

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

**FORM 10-Q**

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2024

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**

(State or other jurisdiction of  
incorporation or organization)

**59-2417093**

(I.R.S. Employer  
Identification No.)

**1655 Roberts Boulevard, NW, Kennesaw, Georgia**

(Address of principal executive offices)

**30144**

(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 November 1, 2024
Common Stock, \$0.01 par value	41,919,896

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**Part I – FINANCIAL INFORMATION**
**Item 1. Financial Statements.**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
<b>Revenues:</b>				
Products	\$ 71,244	\$ 63,747	\$ 215,568	\$ 192,041
Preservation services	24,535	24,107	75,661	68,293
<b>Total revenues</b>	<b>95,779</b>	<b>87,854</b>	<b>291,229</b>	<b>260,334</b>
<b>Cost of products and preservation services:</b>				
Products	24,412	21,574	72,707	62,084
Preservation services	10,358	10,010	31,243	30,169
<b>Total cost of products and preservation services</b>	<b>34,770</b>	<b>31,584</b>	<b>103,950</b>	<b>92,253</b>
<b>Gross margin</b>	<b>61,009</b>	<b>56,270</b>	<b>187,279</b>	<b>168,081</b>
<b>Operating expenses:</b>				
General, administrative, and marketing	50,017	51,093	130,026	158,699
Research and development	6,605	6,421	21,048	21,062
<b>Total operating expenses</b>	<b>56,622</b>	<b>57,514</b>	<b>151,074</b>	<b>179,761</b>
Gain from sale of non-financial assets	—	—	—	(14,250)
<b>Operating income (loss)</b>	<b>4,387</b>	<b>(1,244)</b>	<b>36,205</b>	<b>2,570</b>
Interest expense	8,405	6,603	24,535	19,055
Interest income	(366)	(339)	(1,093)	(679)
Loss on extinguishment of debt	—	—	3,669	—
Other (income) expense, net	(2,386)	1,911	6	5,189
<b>(Loss) income before income taxes</b>	<b>(1,266)</b>	<b>(9,419)</b>	<b>9,088</b>	<b>(20,995)</b>
Income tax expense	1,022	382	5,964	5,720
<b>Net (loss) income</b>	<b>\$ (2,288)</b>	<b>\$ (9,801)</b>	<b>\$ 3,124</b>	<b>\$ (26,715)</b>
<b>(Loss) income per share:</b>				
<b>Basic</b>	<b>\$ (0.05)</b>	<b>\$ (0.24)</b>	<b>\$ 0.07</b>	<b>\$ (0.65)</b>
<b>Diluted</b>	<b>\$ (0.05)</b>	<b>\$ (0.24)</b>	<b>\$ 0.07</b>	<b>\$ (0.65)</b>
<b>Weighted-average common shares outstanding:</b>				
Basic	41,844	40,881	41,607	40,691
Diluted	41,844	40,881	42,621	40,691
<b>Net (loss) income</b>	<b>\$ (2,288)</b>	<b>\$ (9,801)</b>	<b>\$ 3,124</b>	<b>\$ (26,715)</b>
<b>Other comprehensive income (loss):</b>				
Foreign currency translation adjustments	8,393	(7,070)	2,529	(1,423)
Unrealized (loss) gain from foreign currency intra-entity loans, net of tax	(2,060)	2,060	(47)	1,855
<b>Comprehensive income (loss)</b>	<b>\$ 4,045</b>	<b>\$ (14,811)</b>	<b>\$ 5,606</b>	<b>\$ (26,283)</b>

See accompanying Notes to Condensed Consolidated Financial Statements

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

	September 30, 2024	December 31, 2023
	(Unaudited)	
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 56,173	\$ 58,940
Trade receivables, net	75,686	71,796
Other receivables	2,288	2,342
Inventories, net	84,123	81,976
Deferred preservation costs, net	50,421	49,804
Prepaid expenses and other	19,267	15,810
<b>Total current assets</b>	<b>287,958</b>	<b>280,668</b>
Goodwill	248,745	247,337
Acquired technology, net	135,052	142,593
Operating lease right-of-use assets, net	41,206	43,822
Property and equipment, net	38,262	38,358
Other intangibles, net	29,527	29,638
Deferred income taxes	1,458	1,087
Other long-term assets	20,936	8,894
<b>Total assets</b>	<b>\$ 803,144</b>	<b>\$ 792,397</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 11,146	\$ 13,318
Current portion of long-term debt	99,698	1,451
Accrued expenses	15,888	12,732
Accrued compensation	15,236	18,715
Current maturities of operating leases	4,513	3,395
Taxes payable	3,521	3,840
Accrued procurement fees	1,456	1,439
Other current liabilities	1,380	2,972
<b>Total current liabilities</b>	<b>152,838</b>	<b>57,862</b>
Long-term debt	214,270	305,531
Contingent consideration	51,720	63,890
Non-current maturities of operating leases	41,440	43,977
Deferred income taxes	18,538	21,851
Deferred compensation liability	7,930	6,760
Non-current finance lease obligation	3,194	3,405
Other long-term liabilities	8,475	7,341
<b>Total liabilities</b>	<b>\$ 498,405</b>	<b>\$ 510,617</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity:</b>		
Preferred stock	—	—
Common stock (75,000 shares authorized, 43,392 and 42,569 shares issued in 2024 and 2023, respectively)	434	426
Additional paid-in capital	373,264	355,919
Retained deficit	(44,783)	(47,907)
Accumulated other comprehensive loss	(9,528)	(12,010)
Treasury stock, at cost, 1,487 shares as of September 30, 2024 and December 31, 2023	(14,648)	(14,648)
<b>Total stockholders' equity</b>	<b>304,739</b>	<b>281,780</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 803,144</b>	<b>\$ 792,397</b>

See accompanying Notes to Condensed Consolidated Financial Statements

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

	<b>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>
<b>Net cash flows from operating activities:</b>		
Net income (loss)	\$ 3,124	\$ (26,715)
Adjustments to reconcile net income (loss) to net cash from operating activities:		
Depreciation and amortization	17,910	17,260
Change in fair value of contingent consideration	(12,170)	21,900
Non-cash compensation	11,499	10,466
Non-cash lease expense	5,860	5,467
Deferred income taxes	(4,187)	(7,250)
Non-cash debt extinguishment expense	3,669	—
Write-down of inventories and deferred preservation costs	2,911	3,726
Fair value adjustment of Endospan agreements	(195)	5,000
Gain from sale of non-financial assets	—	(14,250)
Other	1,818	2,325
Changes in operating assets and liabilities:		
Accounts payable, accrued expenses, and other liabilities	(5,237)	412
Inventories and deferred preservation costs	(4,791)	(10,592)
Prepaid expenses and other assets	(4,758)	(527)
Receivables	(3,356)	765
<b>Net cash flows provided by operating activities</b>	<b>12,097</b>	<b>7,987</b>
<b>Net cash flows from investing activities:</b>		
Capital expenditures	(9,763)	(7,083)
Payments for Endospan agreements	(7,000)	(5,000)
Proceeds from sale of non-financial assets, net	—	14,250
<b>Net cash flows (used in) provided by investing activities</b>	<b>(16,763)</b>	<b>2,167</b>
<b>Net cash flows from financing activities:</b>		
Proceeds from issuance of debt	190,000	—
Proceeds from revolving credit facility	30,000	—
Proceeds from exercise of stock options and issuance of common stock	5,285	3,467
Proceeds from financing insurance premiums	—	3,558
Repayment of debt	(211,765)	(2,063)
Payment of debt issuance costs	(10,044)	—
Principal payments on short-term notes payable	(1,027)	(1,522)
Other	(420)	(945)
<b>Net cash flows provided by financing activities</b>	<b>2,029</b>	<b>2,495</b>
Effect of exchange rate changes on cash and cash equivalents	(130)	1,481
<b>(Decrease) increase in cash and cash equivalents</b>	<b>(2,767)</b>	<b>14,130</b>
Cash and cash equivalents beginning of period	58,940	39,351
<b>Cash and cash equivalents end of period</b>	<b>\$ 56,173</b>	<b>\$ 53,481</b>

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	
<b>Balance at June 30, 2024</b>	<b>43,279</b>	<b>\$ 433</b>	<b>\$ 367,627</b>	<b>\$(42,495)</b>	<b>\$ (15,861)</b>	<b>(1,487)</b>	<b>\$(14,648)</b>	<b>\$ 295,056</b>
Net loss	—	—	—	(2,288)	—	—	—	(2,288)
Other comprehensive income, net of tax	—	—	—	—	6,333	—	—	6,333
Equity compensation	11	—	3,940	—	—	—	—	3,940
Exercise of options	35	—	676	—	—	—	—	676
Employee stock purchase plan	67	1	1,021	—	—	—	—	1,022
<b>Balance at September 30, 2024</b>	<b>43,392</b>	<b>\$ 434</b>	<b>\$ 373,264</b>	<b>\$(44,783)</b>	<b>\$ (9,528)</b>	<b>(1,487)</b>	<b>\$(14,648)</b>	<b>\$ 304,739</b>

	Common Stock		Additional Paid-In Capital	Retained Deficit	Accumulated Other Comprehensive Loss	Treasury Stock		Total Stockholders' Equity
	Shares	Amount				Shares	Amount	
<b>Balance at December 31, 2023</b>	<b>42,569</b>	<b>\$ 426</b>	<b>\$ 355,919</b>	<b>\$(47,907)</b>	<b>\$ (12,010)</b>	<b>(1,487)</b>	<b>\$(14,648)</b>	<b>\$ 281,780</b>
Net income	—	—	—	3,124	—	—	—	3,124
Other comprehensive income, net of tax	—	—	—	—	2,482	—	—	2,482
Equity compensation	499	5	12,063	—	—	—	—	12,068
Exercise of options	206	2	3,522	—	—	—	—	3,524
Employee stock purchase plan	118	1	1,760	—	—	—	—	1,761
<b>Balance at September 30, 2024</b>	<b>43,392</b>	<b>\$ 434</b>	<b>\$ 373,264</b>	<b>\$(44,783)</b>	<b>\$ (9,528)</b>	<b>(1,487)</b>	<b>\$(14,648)</b>	<b>\$ 304,739</b>

See accompanying Notes to Condensed Consolidated Financial Statements

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

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

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

**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, 2023 has been derived from audited financial statements. The accompanying unaudited Condensed Consolidated Financial Statements as of, and for the three and nine months ended, September 30, 2024 and 2023 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 and nine months ended September 30, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024. 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, 2023 filed with the SEC on February 23, 2024.

***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, 2023. Management believes that the consistent application of these policies enables us to provide users of the financial statements with useful and reliable information about our operating results and financial condition. The Condensed Consolidated Financial Statements are prepared in accordance with US GAAP, which require us to make estimates and assumptions. We did not experience any significant changes during the three and nine months ended September 30, 2024 in any of our Significant Accounting Policies from those contained in our Form 10-K for the year ended December 31, 2023.

***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 financial statements issued for fiscal years beginning after December 15, 2024. We are currently evaluating the impacts of the new standard.

In November 2023 the FASB issued ASU 2023-07, *Segment Reporting Topic 280 - Improvements to Reportable Segment Disclosures*. This amendment requires disclosure of incremental segment information on an annual and interim basis. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, and requires retrospective application to all prior periods presented in the financial statements. We are currently evaluating the impacts of the new standard.



## 2. Sale of PerClot

### *Overview*

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

### *PerClot PMA*

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

Following receipt of the PMA, under the terms of the TMSA, we began manufacturing and supplying PerClot for Baxter and recorded \$994,000 and \$2.3 million of PerClot revenues on the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) during the three and nine months ended September 30, 2024, respectively. We recorded \$2.0 million and \$3.6 million of PerClot revenues on the Condensed Consolidated Statements of Operations and Comprehensive Loss during the three and nine months ended September 30, 2023, respectively.

The Company accounted for this TMSA in accordance with the provision of ASU 2016-02, *Leases Topic 842* (“ASC 842”) by bifurcating the lease and non-lease components and recognizing each component based on ASC 842 and ASU 2014-09, *Revenue from Contracts with Customers Topic 606*.

## 3. Agreements with Endospan

### *Exclusive Distribution Agreement and Securities Purchase Option Agreement*

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

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

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. The value of the Endospan Option was fully impaired during the fourth quarter of fiscal year 2021. We estimated the fair value of the Endospan Option after the Endospan Option Amendment utilizing the Monte Carlo simulation. 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. Based on this calculation, we recorded \$3.1 million for the fair value of the Endospan Option as of the Endospan Option Amendment transaction date and as of September 30, 2024.

### ***Loan Agreement***

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.

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

We elected the fair value option for recording the Endospan Loan. We assess the fair value of the Endospan Loan based on quantitative and qualitative characteristics and adjust the amount recorded to its current fair market value at each reporting period. We performed an assessment of the fair value of the Endospan Loan, including the funding of the third tranche payment in May 2023. We determined that the loan had no fair value as of June 30, 2023 and recorded a \$5.0 million expense included in Other expense, net within the Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2023. After entering into the Endospan Loan Amendment, defined below, we determined that the Endospan Loan had a fair value of \$298,000 as of September 30, 2024.

On July 1, 2024 Artivion and Endospan entered into an Amended and Restated Loan Agreement ("Endospan Loan Amendment") which amended the terms of the previously existing Endospan Loan.

As a part of the Endospan Loan Amendment, Artivion agreed to fund Endospan additional secured loans of up to \$25.0 million. The additional loans are 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 the NEXUS products that are specified in the Endospan Loan Amendment. The first tranche of \$7.0 million was funded following execution of the agreement during the three months ended September 30, 2024.

We elected the fair value option for recording the Endospan Loan and the additional secured loans as part of the Endospan Loan Amendment (collectively the "Endospan Loans"). We performed an assessment of the first tranche loan of \$7.0 million and determined that the first tranche loan had a fair value of \$3.8 million as of September 30, 2024 which is recorded in "Other long-term assets" on the Condensed Consolidated Balance Sheets as of September 30, 2024.

#### 4. Financial Instruments

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

<b>September 30, 2024</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Cash equivalents:</b>				
Money market funds	\$ 21,487	\$ —	\$ —	\$ 21,487
Certificates of deposit	3,490	—	—	3,490
Endospan Loans	—	—	4,059	4,059
<b>Total assets</b>	<b>\$ 24,977</b>	<b>\$ —</b>	<b>\$ 4,059</b>	<b>\$ 29,036</b>
<b>Long-term liabilities:</b>				
Contingent consideration	—	—	(51,720)	(51,720)
<b>Total liabilities</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ (51,720)</b>	<b>\$ (51,720)</b>
<b>December 31, 2023</b>				
<b>Cash equivalents:</b>				
Money market funds	\$ 22,802	\$ —	\$ —	\$ 22,802
Certificates of deposit	3,968	—	—	3,968
<b>Total assets</b>	<b>\$ 26,770</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 26,770</b>
<b>Long-term liabilities:</b>				
Contingent consideration	—	—	(63,890)	(63,890)
<b>Total liabilities</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ (63,890)</b>	<b>\$ (63,890)</b>

We used prices quoted from our investment advisors to determine the Level 1 valuation of our investments in money market funds and certificates of deposit. The estimated market value of all cash equivalents is equal to cost basis as there were no gross realized gains or losses on cash equivalents for the three and nine months ended September 30, 2024 and 2023. We recorded the Endospan Loans, classified as Level 3, as a result of the Endospan Loan Amendment in July 2024. See Note 3 for further discussion of the Endospan Loan Amendment.

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 (“AMDS”) hybrid prosthesis, 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 16% and estimated future achievement of milestone dates between 2025 and 2026 to calculate the fair value of contingent consideration as of September 30, 2024. We will remeasure this liability at each reporting date and will record changes in the fair value of the contingent consideration in General, administrative, and marketing expenses on the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss). Increases or decreases in the fair value of the contingent consideration liability can result from changes in passage of time, discount rates, the timing and amount of our revenue estimates, and the timing and expectation of regulatory approvals.

We performed an assessment of the fair value of the contingent consideration and recorded a fair value increase of \$3.5 million and a fair value reduction of \$12.2 million for the three and nine months ended September 30, 2024, respectively, as compared to a fair value increase of \$6.2 million and \$21.9 million for the three and nine months ended September 30, 2023, respectively, in General, administrative, and marketing expenses on the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss), as a result of this assessment. The reduction in the fair value for the nine months ended September 30, 2024 was primarily due to an increase in the credit risk spread resulting from the change in the inputs related to the newly issued Credit Facilities in the first quarter of 2024, as further discussed in Note 9.

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

	<b>Endospan Loans</b>
Balance as of December 31, 2023	—
Initial value of Endospan Loans	3,517
Change in valuation	542
<b>Balance as of September 30, 2024</b>	<b>\$ 4,059</b>

	<b>Contingent Consideration</b>
Balance as of December 31, 2023	\$ (63,890)
Change in valuation	12,170
<b>Balance as of September 30, 2024</b>	<b>\$ (51,720)</b>

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.

The contingent consideration liability of \$51.7 million and \$63.9 million was included in Long-term liabilities on the Condensed Consolidated Balance Sheets as of September 30, 2024 and the Consolidated Balance Sheets as of December 31, 2023, respectively.

## 5. Inventories, net and Deferred Preservation Costs

Inventories, net at September 30, 2024 and December 31, 2023 were comprised of the following (in thousands):

	<b>September 30, 2024</b>	<b>December 31, 2023</b>
Raw materials and supplies	\$ 36,037	\$ 36,907
Work-in-process	15,602	12,687
Finished goods	32,484	32,382
<b>Total inventories, net</b>	<b>\$ 84,123</b>	<b>\$ 81,976</b>

To facilitate product usage, we maintain consignment inventory of our On-X<sup>®</sup> heart valves at domestic hospital locations and On-X heart valves and aortic stent grafts at international hospital locations. We retain title and control over this consignment inventory until we receive a notification of implantation, at which time we invoice the hospital and recognize revenue. As of September 30, 2024 we had \$10.7 million in consignment inventory, with approximately 40% in domestic locations and 60% in international locations. As of December 31, 2023 we had \$10.7 million in consignment inventory, with approximately 44% in domestic locations and 56% in international locations.

Total deferred preservation costs were \$50.4 million and \$49.8 million as of September 30, 2024 and December 31, 2023, respectively.

Inventory and deferred preservation costs obsolescence reserves were \$3.7 million and \$3.0 million as of September 30, 2024 and December 31, 2023, respectively.

## 6. Goodwill and Other Intangible Assets

### *Indefinite Lived Intangible Assets*

As of September 30, 2024 and December 31, 2023 the carrying values of our indefinite lived intangible assets were as follows (in thousands):

	<b>September 30, 2024</b>	<b>December 31, 2023</b>
Goodwill	\$ 248,745	\$ 247,337
In-process R&D	2,183	2,154
Procurement contracts and agreements	2,013	2,013

We monitor the phases of development of our acquired in-process research and development projects, including the risks associated with further development and the amount and timing of benefits expected to be derived from the completed projects. Incremental costs associated with development are charged to expense as incurred. Capitalized costs are amortized over the estimated useful life of the developed asset once completed. Our in-process research and development projects are reviewed for impairment annually, or more frequently, if events or changes in circumstances indicate that the asset might be impaired. We did not record any impairment of indefinite lived intangible assets during the three and nine months ended September 30, 2024. In-process research and development, procurement contracts and agreements were included in Other intangibles, net on the Condensed Consolidated Balance Sheets as of September 30, 2024 and the Consolidated Balance Sheets as of December 31, 2023.

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

We evaluate our goodwill and non-amortizing intangible assets for impairment on an annual basis during the fourth quarter of the year, and, if necessary, during interim periods if factors indicate that an impairment review is warranted. As of September 30, 2024 we concluded that our assessment of current factors did not indicate that goodwill or non-amortizing intangible assets are more likely than not to be impaired. We will continue to evaluate the recoverability of these non-amortizing intangible assets in future periods as necessary.

As of September 30, 2024 and December 31, 2023 the carrying value of goodwill, all of which is related to our Medical Devices segment, was as follows (in thousands):

	<b>Medical Devices Segment</b>
Balance as of December 31, 2023	\$ 247,337
Foreign currency translation	1,408
<b>Balance as of September 30, 2024</b>	<b>\$ 248,745</b>

### Definite Lived Intangible Assets

The definite lived intangible assets balance includes balances related to acquired technology, customer relationships, distribution and manufacturing rights and know-how, patents, and other definite lived intangible assets. As of September 30, 2024 and December 31, 2023 the gross carrying values, accumulated amortization, and approximate amortization period of our definite lived intangible assets were as follows (in thousands, except weighted average useful life):

<b>September 30, 2024</b>	<b>Gross Carrying Value</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Value</b>	<b>Weighted Average Useful Life (Years)</b>
Acquired technology	\$ 203,219	\$ 68,167	\$ 135,052	18.2
<b>Other intangibles:</b>				
Customer lists and relationships	28,754	11,342	17,412	21.6
Distribution and manufacturing rights and know-how	9,735	9,279	456	5.0
Patents	4,422	3,261	1,161	17.0
Other	11,541	5,239	6,302	5.0
<b>Total other intangibles</b>	<b>\$ 54,452</b>	<b>\$ 29,121</b>	<b>\$ 25,331</b>	<b>9.3</b>

<b>December 31, 2023</b>	<b>Gross Carrying Value</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Value</b>	<b>Weighted Average Useful Life (Years)</b>
Acquired technology	\$ 201,897	\$ 59,304	\$ 142,593	18.2
<b>Other intangibles:</b>				
Customer lists and relationships	28,729	10,334	18,395	21.6
Distribution and manufacturing rights and know-how	9,608	7,807	1,801	5.0
Patents	4,365	3,225	1,140	17.0
Other	7,815	3,680	4,135	5.0
<b>Total other intangibles</b>	<b>\$ 50,517</b>	<b>\$ 25,046</b>	<b>\$ 25,471</b>	<b>10.0</b>

### Amortization Expense

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>	<b>2024</b>	<b>2023</b>
Amortization expense	\$ 3,990	\$ 3,766	\$ 11,650	\$ 11,453

As of September 30, 2024 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	<b>Remainder of 2024</b>	<b>2025</b>	<b>2026</b>	<b>2027</b>	<b>2028</b>	<b>2029</b>	<b>Total</b>
Amortization expense	\$ 4,073	\$ 13,634	\$ 13,249	\$ 13,140	\$ 12,944	\$ 12,745	\$ 69,785

## **7. Income Taxes**

### ***Income Tax Expense***

Our effective income tax rate was an expense of 81% and 66% for the three and nine months ended September 30, 2024, respectively, as compared to an expense of 4% and 27% for the three and nine months ended September 30, 2023, respectively. Our income tax rate for the three and nine months ended September 30, 2024 and 2023 was primarily impacted by changes in anticipated full year pre-tax operating results, profit mix among jurisdictions, our valuation allowance against our net deferred tax assets, non-deductible executive compensation, the foreign derived intangible income deduction, the research and development tax credit, changes in our uncertain tax position liabilities, and tax-effected impact of stock based compensation.

### ***Deferred Income Taxes***

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

We maintained a net deferred tax liability of \$17.1 million and \$20.8 million as of September 30, 2024 and December 31, 2023, respectively. Our valuation allowance against our deferred tax assets was \$34.4 million and \$32.9 million as of September 30, 2024 and December 31, 2023, respectively, primarily related to net operating loss carryforwards, disallowed excess interest carryforwards, change in contingent consideration, and capitalized research and development expenses.

## **8. Leases**

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

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

	September 30, 2024	December 31, 2023
<b>Operating leases:</b>		
<b>Operating lease right-of-use assets, net</b>	<b>\$ 41,206</b>	<b>\$ 43,822</b>
Current maturities of operating leases	\$ 4,513	\$ 3,395
Non-current maturities of operating leases	41,440	43,977
<b>Total operating lease liabilities</b>	<b>\$ 45,953</b>	<b>\$ 47,372</b>
<b>Finance leases:</b>		
Property and equipment, at cost	\$ 7,218	\$ 6,862
Accumulated amortization	(3,637)	(3,136)
<b>Property and equipment, net</b>	<b>\$ 3,581</b>	<b>\$ 3,726</b>
Current maturities of finance leases	\$ 650	\$ 582
Non-current maturities of finance leases	3,194	3,405
<b>Total finance lease liabilities</b>	<b>\$ 3,844</b>	<b>\$ 3,987</b>
<b>Weighted average remaining lease term (in years):</b>		
Operating leases	9.8	10.4
Finance leases	5.9	6.8
<b>Weighted average discount rate:</b>		
Operating leases	6.3%	6.3%
Finance leases	2.3%	2.2%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Amortization of property and equipment	\$ 159	\$ 136	\$ 468	\$ 400
Interest expense on finance leases	22	20	67	62
<b>Total finance lease expense</b>	<b>181</b>	<b>156</b>	<b>535</b>	<b>462</b>
Operating lease expense	1,963	1,836	5,860	5,467
Sublease income	(133)	(87)	(332)	(101)
<b>Total lease expense</b>	<b>\$ 2,011</b>	<b>\$ 1,905</b>	<b>\$ 6,063</b>	<b>\$ 5,828</b>



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

	Nine Months Ended September 30,	
	2024	2023
<b>Cash paid for amounts included in the measurement of lease liabilities:</b>		
Operating cash flows for operating leases	\$ 5,798	\$ 5,422
Financing cash flows for finance leases	469	396
Operating cash flows for finance leases	67	62

Future minimum lease payments are as follows (in thousands):

	Finance Leases	Operating Leases
Remainder of 2024	\$ 183	\$ 1,546
2025	721	7,516
2026	700	6,976
2027	688	6,288
2028	652	5,934
Thereafter	1,155	34,021
<b>Total minimum lease payments</b>	<b>4,099</b>	<b>62,281</b>
Less amount representing interest	(255)	(16,328)
Present value of net minimum lease payments	3,844	45,953
Less current maturities	(650)	(4,513)
<b>Lease liabilities, less current maturities</b>	<b>\$ 3,194</b>	<b>\$ 41,440</b>

## 9. Debt

### *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 “Initial Term Loan Facility”), a \$100.0 million secured delayed draw term loan facility (the “Delayed Draw Term Loan Facility” and, together with the Initial 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”). 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 5.00% if the prepayment occurs prior to January 18, 2025 and 1.00% if the prepayment occurs thereafter and prior to January 18, 2026. Amounts repaid in respect of loans under the Initial Term Loan Facilities may not be reborrowed. 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.

Upon closing, we borrowed \$190.0 million under the Initial Term Loan Facility and \$30.0 million under the Revolving Credit Facility. The remaining \$30.0 million of undrawn availability under the Revolving Credit Facility may be drawn for working capital, capital expenditures, and other general corporate purposes. The Delayed Draw Term Loan Facility remained undrawn as of September 30, 2024.

We paid \$6.5 million of debt issuance costs related to the Initial Term Loan Facility which are included in Long-term debt on the Condensed Consolidated Balance Sheets as of September 30, 2024 and amortized, thereafter, over the life of the Initial Term Loan Facility. We paid \$3.7 million of debt issuance costs related to the Delayed Draw Term Loan Facility and Revolving Credit Facility which are included in Other long-term assets on the Condensed Consolidated Balance Sheets as of September 30, 2024.

We recognized \$7.1 million and \$19.8 million of interest expense on the Credit Facilities for the three and nine months ended September 30, 2024, respectively, of which \$358,000 and \$997,000 represent non-cash amortization of debt issuance costs for the three and nine months ended September 30, 2024, respectively. There was approximately \$5.7 million of unamortized debt issuance costs related to the Initial Term Loan Facility as of September 30, 2024.

The proceeds of the initial borrowings were used along with cash on hand to pay off our previously existing credit agreement, dated as of December 1, 2017, and pay related fees and expenses. As a result of this transaction, we recorded a loss on extinguishment of our previously existing debt of \$3.7 million during the nine months ended September 30, 2024 on our Condensed Consolidated Statements of Operations and Comprehensive Income (Loss). The proceeds of borrowings under the Delayed Draw Term Loan Facility 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 Initial Term Loan Facility.

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 September 30, 2024 we are in compliance with our debt covenants.

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 September 30, 2024 the aggregate interest rate was 11.78% and 9.28% per annum for the Term Loan Facilities and Revolving Credit Facility, respectively.

#### ***Convertible Senior Notes***

On June 18, 2020 we issued \$100.0 million aggregate principal amount of 4.25% Convertible Senior Notes with a maturity date of July 1, 2025 (the "Convertible Senior Notes"). The net proceeds from this offering, after deducting initial purchasers' discounts and costs directly related to this offering, were approximately \$96.5 million. On January 1, 2021 we adopted ASU 2020-06 and adjusted the carrying balance of the Convertible Senior Notes to notional. The Convertible Senior Notes balance was \$100.0 million recorded in Current portion of long-term debt on the Condensed Consolidated Balance Sheets as of September 30, 2024 and Long-term debt on the Consolidated Balance Sheets as of December 31, 2023. The Convertible Senior Notes are scheduled to mature on July 1, 2025. The Convertible Senior Notes may be settled in cash, stock, or a combination thereof, solely at our discretion. The initial conversion rate of the Convertible Senior Notes is 42.6203 shares per \$1,000 principal amount, which is equivalent to a conversion price of approximately \$23.46 per share, subject to adjustments. We use the if-converted method for assumed conversion of the Convertible Senior Notes for the diluted earnings per share calculation. The fair value and the effective interest rate of the Convertible Senior Notes as of September 30, 2024 was approximately \$125.4 million and 5.05%, respectively. The fair value was based on market prices observable for similar instruments and is considered Level 2 in the fair value hierarchy.

The interest expense recognized on the Convertible Senior Notes includes \$1.2 million and \$3.7 million for both the three and nine months ended September 30, 2024 and 2023, respectively, related to the aggregate of the contractual coupon interest and the amortization of the debt issuance costs. Interest on the Convertible Senior Notes began accruing upon issuance and is payable semi-annually. There were approximately \$582,000 and \$1.1 million of unamortized debt issuance costs related to the Convertible Senior Notes as of September 30, 2024 and December 31, 2023, respectively.

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

We became eligible to redeem the Convertible Senior Notes beginning on July 5, 2023, following the expiration of their non-redemption period. We are able to redeem the Convertible Senior Notes in whole or in part, at our option, if the last reported sale price per share of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption. We may redeem for cash all or part of the Convertible Senior Notes at a redemption price equal to 100% of the principal amount of the redeemable Convertible Senior Notes, plus accrued and unpaid interest to, but excluding, the redemption date. No principal payments are due on the Convertible Senior Notes prior to maturity. Other than restrictions relating to certain fundamental changes and consolidations, mergers or asset sales and customary anti-dilution adjustments, the Convertible Senior Notes do not contain any financial covenants and do not restrict us from conducting significant restructuring transactions or issuing or repurchasing any of our other securities. As of September 30, 2024 and December 31, 2023 we are not aware of any current events or market conditions that would allow holders to convert the Convertible Senior Notes.

### ***Loan Balances***

The short-term and long-term balances of our Initial Term Loan Facility, Revolving Credit Facility, Convertible Senior Notes, and other long-term borrowings were as follows (in thousands):

	<b>September 30, 2024</b>	<b>December 31, 2023</b>
Initial Term Loan Facility	\$ 190,000	\$ —
Revolving Credit Facility	30,000	—
Convertible Senior Notes	100,000	100,000
Term loan balance	—	211,500
2.45% Sparkasse Zollernalb (KFW Loan 1)	—	61
1.40% Sparkasse Zollernalb (KFW Loan 2)	280	484
<b>Total loan balance</b>	<b>320,280</b>	<b>312,045</b>
Less unamortized loan origination costs	(6,312)	(5,063)
Net borrowings	313,968	306,982
Less short-term Convertible Senior Notes, net	(99,418)	—
Less short-term loan balance, net	(280)	(1,451)
<b>Long-term loan balance, net</b>	<b>\$ 214,270</b>	<b>\$ 305,531</b>

### ***Interest Expense***

Interest expense was \$8.4 million and \$24.5 million for the three and nine months ended September 30, 2024, respectively, as compared to \$6.6 million and \$19.1 million for the three and nine months ended September 30, 2023, respectively. Interest expense includes interest on debt and uncertain tax positions in both periods.

## 10. Commitments and Contingencies

### *Liability Claims*

In the normal course of business, we are made aware of adverse events involving our products and tissues. Future adverse events could ultimately give rise to a lawsuit against us, and liability claims may be asserted against us in the future based on past events that we are not aware of at the present time. We maintain claims-made insurance policies to mitigate our financial exposure to product and tissue processing liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. The amounts recorded in these Condensed Consolidated Financial Statements as of September 30, 2024 and the Consolidated Financial Statements as of December 31, 2023 represent our estimate of the probable losses and anticipated recoveries for incurred but not reported claims related to products sold and services performed prior to the balance sheet date.

## 11. Revenue Recognition

### *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 for the three and nine months ended September 30, 2024 and 2023 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
North America	\$ 49,089	\$ 48,028	\$ 148,679	\$ 137,541
EMEA	30,423	26,536	98,156	84,608
APAC	10,366	8,402	27,628	24,655
LATAM	5,901	4,888	16,766	13,530
<b>Total revenues</b>	<b>\$ 95,779</b>	<b>\$ 87,854</b>	<b>\$ 291,229</b>	<b>\$ 260,334</b>

Also see segment disaggregation information in Note 14 below.

### *Contract Balances*

We may generate contract assets during the pre-delivery design and manufacturing stage of E-xtra Design Engineering product order fulfillment. We assess the balance related to any arrangements in process and determine if the enforceable right to payment creates a material contract asset requiring disclosure. No material arrangements in process existed as of September 30, 2024 and 2023.

We also incur contract obligations on general customer purchase orders that have been accepted but unfulfilled. Due to the short duration of time between order acceptance and delivery of the related product or service, we have determined that the balance related to these contract obligations is generally immaterial at any point in time. We monitor the value of orders accepted but unfulfilled at the close of each reporting period to determine if disclosure is appropriate. The value of orders accepted but unfulfilled as of September 30, 2024 and 2023 was not material.

## 12. Stock Compensation

### Overview

We have stock option and stock incentive plans for employees and non-employee directors that provide for grants of restricted stock awards (“RSAs”), restricted stock units (“RSUs”), performance stock units (“PSUs”), and options to purchase shares of our common stock at exercise prices generally equal to the fair value of such stock at the dates of grant. We also maintain a 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 nine months ended September 30, 2024 the Compensation Committee of our Board of Directors (the “Committee”) authorized awards from approved stock incentive plans of RSAs to non-employee directors and RSUs and PSUs to certain employees and company officers, which, assuming that performance under the PSUs will be achieved at target levels, together totaled 778,000 shares and had an aggregate grant date fair value of \$16.1 million.

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

The Committee did not authorize any grants of stock options during the nine months ended September 30, 2024. During the nine months ended September 30, 2023 the Committee authorized, from approved stock incentive plans, grants of stock options to purchase a total of 16,000 shares to certain company officers. The exercise prices of the options were equal to the closing stock prices on their respective grant dates.

Employees purchased common stock totaling 67,000 and 118,000 shares in the three and nine months ended September 30, 2024, respectively, as compared to 86,000 and 142,000 shares in the three and nine months ended September 30, 2023, respectively, through the ESPP.

### Stock Compensation Expense

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

	<b>Three Months Ended September 30, 2024</b>	<b>Nine Months Ended September 30, 2024</b>
	<b>ESPP</b>	<b>ESPP</b>
Expected life	0.5 Years	0.5 Years
Expected stock price volatility	0.36	0.48
Risk-free interest rate	5.37%	5.26%

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>	<b>2024</b>	<b>2023</b>
RSA, RSU, and PSU expense	\$ 3,364	\$ 2,647	\$ 10,222	\$ 8,685
Stock option and ESPP expense	576	745	1,846	2,340
<b>Total stock compensation expense</b>	<b>\$ 3,940</b>	<b>\$ 3,392</b>	<b>\$ 12,068</b>	<b>\$ 11,025</b>

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, RSUs, PSUs, and stock options issued in each respective year, as well as those issued in prior periods that continue to vest during the period, and compensation related to the ESPP. These amounts were recorded as stock compensation expense and were subject to our normal allocation of expenses to inventory costs and deferred preservation costs. We capitalized \$171,000 and \$569,000 for the three and nine months ended September 30, 2024, respectively, as compared to \$205,000 and \$559,000 for the three and nine months ended September 30, 2023, respectively, of the stock compensation expense into our inventory costs and deferred preservation costs.

### 13. (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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
<b>Basic (loss) income per common share</b>				
Net (loss) income	\$ (2,288)	\$ (9,801)	\$ 3,124	\$ (26,715)
Net loss (income) allocated to participating securities	3	39	(6)	108
<b>Net (loss) income allocated to common stockholders</b>	<b>\$ (2,285)</b>	<b>\$ (9,762)</b>	<b>\$ 3,118</b>	<b>\$ (26,607)</b>
<b>Basic weighted-average common shares outstanding</b>	<b>41,844</b>	<b>40,881</b>	<b>41,607</b>	<b>40,691</b>
<b>Basic (loss) income per common share</b>	<b>\$ (0.05)</b>	<b>\$ (0.24)</b>	<b>\$ 0.07</b>	<b>\$ (0.65)</b>
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
<b>Diluted (loss) income per common share</b>				
Net (loss) income	\$ (2,288)	\$ (9,801)	\$ 3,124	\$ (26,715)
Net loss (income) allocated to participating securities	3	39	(6)	108
<b>Net (loss) income allocated to common stockholders</b>	<b>\$ (2,285)</b>	<b>\$ (9,762)</b>	<b>\$ 3,118</b>	<b>\$ (26,607)</b>
Basic weighted-average common shares outstanding	41,844	40,881	41,607	40,691
Effect of dilutive stock options and awards	—	—	1,014	—
<b>Diluted weighted-average common shares outstanding</b>	<b>41,844</b>	<b>40,881</b>	<b>42,621</b>	<b>40,691</b>
<b>Diluted (loss) income per common share</b>	<b>\$ (0.05)</b>	<b>\$ (0.24)</b>	<b>\$ 0.07</b>	<b>\$ (0.65)</b>

We excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares because the inclusion of these stock options would be antidilutive to loss per common share. For the three months ended September 30, 2024 all stock options and awards were excluded from the calculation of diluted weighted-average common shares outstanding as these would be antidilutive due to the net loss. For the nine months ended September 30, 2024 591,000 potential common shares related to stock options and awards were antidilutive and excluded from the calculation of diluted weighted-average common shares outstanding. For the three and nine months ended September 30, 2023 all stock options and awards were excluded from the calculation of diluted weighted-average common shares outstanding as these would be antidilutive due to the net loss.

#### 14. Segment Information

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

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
<b>Revenues:</b>				
Medical devices	\$ 71,244	\$ 63,747	\$ 215,568	\$ 192,041
Preservation services	24,535	24,107	75,661	68,293
<b>Total revenues</b>	<b>95,779</b>	<b>87,854</b>	<b>291,229</b>	<b>260,334</b>
<b>Cost of products and preservation services:</b>				
Medical devices	24,412	21,574	72,707	62,084
Preservation services	10,358	10,010	31,243	30,169
<b>Total cost of products and preservation services</b>	<b>34,770</b>	<b>31,584</b>	<b>103,950</b>	<b>92,253</b>
<b>Gross margin:</b>				
Medical devices	46,832	42,173	142,861	129,957
Preservation services	14,177	14,097	44,418	38,124
<b>Total gross margin</b>	<b>\$ 61,009</b>	<b>\$ 56,270</b>	<b>\$ 187,279</b>	<b>\$ 168,081</b>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
<b>Products:</b>				
Aortic stent grafts	\$ 28,643	\$ 25,523	\$ 92,936	\$ 80,032
On-X	21,478	18,744	61,804	54,346
Surgical sealants	18,437	16,234	53,963	49,503
Other	2,686	3,246	6,865	8,160
<b>Total products</b>	<b>71,244</b>	<b>63,747</b>	<b>215,568</b>	<b>192,041</b>
Preservation services	24,535	24,107	75,661	68,293
<b>Total revenues</b>	<b>\$ 95,779</b>	<b>\$ 87,854</b>	<b>\$ 291,229</b>	<b>\$ 260,334</b>

## **15. Subsequent Events**

### *Endospan Loan Amendment Second Tranche Funding*

On November 7, 2024 we funded Endospan \$10.0 million for the second tranche loan payment pursuant to Endospan's achievement of certain milestones as part of the Endospan Loan Amendment described in Part I, Item 1, Note 3 - "Agreements with Endospan". We anticipate funding the remaining third tranche loan payment of \$8.0 million subject to Endospan's achievement of milestones related to its pursuit of regulatory approval for the NEXUS products that are specified in the Endospan Loan Amendment. We are in the process of evaluating the impact of the second tranche loan payment on our financial results and operations.



## Forward-Looking Statements

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

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

- Our belief that new products, new indications, global expansion, and business development are the four growth areas that will drive our business in the future;
- The potential impact the wars in Ukraine and in the Middle East, may have on demand for and sales of our products and services, business operations, manufacturing operations, supply chain, cash flow, workforce, clinical and regulatory timelines, and our research and development projects;
- The potential impact general global, regional, or national economic downturns and macroeconomic trends, including heightened inflation, interest rate and currency fluctuations, as well as general or localized economic slowdowns or recessions may have on demand for and sales of our products and services, including ordering trends for international distributors based on currency 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 of our clinical trials and product launches;
- Our beliefs and anticipation regarding the favorable attributes, benefits, and clinical advantages of our products and services, the basis on which our products and services compete, the benefits of our physician education activities, and the advantages of our relationships with organ and tissue procurement organizations and tissue banks;
- Our beliefs about the future regulatory status of our medical devices 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 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 regarding the impact lower INR anticoagulation therapy and transcatheter heart valve replacement may have on the number of patients choosing On-X mechanical heart valves;
- Our beliefs about the advantages of our intellectual property and its significance to our segments and our business as a whole, and our beliefs about the present value and potential impairment of our intangible assets and leases;
- Our beliefs about our workforce, including our ability to attract and retain talent at all levels, and about our relationship with our workforce, including our works council in Germany and union in Brazil;
- Our beliefs about potential information security vulnerabilities, and the associated potential adverse effects on our business;
- The dependencies affecting our ability to realize the anticipated business opportunities, growth prospects, synergies, and other benefits of the agreements with Endospan and Baxter and our acquisition of Ascyrus, and our beliefs about the costs and timelines for certain regulatory approvals and clinical trial milestones;
- Our beliefs regarding the fair value of our acquisitions, divestitures, and other business development activities and the estimates and assumptions about the future achievements of milestones and future revenues and cash flows related to those business development activities, including our ability to achieve the milestones in the 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 the impact that our cash requirements might have on our cash flows for the next twelve months;
- Our expectation regarding the impact on cash flows of undertaking significant business development activities and the potential need to obtain additional debt financing or equity financing;
- Our belief that we will incur expenses for research and development projects, including for clinical research projects to gain regulatory approvals for products or indications, including On-X, aortic stent grafts, and BioGlue products, and for new products and technologies which will likely require additional investment, research, and new clinical studies or data;
- Our beliefs about pending and potential legal or other governmental or regulatory proceedings;
- Our expectations regarding the timing and impact of clinical research work and regulatory approvals for certain products or indications, including On-X, aortic stent grafts, and BioGlue products, and the CryoValve SG pulmonary heart valve if the US Food and Drug Administration reclassifies allograft heart valves as Class III medical devices;
- Our beliefs and expectations regarding the utilization of net operating loss carryforwards from our acquisitions of JOTEC, On-X 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 GLP-1 drugs, 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, 2023 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, the Ascyrus Medical Dissection Stent (“AMDS”) hybrid prosthesis, the NEXUS® endovascular stent graft system (“NEXUS”), the NEXUS DUO™ aortic arch stent graft (“NEXUS DUO”), and E-vita Thoracic 3G products. Abdominal stent grafts include our E-xtra Design Engineering (including Artivex™), E-nside™, E-tegra™, E-ventus™ BX, and E-liac™ products. Surgical sealants include our BioGlue® Surgical Adhesive products (“BioGlue”). In addition to these four major product families, we also 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 the Transitional Manufacturing and Supply Agreement (“TMSA”) of the Baxter Transaction, described below).

We reported quarterly revenues of \$95.8 million for the three months ended September 30, 2024, a 9% increase from the three months ended September 30, 2023. The increase in revenues for the three months ended September 30, 2024 was due to an increase in revenues from aortic stent grafts, On-X products, surgical sealants, and preservation services, partially offset by a decrease in revenues from other products. Constant currency revenues, as defined below, increased 10% for the three months ended September 30, 2024, as compared to the three months ended September 30, 2023.

See the “Results of Operations” section below for additional analysis of the three and nine months ended September 30, 2024.

#### 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.

#### New Accounting Pronouncements

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

**Results of Operations**
*(Tables in thousands, except percentages)*
**Revenues**

	Revenues for the Three Months Ended September 30,			Revenues as a Percentage of Total Revenues for the Three Months Ended September 30,	
	2024	2023	Percent Change	2024	2023
<b>Products:</b>					
Aortic stent grafts	\$ 28,643	\$ 25,523	12%	30%	29%
On-X	21,478	18,744	15%	22%	21%
Surgical sealants	18,437	16,234	14%	19%	19%
Other	2,686	3,246	-17%	3%	4%
<b>Total products</b>	<b>71,244</b>	<b>63,747</b>	<b>12%</b>	<b>74%</b>	<b>73%</b>
Preservation services	24,535	24,107	2%	26%	27%
<b>Total</b>	<b>\$ 95,779</b>	<b>\$ 87,854</b>	<b>9%</b>	<b>100%</b>	<b>100%</b>

	Revenues for the Nine Months Ended September 30,			Revenues as a Percentage of Total Revenues for the Nine Months Ended September 30,	
	2024	2023	Percent Change	2024	2023
<b>Products:</b>					
Aortic stent grafts	\$ 92,936	\$ 80,032	16%	32%	31%
On-X	61,804	54,346	14%	21%	21%
Surgical sealants	53,963	49,503	9%	19%	19%
Other	6,865	8,160	-16%	2%	3%
<b>Total products</b>	<b>215,568</b>	<b>192,041</b>	<b>12%</b>	<b>74%</b>	<b>74%</b>
Preservation services	75,661	68,293	11%	26%	26%
<b>Total</b>	<b>\$ 291,229</b>	<b>\$ 260,334</b>	<b>12%</b>	<b>100%</b>	<b>100%</b>

Revenues increased 9% and 12% for the three and nine months ended September 30, 2024, respectively, as compared to the three and nine months ended September 30, 2023. The increase in revenues for the three and nine months ended September 30, 2024 was due to an increase in revenues from aortic stent grafts, On-X products, surgical sealants, and preservation services, partially offset by a decrease in revenues from other products.

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

	Revenues for the Three Months Ended September 30,				Percent Change From Prior Year
	2024	2023			
	US GAAP	US GAAP	Exchange Rate Effect	Constant Currency	
<b>Products:</b>					
Aortic stent grafts	\$ 28,643	\$ 25,523	\$ (208)	\$ 25,315	13%
On-X	21,478	18,744	(103)	18,641	15%
Surgical sealants	18,437	16,234	(128)	16,106	14%
Other	2,686	3,246	1	3,247	-17%
<b>Total products</b>	<b>71,244</b>	<b>63,747</b>	<b>(438)</b>	<b>63,309</b>	<b>13%</b>
Preservation services	24,535	24,107	(22)	24,085	2%
<b>Total</b>	<b>\$ 95,779</b>	<b>\$ 87,854</b>	<b>\$ (460)</b>	<b>\$ 87,394</b>	<b>10%</b>
North America	49,089	48,028	(50)	47,978	2%
Europe, the Middle East, and Africa	30,423	26,536	12	26,548	15%
Asia Pacific	10,366	8,402	1	8,403	23%
Latin America	5,901	4,888	(423)	4,465	32%
<b>Total</b>	<b>\$ 95,779</b>	<b>\$ 87,854</b>	<b>\$ (460)</b>	<b>\$ 87,394</b>	<b>10%</b>

	Revenues for the Nine Months Ended September 30,				Percent Change From Prior Year
	2024	2023			
	US GAAP	US GAAP	Exchange Rate Effect	Constant Currency	
<b>Products:</b>					
Aortic stent grafts	\$ 92,936	\$ 80,032	\$ 688	\$ 80,720	15%
On-X	61,804	54,346	(2)	54,344	14%
Surgical sealants	53,963	49,503	(10)	49,493	9%
Other	6,865	8,160	4	8,164	-16%
<b>Total products</b>	<b>215,568</b>	<b>192,041</b>	<b>680</b>	<b>192,721</b>	<b>12%</b>
Preservation services	75,661	68,293	(26)	68,267	11%
<b>Total</b>	<b>\$ 291,229</b>	<b>\$ 260,334</b>	<b>\$ 654</b>	<b>\$ 260,988</b>	<b>12%</b>
North America	148,679	137,541	(57)	137,484	8%
Europe, the Middle East, and Africa	98,156	84,608	994	85,602	15%
Asia Pacific	27,628	24,655	—	24,655	12%
Latin America	16,766	13,530	(283)	13,247	27%
<b>Total</b>	<b>\$ 291,229</b>	<b>\$ 260,334</b>	<b>\$ 654</b>	<b>\$ 260,988</b>	<b>12%</b>

Constant currency revenues increased 10% and 12% for the three and nine months ended September 30, 2024, respectively, as compared to the three and nine months ended September 30, 2023. See “Non-GAAP Measures of Financial Performance” below for further background on our non-GAAP measures.

A detailed discussion of the changes in product revenues and preservation services revenues for the three and nine months ended September 30, 2024 is presented below.

### ***Products***

Revenues from products increased 12% for both the three and nine months ended September 30, 2024, as compared to the three and nine months ended September 30, 2023. The increase for the three and nine months ended September 30, 2024 was due to an increase in revenues from aortic stent grafts, On-X products, and surgical sealants, partially offset by a decrease in revenues from other 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 September 30, 2024, as compared to the three months ended September 30, 2023, the US Dollar strengthened in comparison to major currencies, resulting in revenue decreases when these foreign currency denominated transactions were translated into US Dollars. For the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023, the US Dollar weakened in comparison to major currencies, resulting in revenue increases when these foreign currency denominated transactions were translated into US Dollars. Future changes in these exchange rates could have a material, adverse effect on our revenues denominated in these currencies. Additionally, our sales to many distributors around the world are denominated in US Dollars, and although these sales are not directly impacted by currency exchange rates, we believe that some of our distributors may delay or reduce purchases of products in US Dollars depending on the relative price of these goods in their local currencies.

### ***Aortic Stent Grafts***

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

Revenues from the sales of aortic stent grafts increased 12% for the three months ended September 30, 2024, as compared to the three months ended September 30, 2023. This increase was primarily due to an increase in the volume of units sold and, to a lesser extent, an increase in average sales prices, partially offset by the effect of foreign exchange rates.

Revenues from the sales of aortic stent grafts increased 16% for the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023. This increase was primarily due to an increase in the volume of units sold and, to a lesser extent, an increase in average sales prices, and the effect of foreign exchange rates.

Constant currency revenues from the sales of aortic stent grafts increased 13% and 15% for the three and nine months ended September 30, 2024, respectively, as compared to the three and nine months ended September 30, 2023. Revenues for the three and nine months ended September 30, 2024 increased primarily in Europe, the Middle East, and Africa (collectively, “EMEA”) and, to a lesser extent, in Latin America and Asia Pacific (“APAC”). The revenue increase in EMEA for the three and nine months ended September 30, 2024 was primarily due to an increase in buying patterns in direct (to hospitals) markets.

### *On-X Products*

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<sub>2</sub> diffusion catheters and from the sale of Chord-X® ePTFE sutures for mitral chordal replacement. On-X products revenue also includes revenue generated from pyrolytic carbon coating services for OEM customers.

Revenues from the sales of On-X products increased 15% for the three months ended September 30, 2024, as compared to the three months ended September 30, 2023. This increase was primarily due to an increase in the volume of units sold and, to a lesser extent, an increase in average sales prices, partially offset by the effect of foreign exchange rates.

Revenues from the sales of On-X products increased 14% for the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023. This increase was primarily due to an increase in the volume of units sold and, to a lesser extent, an increase in average sales prices.

Constant currency revenues from the sales of On-X products increased 15% and 14% for the three and nine months ended September 30, 2024, respectively, as compared to the three and nine months ended September 30, 2023. Revenues for the three months ended September 30, 2024 increased primarily in North America, EMEA, and APAC, with the most significant increase in North America. Revenues for the nine months ended September 30, 2024 increased in all geographies, with the most significant increase in North America. The increase in revenues in North America for the three and nine months ended September 30, 2024 was impacted by recent gains in the market share.

Domestic revenues from the sales of On-X products accounted for 59% and 60% of total On-X revenues for the three and nine months ended September 30, 2024, respectively, as compared to 61% and 60% of total On-X revenues for the three and nine months ended September 30, 2023, respectively.

### *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 14% for the three months ended September 30, 2024, as compared to the three months ended September 30, 2023. 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.

Revenues from the sales of surgical sealants increased 9% for the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023. 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.

Constant currency revenues from the sales of surgical sealants increased 14% and 9% for the three and nine months ended September 30, 2024, respectively, as compared to the three and nine months ended September 30, 2023. The increase in revenues for the three months ended September 30, 2024 was due to revenue increases in all geographies, with the most significant increase in APAC. The increase in revenues in APAC for the three months ended September 30, 2024 was impacted by customer buying patterns in certain markets. The increase in revenues for the nine months ended September 30, 2024 was due to revenue increases in all geographies, with the most significant increase in EMEA. The increase in revenues in EMEA for the nine months ended September 30, 2024 was primarily due to an increase in buying patterns in direct markets.

Domestic revenues from the sales of surgical sealants accounted for 44% and 47% of total surgical sealant revenues for the three and nine months ended September 30, 2024, respectively, as compared to 48% and 49% of total surgical sealant revenues for the three and nine months ended September 30, 2023, respectively.

### *Other*

Other revenues are comprised of revenues from PhotoFix and PerClot (as part of the TMSA of the Baxter Transaction described below).

Other revenues decreased 17% and 16% for the three and nine months ended September 30, 2024, respectively, as compared to the three and nine months ended September 30, 2023. The decrease in other revenues for the three and nine months ended September 30, 2024 was primarily due to a decrease in PerClot product revenues as a result of timing of shipments.

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

### ***Preservation Services***

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

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

Revenues from tissue processing increased 2% for the three months ended September 30, 2024, as compared to the three months ended September 30, 2023. This increase was primarily due to an increase in average sales prices, partially offset by a decrease in certain tissues shipped.

Revenues from tissue processing increased 11% for the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023. This increase was primarily due to an increase in average sales prices, and, to a lesser extent, a change in the mix of tissues shipped.

### **Cost of Products and Preservation Services**

#### ***Cost of Products***

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>	<b>2024</b>	<b>2023</b>
Cost of products	\$ 24,412	\$ 21,574	\$ 72,707	\$ 62,084

Cost of products increased 13% and 17% for the three and nine months ended September 30, 2024, respectively, as compared to the three and nine months ended September 30, 2023. Cost of products for the three and nine months ended September 30, 2024 and 2023 included costs related to aortic stent grafts, On-X products, surgical sealants, and other products.

The increase in the cost of products for the three months ended September 30, 2024 was primarily due to an increase in the volume of all products shipped as well as an increase in the cost of certain aortic stent grafts shipped, as compared to the three months ended September 30, 2023.



The increase in the cost of products for the nine months ended September 30, 2024 was primarily due to an increase in the volume of all products shipped and the cost of certain aortic stent grafts and other products shipped, as compared to the nine months ended September 30, 2023.

### *Cost of Preservation Services*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Cost of preservation services	\$ 10,358	\$ 10,010	\$ 31,243	\$ 30,169

Cost of preservation services increased 3% and 4% for the three and nine months ended September 30, 2024, respectively, as compared to the three and nine months ended September 30, 2023. Cost of preservation services included costs for cardiac and vascular tissue preservation services.

Cost of preservation services for the three and nine months ended September 30, 2024 was impacted by an increase in the cost of certain tissues shipped, partially offset by a decrease in the volume of certain tissues shipped as compared to the three and nine months ended September 30, 2023.

### *Gross Margin*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Gross margin	\$ 61,009	\$ 56,270	\$ 187,279	\$ 168,081
Gross margin as a percentage of total revenues	64%	64%	64%	65%

Gross margin increased 8% and 11% for the three and nine months ended September 30, 2024, respectively, as compared to the three and nine months ended September 30, 2023.

The increase in gross margin for the three months ended September 30, 2024, as compared to the three months ended September 30, 2023, was due to an increase in the volume and favorable pricing of surgical sealants, On-X products, certain aortic stent grafts, and tissues shipped during the three months ended September 30, 2024. The gross margin for the three months ended September 30, 2024 was also favorably impacted by a reduction in the cost of On-X products and surgical sealants shipped. This increase was partially offset by an increase in the cost of certain aortic stent grafts and tissues shipped as well as unfavorable geography mix of On-X products during the three months ended September 30, 2024. Gross margin as a percentage of total revenues was flat for the three months ended September 30, 2024, as compared to the three months ended September 30, 2023. Gross margin as a percentage of total revenues was positively impacted by favorable product mix of On-X products shipped and favorable pricing of certain tissues shipped, surgical sealants, and On-X products shipped, offset by unfavorable geography mix of On-X products and an increase in the cost of certain aortic stent grafts and tissues shipped during the three months ended September 30, 2024.

The increase in gross margin for the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023, was due to an increase in the volume and favorable pricing of certain aortic stent grafts, surgical sealants, On-X products, and tissues shipped during the nine months ended September 30, 2024. This increase was partially offset by an increase in the cost of certain aortic stent grafts and certain tissues shipped as well as unfavorable geography mix of On-X products and certain aortic stent grafts shipped during the nine months ended September 30, 2024. Gross margin as a percentage of total revenues decreased for the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023. Gross margin as a percentage of total revenues was negatively impacted by an increase in the cost of certain aortic stent grafts and certain tissues as well as unfavorable geography mix of On-X products shipped, partially offset by favorable product mix of certain aortic stent grafts shipped and favorable pricing of certain tissues, certain aortic stent grafts, On-X products, and surgical sealants shipped during the nine months ended September 30, 2024.

## Operating Expenses

### *General, Administrative, and Marketing Expenses*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
General, administrative, and marketing expenses	\$ 50,017	\$ 51,093	\$ 130,026	\$ 158,699
General, administrative, and marketing expenses as a percentage of total revenues	52%	58%	45%	61%

General, administrative, and marketing expenses decreased 2% and 18% for the three and nine months ended September 30, 2024, respectively, as compared to the three and nine months ended September 30, 2023. The decrease in General, administrative, and marketing expenses for the three and nine months ended September 30, 2024 was primarily due to a decrease in business development expense, partially offset by an increase in personnel-related costs.

General, administrative, and marketing expenses included \$3.4 million of business development expense and \$11.9 million of business development income for the three and nine months ended September 30, 2024, respectively, as compared to \$6.4 million and \$22.5 million of business development expense for the three and nine months ended September 30, 2023, respectively. We incurred \$3.5 million of business development expense and \$12.2 million of business development income during the three and nine months ended September 30, 2024, respectively, related to the fair value adjustments for the Ascyrus contingent consideration, as compared to \$6.2 million and \$21.9 million of business development expense during the three and nine months ended September 30, 2023, respectively. The reduction in the fair value for the nine months ended September 30, 2024 was primarily due to an increase in the credit risk spread resulting from the change in the inputs related to the newly issued Credit Facilities further discussed in Part I, Item 1, Note 9 of the “Notes to Condensed Consolidated Financial Statements.”

### *Research and Development Expenses*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development expenses	\$ 6,605	\$ 6,421	\$ 21,048	\$ 21,062
Research and development expenses as a percentage of total revenues	7%	7%	7%	8%

Research and development expenses increased 3% for the three months ended September 30, 2024, as compared to the three months ended September 30, 2023. Research and development expenses were flat for the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023. Research and development spending for the three and nine months ended September 30, 2024 was primarily focused on clinical work to gain regulatory approvals for certain aortic stent grafts.

### **Gain from Sale of Non-Financial Assets**

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

### **Interest Expense**

Interest expense was \$8.4 million and \$24.5 million for the three and nine months ended September 30, 2024, respectively, as compared to \$6.6 million and \$19.1 million for the three and nine months ended September 30, 2023, respectively. Interest expense for the three and nine months ended September 30, 2024 and 2023 primarily relates to interest on debt. The increase in interest expense for the three and nine months ended September 30, 2024, as compared to the three and nine months ended September 30, 2023, was primarily due to an increase in the interest rate on the Credit Facilities as a result of our debt refinancing in January 2024.

### Loss on Extinguishment of Debt

During the nine months ended September 30, 2024 we recorded a loss on extinguishment of debt of \$3.7 million in connection with the extinguishment of our previously existing term loan. See Part I, Item 1, Note 9 of the “Notes to Condensed Consolidated Financial Statements” for further discussion of our new credit and guaranty agreement.

### Other (Income) Expense, Net

Other (income) expense, net was \$2.4 million of income and \$6,000 of expense for the three and nine months ended September 30, 2024, respectively, as compared to other expense, net of \$1.9 million and \$5.2 million for the three and nine months ended September 30, 2023, respectively. Other (income) expense, net for the three and nine months ended September 30, 2024 primarily included the realized and unrealized effects of foreign currency gains and losses. Other expense, net for the nine months ended September 30, 2023 primarily included a \$5.0 million expense related to a payment to Endospan for achievement of certain milestones related to the NEXUS products.

### Earnings

*(Table in thousands, except per share data)*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
(Loss) income before income taxes	\$ (1,266)	\$ (9,419)	\$ 9,088	\$ (20,995)
Income tax expense	1,022	382	5,964	5,720
<b>Net (loss) income</b>	<b>\$ (2,288)</b>	<b>\$ (9,801)</b>	<b>\$ 3,124</b>	<b>\$ (26,715)</b>
<b>Diluted (loss) income per common share</b>	<b>\$ (0.05)</b>	<b>\$ (0.24)</b>	<b>\$ 0.07</b>	<b>\$ (0.65)</b>
<b>Diluted weighted-average common shares outstanding</b>	<b>41,844</b>	<b>40,881</b>	<b>42,621</b>	<b>40,691</b>

We incurred a loss before income taxes for the three months ended September 30, 2024 and 2023. We incurred income before income taxes for the nine months ended September 30, 2024, as compared to a loss before income taxes for the nine months ended September 30, 2023. The loss before income taxes for the three months ended September 30, 2024 was impacted by certain operating expenses to support revenue expansion, interest expense related to the Credit Facilities, and expenses related to the fair value adjustment of our financial instruments. The income before income taxes for the nine months ended September 30, 2024 was positively impacted by income related to the fair value adjustments of our financial instruments, partially offset by certain operating expenses to support revenue expansion, debt extinguishment costs, and interest expense related to the Credit Facilities. The loss before income taxes for the three and nine months ended September 30, 2023 was impacted by expenses related to the fair value adjustments of our financial instruments, certain operating expenses to support revenue expansion, and interest expense related to our previously existing credit agreement.

Our effective income tax rate was an expense of 81% and 66% for the three and nine months ended September 30, 2024, respectively, as compared to an expense of 4% and 27% for the three and nine months ended September 30, 2023, respectively. The change in the tax rate for the three and nine months ended September 30, 2024 was primarily due to changes in anticipated full year pre-tax operating results, profit mix among jurisdictions, valuation allowance against our net deferred tax assets, non-deductible executive compensation, the foreign derived intangible income deduction, the research and development tax credit, changes in our uncertain tax position liabilities, and tax-effected impact of stock based compensation, as compared to the three and nine months ended September 30, 2023.

We incurred a net loss and a diluted loss per common share for the three months ended September 30, 2024 and 2023. Net loss and diluted loss per common share for the three months ended September 30, 2024 was primarily due to loss before income taxes, as discussed above. We incurred net income and diluted income per common share for the nine months ended September 30, 2024, as compared to a net loss and diluted loss per common share for the nine months ended September 30, 2023. Net income and diluted income per common share for the nine months ended September 30, 2024 was primarily due to income before income taxes, as discussed above. Net loss and diluted loss per common share for the nine months ended September 30, 2023 was primarily due to loss before income taxes, as discussed above.

## **Non-GAAP Measures of Financial Performance**

To supplement our Condensed Consolidated Financial Statements presented in accordance with US GAAP, we use constant currency revenues, which is a non-GAAP financial measure. We define constant currency revenues as revenues 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**

### ***Net Working Capital***

As of September 30, 2024 net working capital (current assets of \$288.0 million less current liabilities of \$152.8 million) was \$135.2 million, with a current ratio (current assets divided by current liabilities) of 2 to 1, as compared to net working capital of \$222.8 million and a current ratio of 5 to 1 at December 31, 2023. The decrease in current ratio as of September 30, 2024, as compared to December 31, 2023, was primarily due to an increase in current portion of long-term debt. This increase was driven by the reclassification of the Convertible Senior Notes to current liabilities, which are scheduled to mature on July 1, 2025. We may use the proceeds from the Delayed Draw Term Loan Facility, as described in the Significant Sources and Uses of Liquidity section below, to fund the repurchase or repayment of the Convertible Senior Notes.

### ***Overall Liquidity and Capital Resources***

Our primary cash requirements for the nine months ended September 30, 2024 were for the payoff of our previously existing credit agreement, debt issuance costs and interest payments under our Credit Facilities (defined below), interest payments under our Convertible Senior Notes (defined below), general working capital needs, and capital expenditures for facilities and equipment.

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

### ***Significant Sources and Uses of Liquidity***

#### *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 “Initial Term Loan Facility”), a \$100.0 million secured delayed draw term loan facility (the “Delayed Draw Term Loan Facility” and, together with the Initial 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 Initial Term Loan Facility and \$30.0 million under the Revolving Credit Facility. The \$100.0 million of undrawn availability under the Delayed Draw Term Loan Facility can be used solely to fund the repurchase or repayment of the Convertible Senior Notes on or prior to scheduled maturity date of July 1, 2025.

We paid \$6.5 million of debt issuance costs related to the Initial Term Loan Facility which are included in Long-term debt on the Condensed Consolidated Balance Sheets as of September 30, 2024 and amortized, thereafter, over the life of the Initial Term Loan Facility. We paid \$3.7 million of debt issuance costs related to the Delayed Draw Term Loan Facility and Revolving Credit Facility which are included in Other long-term assets on the Condensed Consolidated Balance Sheets as of September 30, 2024.

We recognized \$7.1 million and \$19.8 million of interest expense on the Credit Facilities for the three and nine months ended September 30, 2024, respectively, of which \$358,000 and \$997,000 represent non-cash amortization of debt issuance costs for the three and nine months ended September 30, 2024, respectively. There was approximately \$5.7 million of unamortized debt issuance costs related to the Initial Term Loan Facility as of September 30, 2024.

The proceeds of the initial borrowings were used along with cash on hand to pay off our previously existing credit agreement, dated as of December 1, 2017, and pay related fees and expenses. As a result of this transaction, we recorded a loss on extinguishment of debt of \$3.7 million during the nine months ended September 30, 2024 on our Condensed Consolidated Statements of Operations and Comprehensive Income (Loss). See Part I, Item 1, Note 9 of the “Notes to Condensed Consolidated Financial Statements” for further discussion of our new Ares Credit Agreement.

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 5.00% if the prepayment occurs prior to January 18, 2025 and 1.00% if the prepayment occurs thereafter and prior to January 18, 2026. Amounts repaid in respect of loans under the Initial Term Loan Facilities may not be reborrowed. Amounts repaid in respect of loans under the Revolving Credit Facility may be reborrowed. Loans under the Term Loan Facilities 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 Secured Overnight Financing Rate (“Adjusted Term SOFR”) plus a margin of 6.50%; beginning with the second fiscal quarter of 2025, the margin may step down to 5.25% and 6.25%, respectively, based on our total net leverage ratio at such time. Loans under the Revolving Credit Facility bear 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 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.

### 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. The fair value and the effective interest rate of the Convertible Senior Notes as of September 30, 2024 was approximately \$125.4 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.

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

We became eligible to redeem the Convertible Senior Notes beginning on July 5, 2023, following the expiration of their non-redemption period. We are able to redeem the Convertible Senior Notes in whole or in part, at our option, if the last reported sale price per share of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption. We may redeem for cash all or part of the Convertible Senior Notes at a redemption price equal to 100% of the principal amount of the redeemable Convertible Senior Notes, plus accrued and unpaid interest to, but excluding, the redemption date. No principal payments are due on the Convertible Senior Notes prior to the scheduled maturity date on July 1, 2025. As discussed above we are able to use the \$100.0 million of undrawn availability under the Delayed Draw Term Loan Facility to fund the repurchase or repayment of the Convertible Senior Notes. 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. As of September 30, 2024 and December 31, 2023 we are not aware of any current events or market conditions that would allow holders to convert the Convertible Senior Notes.

As of September 30, 2024 approximately 38% of our cash and cash equivalents were held in foreign jurisdictions.

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

	Nine Months Ended September 30,	
	2024	2023
<b>Cash flows provided by (used in):</b>		
Operating activities	\$ 12,097	\$ 7,987
Investing activities	(16,763)	2,167
Financing activities	2,029	2,495
Effect of exchange rate changes on cash and cash equivalents	(130)	1,481
<b>(Decrease) increase in cash and cash equivalents</b>	<b>\$ (2,767)</b>	<b>\$ 14,130</b>

### ***Net Cash Flows from Operating Activities***

Net cash provided by operating activities was \$12.1 million and \$8.0 million for the nine months ended September 30, 2024 and 2023, respectively.

We use the indirect method to prepare our cash flow statement and, accordingly, the operating cash flows are based on our net income, which is then adjusted to remove non-cash items, items classified as investing and financing cash flows, and changes in operating assets and liabilities from the prior year end. For the nine months ended September 30, 2024 these non-cash items primarily included \$17.9 million of depreciation and amortization expenses, \$12.2 million of fair value adjustments of financial instruments, \$11.5 million of non-cash compensation, \$5.9 million of non-cash lease expenses, \$4.2 million of deferred income tax changes, \$3.7 million of loss on extinguishment of debt, and \$2.9 million of write-down of inventories and deferred preservation costs.

Our working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the nine months ended September 30, 2024 these included the unfavorable effect of \$5.2 million due to timing differences between the recording of accounts payable, accrued expenses, and other liabilities, and the payment of cash, \$4.8 million due to an increase in inventory balances and deferred preservation costs, \$4.8 million due to an increase in prepaid expenses and other assets, and the unfavorable effect of \$3.4 million due to the timing differences between recording receivables and the receipt of cash.

### ***Net Cash Flows from Investing Activities***

Net cash used in investing activities was \$16.8 million for the nine months ended September 30, 2024, as compared to net cash provided by investing activities of \$2.2 million for the nine months ended September 30, 2023. During the nine months ended September 30, 2024 cash flows used in investing activities included \$9.8 million of cash used for capital expenditures and a \$7.0 million payment related to the Endospan Loan Amendment.

### ***Net Cash Flows from Financing Activities***

Net cash provided by financing activities was \$2.0 million and \$2.5 million for the nine months ended September 30, 2024 and 2023, respectively. The current year cash provided by financing activities was primarily due to \$190.0 million of proceeds from the Initial Term Loan Facility, \$30.0 million of proceeds from the Revolving Credit Facility, and \$5.3 million of proceeds from the exercise of stock options and issuances of common stock, partially offset by \$211.8 million for the repayment of debt, \$10.0 million for the payment of debt issuance costs, and \$1.0 million for the payments of short-term notes payable.

### **Scheduled Contractual Obligations and Future Payments**

Our short-term debt obligations and interest payments include \$100.3 million of scheduled principal payments and \$4.3 million in anticipated interest payments related to our Convertible Senior Notes and other governmental loans. Our long-term debt obligations and interest payments include \$220.0 million of scheduled principal payments and \$112.9 million in anticipated interest payments related to our Initial Term Loan Facility and Revolving Credit Facility.

We have contingent payment obligations that include up to \$100.0 million to be paid to the former shareholders of Ascyrus upon the achievement of certain milestones. As part of the transaction with Baxter, we may be required to pay up to \$3.0 million if certain milestones are met. Pursuant to the Amended and Restated Loan Agreement with Endospan Ltd. ("Endospan") dated July 1, 2024, we anticipate making the remaining \$8.0 million tranche payment subject to Endospan's achievement of milestones related to its pursuit of regulatory approval for the NEXUS products.

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

## **Capital Expenditures**

Capital expenditures were \$9.8 million and \$7.1 million for the nine months ended September 30, 2024 and 2023, respectively. Capital expenditures for the nine months ended September 30, 2024 were primarily related to routine purchases of computer software, manufacturing and tissue processing equipment, leasehold improvements, and computer equipment needed to support our business.

## **Risks and Uncertainties**

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

## **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

### **Interest Rate Risk**

Our interest income and interest expense are sensitive to changes in the general level of US interest rates. In this regard, changes in US interest rates affect the interest earned on our cash and cash equivalents of \$56.2 million as of September 30, 2024 and interest paid on the outstanding balances, if any, of our variable rate Credit Facilities and Convertible Senior Notes. A 10% adverse change in interest rates, as compared to the rates experienced by us for the nine months ended September 30, 2024, affecting our cash and cash equivalents, Credit Facilities, and Convertible Senior Notes would not have a material effect on our financial position, results of operations, or cash flows.

### **Foreign Currency Exchange Rate Risk**

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

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

An additional 10% adverse change in exchange rates from the exchange rates in effect on September 30, 2024 affecting our balances denominated in foreign currencies could impact our financial position or cash flows by approximately \$9.0 million. An additional 10% adverse change in exchange rates from the weighted-average exchange rates experienced by us for the nine months ended September 30, 2024 affecting our revenue and expense transactions denominated in foreign currencies would not have had a material impact on our financial position or profitability.

## **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 September 30, 2024 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 September 30, 2024 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;
- 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 financial and regulatory consequences resulting from Brexit.

As an example of this risk, via a Ministerial Decree of July 6, 2022, published September 15, 2022, the Italian government stated that the spending ceiling for medical devices at the national and regional levels had been exceeded, requiring medical device companies to pay back alleged overpayments the government claims companies received between 2015 and 2018. Currently, Artivion's repayment exposure for this period is estimated at approximately €215,000, which is subject to change as judicial challenges and negotiations between us, industry, US government representatives, and the Italian government are ongoing.

Our operations and performance have been, and may continue to be, impacted by regional and global geopolitical conditions, domestic and foreign trade and monetary policies, and other factors beyond our control. As an example of these risks, Russia's war with Ukraine has triggered significant sanctions from the US and foreign governments and retaliatory actions from Russia, resulting in significant banking and trade disruptions. There is also war in the Gaza Strip that has expanded into a regional crisis involving an increasing number of countries. These wars have resulted in significant devastation to the people and infrastructure in the affected regions, significantly impacting trade and transportation which may impact our global supply chain, increase prices, and limit our ability to continue to do business in those regions.

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

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

The market for our products and services is competitive and affected by new product introductions and activities of other industry participants, including the introduction of novel products and therapies aimed at unrelated disease states or even overall patient health. In addition, such products and therapies like the recently introduced GLP-1 drugs, which we believe have or will have little to no actual impact on demand for our products, can lead to investor and customer confusion and impact the perceived demand for our products. We face intense competition in virtually all of our product lines. A significant percentage of market revenues from competitive products are generated by Baxter, Ethicon (a Johnson & Johnson Company), Medtronic, Abbott Laboratories, Edwards Lifesciences, C.R. Bard (a subsidiary of Becton, Dickinson and Company), Integra Life Sciences, LifeNet, 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 increased workforce competition;
- Greater name recognition as well as more recognizable trademarks for products similar to products that we sell;
- More established record of obtaining and maintaining regulatory product clearances or approvals;
- More established relationships with healthcare providers and payors;
- Lower cost of goods sold or preservation costs; and
- Larger direct sales forces and more established distribution networks.

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

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

- Source sufficient quantities of some human tissue or address potential excess supply of others. We rely primarily upon the efforts of third parties to educate the public and foster a willingness to donate tissue. Factors beyond our control such as supply, regulatory changes, negative publicity concerning methods of tissue recovery or disease transmission from donated tissue, or public opinion of the donor process as well as our own reputation in the industry can negatively impact the supply of tissue;

- Compete effectively, as we may be unable to capitalize on our clinical advantages or our competitors may have advantages over us in terms of cost structure, pricing, back-office automation, marketing, and sourcing; or
- Mitigate sufficiently the risk that tissue can become contaminated during processing; that processed tissue cannot be end-sterilized and hence carries an inherent risk of infection or disease transmission or that our quality controls can eliminate that risk.

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.

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

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

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

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

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

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

- Compete effectively with some of our major competitors, as they may have advantages over us in terms of cost structure, product development, supply chain, pricing, sales force footprint, and brand recognition;
- Develop innovative, high quality, and in-demand aortic repair products;
- Respond adequately to enhanced regulatory requirements and enforcement activities, and particularly, our ability to obtain regulatory approvals and renewals globally;
- 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:

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

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

**Our charges resulting from acquisitions, 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") and fully wrote-down the value of our original agreement for a secured loan from Artivion to Endospan ("Endospan Loan"), primarily driven by a decrease in forecasted operating results. This impairment, and other potential risks like those mentioned above, may adversely affect the market value of our common stock.

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

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

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

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

### 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.

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

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 wars in Ukraine and the Middle East, work force shortages, exchange rates, and inflation continue to impact the global supply chain; their impact on workforces, global mobility, material availability, demand, and shipping and reorder times and reliability has reportedly continued or worsened in many cases. The ongoing wars may add to or exacerbate challenges faced by the global supply chain. See Part I, Item 1A, “Risk Factors – Business and Economic Risks – We are subject to a variety of risks due to our international operations and continued global expansion.” Although we have yet to experience any material effects of this impact on our supply chain or operations, we face an increasing risk that upstream disruptions may occur. Risks relating to the lingering effects of global supply chain disruptions may even continue after the wars in Ukraine and the Middle East 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, our supplier was unable to fully resume production due to supply-related factors outside of our control and we eventually abandoned the business as of June 2023. As a result, we wrote-off all of our CardioGenesis cardiac laser therapy assets and recorded an expense of \$390,000 during the twelve months ended December 31, 2023 on 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 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, or climate change related event, our business could be substantially disrupted.

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

**We are dependent on our specialized workforce.**

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

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

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

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

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

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

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

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

- Leverage our global infrastructure to sell and cross-market the acquired products;
- Drive adoption of the NEXUS 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 the Endospan Transaction depends on a number of additional factors including Endospan's ability to: (a) comply with the Endospan Loan and other debt obligations, and avoid an event of default; (b) successfully commercialize the NEXUS Products, raise capital and drive adoption in markets in and outside of Europe; (c) meet demand for the NEXUS Products; (d) meet quality and regulatory requirements for the NEXUS Products; (e) manage any intellectual property risks and uncertainties associated with the NEXUS Products; (f) obtain FDA approval of the NEXUS Products; (g) remain a going concern; and (h) develop the NEXUS 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 decreased, resulting in an impairment to the carrying value of the Endospan Option, and a full write-down of the value of the Endospan Loan, reflecting decreased expectations with respect to the anticipated benefits of the Endospan Transaction. 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.

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

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

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

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

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

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

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

Industry Risks

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

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

- Our products and tissues allegedly have caused, and may in the future cause, patient injury, which has exposed, and could in the future expose, us to liability claims that could lead to additional regulatory scrutiny;
- Our manufacturing and tissue processing operations are subject to regulatory scrutiny, inspections and enforcement actions, and regulatory agencies could require us to change or modify our operations or take other action, such as issuing product recalls or holds;
- Regulatory agencies could reclassify, re-evaluate, or suspend our clearances or approvals, or fail 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, on May 25, 2017, the European Union adopted new regulations governing medical devices (the MDR), which were to be fully implemented on May 26, 2021. The MDR places stricter requirements on manufacturers and European Notified Bodies regarding, among other things, product classifications and pre- and post-market clinical studies for product clearances and approvals which could result in product reclassifications or the imposition of other regulatory requirements that could delay, impede, or prevent our ability to commercialize existing, improved, or new products in the European Economic Area and other markets that require 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 as part of that transition. The European Parliament most recently extended the MDR transition period under Regulation (EU) 2023/607 but it is still unclear whether this extension will be able to mitigate the challenges posed by the transition to the MDR. 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. Although we were able to successfully gain CE Mark for BioGlue under the MDR, certification for Chord-X remains outstanding;
- 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-issued certification for PhotoFix; 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 2023, 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. The DSMB found that continuing the trial was unlikely to achieve the primary endpoint while possibly exposing patients to increased risk. 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.

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

**Increased regulatory enforcement activities 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. Although we have a small-scale EtO facility in Austin, Texas, we rely primarily on third-party large-scale EtO facilities to sterilize our products. In addition, some of our suppliers use, or rely upon third parties to use, EtO to sterilize some of our product components. Concerns about the release of EtO into the environment at unsafe levels have led to increased activism and lobbying as well as various regulatory enforcement activities against EtO facilities, including closures and temporary closures, lawsuits against EtO service providers, and proposals increasing regulations related to EtO, including any required reduction in EtO concentration levels. 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. In October 2023, the Environmental Protection Agency released final rules requiring companies to report the manufacture or import of PFAS-containing products. In addition, numerous states have instituted bans on PFAS-containing products and reporting obligations. 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.

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

In response to perceived increases in healthcare costs in recent years, there have been, and continue to be, proposals by the governmental authorities, third-party payors, and elected office holders and candidates to impact public health, control healthcare costs and, more generally, to reform the healthcare systems. A forthcoming transition in the US presidential administration creates uncertainty regarding changes to healthcare policy, including the potential to repeal the Affordable Care Act or enact other changes that may impact costs, reimbursement, and healthcare generally. Additional uncertainty is anticipated as debates about healthcare and public health continue in light of the COVID-19 pandemic which may have an impact on US law relating to the healthcare industry. Many US healthcare laws, including the Affordable Care 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. The application of these laws to us, our customers, or the specific services and relationships we have with our customers is not always clear. Our failure to anticipate accurately any changes to, or the repeal or invalidation of all or part of the Affordable Care Act and similar or future laws and regulations, or our failure to comply with them, could create liability for us, result in adverse publicity and negatively affect our business, results of operations, and financial condition.

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

Legal, Quality, and Regulatory Risks

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

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

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

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

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

Our relationships with physicians, hospitals, 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 the ongoing wars in Ukraine and Gaza, and the current and future sanctions imposed on Russia and others as a result may exacerbate these risks. See also Part I, Item 1A, “Risk Factors – Business and Economic Risks - We are subject to a variety of risks due to our international operations and continued global expansion.” Possible sanctions for violation of these healthcare compliance laws include fines, civil and criminal penalties, exclusion from government healthcare programs, and despite our compliance efforts, we face the risk of an enforcement activity or a finding of a violation of these laws.

We have entered into consulting and product development agreements with healthcare professionals and healthcare organizations, including some who may order our products or make decisions to use them. We have also adopted the AdvaMed Code of Conduct, the MedTech Europe Code of Ethical Business Practice, and the APACMed Code of Ethical Conduct which govern our relationships with healthcare professionals to bolster our compliance with healthcare compliance laws. While our relationships with healthcare professionals, 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.

**The proliferation of new and expanded regulatory regimes like the General Data Protection Regulation and Corporate Sustainability Reporting Directive in the European Union, could adversely affect our business.**

An increasing number of federal, state, and foreign laws and regulations are being promulgated 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. These laws and regulations may include new compliance or disclosure requirements for companies which increases our operating costs and requires significant management time and energy. Many of these laws and regulations, including the European Union’s General Data Protection Regulation (“GDPR”) also include significant penalties for noncompliance. Although our 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 with all applicable laws, 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.

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

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

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

*Risks Relating to Our Indebtedness*

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

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

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

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

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

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

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

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

*Risks Relating to Ownership of our Common Stock*

**Our business could be negatively impacted as a result of 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.

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

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

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

In December 2015 our Board of Directors discontinued dividend payments on our common stock for the foreseeable future. If we do not pay cash dividends, our 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. The effects of reincorporation in Delaware are detailed in our 2021 Special Proxy Statement and Notice of Special Meeting filed with the SEC on October 7, 2021.



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

(c) The Company did not repurchase any of its equity security during the three months ended September 30, 2024.

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.**

During the three months ended September 30, 2024, four of our officers adopted Rule 10b5-1 trading arrangements intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act: (1) on August 13, 2024, Andrew M. Green, our Vice President, Regulatory Affairs, adopted a trading arrangement pursuant to which he may sell up to 10,000 shares of the Company's common stock from November 12, 2024 to May 24, 2025; (2) on August 30, 2024, J. Patrick Mackin, our Chairman, President, and Chief Executive Officer, adopted a trading arrangement pursuant to which he may sell up to 75,615 shares of the Company's common stock from November 29, 2024 to March 12, 2025; (3) on August 30, 2024, Jean F. Holloway, Esq. our Senior Vice President, General Counsel, Chief Compliance Officer, and Corporate Secretary, adopted a trading arrangement pursuant to which she may sell up to 19,092 shares of the Company's common stock from November 29, 2024 to March 12, 2025; and (4) on August 30, 2024, John E. Davis, our Chief Commercial Officer, adopted a trading arrangement pursuant to which he may sell up to 15,910 shares of the Company's common stock from November 29, 2024 to March 12, 2025.

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 September 30, 2024.

**Item 6. Exhibits.**

The exhibit index can be found below.

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">3.1</a>	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).
<a href="#">3.2</a>	Delaware Certificate of Amendment of Certificate of Incorporation, effective January 18, 2022. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed January 20, 2022).
<a href="#">3.3</a>	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).
<a href="#">10.1+*</a>	Amended and Restated Loan Agreement, dated July 1, 2024, by and between Artivion, Inc., as lender, and Endospan Ltd., as borrower. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed August 9, 2024).
<a href="#">31.1*</a>	Certification by J. Patrick Mackin pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
<a href="#">31.2*</a>	Certification by Lance A. Berry pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
<a href="#">32**</a>	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  
J. PATRICK MACKIN  
Chairman, President, and  
Chief Executive Officer  
(Principal Executive Officer)

-----  
/s/ LANCE A. BERRY  
LANCE A. BERRY  
Chief Financial Officer and  
Executive Vice President, Finance  
(Principal Financial Officer)

November 8, 2024  
-----  
DATE

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: November 8, 2024

/s/ J. PATRICK MACKIN

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Chairman, President, and  
Chief Executive Officer

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: November 8, 2024

/s/ LANCE A. BERRY

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Chief Financial Officer and  
Executive Vice President, Finance

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 September 30, 2024, 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  
November 8, 2024

/s/ LANCE A. BERRY

LANCE A. BERRY  
Chief Financial Officer and  
Executive Vice President, Finance  
November 8, 2024