelerated Filer	☒	Accelerated Filer	☐
Non-accelerated Filer	☐	Smaller Reporting Company	☐
		Emerging Growth Company	☐

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

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

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

Class	Outstanding at May 2, 2025
Common Stock, $0.01 par value	42,702,785

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Part I – FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	Three Months Ended March 31,	
	2025	**2024**
Revenues:		
Products	$ 78,798	$ 71,114
Preservation services	20,180	26,317
Total revenues	**98,978**	**97,431**
Cost of products and preservation services:		
Products	25,263	23,750
Preservation services	10,138	10,735
Total cost of products and preservation services	**35,401**	**34,485**
Gross margin	**63,577**	**62,946**
Operating expenses:		
General, administrative, and marketing	54,704	30,689
Research and development	6,728	6,946
Total operating expenses	**61,432**	**37,635**
Operating income	**2,145**	**25,311**
Interest expense	7,663	7,826
Interest income	(144)	(374)
Loss on extinguishment of debt	—	3,669
Other (income) expense, net	(3,079)	1,409
(Loss) income before income taxes	**(2,295)**	**12,781**
Income tax (benefit) expense	(1,790)	5,248
Net (loss) income	**$ (505)**	**$ 7,533**
(Loss) income per share:		
Basic	**$ (0.01)**	**$ 0.18**
Diluted	**$ (0.01)**	**$ 0.18**
Weighted-average common shares outstanding:		
Basic	42,232	41,290
Diluted	42,232	47,886
Net (loss) income	**$ (505)**	**$ 7,533**
Other comprehensive income:		
Foreign currency translation adjustments, net of tax	6,331	(1,528)
Comprehensive income	**$ 5,826**	**$ 6,005**

See accompanying Notes to Condensed Consolidated Financial Statements

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

	March 31, 2025	December 31, 2024
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 37,693	$ 53,463
Trade receivables, net	87,802	79,462
Other receivables	7,956	6,431
Inventories	81,927	79,766
Deferred preservation costs	52,375	51,701
Prepaid expenses and other	19,544	19,257
Total current assets	**287,297**	**290,080**
Goodwill	245,069	240,958
Acquired technology, net	127,530	128,051
Operating lease right-of-use assets, net	39,229	39,726
Property and equipment, net	37,810	36,403
Other intangibles, net	28,517	28,332
Deferred tax assets, net	684	1,068
Other long-term assets	25,027	24,483
Total assets	**$ 791,163**	**$ 789,101**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,695	$ 17,971
Accrued compensation	12,294	18,342
Accrued expenses	11,520	11,834
Accrued interest	6,757	8,170
Taxes payable	1,605	2,934
Accrued procurement fees	1,982	1,704
Current maturities of operating leases	4,575	4,489
Current portion of finance lease obligations	669	601
Current portion of long-term debt, net	135	195
Other current liabilities	708	583
Total current liabilities	**51,940**	**66,823**
Long-term debt, net	314,611	314,152
Contingent consideration	50,050	52,880
Non-current maturities of operating leases	39,353	39,988
Deferred tax liabilities, net	21,532	20,183
Deferred compensation liability	8,070	7,977
Non-current finance lease obligations	3,016	2,833
Other long-term liabilities	8,339	8,065
Total liabilities	**$ 496,911**	**$ 512,901**
Commitments and contingencies		
Stockholders' equity:		
Preferred stock $0.01 par value per share, 5,000 shares authorized, no shares issued	—	—
Common stock $0.01 par value per share, 75,000 shares authorized, 44,190 and 43,432 shares issued as of March 31, 2025 and December 31, 2024, respectively	442	434
Additional paid-in capital	388,825	376,607
Retained deficit	(61,771)	(61,266)
Accumulated other comprehensive loss	(18,596)	(24,927)
Treasury stock, at cost, 1,487 shares as of March 31, 2025 and December 31, 2024	(14,648)	(14,648)
Total stockholders' equity	**294,252**	**276,200**
Total liabilities and stockholders' equity	**$ 791,163**	**$ 789,101**

See accompanying Notes to Condensed Consolidated Financial Statements

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

	Three Months Ended March 31,	
	2025	**2024**
Net cash flows from operating activities:		
Net (loss) income	$ (505)	$ 7,533
Adjustments to reconcile net (loss) income to net cash from operating activities:		
Depreciation and amortization	5,446	5,909
Non-cash compensation	8,045	3,478
Non-cash lease expense	1,226	1,920
Write-down of inventories and deferred preservation costs	1,312	723
Deferred income taxes	—	4,299
Change in fair value of contingent consideration	(2,830)	(17,470)
Loss on extinguishment of debt	—	3,669
Other	(2,891)	644
Changes in operating assets and liabilities:		
Receivables	(7,922)	(3,334)
Inventories and deferred preservation costs	(2,453)	(1,380)
Prepaid expenses and other assets	(327)	(2,268)
Accounts payable, accrued expenses, and other liabilities	(16,054)	(9,216)
Net cash flows used in operating activities	**(16,953)**	**(5,493)**
Net cash flows from investing activities:		
Capital expenditures	(3,638)	(3,611)
Net cash flows used in investing activities	**(3,638)**	**(3,611)**
Net cash flows from financing activities:		
Proceeds from issuance of long-term debt	—	190,000
Proceeds from revolving credit facility	—	30,000
Repayment of debt	(66)	(211,627)
Proceeds from exercise of stock options and issuance of common stock	4,181	3,528
Payment of debt issuance costs	—	(9,998)
Principal payments on short-term notes payable	—	(1,027)
Other	(178)	(139)
Net cash flows provided by financing activities	**3,937**	**737**
Effect of exchange rate changes on cash and cash equivalents	884	545
Decrease in cash and cash equivalents	**(15,770)**	**(7,822)**
Cash and cash equivalents beginning of period	53,463	58,940
Cash and cash equivalents end of period	**$ 37,693**	**$ 51,118**

See accompanying Notes to Condensed Consolidated Financial Statements

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

	Common Stock		Additional Paid-In Capital	Retained Deficit	Accumulated Other Comprehensive Loss	Treasury Stock		Total Stockholders' Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2024	**43,432**	**$ 434**	**$ 376,607**	**$(61,266)**	**$ (24,927)**	**(1,487)**	**$(14,648)**	**$ 276,200**
Net loss	—	—	—	(505)	—	—	—	(505)
Other comprehensive income, net of tax	—	—	—	—	6,331	—	—	6,331
Equity compensation	543	6	8,039	—	—	—	—	8,045
Exercise of options	171	2	3,218	—	—	—	—	3,220
Employee stock purchase plan	44	—	961	—	—	—	—	961
Balance at March 31, 2025	**44,190**	**$ 442**	**$ 388,825**	**$(61,771)**	**$ (18,596)**	**(1,487)**	**$(14,648)**	**$ 294,252**

	Common Stock		Additional Paid-In Capital	Retained Deficit	Accumulated Other Comprehensive Loss	Treasury Stock		Total Stockholders' Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2023	**42,569**	**$ 426**	**$ 355,919**	**$(47,907)**	**$ (12,010)**	**(1,487)**	**$(14,648)**	**$ 281,780**
Net income	—	—	—	7,533	—	—	—	7,533
Other comprehensive loss, net of tax	—	—	—	—	(1,528)	—	—	(1,528)
Equity compensation	436	4	3,668	—	—	—	—	3,672
Exercise of options	168	2	2,787	—	—	—	—	2,789
Employee stock purchase plan	51	—	739	—	—	—	—	739
Balance at March 31, 2024	**43,224**	**$ 432**	**$ 363,113**	**$(40,374)**	**$ (13,538)**	**(1,487)**	**$(14,648)**	**$ 294,985**

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, 2024 has been derived from audited financial statements. The accompanying unaudited Condensed Consolidated Financial Statements as of, and for the three months ended, March 31, 2025 and 2024 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. Certain prior-year amounts have been reclassified to conform to the current year presentation. Operating results for the three months ended March 31, 2025 are not necessarily indicative of the results that may be expected for the year ending December 31, 2025. 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, 2024 filed with the SEC on February 28, 2025.

Foreign Currency Translation and Transactions

Assets and liabilities of international subsidiaries whose functional currency is the local currency are translated at the rate of exchange in effect on the balance sheet date; income and expenses are translated at the average exchange rates throughout the year. Foreign currency exchange rate realized and unrealized gains and losses resulting from transactions are included in Other (income) expense, net in our Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income and resulted in a net gain of $2.9 million and a net loss of $1.4 million for the three months ended March 31, 2025 and 2024, respectively. Currency translation adjustments resulting from intra-entity loans that are of a long-term investment nature, net of tax, are included in Accumulated other comprehensive loss and resulted in a net gain of $3.8 million and $0.2 million for the three months ended March 31, 2025 and 2024, respectively.

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, 2024. 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 months ended March 31, 2025 in any of our Significant Accounting Policies from those contained in our Form 10-K for the year ended December 31, 2024.

New Accounting Standards

Not Yet Effective

In December 2023 the FASB issued ASU 2023-09, *Income Taxes Topic 740 - Improvements to Income Tax Disclosures*. This amendment is expected to enhance the transparency and decision usefulness of income tax disclosures by requiring public business entities, on an annual basis, to disclose specific categories in the rate reconciliation, additional information for reconciling items that meet a quantitative threshold, and certain information about income taxes paid. This revised guidance is effective for annual periods beginning after December 15, 2024. We are currently evaluating the impacts of the new standard.

In November 2024 the FASB issued ASU No. 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses to improve the disclosures about a public business entity's expenses for more detailed information about the types of expenses in commonly presented expense captions such as cost of sales; selling, general, and administrative expenses; and research and development. The updated accounting guidance, among other things, requires quantitative disclosures for employee compensation, selling expenses, and purchases of inventory. The updated guidance is effective for financial statements issued for fiscal years beginning after December 15, 2026. We are currently evaluating the impacts of the new standard.

2. Agreements with Endospan

On September 11, 2019 Artivion's wholly owned subsidiary, JOTEC, entered into an exclusive distribution agreement ("Endospan Distribution Agreement") with Endospan Ltd. ("Endospan"), an Israeli corporation, pursuant to which JOTEC obtained exclusive distribution rights for NEXUS ONE, and under subsequent amendments, the NEXUS DUO and NEXUS TRE (collectively the "NEXUS family of products") and accessories in certain countries in Europe in exchange for a fixed distribution fee of $9.0 million paid in September 2019. The Endospan Distribution Agreement was fully amortized as of December 31, 2024.

Additionally, we entered into a loan agreement to provide Endospan a secured loan of up to $15.0 million ("Endospan Loan") and a securities purchase option agreement ("Endospan Option") with Endospan for $1.0 million paid in September 2019. The Endospan Option Agreement prior to amendment described below 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.

On July 1, 2024 Artivion and Endospan entered into an amendment to the Endospan Option ("Endospan Option Amendment") which amended the terms of the previously existing Endospan Option. Under the terms of the Endospan Option Amendment, the price to acquire all of Endospan's outstanding securities from Endospan's securityholders at the time of acquisition, or the option to acquire all of Endospan's assets under the Endospan Option was reduced from $250.0 million to $175.0 million, resulting in an upfront acquisition purchase price of $135.0 million, inclusive of the loan off-set. There is no longer a minimum earnout payment of $100.0 million and the maximum earnout payment of $200.0 million remains the same. As described in more detail below, we also entered into an amendment to the Endospan Loan (the "Endospan Loan Amendment") whereby we agreed to fund Endospan additional secured loans of up to $25.0 million ("Additional Endospan Loan" and together with the Endospan Loan, the "Endospan Loans").

Valuation

The agreements with Endospan were entered into concurrently and had certain terms that are interrelated. In our evaluation of the initial relative fair value of each of the Endospan agreements to determine the amount to record, we utilized discounted cash flows to estimate the fair market value for the Endospan Loan and for the Endospan Distribution Agreement. We estimated the fair value of the Endospan Option utilizing a Monte Carlo simulation model. Inputs in our valuation of the Endospan agreements included cash payments and anticipated payments based on the executed agreements with Endospan, projected discounted cash flows in connection with the Endospan transaction, our expected internal rate of return and discount rates, and our assessed probability and timing of receipt of certification of certain approvals and milestones in obtaining FDA approval.

Endospan Option

Utilizing a Monte Carlo simulation model, we determined that the fair value of the Endospan Option in 2019 was $4.9 million. As a result of a decrease in forecasted operating results, we fully impaired the value of the Endospan Option primarily during the fourth quarter of December 31, 2021.

Due to the revised terms in the Endospan Option Amendment in July 2024, we performed another fair value measurement utilizing a Monte Carlo simulation model and revalued the Endospan Option. We determined that the fair value of the Endospan Option was $3.1 million as of March 31, 2025 and December 31, 2024, which is reflected in Other long-term assets in the Condensed Consolidated Balance Sheets.

Endospan Loans

Artivion and Endospan also entered into a loan agreement (the "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 in 2019, 2020 and 2023, respectively.

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 assessments of the fair value of the Endospan Loan in previous periods and determined that the Endospan Loan had no fair value. After entering into the Endospan Loan Amendment in July 2024, we determined that the Endospan Loan had a fair value of $0.3 million as of March 31, 2025 and December 31, 2024.

As a part of the Endospan Loan Amendment, Artivion agreed to fund the Additional Endospan Loan up to $25.0 million. The Additional Endospan Loan is contracted to be funded in three tranches of $7.0 million, $10.0 million and $8.0 million, subject to Endospan's achievement of milestones related to its pursuit of regulatory approval for NEXUS ONE that are specified in the Endospan Loan Amendment. The first two tranches totaling $17.0 million were funded during the year ended December 31, 2024. We performed a fair value assessment of the Additional Endospan Loan and determined that the fair value was $9.5 million and $9.2 million as of March 31, 2025 and December 31, 2024, respectively, which is reflected in Other long-term assets in the Condensed Consolidated Balance Sheets.

3. Financial Instruments

A summary of financial instruments measured at fair value was as follows (in thousands):

March 31, 2025	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 2,214	$ —	$ —	$ 2,214
Certificates of deposit	1,239	—	—	1,239
Endospan Loans	—	—	9,808	9,808
Total assets	**$ 3,453**	**$ —**	**$ 9,808**	**$ 13,261**
Long-term liabilities:				
Contingent consideration	$ —	$ —	$ 50,050	$ 50,050
Total liabilities	**$ —**	**$ —**	**$ 50,050**	**$ 50,050**

December 31, 2024	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 18,182	$ —	$ —	$ 18,182
Certificates of deposit	5,069	—	—	5,069
Endospan Loans	—	—	9,535	9,535
Total assets	**$ 23,251**	**$ —**	**$ 9,535**	**$ 32,786**
Long-term liabilities:				
Contingent consideration	$ —	$ —	$ 52,880	$ 52,880
Total liabilities	**$ —**	**$ —**	**$ 52,880**	**$ 52,880**

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 months ended March 31, 2025 and 2024.

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 Ascyrus Medical Dissection Stent hybrid prosthesis ("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 earnout.

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 17% and estimated future achievement of milestone dates between 2025 and 2026 to calculate the fair value of contingent consideration as of March 31, 2025. We remeasure this liability at each reporting date and record changes in the fair value of the contingent consideration in General, administrative, and marketing expenses in the Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income. Increases or decreases in the fair value of the contingent consideration liability can result from changes in the passage of time, discount rates, the timing and amount of our revenue estimates, and the timing and expectation of regulatory approvals.

We perform quarterly assessments of the fair value of the contingent consideration and recorded a net fair value gain of $2.8 million and $17.5 million for the three months ended March 31, 2025 and 2024, respectively, in General, administrative, and marketing expenses in the Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income. The $17.5 million reduction in the fair value of the liability for the three months ended March 31, 2024 was primarily due to an increase in the credit risk spread resulting from the change in the inputs related to the Credit Facilities issued in the first quarter of 2024, as further discussed in Note 7. The contingent consideration liability reflected in the Condensed Consolidated Balances Sheets was $50.1 million and $52.9 million as of March 31, 2025 and December 31, 2024, respectively.

The fair value of the contingent consideration component of the Ascyrus acquisition and Endospan Loans were 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, 2024	$ 52,880
Change in valuation	(2,830)
Balance as of March 31, 2025	**$ 50,050**

	Endospan Loans
Balance as of December 31, 2024	$ 9,535
Change in valuation	273
Balance as of March 31, 2025	**$ 9,808**

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

4. Inventories and Deferred Preservation Costs

Inventories consist of the following (in thousands):

	March 31, 2025	December 31, 2024
Raw materials and supplies	$ 34,494	$ 35,295
Work-in-process	16,278	13,926
Finished goods	31,155	30,545
Total inventories, net	**$ 81,927**	**$ 79,766**

To facilitate product usage, we maintain consignment inventory On-X heart valves at domestic hospital locations and On-X heart valves, aortic stent grafts, and AMDS products at international hospital locations. We retain title and control over this consignment inventory until we receive a notification of implantation, at which time we invoice the hospital and recognize revenue. As of March 31, 2025 we had $11.7 million in consignment inventory, with approximately 38% in domestic locations and 62% in international locations. As of December 31, 2024 we had $12.2 million in consignment inventory, with approximately 39% in domestic locations and 61% in foreign locations.

Total deferred preservation costs were $52.4 million and $51.7 million as of March 31, 2025 and December 31, 2024, respectively.

5. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

The carrying values of our indefinite lived intangible assets were as follows (in thousands):

	March 31, 2025	December 31, 2024
Goodwill	$ 245,069	$ 240,958
In-process R&D	2,109	2,026
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 evaluate our goodwill and indefinite lived 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. We did not record any impairment of indefinite lived intangible assets, including goodwill, during the three months ended March 31, 2025. In-process research and development, procurement contracts and agreements are included in Other intangibles, net in the Condensed Consolidated Balance Sheets as of March 31, 2025 and December 31, 2024.

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.

Changes in the carrying value of our goodwill, all of which was related to our Medical Devices segment, were as follows (in thousands):

	March 31, 2025
Balance as of December 31, 2024	$ 240,958
Foreign currency translation	4,111
Balance as of March 31, 2025	**$ 245,069**

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. The major intangible asset classes consist of the following (in thousands, except weighted average useful life):

March 31, 2025	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Weighted Average Useful Life (Years)
Acquired technology	$ 199,769	$ 72,239	$ 127,530	18.2
Other intangibles:				
Customer lists and relationships	$ 28,687	$ 11,980	$ 16,707	21.6
Patents	4,508	3,476	1,032	17.0
Other	12,599	5,943	6,656	5.0
Other intangibles, net	**$ 45,794**	**$ 21,399**	**$ 24,395**	**11.1**

December 31, 2024	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Weighted Average Useful Life (Years)
Acquired technology	$ 195,912	$ 67,861	$ 128,051	18.3
Other intangibles:				
Customer lists and relationships	$ 28,611	$ 11,617	$ 16,994	21.6
Distribution and manufacturing rights and know-how	9,033	9,033	—	5.0
Patents	4,428	3,460	968	17.0
Other	11,776	5,445	6,331	5.0
Other intangibles, net	**$ 53,848**	**$ 29,555**	**$ 24,293**	**9.4**

Amortization Expense

Amortization expense recorded in General, administrative, and marketing expenses in our Condensed Consolidated Statements of Operations and Comprehensive Loss was as follows (in thousands):

	Three Months Ended March 31,	
	2025	2024
Amortization expense	$ 3,388	$ 3,867

6. Income Taxes

Income Tax Expense

Our effective income tax rate was a benefit of 78% and an expense of 41% for the three months ended March 31, 2025 and 2024, respectively. Our income tax rate was primarily impacted by state income taxes, non-deductible executive compensation, and changes in our valuation allowance against our net deferred tax assets, partially offset by excess tax deductions on stock-based compensation.

7. Debt

Debt consists of the following (in thousands):

	March 31, 2025	December 31, 2024
Term Loan Facility	$ 190,000	$ 190,000
Revolving Credit Facility	30,000	30,000
Convertible Senior Notes	100,000	100,000
1.40% Sparkasse Zollernalb (KFW Loan 2)	135	195
Total principal debt	**320,135**	**320,195**
Less: Unamortized debt issuance costs[(a)]	(5,389)	(5,848)
Total debt	**314,746**	**314,347**
Less: Current portion of long-term debt	(135)	(195)
Long-term debt, net	**$ 314,611**	**$ 314,152**

(a) Additional unamortized debt issuance costs totaling $1.6 million and $1.7 million related to the Revolving Credit Facility are included in "Other long-term assets" in the Condensed Consolidated Balance Sheets as of March 31, 2025 and December 31, 2024, respectively.

Our liquidity needs arise from the funding of our cost of operations and capital expenditures and from debt service on our indebtedness. We believe that cash generated from operations, together with amounts available under our Term Loan Facilities, as defined below, will be adequate to permit us to meet our obligations over the next twelve months from the date of this report.

Credit Facilities

On January 18, 2024 we entered into a credit and guaranty agreement with Ares Management Credit funds for $350.0 million of senior secured, interest-only, credit facilities, consisting of a $190.0 million secured term loan facility (the "Term Loan Facility"), a $100.0 million secured delayed draw term loan facility (the "Delayed Draw Term Loan Facility" and, together with the Term Loan Facility, the "Term Loan Facilities") and a $60.0 million "senior-priority" secured revolving credit facility which has a priority claim ahead of the other secured facilities (the "Revolving Credit Facility" and, together with the Term Loan Facilities, the "Credit Facilities"). Upon closing, we borrowed $190.0 million under the Term Loan Facility and $30.0 million under the Revolving Credit Facility. The proceeds of the borrowings were used along with cash on hand to pay off our previously existing credit agreement (the "Old Credit Facilities" as defined below) and pay related fees and expenses.

The remaining $30.0 million of undrawn availability under the Revolving Credit Facility as of March 31, 2025 may be drawn for working capital, capital expenditures, and other general corporate purposes. The proceeds from borrowings under the Delayed Draw Term Loan Facility, which remains undrawn as of March 31, 2025 may be used solely to repurchase or repay our outstanding 4.25% Convertible Senior Notes due July 1, 2025 and to pay related fees and expenses.

Subject to the satisfaction of a specified maximum total net leverage ratio and other customary conditions, we may borrow under the Delayed Draw Term Loan Facility at any time and from time to time on or prior to the maturity date of the convertible bonds on July 1, 2025. Loans borrowed under the Delayed Draw Term Loan Facility generally have the same terms as the loans under the Term Loan Facility. See Convertible Senior Notes below for additional details.

Ranking; Guarantees

The Credit Facilities are 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.

Maturity and Redemption

The final scheduled maturity date of the Credit Facilities is January 18, 2030. There are no scheduled repayments of principal required to be made prior to the final maturity date. We have the right to prepay loans under the Ares Credit Agreement in whole or in part at any time, provided that any prepayment of loans under the Term Loan Facilities (or loans under the Revolving Credit Facility to the extent of reducing the balance of outstanding loans below $30.0 million) will be subject to a prepayment premium of 1.00% if the prepayment occurs prior to January 18, 2026. Amounts repaid in respect of loans under the Term Loan Facilities may not be reborrowed.

Covenants

The Credit Facilities contain 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. The covenants include a financial maintenance covenant that requires the company's total net leverage ratio, as defined in the agreement, to be not greater than 6.25x for the test periods from the second quarter of fiscal year 2024 through the fourth quarter of fiscal year 2024 and not greater than 5.75x from the first quarter of fiscal year 2025 and thereafter. As of March 31, 2025 we are in compliance with our debt covenants.

Interest

The Revolving Credit Facility bears interest, at our option, at a floating annual rate equal to either the base rate plus a margin of 3.00%, or the Adjusted Term Secured Overnight Financing Rate ("Adjusted Term SOFR") plus a margin of 4.00%. In addition, we will be required to pay fees of 0.50% per annum on the daily unused amount of the Revolving Credit Facility and 1.00% per annum on the daily unused amount of the Delayed Draw Term Loan Facility. The Term Loan Facilities initially bear interest, at our option, at a floating annual rate equal to either the base rate plus a margin of 5.50%, or the Adjusted Term SOFR plus a margin of 6.50%. If, after the second quarter of fiscal year 2025, the company reports total net leverage ratio, as defined in the Credit Facilities, of less than or equal to 3.75x the interest margins applicable to the Term Loan Facilities will be reduced by 25 basis points, to 5.25% and 6.25%, for base rate and Adjusted Term SOFR loans, respectively. As of March 31, 2025 the stated and effective interest rate for the Term Loan Facility was 10.81% and 11.56%, respectively. As of March 31, 2025 the stated interest rate was 8.31% per annum for the Revolving Credit Facility.

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 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 March 31, 2025 was approximately $111.5 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.

Interest expense recognized on the Convertible Senior Notes includes approximately $1.3 million and $1.2 million for the aggregate of the contractual coupon interest and the amortization of the debt issuance costs during the three months ended March 31, 2025 and 2024, respectively. Interest on the Convertible Senior Notes began accruing upon issuance and is payable semi-annually. There were approximately $0.2 million and $0.4 million of unamortized debt issuance costs related to the Convertible Senior Notes as of March 31, 2025 and December 31, 2024, respectively.

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

On December 23, 2024 in accordance with the Indenture (the "Indenture") dated June 23, 2020, between Artivion, Inc. (formerly CryoLife, Inc.) and U.S. Bank Trust Company, National Association, as Trustee, relating to our Convertible Senior Notes, we gave notice to the Trustee, the Conversion Agent, and the Holders (each as defined in the Indenture) that we elected to change the "Default Settlement Method" (as defined in the Indenture) for conversions of Notes to "Physical Settlement" (as defined in the Indenture). As a result, all conversions of Notes after the date of the notice will be settled by delivery of shares of our common stock using Physical Settlement in accordance with the Indenture.

Old Credit Facilities and Loss on Extinguishment of Debt

Our Old Credit Facilities, entered into on December 1, 2017, provided for a $255.0 million senior secured credit facility, consisting of a $225.0 million secured term loan facility (the "Old Term Loan Facility") and a $30.0 million secured revolving credit facility (the "Old Revolving Credit Facility"). On June 2, 2021 we entered into an amendment to our Credit Agreement to extend the maturity dates of both our Term Loan and its 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 as defined.

In connection with the proceeds received from our new Credit Facilities, we repaid all outstanding amounts under the Old Credit Facilities and recorded a loss on extinguishment of debt of $3.7 million, primarily comprised of the write-off of unamortized debt issuance costs, in our Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three months ended March 31, 2024.

Debt Discount and Debt Issuance Costs

In connection with the debt issued under the Credit Facilities, we capitalized $2.7 million in debt issuance costs. The Credit Facilities were also issued at an original issue discount of $7.5 million. Non-cash amortization of debt issuance costs and debt discounts for our Credit Facilities, Convertible Senior Notes, and Old Credit Facilities totaled $0.5 million and $0.6 million for the three months ended March 31, 2025 and 2024, respectively.

8. 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 March 31, 2025 and December 31, 2024 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.

9. Revenue Recognition

Disaggregation of Revenue

Revenues are disaggregated by the following geographic regions:

- North America: consists of the US and Canada. We market our approved medical device products and preservation services (predominantly in the US), primarily to physicians through our direct sales representatives who are managed by regional managers.
- Europe, the Middle East, and Africa ("EMEA"): in certain countries, we market approved medical device products to physicians, hospitals, and distributors through our direct sales force. In countries where we have no direct sales forces, regional sales managers market to distributors who buy medical device products directly from us and sell to hospitals in their respective countries.
- Asia Pacific ("APAC"): we market medical device products that are approved in each country to distributors in the region.
- Latin America ("LATAM"): we market medical device products that are approved in each country to distributors in the region except for Brazil where we sell directly to end customers and distributors.

Net revenues by geographic location based on the location of the customer were as follows (in thousands):

	Three Months Ended March 31,	
	2025	**2024**
North America	$ 47,793	$ 50,928
EMEA	37,045	33,588
APAC	8,214	7,609
LATAM	5,926	5,306
Total revenues	**$ 98,978**	**$ 97,431**

Also see segment disaggregation information in Note 12 below.

10. 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 stockholder-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 three months ended March 31, 2025 the Compensation Committee of our Board of Directors (the "Committee") authorized awards from approved stock incentive plans of RSUs and PSUs to certain employees and company officers, which, assuming that performance under the PSUs will be achieved at target levels, together totaled 748,000 shares and had an aggregate grant date fair value of $19.0 million.

During the three months ended March 31, 2024 the Committee authorized awards from approved stock incentive plans of 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 700,000 shares and had an aggregate grant date fair value of $14.2 million.

The Committee did not authorize any grants of stock options during the three months ended March 31, 2025 and 2024.

Employees purchased common stock totaling 44,000 and 51,000 shares in the three months ended March 31, 2025 and 2024, respectively, through the ESPP.

11. (Loss) Income Per Common Share

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

	Three Months Ended March 31,	
Basic (loss) income per common share	**2025**	**2024**
Net (loss) income	$ (505)	$ 7,533
Net loss (income) allocated to participating securities	1	(22)
Net (loss) income allocated to common stockholders	**$ (504)**	**$ 7,511**
Basic weighted-average common shares outstanding	**42,232**	**41,290**
Basic (loss) income per common share	**$ (0.01)**	**$ 0.18**

	Three Months Ended March 31,	
Diluted (loss) income per common share	**2025**	**2024**
Net (loss) income	$ (505)	$ 7,533
Net loss (income) allocated to participating securities	1	(19)
Net income attributable to convertible senior notes	—	935
Net (loss) income allocated to common stockholders	**$ (504)**	**$ 8,449**
Basic weighted-average common shares outstanding	42,232	41,290
Effect of dilutive stock options and awards	—	889
Effect of convertible senior notes	—	5,707
Diluted weighted-average common shares outstanding	**42,232**	**47,886**
Diluted (loss) income per common share	**$ (0.01)**	**$ 0.18**

We excluded stock options and awards 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 months ended March 31, 2025 all stock options, awards, and potential common shares related to our Convertible Senior Notes were excluded from the calculation of diluted weighted-average common shares outstanding as these would be antidilutive due to the net loss. For the three months ended March 31, 2024 1.3 million of potential common shares related to stock options and awards were antidilutive and excluded from the calculation of diluted weighted-average common shares outstanding.

12. 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™, the NEXUS ONE™, NEXUS DUO™, and NEXUS TRE™ aortic arch stent graft systems (the "NEXUS family of products"), and E-vita Thoracic 3G. Abdominal stent grafts include our E-xtra Design Engineering, E-nside™, Artivex™, E-tegra™, E-ventus™ BX, Tuva™ 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.

Our Chief Operating Decision Maker ("CODM") is the Company's Chairman, President, and CEO. The CODM reviews financial information to assess segment performance and determine how to allocate resources across segments.

The primary measure of segment performance, as assessed by our management, is segment gross margin or net external revenues less cost of products and preservation services. The CODM regularly reviews these costs, recognizing them as significant segment expenses. 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 reportable segments (in thousands):

	Three Months Ended March 31,	
	2025	**2024**
Revenues:		
Medical devices	$ 78,798	$ 71,114
Preservation services	20,180	26,317
Total revenues	**98,978**	**97,431**
Cost of products and preservation services:		
Medical devices	25,263	23,750
Preservation services	10,138	10,735
Total cost of products and preservation services	**35,401**	**34,485**
Gross margin:		
Medical devices	53,535	47,364
Preservation services	10,042	15,582
Total gross margin	**$ 63,577**	**$ 62,946**

Net revenues by product were as follows (in thousands):

	Three Months Ended March 31,	
	2025	**2024**
Products:		
Aortic stent grafts	$ 36,602	$ 32,103
On-X	21,574	19,681
Surgical sealants	18,106	16,981
Other	2,516	2,349
Total products	**78,798**	**71,114**
Preservation services	20,180	26,317
Total revenues	**$ 98,978**	**$ 97,431**

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:

- The potential impact that public health crises and geopolitical conflicts 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 of general global, regional, or national economic downturns and macroeconomic trends, including heightened inflation, interest rate, currency fluctuations, and proposed and enacted tariffs, 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 fluctuations 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 and results of our clinical trials, approvals, and product commercialization and 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 and processed tissues, our compliance with applicable laws and regulations, and our ability to make timely transitions to our Notified Bodies and obtain renewals for our Conformité Européenne Mark ("CE 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 provided by obtaining regulatory approval for BioGlue in China;
- Our beliefs about the potential impact on our business of changes to regulations, regulators, Notified Bodies, and related matters;
- 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;
- Our beliefs about the business impact of, and expenses associated with the 2024 cybersecurity incident, and our beliefs about the cybersecurity threat environment;
- 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 Ascyrus and Baxter transactions;

- 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 expenditures, 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 existing products, and for new products and technologies which will likely require additional investment, research, and new clinical studies or data;
- Our beliefs about market opportunity and our ability to capture market share;
- 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 products, aortic stent grafts, and surgical sealants, and the CryoValve SG pulmonary heart valve if the US Food and Drug Administration ("FDA") 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 GmbH, On-X Life Technologies, Inc., Hemosphere, Inc., and Cardiogenesis Corporation;
- Our beliefs about our operating results which may fluctuate significantly on a periodic basis as a result of internal and external factors, including reduced demand for our products, the potential impact of new therapies, healthcare workforce trends and labor disputes, regulatory challenges, the 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 how our growth relates to our competitors; the robustness and reliability of our workforce and supply chain; future production capacity and product supply; the availability and benefits of our products in the future; and the expected timing and impact of our strategic initiatives.

These and other forward-looking statements reflect the views of management at the time and such statements are originally made based on certain assumptions and analyses made by us in light of our experience and our perception of historical trends, current conditions, and expected future developments as well as other factors we believe are appropriate in the circumstances and are subject to a number of risks, uncertainties, estimates, and assumptions. Whether actual results and developments will conform with our expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially and adversely from our expectations, including, without limitation, in addition to those specified in the text surrounding such statements, the risks described in Part II, Item 1A, "Risk Factors" in this Form 10-Q and elsewhere throughout this report, the risks described in our other filings with the Securities and Exchange Commission including the risks described in Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2024 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, On-X® mechanical heart valves and related surgical products ("On-X" products), surgical sealants, 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™, the NEXUS ONE™, NEXUS DUO™, and NEXUS TRE™ aortic arch stent graft systems (the "NEXUS family of products"), and E-vita Thoracic 3G. Abdominal stent grafts include our E-xtra Design Engineering, E-nside™, Artivex™, E-tegra™, E-ventus™ BX, Tuva™ 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 ("PhotoFix"). We began to manufacture and supply PerClot® hemostatic powder ("PerClot") during the second quarter of 2023 (as part of our Transitional Manufacturing and Supply Agreement with Baxter International, Inc.).

We reported quarterly revenues of $99.0 million for the three months ended March 31, 2025, a 2% increase from the three months ended March 31, 2024. The increase in revenues for the three months ended March 31, 2025 was due to an increase in revenues from aortic stent grafts, On-X products, surgical sealants, and other products, partially offset by a decrease in revenues from preservation services. Constant currency revenues, as defined below, increased 4% for the three months ended March 31, 2025, as compared to the three months ended March 31, 2024.

See the "Results of Operations" section below for additional analysis of the three months ended March 31, 2025.

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 revenues 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.

Results of Operations
($ in thousands)

Revenues

	Revenues for the Three Months Ended March 31,			Revenues as a Percentage of Total Revenues for the Three Months Ended March 31,	
	2025	**2024**	**Percent Change**	**2025**	**2024**
Products:					
Aortic stent grafts	$ 36,602	$ 32,103	14%	37%	33%
On-X	21,574	19,681	10%	22%	20%
Surgical sealants	18,106	16,981	7%	18%	18%
Other	2,516	2,349	7%	3%	2%
Total products	**78,798**	**71,114**	**11%**	**80%**	**73%**
Preservation services	20,180	26,317	-23%	20%	27%
Total	**$ 98,978**	**$ 97,431**	**2%**	**100%**	**100%**

Revenues increased 2% for the three months ended March 31, 2025, respectively, as compared to the three months ended March 31, 2024. The increase in revenues for the three months ended March 31, 2025 was due to an increase in revenues from all products, partially offset by a decrease in revenues from preservation services.

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

	Revenues for the Three Months Ended March 31,				Percent Change From Prior Year
	2025	**2024**			
	US GAAP	**US GAAP**	**Exchange Rate Effect**	**Constant Currency**	**Constant Currency**
Products:					
Aortic stent grafts	$ 36,602	$ 32,103	$ (1,308)	$ 30,795	19%
On-X	21,574	19,681	(272)	19,409	11%
Surgical sealants	18,106	16,981	(317)	16,664	9%
Other	2,516	2,349	(4)	2,345	7%
Total products	**78,798**	**71,114**	**(1,901)**	**69,213**	**14%**
Preservation services	20,180	26,317	(67)	26,250	-23%
Total	**$ 98,978**	**$ 97,431**	**$ (1,968)**	**$ 95,463**	**4%**
North America	47,793	50,928	(152)	50,776	-6%
Europe, the Middle East, and Africa	37,045	33,588	(1,210)	32,378	14%
Asia Pacific	8,214	7,609	—	7,609	8%
Latin America	5,926	5,306	(606)	4,700	26%
Total	**$ 98,978**	**$ 97,431**	**$ (1,968)**	**$ 95,463**	**4%**

A detailed discussion of the changes in product revenues and preservation services revenues for the three months ended March 31, 2025 is presented below.

Products

Revenues from products increased 11% for the three months ended March 31, 2025, as compared to the three months ended March 31, 2024. The increase for the three months ended March 31, 2025 was due to an increase in revenues from all products. 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, Brazilian Reals, Polish Zlotys, British Pounds, Canadian Dollars, and Swiss Francs with a concentration denominated in Euros. Each currency is subject to exchange rate fluctuations. For the three months ended March 31, 2025, as compared to the three months ended March 31, 2024, 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, and synthetic vascular grafts, and original equipment manufacturing ("OEM") aortic stent graft products. Aortic arch stent grafts include our E-vita Open NEO, E-vita Open Plus, AMDS, the NEXUS family of products, and E-vita Thoracic 3G products. Abdominal stent grafts include our E-xtra Design Engineering, E-nside, Artivex, E-tegra, E-ventus BX, Tuva BX, and E-liac products. Aortic stent grafts are used in endovascular and open vascular surgery for the treatment of complex aortic arch, thoracic, and abdominal aortic diseases. Our aortic stent grafts are primarily distributed in international markets.

Revenues from the sales of aortic stent grafts increased 14% for the three months ended March 31, 2025, as compared to the three months ended March 31, 2024. This increase was primarily due to an increase in the volume of units sold, partially offset by the effect of foreign exchange rates.

Constant currency revenues from the sales of aortic stent grafts increased 19% for the three months ended March 31, 2025, respectively, as compared to the three months ended March 31, 2024. Revenues for the three months ended March 31, 2025 increased in all geographies, with the most significant increase in Europe, the Middle East, and Africa (collectively, "EMEA"). The revenue increase in EMEA for the three months ended March 31, 2025 was primarily due to an increase in volume of higher priced products within the aortic stent graft product line in direct (to hospitals) markets.

On-X Products

The On-X products include the On-X aortic and mitral heart valves and the On-X ascending aortic prosthesis ("AAP") for heart valve replacement. Revenues from the sales of On-X products 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 product revenue also includes revenue generated from pyrolytic carbon coating services for OEM customers.

Revenues from the sales of On-X products increased 10% for the three months ended March 31, 2025, as compared to the three months ended March 31, 2024. This increase was primarily due to an increase in the volume of units sold in North America and EMEA as well as an increase in average sales price, partially offset by the effect of foreign exchange rates.

Constant currency revenues from the sales of On-X products increased 11% for the three months ended March 31, 2025, respectively, as compared to the three months ended March 31, 2024. Revenues for the three months ended March 31, 2025 increased primarily in North America and EMEA, partially offset by a decrease in Asia Pacific ("APAC"). The increase in revenues in North America for the three months ended March 31, 2025 was impacted by recent gains in the market share. The increase in revenues from EMEA for the three months ended March 31, 2025 was primarily due to an increase in unit sales in indirect markets. The decrease in revenues in APAC for the three months ended March 31, 2025 was primarily due to a decrease in unit sales as a result of customer buying patterns.

Domestic revenues from the sales of On-X products accounted for 65% of total On-X revenues for the three months ended March 31, 2025, as compared to 62% for the three months ended March 31, 2024.

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 7% for the three months ended March 31, 2025, as compared to the three months ended March 31, 2024. This increase was primarily due to an increase in the volume of milliliters sold and, to a lesser extent, an increase in average sales prices, partially offset by the effect of foreign exchange rates.

Constant currency revenues from the sales of surgical sealants increased 9% for the three months ended March 31, 2025, respectively, as compared to the three months ended March 31, 2024. The increase in revenues for the three months ended March 31, 2025 was due to revenue increases in all geographies, with the most significant increase in LATAM. The increase in revenues in LATAM for the three months ended March 31, 2025 was primarily due to an increase in unit sales in indirect markets.

Domestic revenues from the sales of surgical sealants accounted for 49% of total surgical sealant revenues for the three months ended March 31, 2025, as compared to 51% of total surgical sealant revenues for the three months ended March 31, 2024.

Other

Other revenues are comprised of revenues from PhotoFix and PerClot.

Other revenues increased 7% for the three months ended March 31, 2025, as compared to the three months ended March 31, 2024. The increase in other revenues for the three months ended March 31, 2025 was primarily due to an increase in PhotoFix product revenues.

Preservation Services

Preservation services include 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. Our cardiac tissues are primarily distributed in domestic markets. 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 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 and yields, 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 decreased 23% for the three months ended March 31, 2025, as compared to the three months ended March 31, 2024. The decrease was primarily due to a backlog of tissues to be released for shipments as a result of the 2024 cybersecurity incident which is expected to improve throughout the remainder of 2025.

Cost of Products and Preservation Services

Cost of Products

	Three Months Ended March 31,	
	2025	**2024**
Cost of products	$ 25,263	$ 23,750

Cost of products increased 6% for the three months ended March 31, 2025, respectively, as compared to the three months ended March 31, 2024. Cost of products for the three months ended March 31, 2025 and 2024 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 March 31, 2025 was primarily due to an increase in the volume of all products shipped, as compared to the three months ended March 31, 2024.

Cost of Preservation Services

	Three Months Ended March 31,	
	2025	**2024**
Cost of preservation services	$ 10,138	$ 10,735

Cost of preservation services decreased 6% for the three months ended March 31, 2025, respectively, as compared to the three months ended March 31, 2024. Cost of preservation services included costs for cardiac and vascular tissue preservation services.

The decrease in cost of preservation services for the three months ended March 31, 2025 was primarily due to a decrease in the volume of tissues shipped, partially offset by an increase in cost of tissues shipped, as compared to the three months ended March 31, 2024.

Gross Margin

	Three Months Ended March 31,	
	2025	**2024**
Gross margin	$ 63,577	$ 62,946
Gross margin as a percentage of total revenues	64%	65%

Gross margin increased 1% for the three months ended March 31, 2025, respectively, as compared to the three months ended March 31, 2024.

The increase in gross margin for the three months ended March 31, 2025, as compared to the three months ended March 31, 2024, was primarily due to an increase in the volume of all products shipped and the increase in the average sales price of certain products shipped for the three months ended March 31, 2025. The increase was partially offset by a decrease in the volume of tissues shipped, unfavorable cost of tissues shipped, and the unfavorable effect of foreign currency, as compared to the three months ended March 31, 2024. Gross margin as a percentage of total revenues decreased for the three months ended March 31, 2025, as compared to the three months ended March 31, 2024. Gross margin as a percentage of total revenues was negatively impacted by an unfavorable mix and cost of tissues shipped, partially offset by favorable product mix of certain products shipped including aortic stent grafts and BioGlue as well as a favorable pricing of certain products during the three months ended March 31, 2025.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended March 31,	
	2025	**2024**
General, administrative, and marketing expenses	$ 54,704	$ 30,689
General, administrative, and marketing expenses as a percentage of total revenues	55%	31%

General, administrative, and marketing expenses increased 78% for the three months ended March 31, 2025, respectively, as compared to the three months ended March 31, 2024, which includes the impact of the Ascyrus contingent consideration fair value adjustment gain of $2.8 million and $17.5 million for the three months ended March 31, 2025 and 2024, respectively. The remaining general, administrative, and marketing expenses for the three months ended March 31, 2025 increased $9.4 million as a result of $4.5 million of expenses associated with the 2024 cybersecurity incident as well as higher non-cash stock compensation expenses.

Research and Development Expenses

	Three Months Ended March 31,	
	2025	**2024**
Research and development expenses	$ 6,728	$ 6,946
Research and development expenses as a percentage of total revenues	7%	7%

Research and development expenses decreased 3% for the three months ended March 31, 2025, as compared to the three months ended March 31, 2024. Research and development spending for the three months ended March 31, 2025 was primarily focused on clinical work to gain regulatory approvals for certain aortic stent grafts, and, to a lesser extent, On-X products.

Interest Expense

Interest expense was $7.7 million for the three months ended March 31, 2025, as compared to $7.8 million for the three months ended March 31, 2024. Interest expense for the three months ended March 31, 2025 decreased slightly due to lower variable interest rates on our credit facilities.

Loss on Extinguishment of Debt

During the three months ended March 31, 2024 we recorded a loss on extinguishment of debt of $3.7 million in connection with the extinguishment of our previously existing credit facilities. See Part I, Item 1, Note 7 of the “Notes to Condensed Consolidated Financial Statements” for further discussion of our new credit facilities.

Other (Income) Expense, Net

Other (income) expense, net was $3.1 million of income for the three months ended March 31, 2025, as compared to $1.4 million of expense for the three months ended March 31, 2024. Other (income) expense, net for the three months ended March 31, 2025 primarily included a net $2.9 million gain from realized and unrealized effects of foreign currency gains and losses and a $0.3 million gain associated with fair value adjustments to loans issued pursuant to our Endospan agreements. Other expense, net for the three months ended March 31, 2024 primarily included a net $1.4 million loss from realized and unrealized effects of foreign currency gains and losses.

Income Tax Expense

Our effective income tax rate was a benefit of 78% and an expense of 41% for the three months ended March 31, 2025 and 2024, respectively. Our income tax rate was primarily impacted by state income taxes, non-deductible executive compensation, and changes in our valuation allowance against our net deferred tax assets, partially offset by excess tax deductions on stock-based compensation.

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 adjusted for 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

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.

Historically, we believe the demand for surgical sealants 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 On-X and 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 is primarily due to fewer vascular surgeries being scheduled during the winter holiday months.

Liquidity and Capital Resources

Our primary uses of liquidity include the payment of operating expenses, capital expenditures, servicing of debt and the funding of acquisitions or other collaborative arrangements. Our primary sources of funding are operating cash flows and borrowings under our debt facilities. As of March 31, 2025 we had approximately $320.1 million of total principle indebtedness outstanding.

Our liquidity as of March 31, 2025 consisted of cash and cash equivalents of $37.7 million, unused commitments of $30.0 million under a revolving credit facility and unused commitments of $100.0 million on delayed draw term loan facility (see “Credit Facilities” below). As of March 31, 2025 approximately 57% of our cash and cash equivalents were held in foreign jurisdictions. Our practice is to maintain sufficient liquidity through cash from operations and our revolving credit facility to mitigate the impacts of any adverse financial market conditions on our operations. We believe that cash generated from operations, together with amounts available under our Term Loan Facilities, as defined below, will be sufficient to meet working capital requirements and anticipated capital expenditures, and other strategic uses of cash, if any, and debt payments, if any, over the next twelve months.

Our future cash requirements are expected to include interest payments under our credit facilities, expenditures for clinical trials, research and development expenditures, general working capital needs, capital expenditures, other corporate purposes and may include cash to fund business development activities including obligations pursuant to arrangements with Endopsan and the acquisition of Ascyrus. These items may have a significant effect on our future cash flows during the next twelve months. Subject to the terms of our credit facilities, 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

Credit Facilities

On January 18, 2024 we entered into a credit and guaranty agreement with Ares Management Credit funds (the "Ares Credit Agreement") for $350.0 million of senior secured, interest-only, credit facilities, consisting of a $190.0 million secured term loan facility (the "Term Loan Facility"), a $100.0 million secured delayed draw term loan facility (the "Delayed Draw Term Loan Facility" and, together with the Term Loan Facility, the "Term Loan Facilities") and a $60.0 million "senior-priority" secured revolving credit facility with a priority claim ahead of the other secured facilities (the "Revolving Credit Facility" and, together with the Term Loan Facilities, the "Credit Facilities"). Upon closing, we borrowed $190.0 million under the Term Loan Facility and $30.0 million under the Revolving Credit Facility. The proceeds of the initial borrowings were used along with cash on hand to pay off our previously existing credit agreement and pay related fees and expenses. The $100.0 million of undrawn availability under the Delayed Draw Term Loan Facility was established solely to make funds available in the event of a repurchase or repayment of the Convertible Senior Notes on or prior to a scheduled maturity date of July 1, 2025 (see below).

The final scheduled maturity date of the Credit Facilities is January 18, 2030. There are no scheduled repayments of principal required to be made prior to the final maturity date. We have the right to prepay loans under the Ares Credit Agreement in whole or in part at any time, subject to certain premium payment requirements. Amounts repaid in respect of loans under the Term Loan Facilities may not be reborrowed. The Credit Facilities currently bear interest at the Adjusted Term Secured Overnight Financing Rate ("Adjusted Term SOFR") plus applicable margins. As of March 31, 2025 the aggregate interest rate was 10.81% and 8.31% per annum for the Term Loan Facilities and Revolving Credit Facility, respectively. See Part I, Item 1, Note 7 of the "Notes to Consolidated Financial Statements" for further discussion of our new Ares Credit Agreement.

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 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. 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.

We became eligible to redeem the Convertible Senior Notes beginning on July 5, 2023, following the expiration of their non-redemption period. We are able to redeem the Convertible Senior Notes in whole or in part, at our option, if the last reported sale price per share of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption.

On December 23, 2024 in accordance with an Indenture (the "Indenture") dated June 23, 2020, between Artivion, Inc. (formerly CryoLife, Inc.) and U.S. Bank Trust Company, National Association, as Trustee, relating to our Convertible Senior Notes, we gave notice to the Trustee, the Conversion Agent, and the Holders (each as defined in the Indenture) that we elected to change the "Default Settlement Method" (as defined in the Indenture) for conversions of the Convertible Senior Notes to "Physical Settlement" (as defined in the Indenture). As a result, all conversions after the date of the notice will be settled by delivery of shares of our common stock using Physical Settlement in accordance with the Indenture.

Cash Flows

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

	Three Months Ended March 31,	
	2025	2024
Cash flows (used in) provided by:		
Operating activities	$ (16,953)	$ (5,493)
Investing activities	(3,638)	(3,611)
Financing activities	3,937	737
Effect of exchange rate changes on cash and cash equivalents	884	545
Decrease in cash and cash equivalents	**$ (15,770)**	**$ (7,822)**

Net Cash Flows from Operating Activities

Net cash used in operating activities increased $11.5 million during the three months ended March 31, 2025, as compared to the three months ended March 31, 2024, primarily due to professional fees related to the 2024 cybersecurity incident, an increase in liabilities being paid during the quarter that had been delayed at the end of 2024 due to the cybersecurity incident, and a change in the timing of interest payments on our credit facilities executed in January 2024. We expect to continue to incur professional fees in the remainder of 2025 in connection with enhanced ongoing cybersecurity services.

Net Cash Flows from Investing Activities

Net cash used in investing activities was $3.6 million for both the three months ended March 31, 2025 and 2024. During the three months ended March 31, 2025 cash flows used in investing activities included $3.6 million of cash used for capital expenditures.

Net Cash Flows from Financing Activities

Net cash provided by financing activities was $3.9 million and $0.7 million for the three months ended March 31, 2025 and 2024, respectively. The current year cash provided by financing activities was primarily due to $4.2 million of proceeds from the exercise of stock options and issuances of common stock, partially offset by $0.1 million for the repayment of debt.

Scheduled Contractual Obligations and Future Payments

As of March 31, 2025 there have been no material changes outside of the ordinary course of business with respect to our material cash requirements for our contractual and other obligations as set forth in the table included in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2024.

Capital Expenditures

Capital expenditures were $3.6 million for both the three months ended March 31, 2025 and 2024. Capital expenditures for the three months ended March 31, 2025 were primarily related to routine purchases of manufacturing and tissue processing equipment, computer software, computer equipment, and leasehold improvements to support our business.

Off-Balance Sheet Commitments and Arrangements

As of March 31, 2025 there have been no material changes to our indemnification obligations as disclosed in Part II, Item 8, Note 11 – “Commitments and Contingencies” in our Annual Report on Form 10-K for the year ended December 31, 2024. For information concerning contingencies, see Note 8 – “Commitments and Contingencies” in Part I, Item 1 of this Form 10-Q.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements, see Note 1 – "Basis of Presentation and Summary of Significant Accounting Policies" in Part I, Item 1 of this Form 10-Q.

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.

We are exposed to a variety of market risks, including the effects of changes in interest rates (including credit spreads) and foreign currency exchange rates. We manage our exposure to these market risks through our regular operating and financing activities. As of March 31, 2025 there has been no material change in the information reported under Part II, Item 7A – "Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the year ended December 31, 2024.

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 US Securities and Exchange Commission's ("SEC") 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 March 31, 2025 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 SEC'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 March 31, 2025 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

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 Corporate Sustainability Reporting Directive, and other emerging corruption, sustainability, and data privacy and cybersecurity regulations;
- Overlapping, ambiguous, and potentially conflicting, or unexpected changes in, international legal and regulatory requirements or reimbursement policies and programs;
- Longer and more expensive collection cycles in certain countries, particularly those in which our primary customers are government-funded hospitals;
- Changes in currency exchange rates, particularly fluctuations in the Euro as compared to the US Dollar and other inflationary pressures, given sensitivity to exchange rates that we experience from our product revenue streams and account balances;
- Potential exposure to adverse financial impact and negative erosion of our operating profit margin over time due to increasing inflationary pressures, including impact felt through our supply chain, and this 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 consequences from unexpected global regulatory or tariff and trade developments.

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 alleged overpayments the government claims companies received between 2015 and 2018. Ultimately, we were subject to an immaterial payment obligation following the conclusion of judicial challenges and negotiations between us, industry, US government representatives, and the Italian government.

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

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

The market for our products and services is competitive and affected by new product introductions and activities of other industry participants, including the introduction of novel products and therapies aimed at unrelated disease states or even overall patient health. In addition, such products and therapies like GLP-1 drugs, which we believe have or will have little to no actual impact on demand for our products, can lead to investor and customer confusion, can change investor focus, and can impact the perceived demand for our products, which may affect our stock price even if actual demand for our products is unaffected. We face intense competition in virtually all of our product lines, from, among others, Baxter, Ethicon (a Johnson & Johnson Company), Medtronic, Abbott Laboratories, Edwards Lifesciences, Becton, Dickinson and Company, Integra Life Sciences, LifeNet Health, Corcym, Anteris Technologies, Elutia (formerly Aziyo Biologics), Cook Medical, Gore & Associates, Terumo, LeMaitre Vascular, Maquet, Pfizer, 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 global economic downturns and 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 along with better positioning to minimize the impact of consolidated purchasing and other consolidation within the healthcare industry;
- Lower cost of goods sold or preservation costs; and
- Larger direct sales forces and more established distribution networks.

Our established and early-stage competitors may have advantages over us in terms of cost structure, pricing, back-office automation, product development, marketing, supply chain, and sourcing, and, if we are unable to compete effectively, our financial results will be adversely affected.

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;
- Timely receive and process tissues;
- Capitalize on our clinical advantages that we rely on as competitive strengths; 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.

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

As an example of this risk, in January 2025, the Center for Biologics Evaluation and Research ("CBER") of the FDA issued two "final" guidance documents directed at the reduction of the risk of transmission of tuberculousis (Mtb) in processed human tissue (the "Guidances"), which is already exceedingly low. We believe these Guidances, if implemented as written, could significantly reduce the supply of safe implantable human tissue without simultaneously reducing the risk of Mtb transmission. Although some industry advocates and health care practitioners have expressed strong opposition to these new Guidances, and their implementation has been paused until at least May 2025, if and how they may ultimately be implemented and enforced, and how they may actually impact the availability of our donated tissue, remains to be seen and is difficult to predict.

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:

- 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; 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; and
- 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 regulatory approval for BioGlue in China took significantly longer and required significant additional investment, at least in part, due to BioGlue's animal of origin components. Although we received approval to market BioGlue in China during the third quarter of 2024, we do not expect any revenue until at least the second half of 2025.

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:

- 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;
- Drive timely adoption of new products in our aortic stent graft portfolio;
- Meet demand and manage inventory for aortic stent grafts as we seek to expand our business globally; and
- Maintain a productive working relationship with our Works Council in Germany.

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

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

- 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;
- Keep up with increasing demand for our On-X products globally;
- 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.

Most of our foreign revenues are denominated in Euros, making them sensitive to exchange rate changes. Some sales are made to customers who must convert local currencies into US Dollars or Euros. We hold balances in foreign currencies affected by exchange rates. Global inflation and currency crises could result in foreign currency controls, parallel exchange rates, or highly inflationary economies in certain countries. Fluctuations in exchange rates 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.

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.

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

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. For example, we experienced negative impacts on our business operations and sales during the COVID-19 pandemic, 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. If other public health crises emerge in the future, we may experience similar adverse effects on our business. This impact on healthcare system capacity may also affect our R&D pipeline by lengthening timelines for R&D and clinical research projects and timelines associated with regulatory reviews for new and updated devices, as well as affecting our workforce.

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 and expense the costs of manufacturing or preservation.

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 global supply chain is subject to disruption due to labor, geopolitical, trade and monetary issues, which may be exacerbated by ongoing instability in Ukraine and the Middle East. 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 the potential risk that upstream disruptions may occur. Risks relating to the lingering effects of global supply chain disruptions may even continue after current conflicts 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 also could 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, due to supply-related factors outside of our control, we eventually abandoned the business as of June 2023 resulting in a write-off of all of our CardioGenesis cardiac laser therapy assets and a recorded expense of $0.4 million during the year ended December 31, 2023 in our 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 different 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 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 family of products are solely manufactured by Endospan in Herzliya, Israel. If one of these suppliers or facilities ceases operations temporarily or permanently, for any reason including a pandemic, war, work stoppage, cybersecurity incident, infrastructure or equipment malfunction, or a natural disaster, 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. 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.

Our charges resulting from acquisitions, divestitures, partnerships, and other business development activities 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 additional 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 earnouts, our earnings may be affected by changes in estimates of future contingent consideration; or
- Earnings may be affected by transaction and integration costs, which are expensed immediately.

As an example of this risk, we fully impaired the value of our original securities purchase option agreement with Endospan ("Endospan Option") in the fourth quarter of 2021 and fully wrote-down the value of our loan to Endospan in the second quarter of 2023, primarily driven by a decrease in forecasted operating results. Although the Endospan Option and our loan to Endospan were partially written back up to fair value in the third quarter of 2024, similar impairments, and other potential risks like those mentioned above, may adversely affect the market value of our common stock.

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.

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

- Leverage our global infrastructure to sell and cross-market the acquired products;
- Drive adoption of the NEXUS family of products 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 our 2019 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 the NEXUS family of products, raise capital and drive adoption in markets in and outside of Europe; (c) meet demand for the NEXUS family of products; (d) meet quality and regulatory requirements for the NEXUS family of products; (e) manage any intellectual property risks and uncertainties associated with the NEXUS family of products; (f) obtain FDA approval of the NEXUS family of products; (g) remain as a going concern; and (h) develop the NEXUS family of products, and other product improvements to meet competitive threats and physician demand. As an example of this risk, the forecasted operating results related to NEXUS ONE decreased, resulting in an impairment to the carrying value of the Endospan Option, and a full write-down of the value of our original loan to Endospan, reflecting decreased expectations with respect to the anticipated benefits of the Endospan transaction. Similarly, our ability to realize the anticipated benefits of the Baxter Transaction depends on factors beyond our control, including Baxter's performance against Baxter's originally anticipated demand.

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.

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

We rely upon a combination of 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 and other personally identifiable information). Our business operations rely on critical information technology systems related to systems that power aspects of our Quality System (including our eQMS system) and our global operations (including our ERP systems).

We have experienced, and expect to continue to be subject to the risk of, cybersecurity threats and incidents. For example, we experienced a previously-disclosed cyber-attack in the fourth quarter of 2024 that temporarily disrupted our business operations, including our ERP systems, and had an impact on revenue, manufacturing, order processing, shipping, and other corporate operations. Our claims for reimbursement with our insurer remain outstanding and we continue to incur expenses in connection with improving our global infrastructure and cybersecurity posture, additionally, we remain subject to other risks and uncertainties as a result of the incident, including those related to scrap, inventory levels, and timely shipping releases, as well as the potential to incur additional expenses.

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. In addition, a portion of our employees work remotely, 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.

We have limited cyber-insurance coverage that may not cover all possible events, or the financial expenses or losses associated with any particular event, 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.

Our business could be impacted by environmental, social, and governance matters.

Governments, investors, customers, employees and other stakeholders are continuing to focus on areas of corporate responsibility, and particularly matters related to environmental, social, and governance ("ESG") factors. Stakeholders are looking to companies that demonstrate strong ESG and sustainability practices as an indicator of long-term resilience. However, there is an increasing number of state-level and federal legislation, executive orders and other backlash against ESG matters that may conflict with other regulatory requirements or our various stakeholders' expectations. Keeping up with and meeting these sometimes contradictory and evolving expectations can be difficult and expensive, and may disrupt our business and divert the attention of our management. 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.

Legal, Quality, and Regulatory 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, including product recalls, 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 product recalls and/or 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 to, 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, the European Union's Medical Device Regulation (the MDR), which was to be fully implemented on May 26, 2021, 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. The MDR 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 or rely on CE Marking as a basis for market authorization.

The transition to the MDR has been fraught with difficulties and uncertainty, including delays in audits and approvals. The European Parliament has extended the MDR transition period under Regulation (EU) 2023/607 but it is still unclear whether this extension will be able to mitigate transition challenges. As a result, we face increased risks related to:

- Our Custom Devices: Stricter requirements on manufacturers of custom-made devices may delay, impede, or otherwise impact the availability of our E-xtra Design Engineering services and custom-made products;
- Our Existing CE Marks: The extended timeline for the MDR transition has resulted in certain MDD-based CE Marks expiring prior to the completion of the transition. Our MDD-based CE Mark for BioGlue expired in December 2021, and for Chord-X in September 2022. We have since been able to successfully renew the CE Mark for BioGlue and Chord-X under the MDR;
- Our Notified Bodies: The combination of the increased regulatory framework under the MDR and the UK's exit from the European Union have both had an impact on notified bodies. The MDR has significantly increased the workload on existing notified bodies and as a result, many have elected to leave the space, including our Notified Body in the UK, LRQA. Although we were able to transition our LRQA-issued certification for BioGlue to a new notified body, DEKRA, we are still in the process of transitioning the LRQA-issue certification for PhotoFix and we periodically review the need to change notified bodies; and
- New CE Marks: The increased workload on notified bodies and other uncertainties around the transition to the MDR will likely cause delays in the approval for any new products that we may wish to bring to the EU market.

While we continue to make progress on the MDR transition, the transition to new notified bodies, and the renewal of expired CE Marks, failure to timely complete any transfers or renewals, or to comply with transition to a newly designated UK Approved Body, or further delays in the MDR transition as a whole, may have a material, adverse effect on our ability to supply product in certain 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.

Beginning in December 2019 and most recently in the fall of 2024, the FDA indicated that it was planning 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 any comment period and subsequent publication of a final rule, should the CryoValve SGPV be determined to be MMM or classified as a Class III device, we currently expect to have approximately thirty months to submit a PMA application, after which the FDA will determine if, and for how long, we may continue to provide these tissues to customers during its review of the PMA application. Although this proposed rule change has, to our knowledge, remained on the HHS's unified regulatory agenda since 2019, no final rule has been published at this time.

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 depend 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.

As an 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. Similarly, in November 2023 we announced that we were no longer pursuing a labeling change for our On-X mitral valve in connection with our PROACT Mitral trial due to additional investments that would be required to do so. Finally, although we recently received regulatory approval to market BioGlue in China, it was only after a significantly longer and more expensive regulatory approval process than likely could reasonably have been anticipated when the program began.

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, including, for example, reductions in FDA staff that may affect the agency's response time.

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. 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.

Increased environmental regulations and private litigation activity relating to processes and materials used in our industry could have a material, adverse impact on us.

Some of our products, including certain On-X products, are sterilized using EtO, primarily by third-party large-scale EtO facilities. 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.

The per-and polyfluoroalkyl substances ("PFAS") are used in a wide variety of consumer and industrial products, including medical devices and product packaging. PFAS have been subject to increasing regulations, and in some cases bans, by the Environmental Protection Agency and numerous states. These requirements impose a high compliance burden, and further regulation of PFAS-containing products is expected. Although we have yet to experience any material impact from this activity or identify any of our products materially impacted by PFAS-related regulation, the ultimate impact and associated cost of current and future rulemaking cannot be predicted at this time.

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.

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, government officials, healthcare providers, and others 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, counterintuitive, complex, and subject to change and changing interpretations. Our global expansion into higher-risk regions and Russia's ongoing war with Ukraine and the instability of the Middle East, 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, government officials, 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.

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

The transition to a new presidential administration in the US brings several potential risks that could impact our business operations and financial performance. Changes in policy regarding international trade, including import and export regulation and international trade agreements, along with resulting volatility, could negatively impact our business. The US has imposed tariffs and export controls on certain goods and products imported from abroad, which has resulted in retaliatory tariffs. Additional tariffs imposed by the US on a broader range of imports, or further retaliatory trade measures taken by other countries in response, could result in an increase in supply chain costs that we may not be able to offset or that otherwise adversely impact our results of operations. In addition, political tensions between the US and certain other countries have escalated in recent years. Changes in foreign policy and the imposition of new sanctions could impact our ability to distribute products in certain regions. This could limit our market reach and affect our revenue streams. Changes in tax policy, including changes to corporate tax rates or changes in tax incentives that we currently benefit from, could also negatively impact our results of operations and financial condition.

The new administration has already taken steps that have impacted federal spending and the federal workforce. Policies relating to reductions in spending, reductions in staff, and mandated return-to-office policies, could impact the capabilities of regulatory agencies which could affect the timeliness and efficiency of regulatory reviews and approvals that are critical to our operations. Regulatory focus, particularly with respect to sustainability matters, may change, reducing or changing regulations relating to ethylene oxide (EtO), PFAS, or other sustainability initiatives, potentially requiring us to make additional expenditures to comply with new regulations, or abandon programs we have already invested in.

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. These changes may impact costs and reimbursement, as well as potential changes to the regulatory environment and healthcare generally. Many US healthcare laws, including the Affordable Care Act and the Federal Food, Drug, and Cosmetics Act, are complex, subject to change particularly during a change in administrations, and dependent on interpretation and enforcement decisions from government agencies with broad discretion. Changes in regulations, federal funding or staffing at administrative agencies like the FDA may impact, for example, the speed at which we are able to obtain regulatory reviews and approvals, and changes in the focus of those administrative agencies may result in the repeal of applicable regulations or guidance or impact us in other ways we cannot anticipate. This could delay clinical trials and product launches, impact the regulatory status of current products or services, or affect our competitive position. The impact of this uncertainty on us, our customers, or the specific services and relationships we have with our customers is not always clear. Our failure to accurately anticipate these changes, or our failure to comply with changes to legal and regulatory frameworks, could create liability for us, result in adverse publicity and negatively affect our business, results of operations, and financial condition.

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 potentially 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.

Failure to comply with data privacy and security laws could have a material adverse effect on our business.

We are subject to an increasing number of federal, state, and foreign laws and regulations to address topics relating to data privacy, sustainability, and artificial intelligence. These regulations, some of which can be enforced by private parties or governmental entities, have been or are being promulgated and are constantly evolving and becoming increasingly complex and rigorous. These laws and regulations may include new compliance or disclosure requirements which increases our operating costs and requires significant management investment. Many of these laws and regulations, including the European Union's General Data Protection Regulation ("GDPR") also include significant penalties for noncompliance. Although our practices, policies, and procedures are intended to comply with relevant laws and regulations, there can be no assurance that regulatory or enforcement authorities will view our arrangements as being in compliance, or that one or more of our employees or agents will not disregard aspects of our compliance programs. Any resulting government enforcement activities may be costly, result in negative publicity, or subject us to significant penalties.

Risks Relating to Our Indebtedness

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

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

- Incur or guarantee additional debt or create liens on certain assets;
- Pay dividends on or make distributions of our share capital, including repurchasing or redeeming capital stock, or make other restricted payments, including restricted junior payments;
- Enter into agreements that restrict our subsidiaries' ability to pay dividends to us, repay debt owed to us or our subsidiaries, or make loans or advances to us or our other subsidiaries;
- Enter into certain transactions with our affiliates including any transaction or merger or consolidation, liquidation, winding-up, or dissolution; convey, sell, lease, exchange, transfer or otherwise dispose of all or any part of our business, assets or property; or sell, assign, or otherwise dispose of any capital stock of any subsidiary;
- Enter into certain rate swap transactions, basis swaps, credit derivative transactions, and other similar transactions, whether relating to interest rates, commodities, investments, securities, currencies, or any other relevant measure, or transactions of any kind subject to any form of master purchase agreement governed by the International Swaps and Derivatives Association, Inc., any International Foreign Exchange Master Agreement, or any other master agreement;
- Amend, supplement, waive, or otherwise modify our or our subsidiaries' organizational documents in a manner that would be materially adverse to the interests of the lender, or change or amend the terms of documentation regarding junior financing in a manner that would be materially adverse to the interests of the lender;
- 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.

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

We may need to seek additional debt or equity financing to execute our strategic plan. However, we may be unable to obtain any desired additional financing on terms favorable to us, if at all. 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 stockholder activism.

In recent years, stockholder 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.

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 stockholders 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 stockholders, which could affect our share price adversely and prevent attempts by stockholders 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 stockholder meetings, allow the issuance of blank-check preferred stock without the vote of stockholders, and allow the Board of Directors to fill vacancies and fix the number of directors. These provisions of Delaware law and our Certificate of Incorporation and Bylaws could prevent attempts by stockholders 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 stockholders.

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

The Company did not repurchase any of its equity security during the three months ended March 31, 2025.

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

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

On March 13, 2025 Amy D. Horton, our Chief Accounting Officer, adopted a Rule 10b5-1 trading arrangement, pursuant to which she may sell up to 7,992 shares of the Company's common stock. The duration of the trading arrangement is from June 12, 2025 to March 5, 2026. On March 14, 2025 Marshall S. Stanton, our Chief Medical Officer, adopted a Rule 10b5-1 trading arrangement, pursuant to which he may sell up to 41,132 share of the Company's common stock. The duration of the trading arrangement is from June 13, 2025 to June 13, 2026. These trading arrangements are intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act.

No other directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified, or terminated the contracts, instructions or written plans for the purchase or sale of the Company’s securities during the three months ended March 31, 2025.

Item 6. Exhibits.

The exhibit index can be found below.

Exhibit Number	Description
3.1	Amended and Restated Delaware Certificate of Incorporation, effective May 15, 2024. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed May 16, 2024).
3.2	Amended and Restated Bylaws of Artivion, Inc., effective May 15, 2024, a Delaware Corporation (Incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed May 17, 2024).
31.1*	Certification by J. Patrick Mackin pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by Lance A. Berry 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.

† Indicates management contract or compensatory plan or arrangement.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ARTIVION, INC.
(Registrant)

/s/ J. PATRICK MACKIN	/s/ LANCE A. BERRY
J. PATRICK MACKIN	LANCE A. BERRY
Chairman, President, and Chief Executive Officer (Principal Executive Officer)	Chief Financial Officer and Executive Vice President, Finance (Principal Financial Officer)
May 6, 2025	May 6, 2025
DATE	DATE

Exhibit 31.1

CERTIFICATIONS

I, J. 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: May 6, 2025

/s/ J. PATRICK MACKIN

Chairman, President, and
Chief Executive Officer

Exhibit 31.2

I, Lance A. Berry, 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: May 6, 2025

/s/ LANCE A. BERRY

Chief Financial Officer and
Executive Vice President, Finance

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 ended March 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of J. Patrick Mackin, the Chairman, President, and Chief Executive Officer of the Company, and Lance A. Berry, the Chief Financial Officer and Executive Vice President, Finance 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
May 6, 2025

/s/ LANCE A. BERRY
LANCE A. BERRY
Chief Financial Officer and
Executive Vice President, Finance
May 6, 2025