

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, 2021**

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

**CRYOLIFE INC.**

(Exact name of registrant as specified in its charter)

**Florida**

(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	CRY	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	<input checked="" type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-accelerated Filer	<input type="checkbox"/>	Smaller Reporting Company	<input type="checkbox"/>
		Emerging Growth Company	<input type="checkbox"/>

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

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

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

Class	Outstanding at October 29, 2021
Common Stock, \$0.01 par value	39,329,580

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

**CryoLife, 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,	
	2021	2020	2021	2020
<b>Revenues:</b>				
Products	\$ 53,107	\$ 45,109	\$ 162,528	\$ 128,797
Preservation services	19,100	20,022	56,914	56,534
<b>Total revenues</b>	<b>72,207</b>	<b>65,131</b>	<b>219,442</b>	<b>185,331</b>
<b>Cost of products and preservation services:</b>				
Products	15,503	12,998	46,592	36,078
Preservation services	8,915	9,001	26,710	26,060
<b>Total cost of products and preservation services</b>	<b>24,418</b>	<b>21,999</b>	<b>73,302</b>	<b>62,138</b>
<b>Gross margin</b>	<b>47,789</b>	<b>43,132</b>	<b>146,140</b>	<b>123,193</b>
<b>Operating expenses:</b>				
General, administrative, and marketing	39,053	33,743	118,521	105,033
Research and development	9,972	5,755	26,086	17,633
<b>Total operating expenses</b>	<b>49,025</b>	<b>39,498</b>	<b>144,607</b>	<b>122,666</b>
Gain from sale of non-financial assets	(15,923)	--	(15,923)	--
<b>Operating income</b>	<b>14,687</b>	<b>3,634</b>	<b>17,456</b>	<b>527</b>
Interest expense	4,100	4,940	12,995	11,980
Interest income	(18)	(13)	(60)	(181)
Other expense, net	2,661	2,888	3,261	5,810
<b>Income (loss) before income taxes</b>	<b>7,944</b>	<b>(4,181)</b>	<b>1,260</b>	<b>(17,082)</b>
Income tax benefit	(2,638)	(1,311)	(4,006)	(3,858)
<b>Net income (loss)</b>	<b>\$ 10,582</b>	<b>\$ (2,870)</b>	<b>\$ 5,266</b>	<b>\$ (13,224)</b>
<b>Income (loss) per share:</b>				
<b>Basic</b>	<b>\$ 0.27</b>	<b>(0.08)</b>	<b>\$ 0.13</b>	<b>(0.35)</b>
<b>Diluted</b>	<b>\$ 0.26</b>	<b>(0.08)</b>	<b>\$ 0.13</b>	<b>(0.35)</b>
<b>Weighted-average common shares outstanding:</b>				
Basic	39,086	37,912	38,924	37,608
Diluted	44,453	37,912	39,496	37,608
<b>Net income (loss)</b>	<b>\$ 10,582</b>	<b>\$ (2,870)</b>	<b>\$ 5,266</b>	<b>\$ (13,224)</b>
<b>Other comprehensive income (loss):</b>				
Foreign currency translation adjustments	(5,010)	8,698	(12,327)	8,669
<b>Comprehensive income (loss)</b>	<b>\$ 5,572</b>	<b>\$ 5,828</b>	<b>\$ (7,061)</b>	<b>\$ (4,555)</b>

See accompanying Notes to Condensed Consolidated Financial Statements

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

	September 30, 2021	December 31, 2020
	(Unaudited)	
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 64,587	\$ 61,412
Restricted securities	538	546
Trade receivables, net	49,682	45,964
Other receivables	5,494	2,788
Inventories, net	78,319	73,038
Deferred preservation costs	42,619	36,546
Prepaid expenses and other	16,104	14,295
<b>Total current assets</b>	<b>257,343</b>	<b>234,589</b>
Goodwill	252,441	260,061
Acquired technology, net	171,788	186,091
Operating lease right-of-use assets, net	46,913	18,571
Other intangibles, net	36,001	40,966
Property and equipment, net	36,973	33,077
Deferred income taxes	3,974	1,446
Other assets	13,221	14,603
<b>Total assets</b>	<b>\$ 818,654</b>	<b>\$ 789,404</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Current portion of contingent consideration	\$ 17,600	\$ 16,430
Accounts payable	9,528	9,623
Accrued compensation	11,990	10,192
Accrued expenses	9,091	7,472
Accrued procurement fees	3,296	3,619
Taxes payable	3,129	2,808
Current maturities of operating leases	3,053	5,763
Current portion of long-term debt	1,640	1,195
Other liabilities	1,803	3,366
<b>Total current liabilities</b>	<b>61,130</b>	<b>60,468</b>
Long-term debt	307,765	290,468
Non-current maturities of operating leases	45,765	14,034
Contingent consideration	47,300	43,500
Deferred income taxes	27,339	34,713
Deferred compensation liability	5,571	5,518
Other liabilities	12,243	11,990
<b>Total liabilities</b>	<b>\$ 507,113</b>	<b>\$ 460,691</b>
<b>Commitments and contingencies</b>		
<b>Shareholders' equity:</b>		
Preferred stock	--	--
Common stock (issued shares of 40,816 in 2021 and 40,394 in 2020)	408	404
Additional paid-in capital	309,290	316,192
Retained earnings	22,075	20,022
Accumulated other comprehensive (loss) income	(5,584)	6,743
Treasury stock, at cost, 1,487 shares as of September 30, 2021 and December 31, 2020, respectively	(14,648)	(14,648)
<b>Total shareholders' equity</b>	<b>311,541</b>	<b>328,713</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 818,654</b>	<b>\$ 789,404</b>

See accompanying Notes to Condensed Consolidated Financial Statements

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

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>Net cash flows from operating activities:</b>		
Net income (loss)	\$ 5,266	\$ (13,224)
Adjustments to reconcile net income (loss) to net cash from operating activities:		
Depreciation and amortization	18,008	14,818
Non-cash compensation	7,471	7,432
Non-cash lease expense	5,566	5,324
Change in fair value of contingent consideration	4,970	--
Non-cash interest expense	2,025	2,261
Change in fair value of long-term loan	--	4,949
Deferred income taxes	(8,128)	(4,916)
Gain from sale of non-financial assets	(15,923)	--
Other	4,665	1,631
Changes in operating assets and liabilities:		
Accounts payable, accrued expenses, and other liabilities	65	3,230
Prepaid expenses and other assets	(2,268)	(2,560)
Receivables	(8,032)	7,718
Inventories and deferred preservation costs	(16,986)	(19,744)
<b>Net cash flows (used in) provided by operating activities</b>	<b>(3,301)</b>	<b>6,919</b>
<b>Net cash flows from investing activities:</b>		
Proceeds from sale of non-financial assets, net	19,000	--
Acquisition of Ascyrus, net of cash acquisition	--	(59,643)
Payments for Endospan agreements	--	(5,000)
Capital expenditures	(10,524)	(5,171)
Other	(4)	(968)
<b>Net cash flows provided by (used in) investing activities</b>	<b>8,472</b>	<b>(70,782)</b>
<b>Net cash flows from financing activities:</b>		
Proceeds from exercise of stock options and issuance of common stock	3,531	2,079
Proceeds from issuance of convertible debt	--	100,000
Proceeds from revolving line of credit	--	30,000
Proceeds from financing insurance premiums	--	2,816
Repayment of revolving line of credit	--	(30,000)
Redemption and repurchase of stock to cover tax withholdings	(1,898)	(1,768)
Payment of debt issuance costs	(2,219)	(3,647)
Repayment of debt	(2,397)	(3,727)
Other	(439)	(463)
<b>Net cash flows (used in) provided by financing activities</b>	<b>(3,422)</b>	<b>95,290</b>
Effect of exchange rate changes on cash, cash equivalents, and restricted securities	1,418	(1,086)
<b>Increase in cash, cash equivalents, and restricted securities</b>	<b>3,167</b>	<b>30,341</b>
Cash, cash equivalents, and restricted securities beginning of period	61,958	34,294
<b>Cash, cash equivalents, and restricted securities end of period</b>	<b>\$ 65,125</b>	<b>\$ 64,635</b>

See accompanying Notes to Condensed Consolidated Financial Statements

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

	Common Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss		Treasury Stock		Total Shareholders' Equity
	Shares	Amount			Shares	Amount			
	<b>Balance at June 30, 2021</b>	<b>40,742</b>	<b>\$ 407</b>	<b>\$ 305,157</b>	<b>\$ 11,493</b>	<b>\$ (574)</b>	<b>(1,487)</b>	<b>\$ (14,648)</b>	<b>\$ 301,835</b>
Net income	--	--	--	10,582	--	--	--	10,582	
Other comprehensive loss	--	--	--	--	(5,010)	--	--	(5,010)	
Equity compensation	8	1	2,990	--	--	--	--	2,991	
Exercise of options	18	--	191	--	--	--	--	191	
Employee stock purchase plan	50	--	1,019	--	--	--	--	1,019	
Redemption and repurchase of stock to cover tax withholdings	(2)	--	(67)	--	--	--	--	(67)	
<b>Balance at September 30, 2021</b>	<b>40,816</b>	<b>\$ 408</b>	<b>\$ 309,290</b>	<b>\$ 22,075</b>	<b>\$ (5,584)</b>	<b>(1,487)</b>	<b>\$ (14,648)</b>	<b>\$ 311,541</b>	

	Common Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)		Treasury Stock		Total Shareholders' Equity
	Shares	Amount			Shares	Amount			
	<b>Balance at December 31, 2020</b>	<b>40,394</b>	<b>\$ 404</b>	<b>\$ 316,192</b>	<b>\$ 20,022</b>	<b>\$ 6,743</b>	<b>(1,487)</b>	<b>\$ (14,648)</b>	<b>\$ 328,713</b>
Net income	--	--	--	5,266	--	--	--	5,266	
Other comprehensive loss	--	--	--	--	(12,327)	--	--	(12,327)	
Adoption of ASU 2020-06	--	--	(16,426)	(3,213)	--	--	--	(19,639)	
Equity compensation	252	3	7,892	--	--	--	--	7,895	
Exercise of options	158	1	1,921	--	--	--	--	1,922	
Employee stock purchase plan	87	1	1,608	--	--	--	--	1,609	
Redemption and repurchase of stock to cover tax withholdings	(75)	(1)	(1,897)	--	--	--	--	(1,898)	
<b>Balance at September 30, 2021</b>	<b>40,816</b>	<b>\$ 408</b>	<b>\$ 309,290</b>	<b>\$ 22,075</b>	<b>\$ (5,584)</b>	<b>(1,487)</b>	<b>\$ (14,648)</b>	<b>\$ 311,541</b>	

See accompanying Notes to Condensed Consolidated Financial Statements

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

	Common Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive (Loss) Income	Treasury Stock		Total Shareholders' Equity
	Shares	Amount				Shares	Amount	
	<b>Balance at June 30, 2020</b>	<b>39,288</b>				<b>\$ 393</b>	<b>\$ 293,022</b>	
Net loss	--	--	--	(2,870)	--	--	--	(2,870)
Other comprehensive income	--	--	--	--	8,698	--	--	8,698
Stock issued for Ascyrus transaction	992	10	19,990	--	--	--	--	20,000
Equity compensation	6	--	2,518	--	--	--	--	2,518
Exercise of options	3	--	31	--	--	--	--	31
Employee stock purchase plan	54	--	873	--	--	--	--	873
Redemption and repurchase of stock to cover tax withholdings	(2)	--	(40)	--	--	--	--	(40)
<b>Balance at September 30, 2020</b>	<b>40,341</b>	<b>\$ 403</b>	<b>\$ 316,394</b>	<b>\$ 23,480</b>	<b>\$ 80</b>	<b>(1,484)</b>	<b>\$ (14,591)</b>	<b>\$ 325,766</b>

	Common Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive (Loss) Income	Treasury Stock		Total Shareholders' Equity
	Shares	Amount				Shares	Amount	
	<b>Balance at December 31, 2019</b>	<b>39,018</b>				<b>\$ 390</b>	<b>\$ 271,782</b>	
Net loss	--	--	--	(13,224)	--	--	--	(13,224)
Other comprehensive income	--	--	--	--	8,669	--	--	8,669
Stock issued for Ascyrus transaction	992	10	19,990	--	--	--	--	20,000
Equity compensation	273	3	7,885	--	--	--	--	7,888
Exercise of options	47	1	517	--	--	--	--	518
Employee stock purchase plan	84	--	1,561	--	--	--	--	1,561
Equity component of the convertible note issuance	--	--	16,426	--	--	--	--	16,426
Redemption and repurchase of stock to cover tax withholdings	(73)	(1)	(1,767)	--	--	--	--	(1,768)
<b>Balance at September 30, 2020</b>	<b>40,341</b>	<b>\$ 403</b>	<b>\$ 316,394</b>	<b>\$ 23,480</b>	<b>\$ 80</b>	<b>(1,484)</b>	<b>\$ (14,591)</b>	<b>\$ 325,766</b>

See accompanying Notes to Condensed Consolidated Financial Statements

**CryoLife, 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 CryoLife, Inc. and its subsidiaries (“CryoLife,” the “Company,” “we,” or “us”). All significant intercompany accounts and transactions have been eliminated in consolidation. The accompanying Condensed Consolidated Balance Sheet as of December 31, 2020 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, 2021 and 2020 have been prepared in accordance with (i) accounting principles generally accepted in the U.S. for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U.S. Securities and Exchange Commission (the “SEC”). Accordingly, such statements do not include all the information and disclosures that are required by accounting principles generally accepted in the U.S. for a complete presentation of financial statements. In the opinion of management, all adjustments (including those of a normal, recurring nature) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021. These Condensed Consolidated Financial Statements should be read in conjunction with the Consolidated Financial Statements and Notes included in CryoLife’s Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on February 22, 2021.

**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, 2020. 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 accounting principles generally accepted in the U.S., which require us to make estimates and assumptions. We did not experience any significant changes during the three and nine months ended September 30, 2021 in any of our Significant Accounting Policies from those contained in our Form 10-K for the year ended December 31, 2020.

**New Accounting Standards**

*Recently Adopted*

In August 2020 the Financial Accounting Standards Board (the “FASB”) issued Accounting Standard Update (“ASU”) Update No. 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity’s Own Equity (Subtopic 815-40)* (“ASU 2020-06”). The update simplifies the accounting for convertible instruments by eliminating two accounting models (i.e., the cash conversion model and beneficial conversion feature model) and reducing the number of embedded conversion features that could be recognized separately from the host contract. ASU 2020-06 also enhances transparency and improves disclosures for convertible instruments and earnings per share guidance. On January 1, 2021 we adopted ASU 2020-06 using the modified retrospective approach and recorded \$20.4 million to increase long-term debt, \$3.2 million to reduce retained earnings, and \$16.4 million to reduce additional paid-in capital included on the Condensed Consolidated Balance Sheets. See Note 11 for further discussion of convertible debt.

In December 2019 the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* (“ASU 2019-12”). The amendments in this ASU simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify accounting principles generally accepted in the United States of America (“GAAP”) for other areas of Topic 740 by clarifying and amending existing guidance. The amendments are effective for public entities in fiscal years beginning after December 15, 2020 including interim periods within those fiscal years. We adopted ASU 2019-12 on January 1, 2021 and the adoption did not have a material impact on our financial condition or results of operations.



*Not Yet Effective*

In March 2020 the FASB issued ASU 2020-04, *Reference Rate Reform Topic 848* (“ASC 848”). The amendments in this ASU were put forth in response to the market transition from the LIBOR and other interbank offered rates to alternative reference rates. GAAP requires entities to evaluate whether a contract modification, such as the replacement or change of a reference rate, results in the establishment of a new contract or continuation of an existing contract. ASC 848 allows an entity to elect not to apply certain modification accounting requirements to contracts affected by reference rate reform. The standard provides this temporary election through December 31, 2022 and cannot be applied to contract modifications that occur after December 31, 2022. We are in the process of evaluating the effect that the adoption of this standard will have on our financial position and results of operations.

## **2. Sale of PerClot**

### **Overview**

On July 28, 2021 we entered into an asset purchase agreement 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 \$60.8 million in consideration (we will receive up to \$45.8 million and SMI will receive up to \$15.0 million), consisting of (i) \$25.0 million at closing, of which \$6.0 million was paid to SMI; (ii) up to \$25.0 million upon our receipt of Premarket Approval (“PMA”) approval from the U.S. Food and Drug Administration (the “FDA”) for PerClot and our transfer of the PMA to Baxter, of which up to \$6.0 million is payable to SMI, subject to certain reductions for delay in PMA approval; 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 and manufacturing and supply services relating to the sale of SMI PerClot outside of the US and manufacture and supply of PerClot to Baxter post PMA approval.

### **Accounting for the Transaction**

Upon closing of the Baxter Transaction, we received \$25.0 million from Baxter and paid \$6.0 million to SMI. We derecognized intangible assets with a carrying value of \$1.6 million and wrote-off \$1.5 million of prepaid royalties previously recorded on our Condensed Consolidated Balance Sheets related to PerClot. Under the terms of the agreement, Baxter acquired intellectual property related to our development efforts for PerClot. We recorded a pre-tax gain of \$15.9 million, included as Gain from sale of non-financial assets within the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2021. The PerClot product line was included as part of our Medical Devices segment.

## **3. Acquisition of Ascyrus**

### **Overview**

On September 2, 2020 we entered into a Securities Purchase Agreement (the “Ascyrus 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.

Under the terms of the Ascyrus Agreement, we will pay an aggregate of up to \$200.0 million in consideration, consisting of: (i) a cash payment of approximately \$60.0 million and the issuance of \$20.0 million in shares of CryoLife common stock, in each case, that were delivered at the closing of the acquisition, (ii) if the FDA approves an Investigational Device Exemption (“IDE”) application for the AMDS, a cash payment of \$10.0 million and the issuance of \$10.0 million in shares of CryoLife common stock, (iii) if the FDA approves PMA application submitted for the AMDS, a cash payment of \$25.0 million, (iv) if regulatory approval of the AMDS is obtained in Japan on or before June 30, 2027, a cash payment of \$10.0 million, (v) if regulatory approval of the AMDS is obtained in China on or before June 30, 2027, a cash payment of \$10.0 million and (vi) a potential additional consideration cash payment capped at \$55.0 million (or up to \$65.0 million to \$75.0 million if the Japanese or Chinese approvals are not secured on or before June 30, 2027 and those approval milestone payments are added to the potential additional consideration cash payment cap) calculated as two times the incremental worldwide sales of the AMDS (or any other acquired technology or derivatives of such acquired technology) outside of the European Union during the three-year period following the date the FDA approves a PMA application submitted for the AMDS.

### ***Accounting for the Transaction***

Upon closing of the acquisition on September 2, 2020 we paid \$82.4 million consisting of \$62.4 million in cash consideration and \$20.0 million in shares of CryoLife common stock. The number of shares issued was based on a 10-day moving volume weighted average closing price of a share of CryoLife common stock as of the date immediately prior to closing, resulting in an issuance of 991,800 shares of CryoLife common stock.

As part of the acquisition, we may be required to pay additional consideration in cash and equity up to \$120.0 million to the former shareholders of Ascyrus upon the achievement of certain milestones and the sales-based additional earnout described above. The fair value of the total potential purchase consideration of \$200.0 million was calculated to be \$137.8 million, which includes total purchase consideration, as well as the contingent consideration liability discussed below. Our allocation of the purchase consideration was allocated to Ascyrus’s tangible and identifiable intangible assets acquired and liabilities assumed, based on their estimated fair values as of September 2, 2020.

We recorded the contingent consideration liability of \$17.6 million and \$16.4 million in Current liabilities and \$47.3 million and \$43.5 million in Other long-term liabilities as of September 30, 2021 and December 31, 2020, respectively, in the Condensed Consolidated Balance Sheets, representing 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 presented in Note 5. 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 \$700,000 and \$5.0 million fair value adjustment for the three and nine months ended September 30, 2021, respectively, in General, administrative, and marketing expenses on the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss), as a result of this assessment.

We recorded \$62.4 million of goodwill, all of which was deductible for tax purposes, based on the amount by which the total purchase consideration price exceeded the fair value of the net assets acquired and liabilities assumed. Goodwill from this transaction primarily relates to synergies expected from the acquisition and has been allocated to our Medical devices segment. The allocation of assets acquired and liabilities assumed is based on the information available that would have been known as of the acquisition date. During the nine months ended September 31, 2021 we received a \$777,000 cash distribution from escrow related to the working capital adjustments which reduced the purchase price consideration and goodwill. This adjustment is included in other cash flows used in investing activities on the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2021.

The September 2, 2020 allocation of purchase consideration adjusted as of September 30, 2021 consisted of the following (in thousands):

<b>Consideration</b>		
Cash paid for acquisition	\$	62,359
Common stock issued		20,000
Contingent consideration		55,407
<b>Fair value of total consideration</b>	<b>\$</b>	<b>137,766</b>

#### **Purchase Price Allocation**

Cash and cash equivalents	\$	4,017
Intangible assets		72,600
Net other assets/liabilities acquired		(1,267)
Goodwill		62,416
<b>Net assets acquired</b>	<b>\$</b>	<b>137,766</b>

Pro forma financial information related to the Ascyrus Agreement has not been provided as it is not material to our consolidated results of operations. The results of operations of the Ascyrus acquisition are included in results of operations from the date of acquisition and were not significant for the three and nine months ended September 30, 2021. The results of operations of the Ascyrus acquisition are included in our Medical devices segment.

#### **4. Agreements with Endospan**

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

On September 11, 2019 CryoLife, Inc.'s wholly-owned subsidiary, JOTEC GmbH, ("JOTEC"), entered into an exclusive distribution agreement (the "Endospan Distribution Agreement") with Endospan Ltd. ("Endospan"), an Israeli corporation, pursuant to which JOTEC obtained exclusive distribution rights for Endospan's NEXUS<sup>TM</sup> stent graft system ("NEXUS") and accessories in certain countries in Europe in exchange for a fixed distribution fee of \$9.0 million paid in September 2019.

CryoLife also entered into a securities purchase option agreement (the "Endospan Option Agreement") with Endospan for \$1.0 million paid in September 2019. The Endospan Option Agreement provides CryoLife 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, within a certain period of time, or after FDA approval of NEXUS, with such option expiring if not exercised within 90 days after receiving notice that Endospan has received approval from the FDA for NEXUS.

##### ***Loan Agreement***

CryoLife and Endospan also entered into a loan agreement (the "Endospan Loan"), dated September 11, 2019, in which CryoLife 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. During September 2020 we funded the second tranche payment of \$5.0 million upon the certification of the NEXUS IDE from the FDA. The third tranche is required to be funded upon certification of enrollment of at least 50% of the required number of patients in the primary arm of the FDA approved clinical trial for NEXUS, in each case subject to Endospan's continued compliance with the Endospan Loan and certain other conditions. If a termination fee becomes payable by Endospan under the Endospan Distribution Agreement, it will be added to the amount payable to CryoLife under the Endospan Loan.

##### ***Variable Interest Entity***

We consolidate the results of a variable interest entity ("VIE") when it is determined that we are the primary beneficiary. Based on our initial evaluation of Endospan and the related agreements with Endospan, we determined that Endospan is a VIE. Although the arrangement with Endospan resulted in our holding a variable interest, it did not empower us to direct

those activities of Endospan that most significantly impact the VIE economic performance. Therefore, we are not the primary beneficiary, and we have not consolidated Endospan into our financial results. Our payments to Endospan in September 2019 totaled \$15.0 million which included a \$9.0 million distribution fee, a \$1.0 million securities purchase option, and \$5.0 million for the first tranche of the Endospan Loan. We paid an additional \$5.0 million for the second tranche described above. We evaluated Endospan for VIE classification as of September 30, 2021 and December 31, 2020 and determined that Endospan meets the criteria of a non-consolidating VIE. Our payments to date, including any loans, guarantees, and other subordinated financial support related to this VIE, totaled \$20.0 million as of September 30, 2021, representing our maximum exposure to loss, and were not individually significant to our consolidated financial statements.

### Valuation

The agreements with Endospan were entered into concurrently and had certain terms that are interrelated. In our evaluation of the initial relative fair value of each of the Endospan agreements to determine the amount to record, we utilized discounted cash flows to estimate the fair market value for the Endospan Loan and for the Endospan Distribution Agreement. We estimated the fair value of the Endospan Option Agreement utilizing the Monte Carlo simulation. The 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 as presented in Note 5. 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 the initial fair value of the Endospan Loan and the relative fair values of the Endospan Distribution Agreement and Endospan Option Agreement, we recorded the Endospan Loan value of \$358,000 in Other long-term assets in the Condensed Consolidated Balance Sheets as of December 31, 2019. The Endospan Option Agreement was valued at \$4.8 million in Other long-term assets in the Condensed Consolidated Balance Sheets as of September 30, 2021 and December 31, 2020. The Endospan Distribution Agreement was recorded at \$6.1 million and \$8.0 million in Other intangibles, net in the Condensed Consolidated Balance Sheets as of September 30, 2021 and December 31, 2020, respectively.

We elected the fair value option for recording the Endospan Loan. We assess the fair value of the Endospan Loan based on quantitative and qualitative characteristics and adjust the amount recorded to its current fair market value at each reporting period. The fair value of the Endospan Loan was \$409,000 as of September 30, 2021 and December 31, 2020.

## 5. Financial Instruments

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

<b>September 30, 2021</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Cash equivalents:</b>				
Money market funds	\$ 10,012	\$ --	\$ --	\$ 10,012
<b>Restricted securities:</b>				
Money market funds	538	--	--	538
Endospan loan	--	--	409	409
<b>Total assets</b>	<b>\$ 10,550</b>	<b>\$ --</b>	<b>\$ 409</b>	<b>\$ 10,959</b>
<b>Current liabilities:</b>				
Contingent consideration	--	--	(17,600)	(17,600)
<b>Long-term liabilities:</b>				
Contingent consideration	--	--	(47,300)	(47,300)
<b>Total liabilities</b>	<b>\$ --</b>	<b>\$ --</b>	<b>\$ (64,900)</b>	<b>\$ (64,900)</b>

<b>December 31, 2020</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Cash equivalents:</b>				
Money market funds	\$ 11,484	\$ --	\$ --	\$ 11,484
<b>Restricted securities:</b>				
Money market funds	546	--	--	546
Endospan loan	--	--	409	409
<b>Total assets</b>	<b>\$ 12,030</b>	<b>\$ --</b>	<b>\$ 409</b>	<b>\$ 12,439</b>
<b>Current liabilities:</b>				
Contingent consideration	--	--	(16,430)	(16,430)
<b>Long-term liabilities:</b>				
Contingent consideration	--	--	(43,500)	(43,500)
<b>Total liabilities</b>	<b>\$ --</b>	<b>\$ --</b>	<b>\$ (59,930)</b>	<b>\$ (59,930)</b>

We used prices quoted from our investment advisors to determine the Level 1 valuation of our investments in money market funds. We recorded the Endospan Loan, classified as Level 3, as a result of an agreement with Endospan in September 2019. The fair value of the contingent consideration component of the Ascyrus acquisition was updated using Level 3 inputs. See Note 3 and Note 4 for further discussion of the Ascyrus acquisition and the Endospan Loan, respectively. Changes in fair value of Level 3 assets and liabilities are listed in the tables below (in thousands):

	<b>Endospan Loan</b>	<b>Contingent Consideration</b>
Balance as of December 31, 2020	\$ 409	\$ (59,930)
Change in valuation	--	(4,970)
Balance as of September 30, 2021	<b>\$ 409</b>	<b>\$ (64,900)</b>

## 6. Cash Equivalents and Restricted Securities

The following is a summary of cash equivalents and restricted securities (in thousands):

<b>September 30, 2021</b>	<b>Cost Basis</b>	<b>Unrealized Holding Gains</b>	<b>Estimated Market Value</b>
<b>Cash equivalents:</b>			
Money market funds	\$ 10,012	\$ --	\$ 10,012
<b>Restricted securities:</b>			
Money market funds	538	--	538
<b>Total assets</b>	<b>\$ 10,550</b>	<b>\$ --</b>	<b>\$ 10,550</b>

<b>December 31, 2020</b>	<b>Cost Basis</b>	<b>Unrealized Holding Gains</b>	<b>Estimated Market Value</b>
<b>Cash equivalents:</b>			
Money market funds	\$ 11,484	\$ --	\$ 11,484
<b>Restricted securities:</b>			
Money market funds	546	--	546
<b>Total assets</b>	<b>\$ 12,030</b>	<b>\$ --</b>	<b>\$ 12,030</b>

As of September 30, 2021 and December 31, 2020 \$538,000 and \$546,000, respectively, of our money market funds were designated as short-term restricted securities due to a contractual commitment to hold the securities as pledged collateral relating to international tax obligations.

There were no gross realized gains or losses on cash equivalents and restricted securities for the three and nine months ended September 30, 2021 and 2020. As of September 30, 2021 \$538,000 of our restricted securities had a maturity date within three months. As of December 31, 2020 \$546,000 of our restricted securities had a maturity date within three months.

## 7. Inventories, net and Deferred Preservation Costs

Inventories at September 30, 2021 and December 31, 2020 were comprised of the following (in thousands):

	September 30, 2021	December 31, 2020
Raw materials and supplies	\$ 34,005	\$ 33,625
Work-in-process	12,438	6,318
Finished goods	31,876	33,095
<b>Total inventories, net</b>	<b>\$ 78,319</b>	<b>\$ 73,038</b>

To facilitate product usage, we maintain consignment inventory of our On-X heart valves at domestic hospital locations and On-X heart valves, JOTEC, and AMDS products at international hospital locations. We retain title and control over this consignment inventory until the device is implanted, at which time we invoice the hospital and recognize revenue. As of September 30, 2021 we had \$14.7 million in consignment inventory, with approximately 41% in domestic locations and 59% in international locations. As of December 31, 2020 we had \$11.9 million in consignment inventory, with approximately 47% in domestic locations and 53% in international locations.

Total deferred preservation costs were \$42.6 million and \$36.5 million as of September 30, 2021 and December 31, 2020, respectively.

Inventory and deferred preservation costs obsolescence reserves were \$2.8 million and \$3.5 million as of September 30, 2021 and December 31, 2020, respectively.

## 8. Goodwill and Other Intangible Assets

### *Indefinite Lived Intangible Assets*

As of September 30, 2021 and December 31, 2020 the carrying values of our indefinite lived intangible assets were as follows (in thousands):

	September 30, 2021	December 31, 2020
Goodwill	\$ 252,441	\$ 260,061
In-process R&D	2,258	2,392
Procurement contracts and agreements	2,013	2,013
Trademarks <sup>a</sup>	397	765

<sup>a</sup> During the three and nine months ended September 30, 2021 we transferred \$380,000 of PerClot related trademarks to Baxter as a result of the Baxter Transaction described in Note 2.

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.

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 believe that our trademarks have indefinite useful lives as we currently anticipate that our trademarks will contribute to our cash flows indefinitely.

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, 2021 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, 2021 and December 31, 2020 our entire goodwill balance was related to our Medical devices segment.

	<b>Medical Devices Segment</b>
Balance as of December 31, 2020	\$ 260,061
Ascyrus acquisition	(942)
Revaluation of goodwill denominated in foreign currency	(6,678)
<b>Balance as of September 30, 2021</b>	<b>\$ 252,441</b>

### **Definite Lived Intangible Assets**

The definite lived intangible balance includes balances related to acquired technology, customer relationships, distribution and manufacturing rights and know-how, patents, and other definite lived intangible assets. During the three and nine months ended September 30, 2021 we transferred \$1.2 million of PerClot related distribution and manufacturing rights to Baxter as a result of the Baxter Transaction described in Note 2. As of September 30, 2021 and December 31, 2020 the gross carrying values, accumulated amortization, and approximate amortization period of our definite lived intangible assets were as follows (in thousands):

<b>September 30, 2021</b>	<b>Gross Carrying Value</b>	<b>Accumulated Amortization</b>	<b>Amortization Period</b>
Acquired technology	\$ 215,917	\$ 44,129	11 – 22 Years
Customer lists and relationships	31,192	9,248	13 – 22 Years
Distribution and manufacturing rights and know-how	10,068	3,933	5 – 15 Years
Patents	4,041	3,136	17 Years
Other	3,938	1,589	4 – 5 Years

<b>December 31, 2020</b>	<b>Gross Carrying Value</b>	<b>Accumulated Amortization</b>	<b>Amortization Period</b>
Acquired technology	\$ 222,182	\$ 36,091	11 – 22 Years
Customer lists and relationships	31,316	8,132	13 – 22 Years
Distribution and manufacturing rights and know-how	14,728	5,349	5 – 15 Years
Patents	3,966	3,113	17 Years
Other	3,453	1,073	4 – 5 Years

### **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>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
Amortization expense	\$ 4,203	\$ 3,397	\$ 12,701	\$ 9,430

As of September 30, 2021 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	<b>Remainder of 2021</b>	<b>2022</b>	<b>2023</b>	<b>2024</b>	<b>2025</b>	<b>2026</b>	<b>Total</b>
Amortization expense	\$ 4,121	15,944	15,434	15,050	13,002	12,771	\$ 76,322

## 9. Income Taxes

### *Income Tax Expense*

Our effective income tax rate was a benefit of 33% and 318% for the three and nine months ended September 30, 2021, respectively, as compared to a benefit of 31% and 23% for the three and nine months ended September 30, 2020, respectively. The change in the tax rate for the three and nine months ended September 30, 2021 is primarily due to changes in pre-tax book loss, the excess tax benefit related to stock compensation, and the estimated current year valuation allowance, as compared to the three and nine months ended September 30, 2020. We utilized the interim reporting guidance of ASC 740 to calculate the effective tax rate for the three and nine months ended September 30, 2021 and 2020. We expect the effective income tax rate for the twelve months ended December 31, 2021 to be more in line with applicable statutory tax rates.

The income tax rate for the three and nine months ended September 30, 2021 was favorably impacted by excess tax benefit deductions related to stock compensation, the research and development tax credit, and the reduction of a valuation allowance on prior year items. The tax rate was unfavorably impacted by non-deductible operating expenses, executive compensation expenses, an increase in the valuation allowance on current year items, and the recording of a tax reserve on prior year items.

The income tax rate for the three and nine months ended September 30, 2020 was favorably impacted by excess tax benefit deductions related to stock compensation and the research and development tax credit. These factors were partially offset by the unfavorable impacts of non-deductible operating expenses and executive compensation expenses.

### *Deferred Income Taxes*

We generate deferred tax assets primarily as a result of the difference in fixed asset depreciation lives for book and tax purposes, accruals for which the timing of deductibility is different for book and tax purposes, the timing of tax deductions related to stock compensation, interest expense disallowances, and operating losses. We believe our utilization of net operating losses from previous transactions will not have a material impact on income taxes for the 2021 tax year.

As of September 30, 2021 we maintained a total of \$11.6 million in valuation allowances against deferred tax assets, including state and federal net operating loss carryforwards and interest expense disallowance carryforwards, and a net deferred tax liability of \$23.4 million. As of December 31, 2020 we maintained a total of \$7.2 million in valuation allowances against deferred tax assets, including state and federal net operating loss carryforwards, and a net deferred tax liability of \$33.3 million.

During the nine months ended September 30, 2021 we corrected certain immaterial prior year errors primarily related to the release of a valuation allowance, reduction of income taxes payable, and an increase in the tax reserve. On correcting the errors, we recorded an income tax benefit of \$2.1 million.

### *The Coronavirus Aid, Relief and Economic Security Act ("CARES Act")*

In response to the novel coronavirus disease ("COVID-19") pandemic, the U.S. government enacted the CARES Act on March 27, 2020. The CARES Act provided various forms of relief and assistance to U.S. businesses. We recorded a reduction to income taxes payable and deferred tax assets of approximately \$1.3 million for the change to the 2019 Section 163(j) interest expense deduction limitation for the three months ended March 2020.

## 10. 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.

On January 6, 2021 we executed a modification to extend the lease of our headquarters located in Kennesaw, Georgia. This modification resulted in an increase in the present value of future lease obligations and corresponding right-of-use asset of \$23.3 million, using a discount rate of 6.41%.



On June 1, 2021 we began occupancy of the newly constructed addition to our leased JOTEC headquarters located in Hechingen, Germany. This lease resulted in an increase in the present value of future lease obligations and corresponding right-of-use asset of \$9.8 million, using a discount rate of 5.46%.

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

	<b>September 30, 2021</b>		<b>December 31, 2020</b>	
<b>Operating leases:</b>				
Operating lease right-of-use assets	\$	58,429	\$	28,242
Accumulated amortization		(11,516)		(9,671)
<b>Operating lease right-of-use assets, net</b>	<b>\$</b>	<b>46,913</b>	<b>\$</b>	<b>18,571</b>
Current maturities of operating leases	\$	3,053	\$	5,763
Non-current maturities of operating leases		45,765		14,034
<b>Total operating lease liabilities</b>	<b>\$</b>	<b>48,818</b>	<b>\$</b>	<b>19,797</b>
<b>Finance leases:</b>				
Property and equipment, at cost	\$	6,910	\$	7,620
Accumulated amortization		(2,014)		(1,905)
<b>Property and equipment, net</b>	<b>\$</b>	<b>4,896</b>	<b>\$</b>	<b>5,715</b>
Current maturities of finance leases	\$	537	\$	614
Non-current maturities of finance leases		4,608		5,300
<b>Total finance lease liabilities</b>	<b>\$</b>	<b>5,145</b>	<b>\$</b>	<b>5,914</b>
<b>Weighted average remaining lease term (in years):</b>				
Operating leases		12.4		5.1
Finance leases		9.1		9.8
<b>Weighted average discount rate:</b>				
Operating leases		5.9%		5.2%
Finance leases		2.0%		2.0%

Current maturities of finance leases are included as a component of Other current liabilities and non-current maturities of finance leases are included as a component of Other long-term 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) are as follows (in thousands):

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
Amortization of property and equipment	\$ 190	\$ 164	\$ 500	\$ 487
Interest expense on finance leases	27	30	85	89
<b>Total finance lease expense</b>	<b>217</b>	<b>194</b>	<b>585</b>	<b>576</b>
Operating lease expense	1,989	1,806	5,566	5,324
Sublease income	(92)	(226)	(308)	(679)
<b>Total lease expense</b>	<b>\$ 2,114</b>	<b>\$ 1,774</b>	<b>\$ 5,843</b>	<b>\$ 5,221</b>

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

	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	\$ 4,536	\$ 5,438
Financing cash flows for finance leases	446	465
Operating cash flows for finance leases	82	92

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

	Finance Leases	Operating Leases	Sublease Income
Remainder of 2021	\$ 134	\$ 680	\$ 92
2022	642	6,009	305
2023	641	6,601	--
2024	635	6,212	--
2025	612	5,282	--
Thereafter	2,963	46,618	--
<b>Total minimum lease payments</b>	<b>\$ 5,627</b>	<b>\$ 71,402</b>	<b>\$ 397</b>
Less amount representing interest	(482)	(22,584)	
Present value of net minimum lease payments	5,145	48,818	
Less current maturities	(537)	(3,053)	
<b>Lease liabilities, less current maturities</b>	<b>\$ 4,608</b>	<b>\$ 45,765</b>	

## 11. Debt

### Credit Agreement

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

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

As discussed in our Annual Report on Form 10-K for the year ended December 31, 2020, the Credit Agreement contains certain customary affirmative and negative covenants, including covenants that limit our ability and the ability of our subsidiaries to, among other things, grant liens, incur debt, dispose of assets, make loans and investments, make acquisitions, make certain restricted payments (including cash dividends), merge or consolidate, change business or accounting or reporting practices, in each case subject to customary exceptions for a credit facility of this size and type. Beginning in 2021, if we repay borrowings under our Revolving Credit Facility to 25% or less, no financial maintenance covenants, including the minimum liquidity covenant and the maximum first lien net leverage ratio covenant, are applicable. We are in compliance with our debt covenants as of September 30, 2021.

### **Convertible Senior Notes**

On June 18, 2020 we issued \$100.0 million aggregate principal amount of 4.25% Convertible Senior Notes with a maturity date of July 1, 2025 (the "Convertible Senior Notes"). The net proceeds from this offering, after deducting initial purchasers' discounts and costs directly related to this offering, were approximately \$96.5 million. On January 1, 2021 we adopted ASU 2020-06 and adjusted the carrying balance of the Convertible Senior Notes to notional. The Convertible Senior Notes balance was \$100.0 million recorded in Long-term debt on the Condensed Consolidated Balance Sheets as of September 30, 2021. 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, 2021 was approximately \$124.2 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 approximately \$1.2 million and \$3.7 million for the aggregate of the contractual coupon interest, and the amortization of the debt issuance costs as of the three and nine months ended September 30, 2021, respectively. The interest expense recognized on the Convertible Senior Notes includes approximately \$2.0 million and \$2.2 million for the aggregate of the contractual coupon interest, the accretion of the debt discount, and the amortization of the debt issuance costs as of three and nine months ended September 30, 2020, respectively. Interest on the Convertible Senior Notes began accruing upon issuance and is payable semi-annually. As of September 30, 2021 there were \$2.7 million of unamortized debt issuance costs related to convertible senior notes.

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

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

**Loan Balances**

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

	September 30, 2021	December 31, 2020
Term loan balance	\$ 216,563	\$ 218,250
Convertible senior notes	100,000	79,555
2.45% Sparkasse Zollernalb (KFW Loan 1)	643	886
1.40% Sparkasse Zollernalb (KFW Loan 2)	1,157	1,457
Total loan balance	318,363	300,148
Less unamortized loan origination costs	(8,958)	(8,485)
Net borrowings	309,405	291,663
Less short-term loan balance	(1,640)	(1,195)
Long-term loan balance	\$ 307,765	\$ 290,468

**Interest Expense**

Interest expense was \$4.1 million and \$13.0 million for the three and nine months ended September 30, 2021, respectively, as compared to \$4.9 million and \$12.0 million for the three and nine months ended September 30, 2020, respectively. Interest expense includes interest on debt and uncertain tax positions in both periods.

**12. 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, 2021 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.

**13. Revenue Recognition****Sources of Revenue**

We have identified the following revenues disaggregated by revenue source:

- Domestic hospitals – direct sales of products and preservation services.
- International hospitals – direct sales of products and preservation services.
- International distributors – generally these contracts specify a geographic area that the distributor will service, terms and conditions of the relationship, and purchase targets for the next calendar year.
- CardioGenesis cardiac laser console trials and sales – CardioGenesis cardiac trialed laser consoles are delivered under separate agreements.

For the three and nine months ended September 30, 2021 and 2020 the sources of revenue were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(Unaudited)		(Unaudited)	
Domestic hospitals	\$ 36,129	\$ 36,249	\$ 111,291	\$ 102,813
International hospitals	25,458	20,764	79,219	56,638
International distributors	10,544	8,035	28,694	25,522
CardioGenesis cardiac laser therapy	76	83	238	358
<b>Total sources of revenue</b>	<b>\$ 72,207</b>	<b>\$ 65,131</b>	<b>\$ 219,442</b>	<b>\$ 185,331</b>

Also see segment disaggregation information in Note 16 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, 2021 and 2020.

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, 2021 and 2020 was not material.

## **14. Stock Compensation**

### **Overview**

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

### **Equity Grants**

During the nine months ended September 30, 2021 the Compensation Committee of our Board of Directors (the “Committee”) authorized awards from approved stock incentive plans of RSUs to certain employees, RSAs to non-employee Directors, and RSAs and PSUs to certain Company officers, which, assuming that performance under the PSUs were to be achieved at target levels, together totaled 494,000 shares and had an aggregate grant date market value of \$12.5 million.

During the nine months ended September 30, 2020 the Committee authorized awards from approved stock incentive plans of RSUs to certain employees, RSAs to non-employee Directors, and RSAs and PSUs to certain Company officers, which, assuming that performance under the PSUs were to be achieved at target levels, together totaled 330,000 shares and had an aggregate grant date market value of \$8.2 million. In February 2021, the Committee used structured discretion to determine that the 2020 PSUs were earned and should be paid out at 100% of target resulting in a modification of the award which resulted in \$1.2 million of compensation expense during the nine months ended September 30, 2021 related to these performance awards.

The Committee authorized, from approved stock incentive plans, grants of stock options to purchase a total of 226,000 and 212,000 shares to certain Company officers during the nine months ended September 30, 2021 and 2020, respectively. The exercise prices of the options were equal to the closing stock prices on their respective grant dates.

Employees purchased common stock totaling 51,000 and 87,000 shares in the three and nine months ended September 30, 2021, respectively, as compared to 54,000 and 84,000 shares in the three and nine months ended September 30, 2020, respectively, through the ESPP.

**Stock Compensation Expense**

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

	Three Months Ended September 30, 2021		Nine Months Ended September 30, 2021	
	Stock Options	ESPP	Stock Options	ESPP
Expected life	N/A	0.5 Years	5.0 Years	0.5 Years
Expected stock price volatility	N/A	0.44	0.40	0.46
Risk-free interest rate	N/A	0.05%	0.57%	0.09%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
RSA, RSU, and PSU expense	\$ 2,465	\$ 1,984	\$ 6,211	\$ 6,189
Stock option and ESPP expense	525	534	1,684	1,699
<b>Total stock compensation expense</b>	<b>\$ 2,990</b>	<b>\$ 2,518</b>	<b>\$ 7,895</b>	<b>\$ 7,888</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 \$115,000 and \$424,000 in the three and nine months ended September 30, 2021, respectively, and \$160,000 and \$456,000 in the three and nine months ended September 30, 2020, respectively, of the stock compensation expense into our inventory costs and deferred preservation costs.

## 15. Earnings (Loss) per Common Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Basic income (loss) per common share</b>				
Net income (loss)	\$ 10,582	\$ (2,870)	\$ 5,266	\$ (13,224)
Net (income) loss allocated to participating securities	(63)	20	(34)	93
<b>Net income (loss) allocated to common shareholders</b>	<b>\$ 10,519</b>	<b>\$ (2,850)</b>	<b>\$ 5,232</b>	<b>\$ (13,131)</b>
<b>Basic weighted-average common shares outstanding</b>	<b>39,086</b>	<b>37,912</b>	<b>38,924</b>	<b>37,608</b>
<b>Basic income (loss) per common share</b>	<b>\$ 0.27</b>	<b>\$ (0.08)</b>	<b>\$ 0.13</b>	<b>\$ (0.35)</b>
<b>Diluted income (loss) per common share</b>				
Net income (loss)	\$ 10,582	\$ (2,870)	\$ 5,266	\$ (13,224)
Net (income) loss allocated to participating securities	(55)	20	(34)	93
Net loss attributable to convertible senior notes	919	--	--	--
<b>Net income (loss) allocated to common shareholders</b>	<b>\$ 11,446</b>	<b>\$ (2,850)</b>	<b>\$ 5,232</b>	<b>\$ (13,131)</b>
Basic weighted-average common shares outstanding	39,086	37,912	38,924	37,608
Effect of dilutive stock options and awards	505	--	572	--
Effect of convertible senior notes	4,862	--	--	--
<b>Diluted weighted-average common shares outstanding</b>	<b>44,453</b>	<b>37,912</b>	<b>39,496</b>	<b>37,608</b>
<b>Diluted income (loss) per common share</b>	<b>\$ 0.26</b>	<b>\$ (0.08)</b>	<b>\$ 0.13</b>	<b>\$ (0.35)</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 and nine months ended September 30, 2021 539,000 and 517,000 of potential common shares relating to stock options, respectively, were antidilutive and excluded from the calculation of diluted weighted-average common shares outstanding. For the three and nine months ended September 30, 2020 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. We excluded 4,860,685 of potential common shares related to our Convertible Senior Notes calculated under the if-converted method, as these shares would be antidilutive for the nine months ended September 30, 2021.

## 16. 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 stents and stent grafts, surgical sealants, On-X, and other product revenues. Aortic stents and stent grafts include JOTEC, AMDS, and NEXUS product revenues. Surgical sealants include BioGlue Surgical Adhesive product revenues. 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,	
	2021	2020	2021	2020
<b>Revenues:</b>				
Medical devices	\$ 53,107	\$ 45,109	\$ 162,528	\$ 128,797
Preservation services	19,100	20,022	56,914	56,534
<b>Total revenues</b>	<b>72,207</b>	<b>65,131</b>	<b>219,442</b>	<b>185,331</b>
<b>Cost of products and preservation services:</b>				
Medical devices	15,503	12,998	46,592	36,078
Preservation services	8,915	9,001	26,710	26,060
<b>Total cost of products and preservation services</b>	<b>24,418</b>	<b>21,999</b>	<b>73,302</b>	<b>62,138</b>
<b>Gross margin:</b>				
Medical devices	37,604	32,111	115,936	92,719
Preservation services	10,185	11,021	30,204	30,474
<b>Total gross margin</b>	<b>\$ 47,789</b>	<b>\$ 43,132</b>	<b>\$ 146,140</b>	<b>\$ 123,193</b>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Products:</b>				
Aortic stents and stent grafts	\$ 20,896	\$ 15,290	\$ 62,165	\$ 43,932
Surgical sealants	16,544	15,811	52,236	44,985
On-X	14,022	12,067	41,843	34,385
Other	1,645	1,941	6,284	5,495
<b>Total products</b>	<b>53,107</b>	<b>45,109</b>	<b>162,528</b>	<b>128,797</b>
Preservation services	19,100	20,022	56,914	56,534
<b>Total revenues</b>	<b>\$ 72,207</b>	<b>\$ 65,131</b>	<b>\$ 219,442</b>	<b>\$ 185,331</b>



## 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 of the COVID-19 pandemic on product demand and our product sales, business operations, manufacturing operations, supply chain, cash flow, workforce, clinical and regulatory timelines, and our research and development projects;
- Our belief that our distributors may delay or reduce purchases of products in U.S. Dollars depending on the relative price of goods in their local currencies;
- Our beliefs that the use of surgical adhesives and sealants, with or without sutures and staples, in certain areas can enhance the efficacy of certain procedures through more effective and rapid wound closure;
- Our beliefs and anticipation regarding the favorable attributes and benefits of our products, the basis on which our products compete, our physician education activities, the advantages of our relationships with organ and tissue procurement organizations and tissue banks, the FDA classification of our medical devices, our compliance with applicable laws and regulations, and the advantages of our intellectual property and its significance to our segments and our business as a whole, our relations with our employees, timelines regarding product launches and regulatory certifications, clearances, renewals, and approvals;
- Our beliefs about potential competition and competitive products, potential adverse regulatory consequences, potential security vulnerabilities, and the associated potential adverse effects on our business;
- Our beliefs about the impact of the contaminated saline solution and the tissue processed with contaminated saline solution we identified in the fourth quarter of 2020;
- Our beliefs regarding our global expansion efforts, including the international growth opportunity that would be provided by obtaining regulatory approval for BioGlue in China;
- 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 clinical trial milestones for the regulatory approvals of the NEXUS stent graft system in the U.S. and the AMDS globally;
- Our beliefs regarding the fair value of our business development activities and the estimates and assumptions about the future achievements of milestones and future revenues and cash flows related to those business development activities, including our ability to achieve the milestones in the Baxter Transaction;
- Our beliefs about the present value and potential impairment of our intangible assets and leases;
- Our beliefs about the timing for handpiece availability and CardioGenesis cardiac laser therapy revenue;
- Our beliefs regarding the impact alternative anticoagulation therapy may have on the number of patients choosing On-X mechanical heart valves;
- 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 stents and stent grafts, and BioGlue products, and for research and development for new products despite reduced planned spending due to COVID-19 and that our efforts to develop new products and technologies 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 of clinical research work and regulatory approvals for and expected distribution of products or indications, including On-X, aortic stents and stent grafts, and BioGlue products, and CryoValve SGPV if the FDA reclassifies allograft heart valves as Class III medical devices;
- Our beliefs and expectations regarding the utilization of net operating loss carryforwards from our acquisitions of JOTEC, On-X, Hemosphere, Inc., and Cardiogenesis Corporation;
- Our beliefs about our operating results which may fluctuate significantly on a periodic basis as a result of internal and external factors, including reduced demand for our products, availability of products, materials, and supplies, strategic actions we take such as acquisitions or divestitures, unanticipated costs and expenses, market reception of our new or improved product offerings, and interest rate and currency fluctuations; and
- Other statements regarding projections of future financial and business performance; anticipated growth and trends in our business and the markets relevant to our business, including as our growth relates to our competitors; 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 such statements are originally made based on certain assumptions and analyses made by us in light of our experience and our perception of historical trends, current conditions, and expected future developments as well as other factors we believe are appropriate in the circumstances and are subject to a number of risks, uncertainties, estimates, and assumptions. Whether actual results and developments will conform with our expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially and adversely from our expectations, including, without limitation, in addition to those specified in the text surrounding such statements, the risks described in Part II, Item 1A, “Risks Factors” in this Form 10-Q and elsewhere throughout this report, the risks described in our other filings with the Securities and Exchange Commission including the risks described in Part I, Item 1A, “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2020 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**

CryoLife, Inc. (“CryoLife,” 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 stents and stent grafts, surgical sealants, On-X<sup>®</sup> mechanical heart valves and related surgical products, and implantable human tissues. Aortic stents and stent grafts include JOTEC<sup>®</sup> stent grafts and surgical products (“JOTEC” products), the Ascyrus Medical Dissection Stent hybrid prosthesis (“AMDS”), and the NEXUS<sup>™</sup> endovascular stent graft system (“NEXUS”). Surgical sealants include BioGlue<sup>®</sup> Surgical Adhesive (“BioGlue”) products. In addition to these four major product families, we sell or distribute PhotoFix<sup>®</sup> bovine surgical patches,

CardioGenesis<sup>®</sup> cardiac laser therapy products, and chorioamniotic allografts (previously marketed as NeoPatch<sup>®</sup>), and PerClot<sup>®</sup> hemostatic powder (prior to the Baxter Transaction, described below).

We reported quarterly revenues of \$72.2 million for the three months ended September 30, 2021, an 11% increase from the three months ended September 30, 2020. The increase in revenues for the three months ended September 30, 2021 was primarily due to increases in revenues from aortic stents and stent grafts, On-X, and surgical sealants product revenues, partially offset by decreases in other product revenues and preservation services revenues.

See the “Results of Operations” section below for additional analysis of the three and nine months ended September 30, 2021.

### **Sale of PerClot**

On July 28, 2021 we entered into an asset purchase agreement 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 \$60.8 million in consideration (we will receive up to \$45.8 million and SMI will receive up to \$15.0 million), consisting of (i) \$25.0 million at closing, of which \$6.0 million was paid to SMI; (ii) up to \$25.0 million upon our receipt of Premarket Approval (“PMA”) approval from the U.S. Food and Drug Administration (the “FDA”) for PerClot and our transfer of the PMA to Baxter, of which up to \$6.0 million is payable to SMI, subject to certain reductions for delay in PMA approval; 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 and manufacturing and supply services relating to the sale of SMI PerClot outside of the US and manufacture and supply of PerClot to Baxter post PMA approval.

### **Effects of COVID-19**

In December 2019 an outbreak of a respiratory illness caused by a new coronavirus named “2019-nCoV” (“COVID-19”) was detected, and by March 11, 2020, the World Health Organization (“WHO”) declared the COVID-19 outbreak a “pandemic.”

Beginning in March 2020 we took steps to address the potential impact of COVID-19 on our employees and operations, and to preserve cash, including reducing expenditures and delaying investments. These steps included, but were not limited to, implementing specific protocols to minimize workplace exposures to COVID-19 by our employees; implementing remote work arrangements for most employees we deemed able to do so; restricting business travel; issuing \$100.0 million in aggregate principal amount convertible senior notes (“Convertible Senior Notes”); using portions of those proceeds to repay our Revolving Credit Facility and the remainder for general corporate purposes (see the “Liquidity and Capital Resources” identified in Part I, Item 2 of this form 10-Q for further detail of this transaction); implementing hiring restrictions; reducing planned expenditures on some pending clinical trials; imposing senior management cash salary reductions in exchange for cash payments in the second quarter of 2021; requiring our Board of Directors to accept CryoLife stock instead of cash compensation for a six month period through October 2020; and suspending for seven months 2020 management merit increases.

Our efforts to protect our supply chain and reduce the spread of COVID-19 among our employees, including our work-from-home arrangements, were successful in 2020 and through the first three quarters of 2021 as we continued to operate all manufacturing sites at full production. These efforts have not materially affected our ability to maintain our business operations, including the operation of financial reporting systems, internal control over financial reporting, or disclosure controls and procedures; however, there is no guarantee that these efforts and arrangements, if they are continued, will continue to be successful in the future. Further, our reductions or delays in expenditures slowed our progress on certain key R&D initiatives and could in the future continue to adversely impact our business operations or further delay our recovery from the pandemic.

Although we have scaled back most of our COVID-19 mitigation efforts, we continue to monitor the impact of the COVID-19 pandemic on our business and recognize that it could continue to negatively impact our business and results of operations during the remainder of 2021 and beyond. As an example, the COVID-19 pandemic reportedly has impacted the global supply chain. 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. As global economies have begun to emerge from the COVID-19 downturn, the expiration of COVID-related hiring freezes, increased opportunities for remote work, and increasing compensation pressure have resulted in a war for talent and an unprecedented number of career changes. The resulting worker shortages at all levels have impacted supply chains and distribution channels and employers' and our own ability to adequately staff operations. Impact from these shortages in the third quarter, including a shortage of trained staff capable of meeting the increased demand associated with releasing quarantined tissue, have impacted and may impact our operations going forward. Increasing portions of our operations are being impacted by public and private vaccine mandates which can impact hospital staffing, impact our specialized workforce, and impact the global supply chain, all of which can directly or indirectly impact our product sales, business operations, manufacturing operations, workforce, and research and development projects. The extent to which our operations and financial performance will be impacted by the pandemic during the remainder of 2021 will depend largely on future developments, including the impact of vaccine mandates on the spread of COVID-19, global availability and acceptance of vaccines, the prevalence of vaccine mandates generally, the emergence and prevalence of more virulent COVID-19 variants, disruptions to workforce availability, and any continuing impact on the global supply chain. If COVID-19 or its variants become more contagious, if efforts to further contain the effects of COVID-19 or its variants, including vaccine mandates or adoption, are unsuccessful, if COVID-19, its variants, or disruptions to the global supply chain impact our supply chain or employee availability or productivity, or if we continue to experience periods of uncertainty due to COVID-19 or its variants, it could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

See the "Risk Factors" identified in Part II, Item 1A of this form 10-Q for risks related to COVID-19.

#### **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)*
**Revenues**

	Revenues for the Three Months Ended September 30,		Percent Change From Prior Year	Revenues as a Percentage of Total Revenues for the Three Months Ended September 30,	
	2021	2020		2021	2020
	Products:				
Aortic stents and stent grafts	\$ 20,896	\$ 15,290	37%	29%	24%
Surgical sealants	16,544	15,811	5%	23%	24%
On-X	14,022	12,067	16%	19%	19%
Other	1,645	1,941	-15%	3%	3%
<b>Total products</b>	<b>53,107</b>	<b>45,109</b>	<b>18%</b>	<b>74%</b>	<b>70%</b>
Preservation services	19,100	20,022	-5%	26%	30%
<b>Total</b>	<b>\$ 72,207</b>	<b>\$ 65,131</b>	<b>11%</b>	<b>100%</b>	<b>100%</b>

	Revenues for the Nine Months Ended September 30,		Percent Change From Prior Year	Revenues as a Percentage of Total Revenues for the Nine Months Ended September 30,	
	2021	2020		2021	2020
	Products:				
Aortic stents and stent grafts	\$ 62,165	\$ 43,932	42%	28%	23%
Surgical sealants	52,236	44,985	16%	24%	24%
On-X	41,843	34,385	22%	19%	19%
Other	6,284	5,495	14%	3%	3%
<b>Total products</b>	<b>162,528</b>	<b>128,797</b>	<b>26%</b>	<b>74%</b>	<b>69%</b>
Preservation services	56,914	56,534	1%	26%	31%
<b>Total</b>	<b>\$ 219,442</b>	<b>\$ 185,331</b>	<b>18%</b>	<b>100%</b>	<b>100%</b>

Revenues increased 11% and 18% for the three and nine months ended September 30, 2021, respectively, as compared to the three and nine months ended September 30, 2020. The increase in revenues for the three months ended September 30, 2021 was primarily due to increases in revenues from aortic stents and stent grafts, On-X, and surgical sealants product revenues, partially offset by decreases in other product revenues and preservation services revenues. The increase in revenues for the nine months ended September 30, 2021 was due to increases in revenues from all products and preservation services. Excluding the effects for foreign exchange, revenues increased 10% and 16% for the three and nine months ended September 30, 2021, respectively, as compared to the three and nine months ended September 30, 2020. Revenues for the three and nine months ended September 30, 2021 and 2020 were negatively impacted in certain regions by delays or cancellations of some surgical procedures as a result of reduced hospital capacity and staffing and hospital restrictions due to the COVID-19 pandemic. Additionally, reduced hospital staffing and restricted access resulting from COVID-19 have impacted the adoption rates for newly acquired or newly released products. The revenue impact from COVID-19 was smaller and varied regionally during the three and nine months ended September 30, 2021 as compared to the three and nine months ended September 30, 2020 with the largest negative impact during the three months ended June 30, 2020. A detailed discussion of the changes in product revenues and preservation services revenues for the three and nine months ended September 30, 2021 is presented below.

**Products**

Revenues from products increased 18% and 26% for the three and nine months ended September 30, 2021, respectively, as compared to the three and nine months ended September 30, 2020. The increase for the three months ended September 30, 2021 was primarily due to increases in revenues from aortic stents and stent grafts, On-X, and surgical sealants product

revenues, partially offset by decreases in other product revenues. The increase in revenues for the nine months ended September 30, 2021 was due to increases in revenues from all products. A discussion of the changes in product revenues for aortic stents and stent grafts, surgical sealants, On-X, and other product revenues is presented below.

Sales of certain products through our direct sales force and distributors across Europe and various other countries are denominated in a variety of currencies including Euros, British Pounds, Polish Zlotys, Swiss Francs, Brazilian Reals, and Canadian Dollars, with a concentration denominated in Euros. Each currency is subject to exchange rate fluctuations. For the three and nine months ended September 30, 2021 as compared to the three and nine months ended September 30, 2020, the U.S. Dollar weakened in comparison to major currencies, resulting in revenue increases when these foreign currency denominated transactions were translated into U.S. 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 U.S. 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 U.S. Dollars depending on the relative price of these goods in their local currencies.

#### *Aortic Stents and Stent Grafts*

Aortic stents and stent grafts, including JOTEC, AMDS, and NEXUS products are used in endovascular and open vascular and cardiac surgery as well as for the treatment of complex aortic arch and thoracic aortic diseases. Our aortic stents and stent grafts are primarily distributed in international markets.

On September 11, 2019 CryoLife and its wholly-owned subsidiary JOTEC entered into exclusive distribution and loan agreements with Endospan Ltd. (“Endospan”), an Israeli corporation, under which JOTEC obtained exclusive distribution rights for Endospan’s NEXUS products and accessories in certain countries in Europe.

On September 2, 2020 CryoLife entered into an agreement to acquire all of the equity interests of Ascyrus Medical LLC (“Ascyrus”). Ascyrus has developed the AMDS, an aortic arch remodeling device used for the treatment of acute Type A aortic dissections. The AMDS is currently distributed in Europe, the Middle East, and Africa (collectively, “EMEA”), Canada, and the Asia Pacific region and is included as a component of aortic stents and stent grafts revenues from the date of the acquisition.

Aortic stents and stent grafts revenues increased 37% and 42% for the three and nine months ended September 30, 2021, respectively, as compared to the three and nine months ended September 30, 2020.

Aortic stents and stent grafts revenues, excluding original equipment manufacturing (“OEM”), increased 38% for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020. This increase was primarily due to an increase in volume of units sold, which increased revenues by 38% and the effect of foreign exchange rates, which increased revenues by 3%, partially offset by a decrease in average sales prices of certain products in certain regions, which decreased revenues by 3%.

Aortic stents and stent grafts revenues, excluding OEM, increased 41% for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020. This increase was primarily due to a change in mix of units sold, which increased revenues by 38%, and the effect of foreign exchange rates, which increased revenues by 7%, partially offset by a decrease in average sales prices of certain products in certain regions, which decreased revenues by 4%.

On a constant currency basis, revenues for aortic stents and stent grafts, excluding OEM, increased 34% and 33% for the three and nine months ended September 30, 2021, respectively, as compared to the three and nine months ended September 30, 2020. The increase in revenues was partially due to improved conditions from the COVID-19 pandemic for the three and nine months ended September 30, 2021 as compared to the three and nine months ended September 30, 2020. Revenues for the three and nine months ended September 30, 2021 increased primarily in EMEA. The revenue increase in EMEA is primarily due to an increase in sales of JOTEC new product launches, as well as sales of the AMDS as a result of the Ascyrus acquisition in the third quarter of 2020, and an increase in NEXUS sales as these products continue to penetrate the EMEA market. Aortic stents and stent grafts OEM sales accounted for less than 1% of product revenues for the three and nine months ended September 30, 2021 and 2020.

#### *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 5% for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020. This increase was primarily due to an increase in volume of milliliters sold, which increased revenues by 3%, and the effect of foreign exchange rates, which increased revenues by 2%.

Revenues from the sales of surgical sealants increased 16% for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020. This increase was primarily due to an increase of milliliters sold, which increased revenues by 15%, and the effect of foreign exchange rates, which increased revenues by 2%, partially offset by a decrease in average sales prices of certain products in certain regions, which decreased revenues by 1%.

On a constant currency basis, revenues from the sales of surgical sealants increased 3% and 14% for the three and nine months ended September 30, 2021, respectively, as compared to the three and nine months ended September 30, 2020. The increase in revenues for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020 was primarily due to revenue increases in Latin America and North America, partially offset by decreases in EMEA. The increase in revenues for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020 was primarily due to increases in North America, EMEA and Latin America, partially offset by decreases in Asia Pacific. The revenue increase in these markets was primarily due to an increase of surgical procedures due to improved conditions related to the COVID-19 pandemic during the three and nine months ended September 30, 2021 as compared to the three and nine months ended September 30, 2020. Revenue decreases for the three months ended September 30, 2021 in EMEA and for the nine months ended September 30, 2021 in Asia Pacific were primarily due to changes in distributor buying patterns in those markets.

We are currently seeking regulatory approval for BioGlue in China, where the Chinese regulatory body has made additional requests, and expressed several concerns, related to the application. If we cannot satisfy the regulator's requests and concerns and obtain approval by May 2022, the pending application will expire and no longer be eligible for allowance, requiring the Company to restart or decide to abandon the approval process.

See Part II, Item 1A, "Risk Factors—Operational Risks— We may not be successful in obtaining necessary clinical results or regulatory clearances/approvals for new and existing products and services, and our approved products and services may not achieve market acceptance."

Domestic revenues from surgical sealants accounted for 48% and 52% of total surgical sealant revenues for the three and nine months ended September 30, 2021, respectively, and 50% of total surgical sealant revenues for both the three and nine months ended September 30, 2020.

#### *On-X*

The On-X catalogue of products includes the On-X prosthetic aortic and mitral heart valves and the On-X ascending aortic prosthesis ("AAP") for heart valve replacement. On-X product revenues also include revenues from the distribution of CarbonAid<sup>®</sup> CO<sub>2</sub> diffusion catheters and from the sale of Chord-X<sup>®</sup> ePTFE sutures for mitral chordal replacement. On-X also generates revenue from pyrolytic carbon coating products produced for OEM customers.

On-X product revenues increased 16% and 22% for the three and nine months ended September 30, 2021, respectively, as compared to the three and nine months ended September 30, 2020.

On-X product revenues, excluding OEM, increased 17% for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020. This increase was primarily due to an increase in volume of units sold, which increased revenues by 20%, and the effect of foreign exchange rates, which increased revenues by 1%, partially offset by a decrease in average sales prices, which decreased revenues by 4%.

On-X product revenues, excluding OEM, increased 23% for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020. This increase was primarily due to an increase in volume of units sold, which increased revenues by 27%, and the effect of foreign exchange rates, which increased revenues by 1%, partially offset by a decrease in average sales prices, which decreased revenues by 5%.

On a constant currency basis, On-X revenues, excluding OEM, increased 16% and 22% for the three and nine months ended September 30, 2021, respectively, as compared to the three and nine months ended September 30, 2020. The increase in revenues for the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020 was primarily due to revenue increases in North America, Asia Pacific, and EMEA. The revenue

increases in these markets were partially due to improved conditions from the COVID-19 pandemic for the three and nine months ended September 30, 2021, as compared to the three and nine months ended September 30, 2020. Revenues were also positively impacted in the North American market due to increases in market share, in EMEA due to an increase of shipments in direct markets and in Asia Pacific due to growth in distributor markets. On-X OEM sales accounted for less than 1% of product revenues for each of the three and nine months ended September 30, 2021 and 2020.

Domestic revenues from On-X accounted for 61% and 62% of total On-X revenues for the three and nine months ended September 30, 2021, respectively, and 66% and 65% of On-X revenues for the three and nine months ended September 30, 2020, respectively.

#### *Other*

Other revenues are comprised of PhotoFix, PerClot (prior to the Baxter Transaction), and CardioGenesis cardiac laser therapy product revenues. Other revenues decreased 15% for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020. Other revenues increased 14% for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020.

The decrease in revenues for the three months ended September 30, 2021 was primarily due to a 65% decrease in PerClot revenues partially offset by a 16% increase in PhotoFix revenues. The decrease in PerClot revenues is due to the Baxter Transaction described above. The increase in PhotoFix revenues was primarily due to an increase in volume of units sold, which increased revenues by 14%, the effect of foreign exchange rates, which increased revenues by 1%, and increase in average sales prices, which increased revenues by 1%.

The increase in revenues for the nine months ended September 30, 2021 was primarily due to a 29% increase in PhotoFix revenues. The increase in PhotoFix revenues was primarily due to an increase in volume of units sold, which increased revenues by 27%, the effect of foreign exchange rates, which increased revenues by 1%, and the increase in average sales prices, which increased revenues by 1%.

Revenues from our CardioGenesis cardiac laser therapy product line historically consisted primarily of sales of handpieces and, in certain periods, the sale of laser consoles. During the three and nine months ended September 31, 2021 and 2020 we had minimal revenues from the CardioGenesis cardiac laser therapy product line as we did not have a supply of handpieces. During this period our contract manufacturer of handpieces was unable to supply handpieces until the FDA approved our supplier's change in manufacturing location, which was received in January of 2021, and resumed manufacturing of handpieces. We anticipate resuming limited sales of handpieces during the fourth quarter of 2021.

#### **Preservation Services**

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

We continue to evaluate modifications to our tissue processing procedures in an effort to improve tissue processing throughput, 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.

In the fourth quarter of 2020 we became aware that a supplier shipped to us a saline solution lot that we use in our tissue processing that contained some contamination in a small number of bottles of the solution lot. The contamination was identified by our in-process quality controls. The contaminated solution was estimated to have impacted a small percentage of tissue processed with this solution lot, causing us to write-off approximately \$826,000 of tissue in the fourth quarter of 2020. An additional \$5.0 million of tissue was quarantined in process pending further testing. Upon completion, and FDA acceptance of the testing, we began releasing tissue meeting our release criteria late in the second quarter of 2021. We believe that the written-off and quarantined tissue impacted the availability of tissue for distribution, which had a negative impact on



revenue in the first quarter of 2021 and, to a lesser extent, the second quarter of 2021. However, our ability to release this quarantined and other tissue in the third quarter was negatively impacted by trained staffing availability.

Revenues from tissue processing decreased 5% for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020. Revenues from tissue processing increased 1% for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020.

The decrease in revenues for the three months ended September 30, 2021 was primarily due to a 5% decrease in both cardiac and vascular tissue revenues. The decrease in cardiac tissue revenues was primarily due to a decrease in cardiac tissue shipments due to the staffing impact on tissue release schedules, which decreased revenues 3%, and a decrease in average service fees, which decreased revenues by 2%. The decrease in vascular tissue revenues was primarily due to a decrease in vascular tissue shipments due to the staffing impact on tissue release schedules, which decreased revenues by 4%, and a decrease in average service fees, which decreased revenues by 1%. The decrease in cardiac volume for three months ended September 30, 2021 was primary due to a decrease in the volume of cardiac valve shipments due to the staffing impact on tissue release schedules. The decrease in vascular volume for the three months ended September 30, 2021 was primarily due to a decrease in saphenous vein shipments.

The increase in revenues for the nine months ended September 30, 2021 was primarily due to a 3% increase in vascular tissue revenues, partially offset by a 2% decrease in cardiac tissue revenues. The increase in vascular tissue revenues was primarily due to an increase in vascular tissue shipments, which increased revenues by 4%, partially offset by a decrease in average service fees, which decreased revenues by 1%. The decrease in cardiac tissue revenues was primarily due to a decrease in average service fees, which decreased revenues by 2%.

## Cost of Products and Preservation Services

### Cost of Products

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of products	\$ 15,503	\$ 12,998	\$ 46,592	\$ 36,078

Cost of products increased 19% and 29% for the three and nine months ended September 30, 2021, respectively, as compared to the three and nine months ended September 30, 2020. Cost of products for the three and nine months ended September 30, 2021 and 2020 included costs related to aortic stents and stent grafts, surgical sealants, On-X, and other products.

The increase in cost of products for the three and nine months ended September 30, 2021 was primarily due to an increase in shipments due to improved conditions from the COVID-19 pandemic, JOTEC product launches in late 2020, AMDS which was acquired in the third quarter of 2020, and write-downs of certain products, as compared to the three and nine months ended September 30, 2020.

### Cost of Preservation Services

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of preservation services	\$ 8,915	\$ 9,001	\$ 26,710	\$ 26,060

Cost of preservation services decreased 1% for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. Cost of preservation services increased 2% for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

The decrease in cost of preservation services for the three months ended September 30, 2021 was primarily due to a decrease in shipments during the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. The increase in cost of preservation services for the nine months ended September 30, 2021 was primarily due to an

increase in shipments due to improved conditions from the COVID-19 pandemic as compared to the nine months ended September 30, 2020.

### Gross Margin

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Gross margin	\$ 47,789	\$ 43,132	\$ 146,140	\$ 123,193
Gross margin as a percentage of total revenues	66%	66%	67%	66%

Gross margin increased 11% for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. The increase for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020 was primarily due to favorable gross margins of newly launched JOTEC products and AMDS, partially offset by the write-down of certain products. Gross margin as a percentage of total revenues was flat for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. Gross margin as a percentage of revenues was favorably impacted by the mix of products sold, offset by write-downs of certain products.

Gross margin increased 19% for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020. The increase for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020 was primarily due to favorable pricing of certain products and an increase in the volume of products sold. Gross margin as a percentage of total revenues increased for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020 primarily due to favorable gross margins of newly launched JOTEC products and AMDS, and mix of products sold, partially offset by write-downs of certain products.

### Operating Expenses

#### General, Administrative, and Marketing Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
General, administrative, and marketing expenses	\$ 39,053	\$ 33,743	\$ 118,521	\$ 105,033
General, administrative, and marketing expenses as a percentage of total revenues	54%	52%	54%	57%

General, administrative, and marketing expenses increased 16% and 13% for the three and nine months ended September 30, 2021, respectively, as compared to the three and nine months ended September 30, 2020. The increase in General, administrative, and marketing expenses for the three and nine months ended September 30, 2021 was primarily due to an increase in personnel, commission, amortization, business development, integration, and severance expenses. General, administrative, and marketing expenses included \$1.3 million and \$6.1 million of business development, integration, and severance expenses for the three and nine months ended September 30, 2021, respectively, as compared to \$1.1 million and \$2.5 million for the three and nine months ended September 30, 2020, respectively. Business development, integration, and severance expenses during the three and nine months ended September 30, 2021 primarily consisted of charges related to the Ascyrus acquisition. Business development, integration, and severance expenses during the three and nine months ended September 30, 2020 primarily consisted of expenses related to the Endospan agreements.

### Research and Development Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development expenses	\$ 9,972	\$ 5,755	\$ 26,086	\$ 17,633
Research and development expenses as a percentage of total revenues	14%	9%	12%	10%

Research and development expenses increased 73% and 48% for the three and nine months ended September 30, 2021, respectively, as compared to the three and nine months ended September 30, 2020. Research and development spending for the three and nine months ended September 30, 2021 was primarily focused on clinical work to gain regulatory approvals for On-X, JOTEC, and PerClot products. Research and development spending for the three and nine months ended September 30, 2020 was primarily focused on clinical work to gain regulatory approval for On-X and JOTEC products.

### Gain from Sale of Non-Financial Assets

Gain from sale of non-financial assets for the three and nine months ended September 30, 2021 consisted of the net \$15.9 million gain from the sale of PerClot assets as part of the Baxter Transaction on July 28, 2021.

### Interest Expense

Interest expense was \$4.1 million and \$13.0 million for the three and nine months ended September 30, 2021, respectively, as compared to \$4.9 million and \$12.0 million for the three and nine months ended September 30, 2020, respectively. Interest expense for the three and nine months ended September 30, 2021 and 2020 relates to interest on debt and uncertain tax positions.

### Other Expense, Net

Other expense, net was \$2.7 million and \$3.3 million for the three and nine months ended September 30, 2021, respectively, as compared to \$2.9 million and \$5.8 million for the three and nine months ended September 30, 2020, respectively. Other expense, net for the three and nine months ended September 30, 2021 and 2020 primarily includes the realized and unrealized effects of foreign currency gains and losses. Other expense, net for the three and nine months ended September 30, 2020 includes fair value adjustments of financial instruments.

### Earnings

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Income (loss) before income taxes	\$ 7,944	\$ (4,181)	\$ 1,260	\$ (17,082)
Income tax benefit	(2,638)	(1,311)	(4,006)	(3,858)
<b>Net income (loss)</b>	<b>\$ 10,582</b>	<b>\$ (2,870)</b>	<b>\$ 5,266</b>	<b>\$ (13,224)</b>
<b>Diluted income (loss) per common share</b>	<b>\$ 0.26</b>	<b>\$ (0.08)</b>	<b>\$ 0.13</b>	<b>\$ (0.35)</b>
<b>Diluted weighted-average common shares outstanding</b>	<b>44,453</b>	<b>37,912</b>	<b>39,496</b>	<b>37,608</b>

We experienced income before income taxes for the three and nine months ended September 30, 2021, as compared to a loss before income taxes for the three and nine months ended September 30, 2020. The income before income taxes for the three and nine months ended September 30, 2021 was primarily due to a gain from sale of non-financial assets related to the Baxter Transaction described above, partially offset by business development, integration and severance expenses primarily related to the Ascyrus acquisition, investments in the research and development pipeline, and delays and cancellations of some surgical procedures as a result of reduced hospital capacity and hospital restrictions due to the COVID-19 pandemic.

Our effective income tax rate was a benefit of 33% and 318% for the three and nine months ended September 30, 2021, respectively, as compared to a benefit of 31% and 23% for the three and nine months ended September 30, 2020, respectively. The change in the tax rate for the three and nine months ended September 30, 2021 is primarily due to changes

in pre-tax book loss, the excess tax benefit related to stock compensation, and the estimated current year valuation allowance, as compared to the three and nine months ended September 30, 2020.

The income tax rate for the three and nine months ended September 30, 2021 was favorably impacted by excess tax benefit deductions related to stock compensation, the research and development tax credit, and the reduction of a valuation allowance on prior year items. The tax rate was unfavorably impacted by non-deductible operating expenses, executive compensation expenses, an increase in the valuation allowance on current year items, and the recording of a tax reserve on prior year items.

The income tax rate for the three and nine months ended September 30, 2020 was favorably impacted by excess tax benefit deductions related to stock compensation and the research and development tax credit. These factors were partially offset by the unfavorable impacts of non-deductible operating expenses and executive compensation expenses.

In response to the COVID-19 pandemic, the U.S. government enacted the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”) on March 27, 2020. The CARES Act provided various forms of relief and assistance to U.S. businesses. We recorded a reduction to income taxes payable and deferred tax assets of approximately \$1.3 million for the change to the 2019 Section 163(j) interest expense deduction limitation for the three months ended March 2020.

We experienced net income and diluted income per common share for the three and nine months ended September 30, 2021, as compared to a net loss and diluted loss per common share for the three and nine months ended September 30, 2020. Net income and diluted income per common share for the three months and nine months ended September 30, 2021 was primarily due to income before income taxes, as discussed above.

### **Seasonality**

As result of the uncertainty and other impacts of the COVID-19 pandemic and the resulting shifts of timing in some revenue, our historically observable seasonality of revenues has been impacted or obscured in 2020 and 2021 and may be obscured for the remainder of 2021 and potentially beyond.

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

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

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

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

Demand for our vascular preservation services has also traditionally been seasonal, with lowest demand generally occurring in the fourth quarter. We believe this trend for vascular preservation services 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, 2021 net working capital (current assets of \$257.3 million less current liabilities of \$61.1 million) was \$196.2 million, with a current ratio (current assets divided by current liabilities) of 4 to 1, compared to net working capital of \$174.1 million and a current ratio of 4 to 1 at December 31, 2020.

## **Overall Liquidity and Capital Resources**

Our primary cash requirements for the nine months ended September 30, 2021 were for general working capital needs, capital expenditures for facilities and equipment, interest and principal payments under our Credit Agreement (defined below), interest payments under our Convertible Senior Notes (defined below), and repurchases of stock to cover tax withholdings. We funded our cash requirements through our existing cash reserves, proceeds from stock option exercises, and the Baxter Transaction described above.

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

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

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

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

On June 18, 2020 we issued \$100.0 million aggregate principal amount of 4.25% Convertible Senior Notes with a maturity date of July 1, 2025 (the “Convertible Senior Notes”). The net proceeds from this offering, after deducting initial purchasers’ discounts and costs directly related to this offering, were approximately \$96.5 million. On January 1, 2021 we adopted ASU 2020-06 and adjusted the carrying balance of the Convertible Senior Notes to notional. The Convertible Senior Notes balance was \$100.0 million recorded in Long-term debt on the Condensed Consolidated Balance Sheets as of September 30, 2021. 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, 2021 was approximately \$124.2 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 approximately \$1.2 million and \$3.7 million for the aggregate of the contractual coupon interest, and the amortization of the debt issuance costs as of the three and nine months ended September 30, 2021, respectively. Interest on the Convertible Senior Notes began accruing upon issuance and is payable semi-annually.

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

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

As of September 30, 2021 approximately 33% of our cash and cash equivalents were held in foreign jurisdictions.

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

Net cash used in operating activities was \$3.3 million for the nine months ended September 30, 2021, as compared to cash provided from operating activities of \$6.9 million for the nine months ended September 30, 2020.

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, 2021 these non-cash items included \$18.0 million in depreciation and amortization expenses, \$15.9 million of gain from sale of non-financial assets, \$7.5 million in non-cash compensation, \$5.6 million of lease expenses, and \$8.1 million of deferred income tax changes.

Our working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the nine months ended September 30, 2021 these included the unfavorable effect of a \$17.0 million increase in inventory balances and deferred preservation costs, the unfavorable effect of a \$8.0 million increase in receivables, and the unfavorable effect of a \$2.3 million increase in prepaid expenses and other assets.

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

Net cash provided by investing activities was \$8.5 million for the nine months ended September 30, 2021. Net cash used by investing activities was \$70.8 million for the nine months ended September 30, 2020. During the nine months ended September 30, 2021 cash flows provided by investing activities included \$19.0 million of net proceeds from the sale of non-financial assets, partially offset by \$10.5 million of cash used related to capital expenditures.

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

Net cash used in financing activities was \$3.4 million for the nine months ended September 30, 2021, as compared to cash provided by financing activities of \$95.3 million for the nine months ended September 30, 2020. The current year cash

used in financing activities was primarily due to \$2.4 million repayment of debt, \$2.2 million payment of debt issuance costs, and \$1.9 million for repurchases of common stock to cover tax withholdings, partially offset by \$3.5 million of proceeds from exercise of stock options and issuances of common stock.

### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements.

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

Our long-term debt obligations and interest payments include \$318.4 million of scheduled principal payments and \$70.7 million in anticipated interest payments related to our Credit Agreement, Convertible Senior Notes, and JOTEC governmental loans.

We have contingent payment obligations that include up to \$120.0 million to be paid to the former shareholders of Ascyrus, of which \$10.0 million is expected to be paid in CryoLife common stock, upon the achievement of certain milestones. We anticipate making a \$5.0 million third tranche payment under our loan agreement with Endospan upon receipt of certification that certain approvals and clinical trial milestones have been achieved.

As part of the Baxter Transaction, we may be required to pay up to \$9.0 million if certain milestones are met. See “Overview” identified in Part I, Item 2 of this Form 10-Q.

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 equipment and other equipment.

### **Capital Expenditures**

Capital expenditures were \$10.5 million and \$5.2 million for the nine months ended September 30, 2021 and 2020, respectively. Capital expenditures for the nine months ended September 30, 2021 were primarily related to leasehold improvements needed to support our business, routine purchases of manufacturing and tissues processing equipment, computer software, and equipment.

### **Risks and Uncertainties**

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

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

### **Interest Rate Risk**

Our interest income and interest expense are sensitive to changes in the general level of U.S. interest rates. In this regard, changes in U.S. interest rates affect the interest earned on our cash and cash equivalents of \$64.6 million as of September 30, 2021 and interest paid on the outstanding balances, if any, of our variable rate Revolving Credit Facility, Term Loan Facility, and Convertible Senior Notes. A 10% adverse change in interest rates, as compared to the rates experienced by us for the nine months ended September 30, 2021, affecting our cash and cash equivalents, restricted cash and securities, Term Loan Facility, Revolving Credit Facility, and Convertible Senior Notes would not have a material effect on our financial position, results of operations, or cash flows.

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

We have balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency denominated balances are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the U.S. 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 BioGlue, On-X, PerClot, and aortic stents and stent grafts revenues are denominated in Euros, British Pounds, Swiss Francs,

Polish Zlotys, Canadian Dollars, and Brazilian Reals, and a portion of our General, administrative, and marketing expenses are denominated in Euros, British Pounds, Swiss Francs, Polish Zlotys, Canadian Dollars, Brazilian Reals, and Singapore Dollars. These foreign currency transactions are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the U.S. Dollar equivalent of net income from transactions conducted in other currencies. As a result, revenues and expenses could fluctuate related to a change in exchange rates.

An additional 10% adverse change in exchange rates from the exchange rates in effect on September 30, 2021 affecting our balances denominated in foreign currencies could impact our financial position or cash flows by approximately \$8.0 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, 2021 affecting our revenue and expense transactions denominated in foreign currencies, would not have had a material impact on our financial position, profitability, or cash flows.

#### **Item 4. Controls and Procedures.**

##### **Evaluation of Disclosure Controls and Procedures**

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

Our management, including our President and CEO and our Executive Vice President of Finance, Chief Operating Officer, 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 CryoLife 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, 2021, 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 U.S. Securities and Exchange Commission’s rules and forms.

##### **Changes to Disclosure Controls and Procedures**

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **Part II – OTHER INFORMATION**

##### **Item 1. Legal Proceedings.**

From time to time, we 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 our Annual Report on Form 10-K and in our other filings with 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**

**COVID-19, and similar outbreaks, could have a material, adverse impact on us.**

During 2020 and 2021, businesses, communities, and governments worldwide have taken, and continue to take, a wide range of actions to mitigate the spread and impact of COVID-19, leading to an unprecedented impact on the global economy. Hospitals and other healthcare providers have adopted differing approaches to address the surge and resurgence of COVID-19 cases, including their impact on healthcare workers, such as postponing elective and non-emergent procedures, restricting access to their facilities, cancelling elective procedures, or re-allocating scarce resources to some critically ill patients. Although some areas have seen a decline in COVID-19 cases, the potential for additional impact from new variants of COVID-19 and longer than anticipated timelines for widespread therapeutic and vaccine availability and acceptance remain. These conditions have and could continue to impact our activities, including:

- Our product sales. Certain regions have experienced an impact on revenues for the three and nine months ended September 30, 2021, due to the COVID-19 pandemic. In addition to COVID-19's impact on procedure volumes, including an impact on procedure volumes due in part to COVID-19-related healthcare staffing shortages, we have begun to observe additional downstream effects on our business, including restrictions on sales representative access in hospitals due to vaccine mandates and an increase in delays or difficulty in collecting certain outstanding receivables, particularly with certain governmental payors in regions heavily impacted by COVID-19. The extent to which our financial performance will be impacted by the pandemic in 2021 and beyond will depend largely on future developments, including global availability and acceptance of the vaccine, and the prevalence of public and private vaccine mandates. COVID-19's continued or increased impact on our financial performance may also increase the risks we face with respect to managing our indebtedness.
- Our business operations. In 2020 we took several steps to address the impact of COVID-19 on our employees, cash consumption, and operations, including reducing expenditures and delaying investments. The reductions and delays we adopted could adversely impact our business operations or delay our recovery from the effects of the pandemic. Although we have begun to scale back many of these steps in most geographies, the COVID-19 virus and its variants remain highly contagious and our efforts to contain the spread of COVID-19 and its variants among our employees, including our key personnel, and to protect our supply chain, may not succeed. COVID-19 also continues to impact our business partners, including the various regulators and notified bodies that we rely on, which increases the regulatory risks we face, and specifically, the risks we face with respect to timely review and approval of new and renewal certifications, clearances, and approvals for our products.
- Our manufacturing operations. The COVID-19 pandemic has continued to impact the global supply chain; the pandemic's impact on workforces, global mobility, material availability, and demand has reportedly continued or worsened in many cases. Although we have yet to experience any material effects of this impact on our supply chain or operations, we face an increasing risk that upstream disruptions may occur. Risks relating to the lingering effects of global supply chain disruptions may even continue after COVID-19's risk as a global pandemic has subsided.
- Our workforce. As global economies have begun to emerge from the COVID-19 downturn, the expiration of COVID-related hiring freezes, increased opportunities for remote work, and increasing compensation pressure have resulted in a war for talent and an unprecedented number of career changes. The resulting worker shortages

at all levels have impacted supply chains and distribution channels and employers' ability to adequately staff their operations. This has impacted not only our own ability to attract and retain employees, but also the ability of our customers who face increasing staffing pressures throughout their healthcare organizations.

- Our research and development projects. In 2020 and year to date 2021 we have reduced spending on research and development projects, including clinical research projects. These reductions could adversely impact future revenue, and additional reductions in spending could be implemented, further impacting future revenue. In addition, our ability to conduct our ongoing research and development projects in markets that are affected by COVID-19 has been, and could continue to be, adversely impacted. Enrollment and timelines for our clinical trials have been, and might continue to be, impacted as healthcare providers reprioritize resources, address staffing shortages, and limit access to healthcare facilities or as patients decline to participate or are hesitant to voluntarily visit healthcare facilities. In addition, COVID-19-related impacts on government and regulatory agencies have slowed and might continue to slow timelines for regulatory actions, including approvals.

If COVID-19 or its variants continue to spread, if efforts to contain COVID-19 or its variants continue or are unsuccessful, if we experience new infections of COVID-19 in areas previously successful in containing its spread, if staffing shortages continue for us or our customers, if vaccine mandates become more prevalent, or if COVID-19, its variants, or disruptions to the global supply chain impact our supply chain or employee productivity, it could materially, adversely affect our revenues, financial condition, profitability, and cash flows. The nature and extent of these developments are highly uncertain and unpredictable and may vary greatly by region. These adverse developments or a prolonged period of uncertainty could adversely affect our financial performance.

**We are subject to a variety of risks due to our global expansion.**

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

- Greater difficulties and costs associated with staffing, 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 U.K. Bribery Law, local anti-corruption laws, Office of Foreign Asset Control administered sanction programs, the European Union's General Data Protection Regulation, and other emerging corruption and data privacy regulations;
- Overlapping and potentially conflicting, or unexpected changes in, international legal and regulatory requirements or reimbursement policies and programs;
- Longer and more expensive collection cycles in certain countries, particularly those in which our primary customers are government-funded hospitals;
- Changes in currency exchange rates, particularly fluctuations in the Euro as compared to the U.S. Dollar;
- Potential adverse tax consequences of overlapping tax structures; and
- Potential adverse financial and regulatory consequences resulting from the exit of the U.K. from the European Union, or "Brexit."

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

The market for our products and services is competitive and affected by new product introductions and activities of other industry participants. We face intense competition in virtually all of our product lines. A significant percentage of market revenues from competitive products are generated by Baxter International, Inc.; Ethicon (a Johnson & Johnson Company); Medtronic, Inc.; Abbott Laboratories; Edwards Lifesciences Corp.; Bard, a subsidiary of Becton, Dickinson and Company; Integra Life Sciences Holdings; LifeNet; Anteris Technologies, Inc.; Aziyo Biologics; Cook Medical; Gore & Associates; Terumo Aortic Corp.; LeMaitre Vascular, Inc.; Maquet, Inc.; Pfizer, Inc.; and BioCer Entwicklungs-GmbH. Several of our competitors enjoy competitive advantages over us, including:

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

- Larger direct sales forces and more established distribution networks.

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

Tissue preservation services are a significant source of our revenues, accounting for 26% and 30% of revenues for the three months ended September 30, 2021 and 2020, respectively, and as such, we face risks if we are unable to:

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

As an example of 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 approximately \$826,000 in contaminated tissues in the fourth quarter of 2020. The written off and temporarily quarantined tissue impacted our ability to fully meet demand for certain tissues and sizes in the fourth quarter of 2020, the first quarter of 2021, and to a lesser extent the second quarter of 2021. Our inability to meet some demand for tissue in the third quarter resulted in part from a shortage of trained staff capable of meeting the increased demand for releasing this quarantined tissue. See also, Part I, Item 1A, “Risk Factors—Operational Risks— We are dependent on our specialized workforce.”

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

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

BioGlue Surgical Adhesive (“BioGlue”) is a significant source of our revenues, accounting for 23% and 24% of revenues for the three months ended September 30, 2021 and 2020, respectively, 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 related to BioGlue:

- Competing effectively with our major 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 U.S. countries as fast as our competitors do of their products or at all. We also may not be able to capitalize on new BioGlue approvals, including for new indications, in non U.S. countries;
- BioGlue contains a bovine blood protein. Animal-based products are subject to increased scrutiny from the public and regulators, who may seek to impose additional regulations, regulatory hurdles or product bans in certain countries on such products; BioGlue is a mature product and other companies may use the inventions disclosed in expired BioGlue patents to develop and make competing products; and
- BioGlue faces potential adverse regulatory consequences resulting from the exit of the U.K. from the European Union, or “Brexit.” See Part I, Item 1A, “Risk Factors—Industry Risks— Our products and tissues are highly regulated and subject to significant quality and regulatory risks.”

As an example of this risk, we recently experienced delayed regulatory processes with respect to our application for approval of BioGlue in China due, in part, to requests for additional information related to the fact that BioGlue contains a bovine blood protein.

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

Aortic stents and stent grafts is a significant source of our revenues, accounting for 29% and 24% of revenues for the three months ended September 30, 2021 and 2020, respectively, and as such, any risk adversely affecting aortic stents and stent grafts would likely be material to our financial results. We face the following aortic stents and stent grafts related risks based on our ability to:

- Compete effectively with our major competitors, as they may have advantages over us in terms of cost structure, supply chain, pricing, sales force footprint, and brand recognition;
- Develop innovative and in-demand aortic repair products;
- Respond adequately to enhanced regulatory requirements and enforcement activities, and particularly, our ability to obtain regulatory approvals and renewals globally;
- Meet demand for aortic stents and 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 and are subject to a variety of related risks.**

On-X is a significant source of our revenues, accounting for 19% of revenues for the three months ended September 30, 2021 and 2020 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 market share in the mechanical heart valve market based on the FDA's approved lower International Normalized Ratio ("INR") indication 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 transcatheter aortic valve replacement, or "TAVR" devices;
- Manage risks associated with less favorable contract terms for On-X products on consignment at hospitals;
- Respond adequately to enhanced OUS regulatory requirements or enforcement activities; and
- Receive timely renewal certifications in certain markets.

**Continued fluctuation of foreign currencies relative to the U.S. 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 U.S. 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. Fluctuations in exchange rates of Euros or other local currencies in relation to the U.S. Dollar could materially reduce our future revenues as compared to the comparable prior periods. Should this occur, it could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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

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

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

**Our existing insurance coverage may be insufficient, and we may be unable to obtain insurance in the future.**

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.

**Operational Risks**

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

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

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

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

Finally, the COVID-19 pandemic has continued to impact the global supply chain; the pandemic's impact on workforces, global mobility, material availability, and demand has reportedly continued or worsened in many cases. Although we have yet to experience any material effects of this impact on our supply chain or operations, we face an increasing risk that upstream disruptions may occur. Risks relating to the lingering effects of global supply chain disruptions may even continue after COVID-19's risk as a global pandemic has 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, we could be forced to cease product manufacturing or tissue processing until the suppliers resume operations, until alternative suppliers could be identified and qualified, or permanently if the suppliers do not resume operations and no alternative suppliers could be identified and qualified. We could also be forced to purchase alternative materials, supplies, or services with unfavorable terms due to diminished bargaining power.

As an example of these risks, in 2019 we lost our supply of handpieces for cardiac laser therapy resulting from a manufacturing location change at our supplier that ultimately required a Premarket Approval (“PMA”) supplement and FDA approval before handpiece manufacturing and distribution could resume. Even though the FDA approved the PMA-S, our supplier has been unable to fully resume production due to factors outside of our control. Due to these and other supplier issues, we had virtually no supply of handpieces during the first three quarters of 2021 but anticipate resumption of a limited supply during the last quarter of 2021.

We also conduct all of our own manufacturing operations at three facilities: Austin, Texas for On-X products, Hechingen, Germany for JOTEC products, and Kennesaw, Georgia for all other products and services. The NEXUS product is solely manufactured by Endospan in Herzelia, Israel, and the AMDS product is solely manufactured by a supplier in Charlotte, North Carolina. If one of these facilities ceases operations temporarily or permanently, for any reason including a pandemic or climate change related event, our business could be substantially disrupted.

**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 field-based workforce is increasingly being subject to public and private vaccine mandates, including mandates without exception, which may impact unvaccinated personnel’s ability to fulfill or stay in their roles. 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 has been exacerbated in the first three quarters of 2021, and is expected to continue, as the competition for talent in the medical device industry and in the workforce generally has intensified substantially. As global economies have begun to emerge from the COVID-19 downturn, the expiration of COVID-related hiring freezes, increased opportunities for remote work, and increasing compensation pressure have resulted in a war for talent and an unprecedented number of career changes. The resulting competition and worker shortages at all levels have impacted supply chains and distribution channels and our ability to attract and retain the specialized workforce necessary for our business and operations.

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

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

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

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

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

- On December 1, 2017 we acquired JOTEC AG, a Swiss entity that we converted to JOTEC GmbH and subsequently merged with our Swiss acquisition entity, Jolly Buyer Acquisition GmbH and its subsidiaries;

- On September 11, 2019 we entered into various agreements with Endospan, Ltd. (“Endospan”), an Israeli medical device manufacturer (the “Endospan Transaction”). The Endospan Transaction included an exclusive distribution agreement for the NEXUS stent graft system (“NEXUS”) in Europe; an agreement (“Endospan Loan”) for a secured loan from CryoLife to Endospan; and a security purchase option agreement for CryoLife to purchase all the then outstanding Endospan securities from Endospan’s existing securityholders upon FDA approval of NEXUS;
- On September 2, 2020 we acquired 100% of the outstanding shares of Ascyrus Medical LLC (“Ascyrus”), the developer of the Ascyrus Medical Dissection Stent (“AMDS”);
- On July 28, 2021 we entered into various agreements with Baxter International, Inc. (“Baxter”) and Starch Medical, Inc. (“SMI”) related to the sale of our PerClot assets to Baxter and the termination of our existing material agreements with SMI.

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

- Leverage our global infrastructure to sell and cross-market the acquired products;
- Drive adoption of NEXUS and AMDS in the European and other markets, including our ability to manage the substantial requirements for NEXUS procedures for product training, implant support, and proctoring;
- Bring acquired products to the U.S. market, including AMDS and the JOTEC products;
- Harness the JOTEC product pipeline and research and development capabilities;
- Obtain regulatory approvals in relevant markets, including our ability to timely obtain PMA for PerClot as contemplated under the terms of the Baxter Transaction, to obtain Conformité Européenne Mark product certification (“CE Mark”) for pipeline products, and to obtain or maintain certification for pipeline and current products at all;
- Execute on development and clinical trial timelines for acquired products;
- Carry, service, and manage significant debt and repayment obligations; and
- Manage the unforeseen risks and uncertainties related to these transactions, including any related to intellectual property rights.

Additionally, our ability to realize the anticipated business opportunities, growth prospects, synergies, and other benefits of the Endospan Transaction depends on a number of additional factors including Endospan’s ability to: (a) comply with the Endospan Loan and other debt obligations, and avoid an event of default; (b) successfully commercialize NEXUS, raise capital and drive adoption in markets in and outside of Europe; (c) meet demand for NEXUS; (d) meet quality and regulatory requirements; (e) manage any intellectual property risks and uncertainties associated with NEXUS; (f) obtain FDA approval of NEXUS; and (g) develop NEXUS product improvements to meet competitive threats and physician 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 acquisition, and negatively impact the price of our common stock. In addition, if we fail to realize the anticipated benefits of an acquisition, we could experience an interruption or loss of momentum in our existing business activities.

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

We rely upon a combination of 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, personal data, intellectual property, and, in some instances, patient data). Our information technology and information security systems and records are potentially vulnerable to security breaches, service interruptions, data loss, or malicious attacks resulting from inadvertent or intentional actions by our employees, vendors, or other third parties. In addition, due to the COVID-19 pandemic, we have implemented remote work arrangements for some employees, and those employees may use outside technology and systems that are vulnerable to security breaches, service interruptions, data loss or malicious attacks, including by third parties.

As an example of these risks, on November 1, 2019 we were notified that we had become a victim of a business e-mail compromise. During the fourth quarter of 2019, a company email account was compromised by a third-party impersonator

and a payment intended for one of our U.S. vendors in the amount of \$2.6 million was fraudulently re-directed into an individual bank account controlled by this third-party impersonator. Our cyber-insurance covered all but \$25,000 of the unrecovered losses from this compromise.

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. We have limited cyber-insurance coverage that may not cover all possible events, and this insurance is subject to deductibles and coverage limitations. Any security breaches, service interruptions, or data losses could adversely affect our business operations or result in the loss of critical or sensitive confidential information or intellectual property, or in financial, legal, business, and reputational harm to us or allow third parties to gain material, inside information that they may use to trade in our securities.

## **Industry Risks**

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

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

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

Further, on May 25, 2017 the European Union adopted a new Medical Device Regulation (MDR 2017/745) (“MDR”), which was 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 (“EEA”) and other markets that require CE Marking. Additionally, to the extent the MDR places stricter requirements on manufacturers of custom-made devices, those new requirements could delay, impede, or otherwise impact the availability of our E-xtra DESIGN ENGINEERING products. Finally, COVID-19 has impacted the predictability and timelines associated with the MDR transition.

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



Finally, we anticipate additional regulatory impact as a result of the United Kingdom's exit from the European Union ("Brexit"). The U.K. Medicines and Healthcare Products Regulatory Agency ("MHRA") has announced that CE Marking will continue to be recognized in the U.K. and certificates issued by EU-recognized Notified Bodies will continue to be valid in the U.K. market until June 30, 2023. Going forward, all devices marketed in the U.K. will require U.K. Conformity Assessed Marks certified by a U.K. Approved Body (the re-designation of the U.K. Notified Body). In 2019 we were informed of the cancellation of notified body services by our former Notified Body for BioGlue and PhotoFix, Lloyd's Register Quality Assurance Limited. Presently, the MHRA and the German competent authority, Regierungspraesidium-Tubingen, have granted us extended grace periods to complete the transfers of our registrations to a new notified body, provided that we meet certain conditions, including the demonstration of adequate progress in the CE Mark certification process with our new Notified Body. If we are delayed or unsuccessful in transferring to a new notified body for BioGlue and PhotoFix in the EEA, or if we are otherwise unable to timely meet applicable regulatory requirements, we may be unable to place BioGlue or PhotoFix on the market in the EEA until we resolve the situation. Any delays in this process may also impact our Medical Device Single Audit Program ("MDSAP") certifications, and failure to timely obtain new MDSAP certifications following their expiration may impact our ability to distribute covered products in Australia, Brazil, Canada, and Japan.

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

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

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

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

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

We are currently seeking regulatory approval for BioGlue in China, where the Chinese regulatory body has made additional requests, and expressed several concerns, related to the application. If we cannot satisfy the regulator's requests and concerns and obtain approval by May 2022, the pending application will expire and no longer be eligible for allowance, requiring the Company to restart or decide to abandon the approval process.

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. Even the successful commercialization of a new product or service in the medical industry can be characterized by slow growth and high costs associated with marketing, under-utilized production capacity, and continuing research and development and education costs, among other things. The introduction of new products or services may require significant physician training or years of clinical evidence in order to gain acceptance in the medical community.

**Regulatory enforcement activities regarding Ethylene Oxide, which is used to sterilize some of our products and components, could have a material, adverse impact on us.**

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

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

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

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

In response to perceived increases in healthcare costs in recent years, there have been, and continue to be, proposals by the governmental authorities, third-party payors, and elected office holders and candidates to impact public health, control healthcare costs and, more generally, to reform the healthcare systems. Additional uncertainty is anticipated particularly in light of the recent presidential election in the United States and the impact the results of the presidential and congressional elections may have on U.S. law relating to the healthcare industry. Many U.S. healthcare laws, such as the Affordable Care Act, are complex, subject to change, and dependent on interpretation and enforcement decisions from government agencies with broad discretion. The application of these laws to us, our customers, or the specific services and relationships we have with our customers is not always clear. Our failure to anticipate accurately any changes to, or the repeal or invalidation of all or part of the Affordable Care Act and similar or future laws and regulations, or our failure to comply with them, could create liability for us, result in adverse publicity and negatively affect our business, results of operations, and financial condition. As an example, the President of the United States recently issued two vaccine mandates that may cover all, or groups of, our U.S. workforce. We are currently evaluating the applicability of these mandates to us. If we determine that either or both mandates apply to us, compliance with such laws could cause disruption in our workforce that could have an impact on our ability to attract or retain talent and increase our costs, and could adversely affect our business and profitability.

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, however, could adversely affect our business and profitability.

### **Legal, Quality, and Regulatory Risks**

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

Our relationships with physicians, hospitals, and other healthcare providers are subject to scrutiny under various U.S. and international bribery, anti-kickback, false claims, privacy, transparency, and similar laws, often referred to collectively as “healthcare compliance laws.” Healthcare compliance laws are broad, sometimes ambiguous, complex, and subject to change and changing interpretations. Possible sanctions for violation of these healthcare compliance laws include fines, civil and criminal penalties, exclusion from government healthcare programs, and despite our compliance efforts, we face the risk of an enforcement activity or a finding of a violation of these laws.

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

**The implementation of new data privacy laws, including the General Data Protection Regulation in the European Union in May 2018, could adversely affect our business.**

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

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

In recent years, shareholder activists have become involved in numerous public companies. Shareholder activists from time to time propose to involve themselves in the governance, strategic direction, and operations of a company. Such involvement 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.

**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, 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 patent that we own or license. Competitors may independently develop our proprietary technologies or design non-infringing alternatives to patented inventions. We do not control the maintenance, prosecution, enforcement, or strategy for in-licensed intellectual property and as such are dependent in part on the owners of these rights to maintain their viability. Their failure to do so could significantly impair our ability to exploit those technologies. Additionally, our technologies, products, or services could infringe intellectual property rights owned by others, or others could infringe our intellectual property rights.

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

**Risks Relating to Our Indebtedness**

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

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

- Incur or guarantee additional debt or create liens on certain assets;
- Deviate from a minimum liquidity of at least \$12.0 million as of the last day of any of the first three quarters of 2021 when our Revolving Credit Facility is drawn in excess of 25% of the amount available as of the last day of any fiscal quarter during that period (currently \$7.5 million);
- 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;
- Comply with certain financial ratios set forth in the agreement;
- Enter into certain transactions with our affiliates including any transaction or merger or consolidation, liquidation, winding-up, or dissolution; convey, sell, lease, exchange, transfer or otherwise dispose of all or any part of our business, assets or property; or sell, assign, or otherwise dispose of any capital stock of any subsidiary;
- Enter into certain rate swap transactions, basis swaps, credit derivative transactions, and other similar transactions, whether relating to interest rates, commodities, investments, securities, currencies, or any other relevant measure, or transactions of any kind subject to any form of master purchase agreement governed by the International Swaps and Derivatives Association, Inc., any International Foreign Exchange Master Agreement, or any other master agreement;
- Amend, supplement, waive, or otherwise modify our or our subsidiaries organizational documents in a manner that would be materially adverse to the interests of the lenders, or change or amend the terms of documentation regarding junior financing in a manner that would be materially adverse to the interests of the lenders;
- Make changes to our and our subsidiaries' fiscal year without notice to the administrative agent under the agreement;
- 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 expose us to increased interest rate fluctuation risk as most of our borrowings are at a variable rate of interest.

**We have pledged substantially all of our U.S. 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;
- 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; or
- Could require us to apply all of our available cash to repay such indebtedness.

If we are unable to repay those amounts, the holders of our secured indebtedness could proceed against their secured collateral. 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 Related to Ownership of our Common Stock**

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

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

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

We are subject to the Florida affiliated transactions statute, which generally requires approval by the disinterested directors or supermajority approval by shareholders for “affiliated transactions” between a corporation and an “interested stockholder.” Additionally, our organizational documents contain provisions that restrict persons who may call shareholder meetings, allow the issuance of blank-check preferred stock without the vote of shareholders, and allow the Board of Directors to fill vacancies and fix the number of directors. These provisions of Florida law and our articles of incorporation and bylaws could prevent attempts by shareholders to remove current management, prohibit or delay mergers or other changes of control transactions, and discourage attempts by other companies to acquire us, even if such a transaction would be beneficial to our shareholders. While we have recently sought shareholder approval to reincorporate into Delaware, these provisions of Florida law will continue to apply unless and until such reincorporation is effectuated. The effects of reincorporation in Delaware are detailed in our 2021 Special Proxy Statement and Notice of Special Meeting filed with the SEC on October 7, 2021.

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

(c) The following table provides information about purchases by us during the three months ended September 30, 2021 of equity securities that are registered by us pursuant to Section 12 of the Securities Exchange Act of 1934:

<b>Period</b>	<b>Total Number of Common Shares and Common Stock Units Purchased</b>	<b>Average Price Paid per Common Share</b>	<b>Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Dollar Value of Common Shares That May Yet Be Purchased Under the Plans or Programs</b>
07/01/21 - 07/31/21	--	\$ --	--	\$ --
08/01/21 - 08/31/21	1,882	26.80	--	--
09/01/21 - 09/30/21	648	24.63	--	--
<b>Total</b>	<b>2,530</b>	<b>\$ 26.24</b>	<b>--</b>	<b>\$ --</b>

The common shares purchased during the three months ended September 30, 2021 were tendered to us in payment of taxes on stock compensation and were not part of a publicly announced plan or program.

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

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

The exhibit index can be found below.

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">2.1</a>	Securities Purchase Agreement, dated September 2, 2020, by and among CryoLife, Inc., Ascyrus Medical LLC, the securityholders of Ascyrus Medical LLC and the Securityholder Representative (as defined therein) (Incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed September 2, 2020.)
<a href="#">3.1</a>	Amended and Restated Articles of Incorporation of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed July 31, 2020.)
<a href="#">3.2</a>	Amended and Restated By-Laws of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed February 22, 2018.)
<a href="#">10.1</a>	Asset Purchase Agreement dated July 28, 2021, by among CryoLife, Inc., and Baxter Healthcare Company. (Incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed July 29, 2021.)
<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 D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
<a href="#">32</a> **	Certification Pursuant To 18 U.S.C. 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.

† Portions of the exhibit have been omitted.

**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.

CRYOLIFE, INC.  
(Registrant)

/s/ J. PATRICK MACKIN

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

November 5, 2021

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DATE

/s/ D. ASHLEY LEE

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



CERTIFICATIONS

I, James Patrick Mackin, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CryoLife, 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 5, 2021

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

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I, David Ashley Lee, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CryoLife, 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 5, 2021

/s/ D. ASHLEY LEE  
Executive Vice President,  
Chief Operating Officer, and  
Chief Financial Officer

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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 CryoLife, Inc. (the "Company") on Form 10-Q for the quarter ending September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of James Patrick Mackin, the Chairman, President, and Chief Executive Officer of the Company, and David Ashley Lee, the Executive Vice President, Chief Operating Officer, and Chief Financial Officer of the Company, hereby certifies, pursuant to and for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, in his capacity as an officer of the Company and to his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ J. PATRICK MACKIN

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J. PATRICK MACKIN  
Chairman, President, and  
Chief Executive Officer  
November 5, 2021

/s/ D. ASHLEY LEE

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D. ASHLEY LEE  
Executive Vice President,  
Chief Operating Officer, and Chief Financial Officer  
November 5, 2021

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