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, 2019**

OR

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

For the transition period from _____ to _____

Commission file number: 1-13165

CRYOLIFE INC.

(Exact name of registrant as specified in its charter)

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

(770) 419-3355
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	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 re
Yes x No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for su
Yes x No o

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

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

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

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

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

Class	Outstanding at October 21, 2019
Common Stock, $0.01 par value	37,503,707

TABLE OF CONTENTS

Part I – FINANCIAL INFORMATION

Item 1. Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES
SUMMARY CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
Revenues:				
Products	$ 47,484	$ 45,152	$ 147,053	$ 138,063
Preservation services	20,397	19,446	59,472	56,979
Total revenues	**67,881**	**64,598**	**206,525**	**195,042**
Cost of products and preservation services:				
Products	12,706	12,459	41,021	40,166
Preservation services	9,953	9,425	29,043	27,083
Total cost of products and preservation services	**22,659**	**21,884**	**70,064**	**67,249**
Gross margin	**45,222**	**42,714**	**136,461**	**127,793**
Operating expenses:				
General, administrative, and marketing	34,259	32,871	105,402	104,946
Research and development	6,259	5,225	17,648	16,314
Total operating expenses	**40,518**	**38,096**	**123,050**	**121,260**
Operating income	**4,704**	**4,618**	**13,411**	**6,533**
Interest expense	3,555	4,104	11,260	11,863
Interest income	(259)	(52)	(608)	(141)
Other expense (income), net	2,400	(1,542)	2,662	(257)
(Loss) income before income taxes	**(992)**	**2,108**	**97**	**(4,932)**
Income tax (benefit) expense	(858)	543	(2,304)	(2,868)
Net (loss) income	$ **(134)**	$ **1,565**	$ **2,401**	$ **(2,064)**
(Loss) income per common share:				
Basic	$ **0.00**	$ **0.04**	$ **0.06**	$ **(0.06)**
Diluted	$ **0.00**	$ **0.04**	$ **0.06**	$ **(0.06)**
Weighted-average common shares outstanding:				
Basic	37,255	36,526	37,065	36,331
Diluted	37,255	37,610	37,850	36,331
Net (loss) income	$ **(134)**	$ **1,565**	$ **2,401**	$ **(2,064)**
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(8,017)	(514)	(8,803)	(5,140)
Comprehensive (loss) income	$ **(8,151)**	$ **1,051**	$ **(6,402)**	$ **(7,204)**

See accompanying Notes to Summary Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES
SUMMARY CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)

	September 30, 2019	December 31, 2018
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 36,685	$ 41,489
Restricted securities	492	747
Trade receivables, net	50,550	47,108
Other receivables	4,322	4,324
Inventories	48,403	45,478
Deferred preservation costs	32,352	33,174
Prepaid expenses and other	8,550	6,848
Total current assets	**181,354**	**179,168**
Property and equipment, net	30,434	31,028
Operating lease right-of-use assets, net	21,841	--
Goodwill	183,368	188,781
Acquired technology, net	107,863	118,184
Other intangibles, net	49,806	41,897
Deferred income taxes	3,872	4,111
Other assets	14,064	7,922
Total assets	**$ 592,602**	**$ 571,091**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,455	$ 7,547
Accrued compensation	11,628	10,733
Current portion of long-term debt	1,144	1,160
Current maturities of operating leases	5,270	--
Taxes payable	2,324	2,250
Accrued expenses and other	14,369	12,833
Total current liabilities	**42,190**	**34,523**
Long-term debt	214,793	215,721
Non-current maturities of operating leases	18,046	--
Deferred income taxes	24,699	27,267
Other	15,373	18,513
Total liabilities	**315,101**	**296,024**
Commitments and contingencies		
Shareholders' equity:		
Preferred stock	--	--
Common stock (issued shares of 38,988 in 2019 and 38,463 in 2018)	390	385
Additional paid-in capital	269,192	260,361
Retained earnings	37,385	34,984
Accumulated other comprehensive loss	(14,875)	(6,072)
Treasury stock at cost (shares of 1,484 in each of 2019 and 2018)	(14,591)	(14,591)
Total shareholders' equity	**277,501**	**275,067**
Total liabilities and shareholders' equity	**$ 592,602**	**$ 571,091**

See accompanying Notes to Summary Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES
SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)

	Nine Months Ended September 30,	
	2019	**2018**
	(Unaudited)	
Net cash flows from operating activities:		
Net income (loss)	$ 2,401	$ (2,064)
Adjustments to reconcile net income (loss) to net cash from operating activities:		
Depreciation and amortization	13,257	13,636
Non-cash compensation	6,581	4,685
Other non-cash adjustments to income (loss)	5,021	(1,330)
Changes in operating assets and liabilities:		
Receivables	(4,496)	(2,310)
Inventories and deferred preservation costs	(3,864)	1,697
Prepaid expenses and other assets	(3,020)	(2,481)
Accounts payable, accrued expenses, and other liabilities	(1,113)	(12,473)
Net cash flows provided by (used in) operating activities	**14,767**	**(640)**
Net cash flows from investing activities:		
Payments for Endospan agreements	(15,000)	--
Capital expenditures	(5,222)	(4,275)
Other	(531)	(722)
Net cash flows used in investing activities	**(20,753)**	**(4,997)**
Net cash flows from financing activities:		
Repayment of term loan	(2,072)	(2,098)
Proceeds from exercise of stock options and issuance of common stock	4,519	3,793
Redemption and repurchase of stock to cover tax withholdings	(2,723)	(2,085)
Other	(560)	(888)
Net cash flows used in financing activities	**(836)**	**(1,278)**
Effect of exchange rate changes on cash, cash equivalents, and restricted securities	1,763	1,473
Decrease in cash, cash equivalents, and restricted securities	**(5,059)**	**(5,442)**
Cash, cash equivalents, and restricted securities beginning of period	42,236	40,753
Cash, cash equivalents, and restricted securities end of period	**$ 37,177**	**$ 35,311**

See accompanying Notes to Summary Consolidated Financial Statements

CRYOLIFE, INC. AND SUBSIDIARIES
SUMMARY CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(IN THOUSANDS)

	Common Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Total Shareholders' Equity
	Shares	Amount				Shares	Amount	
Balance at June 30, 2019	**38,943**	**$ 389**	**$ 265,694**	**$ 37,519**	**$ (6,858)**	**(1,484)**	**$ (14,591)**	**$ 282,153**
Net loss	--	--	--	(134)	--	--	--	(134)
Other comprehensive loss:								
Foreign currency translation adjustment	--	--	--	--	(8,017)	--	--	(8,017)
Comprehensive loss								(8,151)
Equity compensation	6	--	2,620	--	--	--	--	2,620
Exercise of options	5	--	53	--	--	--	--	53
Employee stock purchase plan	36	1	884	--	--	--	--	885
Redemption and repurchase of stock to cover tax withholdings	(2)	--	(59)	--	--	--	--	(59)
Balance at September 30, 2019	**38,988**	**$ 390**	**$ 269,192**	**$ 37,385**	**$ (14,875)**	**(1,484)**	**$ (14,591)**	**$ 277,501**

	Common Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Total Shareholders' Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2018	**38,463**	**$ 385**	**$ 260,361**	**$ 34,984**	**$ (6,072)**	**(1,484)**	**$ (14,591)**	**$ 275,067**
Net income	--	--	--	2,401	--	--	--	2,401
Other comprehensive loss:								
Foreign currency translation adjustment	--	--	--	--	(8,803)	--	--	(8,803)
Comprehensive loss								(6,402)
Equity compensation	251	2	7,037	--	--	--	--	7,039
Exercise of options	306	3	3,054	--	--	--	--	3,057
Employee stock purchase plan	61	1	1,462	--	--	--	--	1,463
Redemption and repurchase of stock to cover tax withholdings	(93)	(1)	(2,722)	--	--	--	--	(2,723)
Balance at September 30, 2019	**38,988**	**$ 390**	**$ 269,192**	**$ 37,385**	**$ (14,875)**	**(1,484)**	**$ (14,591)**	**$ 277,501**

See accompanying Notes to Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES
SUMMARY CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(IN THOUSANDS)

	Common Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Total Shareholders' Equity
	Shares	Amount				Shares	Amount	
Balance at June 30, 2018	**38,204**	**$ 382**	**$ 254,288**	**$ 34,195**	**$ (2,769)**	**(1,484)**	**$ (14,591)**	**$ 271,505**
Net income	--	--	--	1,565	--	--	--	1,565
Other comprehensive income:								
Foreign currency translation adjustment	--	--	--	--	(514)	--	--	(514)
Comprehensive income								1,051
Equity compensation	(14)	1	1,692	--	--	--	--	1,693
Exercise of options	218	1	2,098	--	--	--	--	2,099
Employee stock purchase plan	46	1	750	--	--	--	--	751
Redemption and repurchase of stock to cover tax withholdings	(9)	(1)	(273)	--	--	--	--	(274)
Balance at September 30, 2018	**38,445**	**$ 384**	**$ 258,555**	**$ 35,760**	**$ (3,283)**	**(1,484)**	**$ (14,591)**	**$ 276,825**

	Common Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Total Shareholders' Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2017	**37,618**	**$ 376**	**$ 249,935**	**$ 37,609**	**$ 1,857**	**(1,386)**	**$ (12,719)**	**$ 277,058**
Cumulative effect of ASC 606 Adjustment	--	--	--	215	--	--	--	215
Net loss	--	--	--	(2,064)	--	--	--	(2,064)
Other comprehensive loss:								
Foreign currency translation adjustment	--	--	--	--	(5,140)	--	--	(5,140)
Comprehensive loss								(6,989)
Equity compensation	275	2	5,046	--	--	--	--	5,048
Exercise of options	572	6	4,320	--	--	(98)	(1,872)	2,454
Employee stock purchase plan	83	1	1,338	--	--	--	--	1,339
Redemption and repurchase of stock to cover tax withholdings	(103)	(1)	(2,084)	--	--	--	--	(2,085)
Balance at September 30, 2018	**38,445**	**$ 384**	**$ 258,555**	**$ 35,760**	**$ (3,283)**	**(1,484)**	**$ (14,591)**	**$ 276,825**

See accompanying Notes to Consolidated Financial Statements

1. Basis of Presentation

Overview

The accompanying summary 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 Summary Consolidated Balance Sheet as of December 31, 2018 has been derived from audited financial statements. The accompanying unaudited summary consolidated financial statements as of, and for the three and nine months ended, September 30, 2019 and 2018 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 ("SEC"). Accordingly, such statements do not include all of the information and disclosures 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, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019. These summary consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in CryoLife's Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on February 26, 2019.

New Accounting Standards

Recently Adopted

As of January 1, 2019 we adopted the Accounting Standards Codification ("ASC") Topic 842, *Leases* ("ASC 842"). The final guidance requires lessees to recognize a right-of-use asset and a lease liability for all leases (with the exception of short-term leases) at the commencement date and recognize expenses on their income statements similar to former Topic 840, *Leases*. We used the modified retrospective approach, which allows application of the standard at the adoption date rather than at the beginning of the earliest comparative period presented. The adoption of this standard resulted in the recognition of operating lease agreements with a net present value of $22.7 million and corresponding right-of-use assets obtained in the same amount at January 1, 2019. See Note 8 for further discussion of leases.

Not Yet Effective

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASC Update No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The purpose of Update No. 2016-13 is to replace the current incurred loss impairment methodology for financial assets measured at amortized cost with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information, including forecasted information, to develop credit loss estimates. Update No. 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those annual periods and early adoption is permitted. 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. 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 ("Endospan Distribution Agreement") with Endospan Ltd. ("Endospan") an Israeli corporation, pursuant to which JOTEC obtained exclusive distribution rights for Endospan's Nexus stent graft system ("Nexus Product") and accessories in certain countries in Europe in exchange for a fixed distribution fee of $9.0 million paid in September 2019. Under the terms of the Endospan Distribution Agreement, JOTEC agreed to use its best efforts to market, promote, distribute, sell, and support the Nexus products for approved uses in the countries included within JOTEC's exclusive distribution rights. JOTEC is obligated to satisfy a minimum purchase amount beginning in 2020.

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

The term of JOTEC's Endospan Distribution Agreement expires upon the earliest to occur of (i) the date on which the acquisition contemplated by the Endospan Option Agreement can no longer be consummated under its terms, or (ii) the date on which the Endospan Option Agreement is terminated pursuant to its terms, or by either party under certain circumstances. JOTEC would be entitled to a termination fee in the event the Endospan Distribution Agreement is terminated by JOTEC due to a suspension of approvals related to the Nexus Product lasting more than six months or the withdrawal of such approvals, an injunction on the Nexus Product lasting more than six months or a permanent injunction on the Nexus Product (unless such injunction resulted solely from an act or omission of JOTEC, its affiliates, or their sub-distributors), and other significant breaches.

Loan Agreement

CryoLife and Endospan also entered into a loan agreement ("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. The second tranche is required to be funded generally under the same terms as the first tranche, upon certification of Investigational Device Exemption ("IDE") approval from the FDA of the Nexus Product, and 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 the Nexus Product, 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.

The Endospan Loan is secured by substantially all of Endospan's assets. Such security interest is a first priority security interest, except as to a pre-existing security interest granted to a third party over certain of these assets. The Endospan Loan bears interest at a rate of 5% per annum and is subject to acceleration upon an event of default. Interest on the Endospan Loan is payable upon the closing of the acquisition contemplated in the Endospan Option Agreement, and the principal amount and any additional interest or other obligations are payable upon the first anniversary of the closing of such acquisition. The amounts advanced under the Endospan Loan could be forgiven if Endospan is not in default of the Endospan Loan and certain events as defined in the Endospan agreements have occurred.

Variable Interest Entity

We consolidate the results of a variable interest entity ("VIE") when it is determined that we are the primary beneficiary. 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. Based on our evaluation of Endospan and the related agreements with Endospan, we determined that Endospan is a VIE. We evaluated whether we are the primary beneficiary of the Endospan VIE by considering whether we have (1) the power to direct those activities of the VIE that most significantly impact the entity's economic performance and (2) the obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE.

In evaluating whether we have the power to direct those activities of a VIE that most significantly impact its economic performance, we considered the purpose for which the VIE was created, the importance of each of the activities in which the VIE is engaged, and our decision-making role, if any, in those activities that significantly determine the VIE's economic performance, as compared to the role of other economic interest holders. In determining whether we have the right to receive benefits or the obligation to absorb losses that could potentially be significant to the VIE, we considered our economic interests in Endospan, regardless of form. This evaluation considered the relevant factors of Endospan's design, including: Endospan's capital structure, contractual rights to earnings (losses), and subordination of our interests relative to those of other investors, contingent payments, as well as other contractual arrangements that have the potential to be economically significant.

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 date, including any loans and guarantees and other subordinated financial support related to this VIE, totaled $15.0 million as of September 30, 2019, representing our maximum exposure to loss and was 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. 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 that certain approvals and milestones in obtaining FDA approval. Based on the 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 and the Endospan Option Agreement of $4.8 million in "Other long-term assets" and the Endospan Distribution Agreement of $9.8 million in "Other intangibles, net" in the Summary Consolidated Balance Sheets as of September 30, 2019.

We have elected the fair value option for recording the Endospan Loan. We will assess the fair value of the Endospan Loan based on quantitative and qualitative characteristics, and we will adjust the amount recorded to its current fair market value at each reporting period. As of the transaction date, the initial relative fair value calculations to determine the amounts to be recorded for the Endospan Distribution Agreement and the Endospan Option Agreement represent non-recurring Level 3 fair value calculations. The Endospan Distribution Agreement will be amortized over five years, which is the expected timeframe to achieve FDA approval. The Endospan Option Agreement will remain at the recorded value and will be periodically assessed for impairment based on qualitative and quantitative factors.

3. Financial Instruments

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

September 30, 2019	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market funds	$ 1,466	$ --	$ --	$ 1,466
Restricted securities:				
Money market funds	492	--	--	492
Endospan Loan	--	--	358	358
Total assets	**$ 1,958**	**$ --**	**$ 358**	**$ 2,316**

December 31, 2018	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market funds	$ 1,445	$ --	$ --	$ 1,445
Restricted securities:				
Money market funds	747	--	--	747
Total assets	**$ 2,192**	**$ --**	**$ --**	**$ 2,192**

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. See Note 2 for further discussion of the Endospan Loan. Changes in fair value of Level 3 assets are listed in the table below (in thousands):

	Endospan Loan
Balance as of December 31, 2018	$ --
Initial value of Endospan Loan	358
Change in valuation of Endospan Loan	--
Balance as of September 30, 2019	$ 358

4. Cash Equivalents and Restricted Securities

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

September 30, 2019	**Cost Basis**	**Unrealized Holding Gains**	**Estimated Market Value**
Cash equivalents:			
Money market funds	$ 1,466	$ --	$ 1,466
Restricted securities:			
Money market funds	492	--	492

December 31, 2018	**Cost Basis**	**Unrealized Holding Gains**	**Estimated Market Value**
Cash equivalents:			
Money market funds	$ 1,445	$ --	$ 1,445
Restricted securities:			
Money market funds	747	--	747

As of September 30, 2019 and December 31, 2018 all 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 primarily to international tax obligations.

There were no gross realized gains or losses on cash equivalents and restricted securities in the three and nine months ended September 30, 2019 and 2018. As of September 30, 2019 $492,000 of our restricted securities had a maturity date within three months. As of December 31, 2018 $512,000 of our restricted securities had a maturity date within three months and $235,000 had a maturity date between three months and one year.

5. Inventories and Deferred Preservation Costs

Inventories at September 30, 2019 and December 31, 2018 were comprised of the following (in thousands):

	September 30, 2019	**December 31, 2018**
Raw materials and supplies	$ 19,584	$ 17,381
Work-in-process	5,183	3,858
Finished goods	23,636	24,239
Total inventories	**$ 48,403**	**$ 45,478**

Deferred preservation costs at September 30, 2019 and December 31, 2018 were comprised of the following (in thousands):

	September 30, 2019	December 31, 2018
Cardiac tissues	$ 15,512	$ 15,972
Vascular tissues	16,840	17,202
Total deferred preservation costs	**$ 32,352**	**$ 33,174**

We maintain consignment inventory of our On-X heart valves at domestic hospital locations and On-X heart valves and JOTEC products at international hospital locations to facilitate usage. 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, 2019 we had $11.8 million in consignment inventory, with approximately 52% in domestic locations and 48% in international locations. As of December 31, 2018 we had $11.2 million in consignment inventory, with approximately 55% in domestic locations and 45% in international locations.

6. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

As of September 30, 2019 and December 31, 2018 the carrying values of our indefinite lived intangible assets were as follows (in thousands):

	September 30, 2019	December 31, 2018
Goodwill	$ 183,368	$ 188,781
In-process R&D	8,922	9,382
Procurement contracts and agreements	2,013	2,013
Trademarks	844	844

We monitor the phases of development of our acquired in-process R&D 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 R&D 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.

As of September 30, 2019 and December 31, 2018 our entire goodwill balance was related to our Medical Devices segment.

	Medical Devices Segment
Balance as of December 31, 2018	$ 188,781
Revaluation of goodwill denominated in foreign currency	(5,413)
Balance as of September 30, 2019	**$ 183,368**

Definite Lived Intangible Assets

As of September 30, 2019 and December 31, 2018 the gross carrying values, accumulated amortization, and approximate amortization period of our definite lived intangible assets were as follows (in thousands):

September 30, 2019	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	$ 130,270	$ 22,407	11 – 22 Years
Customer lists and relationships	31,070	6,196	13 – 22 Years
Distribution and manufacturing rights and know-how	13,757	2,429	5 – 15 Years
Patents	3,714	3,080	17 Years
Other	1,672	481	3 – 5 Years

December 31, 2018	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	$ 134,999	$ 16,815	11 – 22 Years
Customer lists and relationships	31,169	5,068	13 – 22 Years
Distribution and manufacturing rights and know-how	4,059	2,107	11 – 15 Years
Patents	3,656	2,970	17 Years
Other	1,154	235	3 – 5 Years

Amortization Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Amortization expense	$ 2,660	$ 2,707	$ 7,796	$ 8,195

As of September 30, 2019 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	Remainder of 2019	2020	2021	2022	2023	2024	Total
Amortization expense	$ 3,029	$ 11,773	$ 11,750	$ 11,205	$ 10,797	$ 10,569	$ 59,123

7. Income Taxes

Income Tax Expense

Our effective income tax rate was a benefit of 87% and 2,375% for the three and nine months ended September 30, 2019, respectively, as compared to an expense of 26% and a benefit of 58% for the three and nine months ended September 30, 2018, respectively. The change in the tax rate for the three and nine months ended September 30, 2019 is primarily due to a change in pre-tax book income for the three and nine months ended September 30, 2019, as compared to the three and nine months ended September 30, 2018.

The income tax rate for the three and nine months ended September 30, 2019 was impacted by excess tax benefit deductions related to stock compensation, which increased income tax benefits by approximately $2,000 and $2.0 million, respectively, as well as the recognition of a benefit of approximately $900,000 related to the expiration of certain federal tax statutes of limitation. These factors were partially offset by unfavorable impacts of non-deductible operating expenses and executive compensation expenses.

The income tax rate for the three and nine months ended September 30, 2018 was impacted by excess tax benefit deductions related to stock compensation, which increased year-to-date income tax benefits by approximately $1.4 million, and losses in high rate jurisdictions. These factors were partially offset by impacts of non-deductible operating expenses and executive compensation expenses.

Deferred Income Taxes

We generate deferred tax assets primarily as a result of write-downs of inventory and deferred preservation costs, accruals for product and tissue processing liability claims, investment and asset impairments, and operating losses. We acquired significant deferred tax assets, primarily net operating loss carryforwards, from our acquisitions of JOTEC and its subsidiaries in 2017, On-X in 2016, Hemosphere, Inc. in 2012, and Cardiogenesis Corporation in 2011. We believe utilization of these net operating losses will not have a material impact on income taxes for the 2019 tax year.

As of September 30, 2019 we maintained a total of $4.2 million in valuation allowances against deferred tax assets, primarily related to state net operating loss carryforwards, and had a net deferred tax liability of $20.8 million. As of December 31, 2018 we had a total of $3.4 million in valuation allowances against deferred tax assets, primarily related to state net operating loss carryforwards, and a net deferred tax liability of $23.2 million.

8. Leases

In February 2016 the FASB amended its ASC and created a new Topic 842, Leases. The final guidance requires lessees to recognize a right-of-use asset and a lease liability for all long-term leases at the commencement date and recognize expenses on their statements of income similar to the former Topic 840, Leases. It is effective for fiscal years and interim periods beginning after December 15, 2018 and early adoption was permitted. We adopted ASC 842, Leases effective January 1, 2019 using the modified retrospective approach, which allows application of the standard at the adoption date rather than at the beginning of the earliest comparative period presented. Therefore, no changes have been made to the 2018 financial statements.

The adoption of this standard resulted in the recognition of operating lease liability with a net present value of $22.7 million, and corresponding right-of-use assets obtained in the same amount, at January 1, 2019. The leases were recognized with a weighted average discount rate of 5.5% and a weighted average remaining lease term of six years. In addition, deferred rent obligations of approximately $2.4 million recognized under prior lease rules were offset against the corresponding right-of-use asset and will be reflected in amortization over the remaining life of the lease. Our leases had remaining lease terms of one year up to 11 years, some of which had options to extend the leases for up to 29 years and one lease contained a termination option with a two year notice requirement. The adoption of the new leasing standard had no significant impact on covenants or other provisions of our current term and revolver loan facility agreements.

We exercised judgment in the adoption of the new leasing standard, including the determination of whether a financial arrangement includes a lease and in determining the appropriate discount rates to be applied to leases based on our general collateralized credit standing and the geographical market considerations impacting lease rates across all locations. When available, we used the implicit discount rate in the lease contract to discount lease payments to present value. If an implicit discount rate was not available in the lease contract, we used our incremental borrowing rate. We elected the package of practical expedients permitted under the transition guidance of the new leasing standard which includes a provision that allows us to carry forward the historical lease classification of identified leasing arrangements and not reassess (i) classification for any existing leases, (ii) whether any expired or existing agreements are or contain a lease, or (iii) whether any initial direct costs qualified for capitalization. We have also elected the practical expedients that allow us to omit leases with initial terms of 12 months or less from our balance sheet, which are expensed on a straight-line basis over the life of the lease. We have elected not to separate lease and non-lease components for future leases.

Our operating and finance lease liabilities result from the lease of land and buildings that comprise our corporate headquarters, various manufacturing facilities and related space, leases on company vehicles, and leases on a variety of office and other equipment. Our leases do not include terms or conditions which would result in variable lease payments other than for small office equipment leases with an additional charge for volume of usage. These incremental payments are excluded from our calculation of lease liability and the related right-of-use asset. We do not include option terms in the determination of lease liabilities and the related right-of-use assets until we determine the exercise of the option is reasonably certain. Our leases do not contain residual value guarantee provisions or other restrictions or financial covenant provisions.

On March 8, 2019 we executed a modification to extend the lease of our On-X manufacturing facilities. This modification resulted in an increase in the net present value and corresponding right-of-use asset of $3.7 million, using a discount rate of 5.83%. We have not executed any material lease arrangements which have not commenced. We do not have any related party leasing arrangements.

We sublease, on an operating lease basis, two unused office space facilities near our corporate office. Total annual rental income for these facilities is approximately $910,000.

Supplemental consolidated balance sheet information related to leases was as follows (in thousands, except lease term and discount rate):

Operating leases:	**September 30, 2019**
Operating lease right-of-use assets	$ 25,576
Accumulated amortization	(3,735)
Operating lease right-of-use assets, net	**$ 21,841**
Current maturities of operating leases	$ 5,270
Non-current maturities of operating lease	18,046
Total operating lease liabilities	**$ 23,316**
Finance leases:	
Property and equipment, at cost	$ 6,750
Accumulated amortization	(1,079)
Property and equipment, net	**$ 5,671**
Current maturities of finance leases	$ 636
Non-current maturities of finance leases	5,144
Total finance lease liabilities	**$ 5,780**
Weighted average remaining lease term (in years):	
Operating leases	5.7
Finance leases	11
Weighted average discount rate:	
Operating leases	5.4%
Finance leases	2.0%

Current maturities of finance leases are included as a component of Accrued Expenses and Other and non-current maturities of finance leases are included as a component of Other Long-Term Liabilities on our Summary Consolidated Balance Sheets. A summary of lease expenses for our finance and operating leases included in General, Administrative, and Marketing Expenses on our Summary Consolidated Statements of Operations and Comprehensive (Loss) Income are as follows (in thousands):

	Three Months Ended September 30, 2019	**Nine Months Ended September 30, 2019**
Amortization of property and equipment	$ 188	$ 608
Interest expense on finance leases	30	93
Total finance lease expense	218	701
Operating lease expense	1,717	4,870
Sublease income	(227)	(679)
Total lease expense	**$ 1,708**	**$ 4,892**

A summary of our supplemental cash flow information is as follows (in thousands):

Cash paid for amounts included in the measurement of lease liabilities:	Nine Months Ended September 30, 2019
Operating cash flows for finance leases	$ 91
Operating cash flows for operating leases	5,004
Financing cash flows for finance leases	561

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

	Finance Leases	Operating Leases	Sublease Income
Remainder of 2019	$ 256	$ 1,347	$ 227
2020	554	6,632	921
2021	609	5,908	930
2022	557	3,459	316
2023	557	2,300	--
Thereafter	3,900	7,228	--
Total minimum lease payments	$ 6,433	$ 26,874	$ 2,394
Less amount representing interest	(653)	(3,558)	
Present value of net minimum lease payments	5,780	23,316	
Less current maturities	(636)	(5,270)	
Lease liabilities, less current maturities	**$ 5,144**	**$ 18,046**	

9. Debt

Credit Agreement

On December 1, 2017 we entered into a credit and guaranty agreement for a new $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 December 1, 2017 we borrowed the entire $225.0 million Term Loan Facility. The proceeds of the Term Loan Facility were used along with cash on hand and shares of CryoLife common stock to (i) fund the acquisition of JOTEC and its subsidiaries (the "JOTEC Acquisition"), (ii) pay certain fees and expenses related to the JOTEC Acquisition and the Credit Agreement, and (iii) pay the outstanding balance of our prior credit facility. The Revolving Credit Facility is undrawn following the JOTEC Acquisition and may be used for working capital, capital expenditures, acquisitions permitted under the Credit Agreement, and other general corporate purposes pursuant to the terms of the Credit Agreement.

The loan under the Term Loan Facility is repayable on a quarterly basis according to the amortization provisions set forth in the Credit Agreement. We have the right to repay the loan under the Credit Agreement in whole or in part at any time. Amounts repaid in respect of the loan under the Term Loan Facility may not be reborrowed. Amounts repaid in respect of the loan under the Revolving Credit Facility may be reborrowed. All outstanding principal and interest in respect of (i) the Term Loan Facility must be repaid on or before December 1, 2024 and (ii) the Revolving Credit Facility must be repaid on or before December 1, 2022.

In October 2018 we finalized an amendment to the Credit Agreement to reprice interest rates, resulting in a reduction in the interest rate margins over base rates on the Term Loan Facility. The loan under the Term Loan Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of 2.25%, or LIBOR, plus a margin of 3.25%. Prior to the repricing, the optional floating annual rate was equal to either the base rate plus a margin of 3.00%, or LIBOR, plus a margin of 4.00%. The loan under the Revolving Credit Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of between 3.00% and 3.25%, depending on our consolidated leverage ratio, or LIBOR, plus a margin of between 4.00% and 4.25%, depending on our consolidated leverage ratio. While a payment or bankruptcy event of default exists, we are obligated to pay a per annum default rate of interest of 2.00% in excess of the interest rate otherwise payable with respect to the overdue principal amount of any loans outstanding and overdue interest payments and other overdue fees and amounts. As of September 30, 2019 the aggregate interest rate was 5.35% per annum. We are obligated to pay an unused commitment fee equal to 0.50% of the unutilized portion of the revolving loans. In addition, we are also obligated to pay other customary fees for a credit facility of this size and type.

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, merge or consolidate, change their business or accounting or reporting practices, in each case subject to customary exceptions for a credit facility of this size and type. In addition, with respect to the Revolving Credit Facility, when the principal amount of loans outstanding thereunder is in excess of 25% of the Revolving Credit Facility, the Credit Agreement requires us to comply with a specified maximum first lien net leverage ratio. The Credit Agreement prohibits the payment of certain restricted payments, including cash dividends.

The Credit Agreement includes certain customary events of default that include, among other things, non-payment of principal, interest, or fees; inaccuracy of representations and warranties; breach of covenants; cross-default to certain material indebtedness; bankruptcy and insolvency; and change of control. Upon the occurrence and during the continuance of an event of default, the lenders may declare all outstanding principal and accrued but unpaid interest under the Credit Agreement immediately due and payable and may exercise the other rights and remedies provided under the Credit Agreement and related loan documents. As of September 30, 2019 and December 31, 2018 there were no outstanding balances on our Revolving Credit Facility and the remaining availability was $30.0 million.

Government Supported Bank Debt

In June 2015 JOTEC obtained two loans from Sparkasse Zollernalb, which are government sponsored by the Kreditanstalt für Wiederaufbau Bank ("KFW"). Both KFW loans have a term of nine years and the interest rates are 2.45% and 1.40%.

Loan Balances

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

	September 30, 2019	December 31, 2018
Term loan balance	$ 221,063	$ 222,750
2.45% Sparkasse Zollernalb (KFW Loan 1)	1,089	1,318
1.40% Sparkasse Zollernalb (KFW Loan 2)	1,633	1,885
Total loan balance	223,785	225,953
Less unamortized loan origination costs	(7,848)	(9,072)
Net borrowings	215,937	216,881
Less short-term loan balance	(1,144)	(1,160)
Long-term loan balance	$ 214,793	$ 215,721

Interest Expense

Interest expense was $3.6 million and $11.3 million for the three and nine months ended September 30, 2019, respectively, as compared to $4.1 million and $11.9 million for the three and nine months ended September 30, 2018, respectively. Interest expense includes interest on debt and uncertain tax positions in both periods.

10. Commitments and Contingencies

Liability Claims

Our estimated unreported loss liability was $1.9 million and $1.7 million as of September 30, 2019 and December 31, 2018, respectively. As of September 30, 2019 and December 31, 2018, the related recoverable insurance amounts were $943,000 and $693,000, respectively. We accrue our estimate of unreported product and tissue processing liability claims as a component of other long-term liabilities and record the related recoverable insurance amount as a component of other long-term assets, as appropriate. Further analysis indicated that the estimated liability as of September 30, 2019 could have been as high as $3.8 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

Employment Agreements

The employment agreement of our Chairman, President, and Chief Executive Officer ("CEO"), Mr. J. Patrick Mackin, provides for a severance payment, which would become payable upon the occurrence of certain employment termination events, including termination by us without cause.

PerClot Technology

On September 28, 2010 we entered into a worldwide distribution agreement (the "Distribution Agreement") and a license and manufacturing agreement (the "License Agreement") with Starch Medical, Inc. ("SMI"), for PerClot®, a polysaccharide hemostatic agent used in surgery. The Distribution Agreement has a term of 15 years but can be terminated for any reason before the expiration date by us by providing 180 days' notice. The Distribution Agreement also contains minimum purchase requirements that expire upon the termination of the Distribution Agreement or following U.S. regulatory approval for PerClot. Separate and apart from the terms of the Distribution Agreement, pursuant to the License Agreement, as amended by a September 2, 2011 technology transfer agreement, we can manufacture and sell PerClot, assuming appropriate regulatory approvals, in the U.S. and certain other jurisdictions and may be required to pay royalties to SMI at certain rates on net revenues of products.

We may make contingent payments to SMI of up to $1.0 million if certain U.S. regulatory and certain commercial milestones are achieved.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Enrollment was completed in January 2019. We anticipate Premarket Approval ("PMA") submission to the FDA in early 2020.

As of September 30, 2019 we had $1.5 million in prepaid royalties, $2.1 million in intangible assets, net, and $1.2 million in property and equipment, net on our Summary Consolidated Balance Sheets related to the PerClot product line. If we do not ultimately pursue or receive FDA approval to commercialize PerClot in the U.S., these assets could be materially impaired in future periods.

11. Revenue Recognition

Sources of Revenue

We have identified the following revenues disaggregated by revenue source:

- Domestic Hospitals – direct sales of products and preservation services.
- International Hospitals – direct sales of products and preservation services.
- International Distributors – generally these contracts specify a geographic area that the distributor will service, terms and conditions of the relationship, and purchase targets for the next calendar year.
- 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, 2019 and 2018 the sources of revenue were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
Domestic hospitals	$ 36,627	$ 34,924	$ 108,582	$ 103,606
International hospitals	20,246	19,001	63,204	56,440
International distributors	9,654	9,083	29,773	30,482
CardioGenesis cardiac laser therapy	1,354	1,590	4,966	4,514
Total sources of revenue	**$ 67,881**	**$ 64,598**	**$ 206,525**	**$ 195,042**

Also see segment disaggregation information in Note 14 below.

Contract Balances

We may generate contract assets during the pre-delivery design and manufacturing stage of E-xtra DESIGN ENGINEERING product order fulfillment. We assess the balance related to any arrangements in process and determine if the enforceable right to payment creates a material contract asset requiring disclosure. No material arrangements in process existed as of September 30, 2019 and 2018.

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, 2019 and 2018 was not material.

12. Stock Compensation

Overview

We have stock option and stock incentive plans for employees and non-employee Directors that provide for grants of restricted stock awards ("RSAs"), restricted stock units ("RSUs"), performance stock units ("PSUs"), and options to purchase shares of our common stock at exercise prices generally equal to the fair value of such stock at the dates of grant. We also maintain a shareholder-approved Employee Stock Purchase Plan (the "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, 2019 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 503,000 shares and had an aggregate grant date market value of $14.9 million. Two types of PSUs have been granted in 2019, one with a short-term performance component and the other with a long-term performance component. If performance thresholds are met, the short-term PSUs granted in 2019 represent the right to receive up to 150% of the target number of shares of common stock. The performance component of the short-term PSU awards granted in 2019 is based on attaining specified levels of adjusted earnings before interest, taxes, depreciation, and amortization, ("EBITDA"), as defined in the PSU grant documents, for the 2019 calendar year. If performance thresholds are met, the long-term PSUs granted in 2019 represent the right to receive up to 288% of the target number of shares of common stock. The performance component of the long-term PSU awards granted in 2019 is based on attaining specified levels of adjusted revenue growth and gross margin, as defined in the PSU grant document, for the years 2019 through 2023. We currently believe that achievement of the performance component for both types of PSUs is probable, and we reevaluate this likelihood on a quarterly basis.

During the nine months ended September 30, 2018 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, including PSUs at target levels, together totaled 317,000 shares of common stock and had an aggregate grant date market value of $7.1 million. The PSUs granted in 2018 represented the right to receive up to 150% of the target number of shares of common stock based on meeting performance thresholds. The performance component of PSU awards granted in 2018 was based on attaining specified levels of adjusted EBITDA, as defined in the PSU grant documents, for the 2018 calendar year. The PSUs granted in 2018 earned 80% of the target number of shares.

The Committee authorized, from approved stock incentive plans, grants of stock options to purchase a total of 169,000 and 219,000 shares to certain Company officers during the nine months ended September 30, 2019 and 2018, respectively. The exercise prices of the options were equal to the closing stock prices on their respective grant dates.

Employees purchased common stock totaling 61,000 shares and 82,000 shares in the nine months ended September 30, 2019 and 2018, respectively, through the ESPP. There were no purchases of shares through the ESPP during the three months ended September 30, 2019 and 2018.

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, 2019		Nine Months Ended September 30, 2019	
	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	0.39	0.40	0.39
Risk-free interest rate	N/A	2.10%	2.54%	2.56%

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,	
	2019	**2018**	**2019**	**2018**
RSA, RSU, and PSU expense	$ 2,133	$ 1,281	$ 5,579	$ 3,750
Stock option and ESPP expense	487	412	1,460	1,301
Total stock compensation expense	**$ 2,620**	**$ 1,693**	**$ 7,039**	**$ 5,051**

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 $158,000 and $458,000 in the three and nine months ended September 30, 2019, respectively, and $125,000 and $363,000 in the three and nine months ended September 30, 2018, respectively, of the stock compensation expense into our inventory costs and deferred preservation costs.

As of September 30, 2019 we had total unrecognized compensation costs of $14.3 million related to RSAs, RSUs, and PSUs and $2.4 million related to unvested stock options. As of September 30, 2019 this expense is expected to be recognized over a weighted-average period of 2.6 years for PSUs, 1.7 years for stock options, 1.7 years for RSUs, and 1.3 years for RSAs.

13. (Loss) Income Per Common Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Basic (loss) income per common share	**2019**	**2018**	**2019**	**2018**
Net (loss) income	$ (134)	$ 1,565	$ 2,401	$ (2,064)
Net loss (income) allocated to participating securities	1	(15)	(17)	20
Net (loss) income allocated to common shareholders	**$ (133)**	**$ 1,550**	**$ 2,384**	**$ (2,044)**
Basic weighted-average common shares outstanding	**37,255**	**36,526**	**37,065**	**36,331**
Basic (loss) income per common share	**$ 0.00**	**$ 0.04**	**$ 0.06**	**$ (0.06)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
Diluted (loss) income per common share	**2019**	**2018**	**2019**	**2018**
Net (loss) income	$ (134)	$ 1,565	$ 2,401	$ (2,064)
Net loss (income) allocated to participating securities	1	(14)	(16)	20
Net (loss) income allocated to common shareholders	**$ (133)**	**$ 1,551**	**$ 2,385**	**$ (2,044)**
Basic weighted-average common shares outstanding	37,255	36,526	37,065	36,331
Effect of dilutive stock options and awards	--	1,084	785	--
Diluted weighted-average common shares outstanding	**37,255**	**37,610**	**37,850**	**36,331**
Diluted (loss) income per common share	**$ 0.00**	**$ 0.04**	**$ 0.06**	**$ (0.06)**

We excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares because the inclusion of these stock options would be antidilutive to loss per common share.

For the three months ended September 30, 2019 all stock options and awards were excluded from the calculation of diluted weighted-average common shares outstanding as these would be antidilutive due to the net loss. For the nine months ended September 30, 2019 stock options to purchase a weighted-average of 123,000 shares were antidilutive and excluded from the calculation of diluted weighted-average common shares outstanding.

For the three months ended September 30, 2018 none of the stock options to purchase shares were antidilutive; therefore, no shares were excluded from the calculation of diluted weighted-average common shares outstanding. For the nine months ended September 30, 2018 all stock options and awards were excluded from the calculation of diluted weighted-average common shares outstanding as these would be antidilutive due to the net loss.

14. Segment Information

We have two reportable segments organized according to our products and services: Medical Devices and Preservation Services. The Medical Devices segment includes external revenues from product sales of BioGlue, JOTEC products, On-X products, CardioGenesis cardiac laser therapy, PerClot, and PhotoFix. 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,	
	2019	2018	2019	2018
Revenues:				
Medical devices	$ 47,484	$ 45,152	$ 147,053	$ 138,063
Preservation services	20,397	19,446	59,472	56,979
Total revenues	**67,881**	**64,598**	**206,525**	**195,042**
Cost of products and preservation services:				
Medical devices	12,706	12,459	41,021	40,166
Preservation services	9,953	9,425	29,043	27,083
Total cost of products and preservation services	**22,659**	**21,884**	**70,064**	**67,249**
Gross margin:				
Medical devices	34,778	32,693	106,032	97,897
Preservation services	10,444	10,021	30,429	29,896
Total gross margin	**$ 45,222**	**$ 42,714**	**$ 136,461**	**$ 127,793**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Products:				
BioGlue	$ 15,679	$ 15,646	$ 50,834	$ 48,685
JOTEC	15,774	15,004	48,936	46,669
On-X	12,610	11,298	36,751	33,495
CardioGenesis cardiac laser therapy	1,354	1,590	4,966	4,514
PerClot	980	882	2,814	2,822
PhotoFix	1,087	732	2,752	1,878
Total products	**47,484**	**45,152**	**147,053**	**138,063**
Preservation services:				
Cardiac tissue	11,304	9,502	30,734	26,660
Vascular tissue	9,093	9,944	28,738	30,319
Total preservation services	**20,397**	**19,446**	**59,472**	**56,979**
Total revenues	**$ 67,881**	**$ 64,598**	**$ 206,525**	**$ 195,042**

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. The words "could," "may," "might," "will," "would," "shall," "should," "pro forma," "potential," "pending," "intend," "believe," "expect," "anticipate," "estimate," "plan," "future," "assume," and other similar expressions generally 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 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 belief regarding the international growth opportunity that would be provided by obtaining regulatory approval for BioGlue in China;
- Our beliefs about the unavailability of handpieces for cardiac laser therapy in the fourth quarter of 2019, the temporary nature of this unavailability, and a possible resolution of this unavailability by the first quarter of 2020;
- Our belief that revenue from cardiac laser therapy can vary from quarter to quarter and year to year due to the use of cardiac laser therapy adjunctively with cardiac bypass surgery by a limited number of physicians;
- Our ability to realize the anticipated business opportunities, growth prospects, synergies, and other benefits of the agreements with Endospan, and our beliefs about the costs and expected timeline regarding certain clinical trial milestones for the regulatory approval of the Nexus stent graft system in the U.S.;
- Our plans, costs, and expected timeline regarding regulatory approval for PerClot in the U.S. and additional international markets and the distribution of PerClot in those markets after the requisite regulatory approvals are obtained;
- 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, 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;
- 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 borrowing capacity or financing;
- Our belief that we will incur expenses for clinical research work to gain regulatory approvals for products or indications, including JOTEC, On-X, PerClot, and BioGlue products, and expenses for research and development for new products;
- Our belief that the utilization of net operating loss carryforwards from our acquisitions of JOTEC, On-X, Hemosphere, Inc., and Cardiogenesis Corporation will not have a material impact on income taxes for the 2019 tax year; and
- Other statements regarding future plans and strategies, anticipated events, or trends.

These and other forward-looking statements reflect the views of management at the time such statements are 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 from our expectations, including, without limitation, in addition to those specified in the text surrounding such statements, the risks described under Part II, Item 1A, "Risks Factors" in this Form 10-Q and elsewhere throughout this report, the risks described under in Part I, Item 1A, "Risks Factors" in our Annual Report on Form 10-K for

the year ended December 31, 2018 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"), incorporated in 1984 in Florida, is a leader in the manufacturing, processing, and distribution of medical devices and implantable human tissues used in cardiac and vascular surgical procedures focused on aortic repair. Our medical devices and processed tissues primarily include four product families: BioGlue® Surgical Adhesive ("BioGlue"); JOTEC GmbH ("JOTEC") endovascular and surgical products; On-X Life Technologies Holdings, Inc. ("On-X") mechanical heart valves and surgical products; and cardiac and vascular human tissues including the CryoValve® SG pulmonary heart valve ("CryoValve SGPV") and the CryoPatch® SG pulmonary cardiac patch ("CryoPatch SG"), both of which are processed using our proprietary SynerGraft® technology. Additional products include CardioGenesis cardiac laser therapy, PerClot®, and PhotoFix™.

We reported quarterly revenues of $67.9 million in the three months ended September 30, 2019, a 5% increase from the quarter ended September 30, 2018 primarily due to an increase in revenues from On-X, preservation services, and JOTEC product revenues. See the "Results of Operations" section below for additional analysis of the three and nine months ended September 30, 2019.

Agreements with Endospan

On September 11, 2019 CryoLife or its wholly-owned subsidiary, JOTEC GmbH ("JOTEC"), entered into exclusive distribution and loan agreements with Endospan Ltd. ("Endospan"), an Israeli corporation, as well as a securities purchase option agreement to purchase Endospan. We paid Endospan $15.0 million in September 2019 related to these agreements.

JOTEC entered into an exclusive distribution agreement ("Endospan Distribution Agreement") with Endospan, pursuant to which JOTEC obtained exclusive distribution rights for Endospan's Nexus stent graft system (the "Nexus Product") and accessories in certain countries in Europe. In addition, CryoLife entered into a securities purchase option agreement ("Endospan Option Agreement") with Endospan which provides CryoLife the option to purchase all of the outstanding securities of Endospan from Endospan's securityholders at the time of the acquisition, or the option to acquire all of Endospan's assets, in each case, for a price between $350.0 and $450.0 million before, or within, a certain period of time after U.S. Food and Drug Administration ("FDA") approval of the Nexus Product, with such option expiring 90 days after receiving notice that Endospan has received approval from the FDA for its Nexus Product. Lastly, CryoLife and Endospan entered into a loan agreement ("Endospan Loan Agreement"), in which CryoLife agreed to provide Endospan a secured loan to be funded in three tranches of $5.0 million each, of which the first tranche was funded in September of 2019.

Critical 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, 2018. 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 summary 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 quarter ended September 30, 2019 in any of our Critical Accounting Policies from those contained in our Form 10-K for the year ended December 31, 2018.

New Accounting Pronouncements

See Note 1 of "Notes to Summary Consolidated Financial Statements" for further discussion of new accounting standards that have been adopted or are being evaluated for future adoption.

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,	
	2019	**2018**		**2019**	**2018**
Products:					
BioGlue	$ 15,679	$ 15,646	--%	23%	24%
JOTEC	15,774	15,004	5%	23%	23%
On-X	12,610	11,298	12%	19%	18%
CardioGenesis cardiac laser therapy	1,354	1,590	-15%	2%	3%
PerClot	980	882	11%	1%	1%
PhotoFix	1,087	732	48%	2%	1%
Total products	**47,484**	**45,152**	**5%**	**70%**	**70%**
Preservation services:					
Cardiac tissue	11,304	9,502	19%	17%	15%
Vascular tissue	9,093	9,944	-9%	13%	15%
Total preservation services	**20,397**	**19,446**	**5%**	**30%**	**30%**
Total	**$ 67,881**	**$ 64,598**	**5%**	**100%**	**100%**

	Revenues for the Nine Months Ended September 30,		Percent Change From Prior Year	Revenues as a Percentage of Total Revenues for the Nine Months Ended September 30,	
	2019	**2018**		**2019**	**2018**
Products:					
BioGlue	$ 50,834	$ 48,685	4%	25%	25%
JOTEC	48,936	46,669	5%	24%	24%
On-X	36,751	33,495	10%	18%	17%
CardioGenesis cardiac laser therapy	4,966	4,514	10%	2%	3%
PerClot	2,814	2,822	--%	1%	1%
PhotoFix	2,752	1,878	47%	1%	1%
Total products	**147,053**	**138,063**	**7%**	**71%**	**71%**
Preservation services:					
Cardiac tissue	30,734	26,660	15%	15%	14%
Vascular tissue	28,738	30,319	-5%	14%	15%
Total preservation services	**59,472**	**56,979**	**4%**	**29%**	**29%**
Total	**$ 206,525**	**$ 195,042**	**6%**	**100%**	**100%**

Revenues increased 5% and 6% for the three and nine months ended September 30, 2019, respectively, as compared to the three and nine months ended September 30, 2018. The increase in revenues for the three months ended September 30, 2019 was primarily due to increases in On-X product revenues, preservation services revenues, and JOTEC product revenues. The increase in revenues for the nine months ended September 30, 2019 was primarily due to increases in On-X product revenues, preservation services, JOTEC product revenues, and BioGlue revenues. Excluding the effects for foreign exchange, revenues increased 6% and 8% for the three and nine months ended September 30, 2019, respectively, as compared to the three and nine months ended September 30, 2018. A detailed discussion of the changes in product revenues and preservation services revenues for the three and nine months ended September 30, 2019 is presented below.

Products

Revenues from products increased 5% and 7% for the three and nine months ended September 30, 2019, respectively, as compared to the three and nine months ended September 30, 2018. The increase in the three months was primarily due to the increase in revenues from the sale of On-X products. The increase in the nine months was primarily due to the increase in revenues from the sale of On-X, JOTEC, and BioGlue products. A detailed discussion of the changes in product revenues for BioGlue, JOTEC, On-X, CardioGenesis cardiac laser therapy, PerClot, and PhotoFix 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, with a concentration in Euros, but also including British Pounds, Polish Zlotys, Swiss Francs, Brazilian Reals, and Canadian Dollars, which are subject to exchange rate fluctuations. For the three and nine months ended September 30, 2019 as compared to the three and nine months ended September 30, 2018, the U.S. Dollar strengthened in comparison to the major currencies, resulting in revenue decreases 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.

BioGlue

The BioGlue catalogue of products is 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 BioGlue were flat for the three months ended September 30, 2019, as compared to the three months ended September 30, 2018. The factors affecting revenues during this period included a change in the mix of milliliters sold, which increased revenues by 3%, offset by a change in average sales prices, which decreased revenues by 2%, and the effect of foreign exchange rates, which decreased revenues by 1%. Excluding the effects for foreign exchange, revenues increased 2% for the three months ended September 30, 2019, as compared to the three months ended September 30, 2018.

Revenues from the sale of BioGlue increased 4% for the nine months ended September 30, 2019, as compared to the nine months ended September 30, 2018. This increase was primarily due to a 7% increase in the volume of milliliters sold, which increased revenues by 7%, partially offset by the effect of foreign exchange rates, which decreased revenues by 2%, and a decrease in average sales prices, which decreased revenues by 1%. Excluding the effects for foreign exchange, revenues increased 6% for the nine months ended September 30, 2019, as compared to the three and nine months ended September 30, 2018.

Revenues for BioGlue increased in the first three quarters of 2019 compared to the first three quarters of 2018 in all international markets with the largest growth in Asia Pacific, primarily due to changes in distributor buying patterns in those markets, partially offset by decreases in the domestic markets.

We are currently seeking regulatory approval for BioGlue in China, and if this effort is successful, management believes this will provide an additional international growth opportunity for BioGlue in future years.

Domestic revenues from BioGlue accounted for 53% and 51% of total BioGlue revenues for the three and nine months ended September 30, 2019, respectively, and 54% of total BioGlue revenues for both the three and nine months ended September 30, 2018.

JOTEC

On December 1, 2017 CryoLife acquired JOTEC AG and its subsidiaries (the "JOTEC Acquisition"), a German-based, privately held developer of technologically differentiated endovascular stent grafts, and cardiac and vascular surgical grafts, focused on aortic repair. The JOTEC catalogue of products is used in endovascular and open vascular surgery, as well as for the treatment of complex aortic arch and thoracic aortic diseases.

JOTEC revenues, excluding original equipment manufacturing ("OEM"), increased 5% for the three months ended September 30, 2019, as compared to the three months ended September 30, 2018. This increase was primarily due to a 2% increase in volume of units sold, which increased revenues by 7%, primarily due to a mix of products sold in EMEA with higher average sales prices. An overall increase in average sales prices increased revenues by 2%, partially offset by the effect of foreign exchange rates, which decreased revenues by 4%.

JOTEC revenues, excluding OEM, increased 5% for the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018. This increase in revenues was primarily due to an 11% increase in volume of units sold, which increased revenues by 12%, partially offset by the effect of foreign exchange rates, which decreased revenues by 7%.

Excluding the effects for foreign exchange, revenues increased 9% and 12% for the three and nine months ended September 30, 2019, respectively, as compared to the three and nine months ended September 30, 2018.

Revenues for JOTEC increased in the first three quarters of 2019 compared to first three quarters of 2018 in EMEA, Latin America, and Asia Pacific with the largest growth in EMEA, on a constant currency basis, due to growth in distributor markets.

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 CO_2 diffusion catheters and from the sale of Chord-X ePTFE sutures for mitral chordal replacement. On-X also generates revenue from pyrolytic carbon coating products produced for OEM.

On-X product revenues, excluding OEM, increased 9% for the three months ended September 30, 2019, as compared to the three months ended September 30, 2018. This increase was primarily due to a change in mix of units sold, which increased revenues by 7%, and an increase in average sales prices, which increased revenues by 2%. The increase in revenue was due to an increase in volume in direct markets as well as an increase in average sales prices in the Asia Pacific market. Revenues in the direct markets increased 11% for the three months ended September 30, 2019, as compared to the three months ended September 30, 2018. This increase was primarily due to an 10% increase in volume of units sold, which increased revenue by 12%, partially offset by decreases of average sales prices which decreased revenues 2% and the effect of foreign exchange rates, which decreased revenues by 1%.

On-X product revenues, excluding OEM, increased 9% for the nine months ended September 30, 2019, as compared to the nine months ended September 30, 2018. This increase was primarily due to an increase in average sales prices, which increased revenues by 11%, partially offset by the effect of foreign exchange rates, which decreased revenues by 1%, and a 6% increase in volume of units sold, which decreased revenues by 1%. The decrease in revenue with an increase in units sold was due to an increase in units sold in Latin America with a lower average sales price. Revenues in the direct markets increased 12% for the nine months ended September 30, 2019, as compared to the nine months ended September 30, 2018. This increase was primarily due to an 11% increase in volume of units sold, which increased revenue by 13%, partially offset by the effect of foreign exchange rates, which decreased revenues by 1%.

Excluding the effects for foreign exchange, On-X revenues, excluding OEM, increased 10% for both the three and nine months ended September 30, 2019, as compared to the three and nine months ended September 30, 2018.

On-X revenues, excluding OEM, for the three months ended September 30, 2019 increased in North America and Asia Pacific as a result of increases in market share. On-X revenues for the nine months ended September 30, 2019 increased primarily in North America as a result of increases in market share. On-X OEM sales accounted for less than 1% of product revenues for both the three and nine months ended September 30, 2019 and 2018.

CardioGenesis Cardiac Laser Therapy

Revenues from our CardioGenesis cardiac laser therapy product line consist primarily of sales of handpieces and, in certain periods, the sale of laser consoles. Revenues from cardiac laser therapy decreased 15% for the three months ended September 30, 2019, as compared to the three months ended September 30, 2018. This decrease in the three months ended September 30, 2019 was due to a 14% decrease in unit shipments of handpieces, which decreased revenues by 14%, partially offset by an increase in average sales prices, which increased revenues by 5%, and due to a laser console that was sold in the three months ended September 30, 2018. No laser consoles were sold in the three months ended September 30, 2019.

Revenues from cardiac laser therapy increased 10% for the nine months ended September 30, 2019, as compared to the nine months ended September 30, 2018. This increase was primarily due to an increase in service fees and an increase in revenues due to laser console sales. The nine months ended September 30, 2019 had a 1% increase in unit shipments of handpieces, which increased revenues by 1%.

Cardiac laser therapy is generally used adjunctively with cardiac bypass surgery by a limited number of physicians who perform these procedures, which usage patterns can cause period over period revenue fluctuations. There was an increase in physician usage during the first quarter of 2019, which increased shipments overall during the first three quarters of 2019.

During the third quarter of 2019, we determined that we will not have a supply of handpieces for at least most of the fourth quarter of 2019 until the FDA approves our supplier's change in manufacturing location, pending resolution of several observations the FDA raised during a manufacturing site change reinspection. We do not believe these observations relate to quality or safety. We will not have any handpieces available to ship until our supplier resolves these issues with the FDA. We currently anticipate resumption of supply by the first quarter of 2020.

PerClot

Revenues from the sale of PerClot increased 11% for the three months ended September 30, 2019, as compared to the three months ended September 30, 2018. The increase in the three months ended September 30, 2019 was primarily due to a 10% increase in the volume of grams sold, which increased revenue by 31%, partially offset by a decrease in average sales price, which decreased revenues by 17%, and the effect of foreign exchange rates, which decreased revenues by 3%.

Revenues from the sale of PerClot were flat for the nine months ended September 30, 2019, as compared to the nine months ended September 30, 2018. The key factors affecting revenue this period included a 4% increase in the volume of grams sold, which increased revenue by 14%, offset by a decrease in average sales price, which decreased revenues by 11%, and the effect of foreign currency exchange, which decreased revenue by 3%.

The decrease in average selling prices for the nine months ended September 30, 2019 was in both indirect and direct markets. The increase in volume for the three and nine months ended September 30, 2019 was primarily due to an increase in sales of PerClot in EMEA in the direct markets.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Enrollment was completed in January 2019. We anticipate PMA submission to the FDA in the first half of 2020.

PhotoFix

PhotoFix revenues increased 48% and 47% for the three and nine months ended September 30, 2019, respectively, as compared to the three and nine months ended September 30, 2018. The revenue increase was primarily due to an increase in units sold, which increased revenues by 49% and 47% for the three and nine months ended September 30, 2019, respectively, partially offset by a decrease in average sales price, which decreased revenues by 1% during the three months ended September 30, 2019.

The increase in units sold for the three and nine months ended September 30, 2019 was primarily due to an increase in the number of implanting physicians when compared to the prior year period, as this product continues to penetrate domestic markets. Additional increases in unit shipments for the three and nine months ended September 30, 2019 were from sales in EMEA, which is a new market in 2019, as well as from the introduction of smaller sized PhotoFix patches in 2018 and a larger sized PhotoFix patch in the second quarter of 2019.

Preservation Services

Preservation services include services revenues from the preservation of cardiac and vascular tissues. Revenues from preservation services increased 5% and 4% for three and nine months ended September 30, 2019, respectively, as compared to the three and nine months ended September 30, 2018.

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. See further discussion below of specific items affecting cardiac and vascular preservation services revenues for the three and nine months ended September 30, 2019.

Cardiac Preservation Services

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.

Revenues from cardiac preservation services, consisting of revenues from the distribution of heart valves and cardiac patch tissues, increased 19% and 15% for the three and nine months ended September 30, 2019, respectively, as compared to the three and nine months ended September 30, 2018. This increase during the three and nine months ended September 30, 2019 was primarily due to an 18% and 15% increase in unit shipments of cardiac tissues, which increased revenues by 19% and 15%, respectively.

The increase in cardiac volume for the three and nine months ended September 30, 2019 was primarily due to an increase in the volume of cardiac valve shipments and, to a lesser extent, cardiac patch shipments.

Vascular Preservation Services

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.

Revenues from vascular preservation services decreased 9% for the three months ended September 30, 2019, as compared to the three months ended September 30, 2018. This decrease was primarily due to a 7% decrease in vascular tissue shipments, which decreased revenues by 7%, and a decrease in average service fees, which decreased revenues by 2%.

Revenues from vascular preservation services decreased 5% for the nine months ended September 30, 2019, as compared to the nine months ended September 30, 2018. This decrease was primarily due to a 3% decrease in vascular tissue shipments, which decreased revenues by 3%, and a decrease in average service fees, which decreased revenues by 2%.

The decrease in average service fees for the three and nine months ended September 30, 2019 was primarily driven by fee differences due to physical characteristics of vascular tissues, the routine negotiation of pricing contracts with certain customers, as well as competitive pricing pressures. The decrease in vascular volume for the three and nine months ended September 30, 2019 was primarily due to decreases in saphenous vein shipments.

Cost of Products and Preservation Services

Cost of Products

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Cost of products	$ 12,706	$ 12,459	$ 41,021	$ 40,166

Cost of products increased 2% for both the three and nine months ended September 30, 2019, as compared to the three and nine months ended September 30, 2018. Cost of products for the three and nine months ended September 30, 2019 and 2018 included costs related to JOTEC, On-X, BioGlue, PhotoFix, PerClot, and CardioGenesis cardiac laser therapy.

Cost of products for the three and nine months ended September 30, 2018 includes $62,000 and $2.8 million, respectively, in inventory basis step-up expense, primarily related to the JOTEC inventory fair value adjustment recorded in purchase accounting for the JOTEC acquisition.

The increase in cost of products for the three months ended September 30, 2019 is due to an increase in shipments of higher cost products as a percentage of overall shipments. The increase in cost of products for the nine months ended September 30, 2019 was primarily due to increases in unit shipments.

Cost of Preservation Services

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Cost of preservation services	$ 9,953	$ 9,425	$ 29,043	$ 27,083

Cost of preservation services increased 6% and 7% for the three and nine months ended September 30, 2019, respectively, as compared to the three and nine months ended September 30, 2018. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services increased in the three and nine months ended September 30, 2019 primarily due to an increase in the unit shipment of tissues.

Gross Margin

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Gross margin	$ 45,222	$ 42,714	$ 136,461	$ 127,793
Gross margin as a percentage of total revenues	67%	66%	66%	66%

Gross margin increased 6% for the three months ended September 30, 2019, as compared to the three months ended September 30, 2018, primarily due to increases in On-X, BioGlue, PhotoFix and tissue revenues. Gross margin as a percentage of total revenues increased in the three months ended September 30, 2019, as compared to the three months ended September 30, 2018, primarily due to an increase in On-X margins driven by an increase in revenue as described above.

Gross margin increased 7% for the nine months ended September 30, 2019, as compared to the nine months ended September 30, 2018, primarily due to increases in On-X, BioGlue, JOTEC and tissue revenues. Gross margin as a percentage of total revenues remained flat in the nine months ended September 30, 2019, as compared to the nine months ended September 30, 2018, primarily due to additional costs in 2018 for the inventory fair value adjustment recorded in purchase accounting for the JOTEC acquisition.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
General, administrative, and marketing expenses	$ 34,259	$ 32,871	$ 105,402	$ 104,946
General, administrative, and marketing expenses as a percentage of total revenues	50%	51%	51%	54%

General, administrative, and marketing expenses increased 4% for the three months ended September 30, 2019 as compared to three months ended September 30, 2018 and remained flat for the nine months ended September 30, 2019 as compared to September 30, 2018. The increases in general, administrative, and marketing expenses for the three and nine months ended September 30, 2019 were primarily due to higher expenses to support our increased revenue base and employee headcount, offset by decreased business development and integration expenses primarily related to the JOTEC acquisition. General, administrative, and marketing expenses for the three and nine months ended September 30, 2019 included $1.2 million and $2.6 million, respectively, in business development and integration expenses, as compared to $1.9 million and $6.9 million for the three and nine months ended September 30, 2018, respectively, primarily related to the JOTEC acquisition.

Research and Development Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Research and development expenses	$ 6,259	$ 5,225	$ 17,648	$ 16,314
Research and development expenses as a percentage of total revenues	9%	8%	9%	8%

Research and development expenses increased 20% and 8% for the three and nine months ended September 30, 2019, respectively, as compared to the three and nine months ended September 30, 2018. Research and development spending in the three and nine months ended September 30, 2019 was primarily focused on clinical work with respect to our pivotal clinical trial to gain regulatory approval for JOTEC products, and to a lesser extent, to gain regulatory approval for On-X products as well as approval to commercialize PerClot for surgical indications in the U.S. Research and development spending in the three and nine months ended September 30, 2018 was primarily focused on JOTEC products and clinical work with respect to our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. and, to a lesser extent, On-X and BioGlue products.

Interest Expense

Interest expense was $3.6 million and $11.3 million for the three and nine months ended September 30, 2019, respectively, as compared to $4.1 million and $11.9 million for the three and nine months ended September 30, 2018, respectively. Interest expense in the three and nine months ended September 30, 2019 and 2018 included interest on debt and uncertain tax positions.

Other Expense (Income), Net

Other expense, net was $2.4 million and $2.7 million for the three and nine months ended September 30, 2019, respectively, as compared to other income of $1.5 million and $257,000 for the three and nine months ended September 30, 2018, respectively. Other income and other expense primarily includes the realized and unrealized effects of foreign currency gains and losses.

Earnings

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
(Loss) income before income taxes	$ (992)	$ 2,108	$ 97	$ (4,932)
Income tax (benefit) expense	(858)	543	(2,304)	(2,868)
Net (loss) income	**$ (134)**	**$ 1,565**	**$ 2,401**	**$ (2,064)**
Diluted (loss) income per common share	**$ 0.00**	**$ 0.04**	**$ 0.06**	**$ (0.06)**
Diluted weighted-average common shares outstanding	**37,255**	**37,610**	**37,850**	**36,331**

We experienced a loss before income taxes for the three months ended September 30, 2019 and income before income taxes for the three months ended September 30, 2018. We experienced income before income taxes for the nine months ended September 30, 2019 and a loss before income taxes for the nine months ended September 30, 2018. Loss before income taxes for the three months ended September 30, 2019, as compared to income for the three months ended September 30, 2018, was primarily due the effect of foreign currency gains and losses. Income before income taxes for the nine months ended September 30, 2019, as compared to a loss for the nine months ended September 30, 2018, was primarily due to a decrease in integration and business development expenses and inventory basis step-up expense related to the JOTEC acquisition.

Our effective income tax rate was a benefit of 87% and 2,375% for the three and nine months ended September 30, 2019, respectively, as compared to an expense of 26% and a benefit of 58% for the three and nine months ended September 30, 2018, respectively. The change in the tax rate for the three and nine months ended September 30, 2019 is primarily due to a change in pre-tax book income for the three and nine months ended September 30, 2019, as compared to the three and nine months ended September 30, 2018.

The income tax rate for the three and nine months ended September 30, 2019 was impacted by excess tax benefit deductions related to stock compensation, which increased income tax benefits by approximately $2,000 and $2.0 million, respectively, as well as the recognition of a benefit of approximately $900,000 related to the expiration of certain federal tax statutes of limitations. These factors were partially offset by unfavorable impacts of non-deductible operating expenses and executive compensation expenses.

The income tax rate for the three and nine months ended September 30, 2018 was impacted by excess tax benefit deductions related to stock compensation, which increased year-to-date income tax benefits by approximately $1.4 million, and losses in high rate jurisdictions. These factors were partially offset by impacts of non-deductible operating expenses and executive compensation expenses.

Net income and diluted income per common share decreased for the three months ended September 30, 2019, as compared to the three months ended September 30, 2018. The decrease for the three months ended September 30, 2019 was primarily due to a decrease in income before income taxes, partially offset by an income tax benefit, as discussed above. Net income and diluted income per common share increased for the nine months ended September 30, 2019, as compared to the nine months ended September 30, 2018, primarily due to the increase in income before income taxes, partially offset by a lessor income tax benefit in the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018.

Seasonality

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 believe the seasonality for On-X products may be obscured as the On-X products have not fully penetrated many markets.

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. However, the nature of any seasonal trends may be obscured due to integration activities in 2018 subsequent to the JOTEC Acquisition including the implementation of our distributor-to-direct strategy and our European sales force realignment.

We do not believe the demand for CardioGenesis cardiac laser therapy is seasonal.

We are uncertain whether the demand for PerClot or PhotoFix is seasonal, as these products have not fully penetrated many markets and, therefore, the nature of any seasonal trends may not yet be obvious.

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 is 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, 2019 net working capital (current assets of $181.4 million less current liabilities of $42.2 million) was $139.2 million, with a current ratio (current assets divided by current liabilities) of 4 to 1, compared to net working capital of $144.7 million and a ratio of 5 to 1 at December 31, 2018.

Overall Liquidity and Capital Resources

Our primary cash requirements for the nine months ended September 30, 2019 were general working capital needs, funding of the Endospan agreements, interest and principal payments under our debt agreement, capital expenditures for facilities and equipment, repurchases of stock to cover tax withholdings, and business development and integration expenses. We funded our cash requirements through our existing cash reserves and proceeds from stock option exercises.

We believe our cash from operations and existing cash and cash equivalents will enable us to meet our current operational liquidity needs for at least the next twelve months. Our future cash requirements are expected to include interest and principal payments under our debt agreement, expenditures for clinical trials, additional 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 as defined in the Endospan 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 facility, considering our revolving credit availability and other obligations, 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 drawing down monies under our credit agreement, discussed below, obtaining additional debt financing, or using a registration statement to sell equities. 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

In connection with the closing of the JOTEC acquisition, we entered into a credit and guaranty agreement for a new $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 December 1, 2017 CryoLife borrowed the entire $225.0 million Term Loan Facility. The proceeds of the Term Loan Facility were used along with cash on hand and shares of CryoLife common stock to (i) fund the JOTEC acquisition, (ii) pay certain fees and expenses related to the JOTEC acquisition and the Credit Agreement, and (iii) pay the outstanding balance of our prior credit facility.

In October 2018 we finalized an amendment to the Credit Agreement to reprice interest rates, resulting in a reduction in the interest rate margins over base rates on the Term Loan Facility. The loan under the Term Loan Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of 2.25%, or LIBOR, plus a margin of 3.25%. Prior to the repricing, the optional floating annual rate was equal to either the base rate, plus a margin of 3.00%, or LIBOR, plus a margin of 4.00%. The loan under the Revolving Credit Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of between 3.00% and 3.25%, depending on our consolidated leverage ratio, or LIBOR, plus a margin of between 4.00% and 4.25%, depending on our consolidated leverage ratio. While a payment or bankruptcy event of default exists, we are obligated to pay a per annum default rate of interest of 2.00% in excess of the interest rate otherwise payable with respect to the overdue principal amount of any loans outstanding and overdue interest payments and other overdue fees and amounts. As of September 30, 2019 the remaining availability on our revolving credit facility was $30.0 million.

We intend to incur expenses for clinical research work to gain regulatory approvals for new products or indications, including JOTEC, On-X, PerClot, and BioGlue products, and to incur expenses for research and development for new products.

We also intend to fund two additional $5.0 million tranches upon completion of certain clinical trial milestones in connection with the Endospan Loan.

We believe utilization of net operating loss carryforwards from our acquisitions of JOTEC, On-X, Hemosphere, Inc., and Cardiogenesis Corporation will not have a material impact on income taxes for the 2019 tax year.

As of September 30, 2019 approximately 28% of our cash and cash equivalents were held in foreign jurisdictions.

Net Cash Flows from Operating Activities

Net cash provided by operating activities was $14.8 million for the nine months ended September 30, 2019, as compared to net cash used in operating activities of $640,000 for the nine months ended September 30, 2018. The prior year cash used in operating activities was largely a result of increased integration and business development costs resulting in a higher net loss, primarily related to the JOTEC acquisition. These expenses made up a large portion of the $12.5 million unfavorable adjustment due to the timing differences between recording accounts payable, accrued expenses, and other liabilities and the payment of cash.

We use the indirect method to prepare our cash flow statement and, accordingly, the operating cash flows are based on our net (loss) 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, 2019 these non-cash items included $13.3 million in depreciation and amortization expenses and $6.6 million in non-cash compensation.

Our working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the nine months ended September 30, 2019 these changes included unfavorable adjustments of $4.5 million due to the timing difference between recording receivables and the receipt of cash, $3.9 million due to an increase in inventory balances and deferred preservation costs, and $3.0 million due to an increase in prepaid expenses and other assets.

Net Cash Flows from Investing Activities

Net cash used in investing activities was $20.8 million for the nine months ended September 30, 2019, as compared to $5.0 million for the nine months ended September 30, 2018. The increase is primarily due to cash payments totaling $15.0 million in connection with the agreements with Endospan made in the third quarter of 2019.

Net Cash Flows from Financing Activities

Net cash used in financing activities was $836,000 for the nine months ended September 30, 2019, as compared to $1.3 million for the nine months ended September 30, 2018. The current year cash used was primarily due to $2.7 million for repurchases of common stock to cover tax withholdings and $2.1 million in principal payments on debt, partially offset by $4.5 million in proceeds from the exercise of options and issuance of common stock.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Scheduled Contractual Obligations and Future Payments

Scheduled contractual obligations and the related future payments as of September 30, 2019 were as follows (in thousands):

	Total	Remainder of 2019	2020	2021	2022	2023	Thereafter
Long-term debt obligations	$ 223,785	$ 691	2,764	2,764	2,764	2,764	$ 212,038
Interest payments	59,709	2,969	11,795	11,664	11,534	11,404	10,343
Research Obligations	31,222	3,897	5,186	8,413	7,483	5,900	343
Operating Leases	26,874	1,347	6,632	5,908	3,459	2,300	7,228
Contingent payments	11,000	--	5,000	6,000	--	--	--
Purchase Commitments	8,445	5,331	2,836	132	110	15	21
Finance leases	6,433	256	554	609	557	557	3,900
Total contractual obligations	**$ 367,468**	**$ 14,491**	**$ 34,767**	**$ 35,490**	**$ 25,907**	**$ 22,940**	**$ 233,873**

Our long-term debt obligations and interest payments above result from scheduled principal payments and anticipated interest payments related to our Credit Agreement and the JOTEC governmental loans.

Our research obligations represent commitments for ongoing studies and payments to support research and development activities.

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. The operating and finance lease obligations in this schedule are based on actual payments which includes both interest and lease liability.

The contingent payments obligation includes two additional $5.0 million tranches under the Endospan Loan that we are required, subject to certain conditions, to advance to Endospan upon receipt of certification that certain approvals and clinical trial milestones have been achieved. The contingent payments that we may make if certain U.S. regulatory approvals and certain commercial milestones are achieved related to our transaction with Starch Medical, Inc. ("SMI") for PerClot.

Our purchase commitments include obligations from agreements with suppliers, one of which is the minimum purchase requirements for PerClot under a distribution agreement with SMI. Pursuant to the terms of the distribution agreement, we may terminate that agreement, including the minimum purchase requirements set forth in the agreement for various reasons, one of which is if we obtain FDA approval for PerClot. These minimum purchases are included in the table above through 2020, based on the assumption that we will not terminate the distribution agreement before receiving FDA approval for PerClot. However, if we do not obtain FDA approval for PerClot and/or we choose not to terminate the distribution agreement, we may have minimum purchase obligations of up to $1.75 million per year through the end of the contract term in 2025.

The schedule of contractual obligations above excludes (i) obligations for estimated liability claims unless they are due as a result of a settlement agreement or other contractual obligation, as no assessments have been made for specific litigation, and (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be $3.3 million, as no specific assessments have been made by any taxing authorities.

Capital Expenditures

Capital expenditures were $5.2 million and $4.3 million for the nine months ended September 30, 2019 and 2018, respectively. Capital expenditures in the nine months ended September 30, 2019 were primarily related to the routine purchases of manufacturing and tissue processing equipment, leasehold improvements needed to support our business, computer software, and computer and office equipment.

Risks and Uncertainties

See the risks 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 $36.7 million as of September 30, 2019 and interest paid on the outstanding balances, if any, of our variable rate Revolving Credit Facility and $225.0 million secured Term Loan Facility. A 10% adverse change in interest rates, as compared to the rates experienced by us in the nine months ended September 30, 2019, affecting our cash and cash equivalents, restricted cash and securities, $225.0 million secured Term Loan Facility, and Revolving Credit Facility 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 JOTEC 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.

Item 4. 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 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, 2019, the CEO and CFO have concluded that our Disclosure Controls were effective at the 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.

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

We may not realize all the anticipated benefits of the JOTEC Acquisition.

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 ("JOTEC"), and its subsidiaries (the "JOTEC Acquisition") for $169.1 million in cash and 2,682,754 shares of CryoLife common stock with a value of $53.1 million on the date of closing, for a total purchase price of approximately $222.2 million, including debt and cash acquired on the date of closing. We paid part of the cash portion of the purchase price using available cash on hand and financed the remainder of the cash portion of the purchase price and related expenses and refinanced our then existing approximately $69.0 million term loan, with a new $255.0 million senior secured credit facility, consisting of a $225.0 million secured term loan facility and a $30.0 million undrawn secured revolving credit facility.

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

- The continued growth of the global market for stent grafts used in endovascular and open repair of aortic disease;
- Our ability to leverage our global infrastructure, including in the markets in which JOTEC is already direct; minimize difficulties and costs associated with transitioning away from distributors in key markets; and accelerate our ability to go direct in Europe in developed markets with the CryoLife and JOTEC product portfolios;
- Our ability to foster cross-selling opportunities between the CryoLife and JOTEC product portfolios;
- Our ability to bring JOTEC products to the U.S. market;
- Our ability to harness the JOTEC new product pipeline and R&D capabilities to drive long-term growth, including our ability to obtain Conformité Européene Mark product certification ("CE Mark") for pipeline products;
- Our ability to drive gross margin expansion;
- Our ability to compete effectively;
- Our ability to carry, service, and manage significantly more debt and repayment obligations; and
- Our ability to manage the unforeseen risks and uncertainties related to JOTEC's business, including any related to intellectual property rights.

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, which could materially, adversely impact our business, financial condition, profitability, and cash flows. These benefits 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 the acquisition, we could experience an interruption or loss of momentum in our existing business activities, which could adversely affect our revenues, financial condition, profitability, and cash flows.

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

Our current and future levels of indebtedness could:

- Limit our ability to borrow money for our working capital, capital expenditures, development projects, strategic initiatives, or other purposes;
- Require us to dedicate a substantial portion of our cash flow from operations to the repayment of our indebtedness, thereby reducing funds available to us for other purposes;
- Limit our flexibility in planning for, or reacting to, changes in our operations or business;
- Make us more vulnerable to downturns in our business, the economy, or the industry in which we operate;
- Restrict us from making strategic acquisitions, introducing new technologies, or exploiting business opportunities; and
- Expose us to the risk of increased interest rates as most of our borrowings are at a variable rate of interest.

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;
- Pay dividends on or make distributions in respect 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 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;
- Create liens on certain assets;
- Enter into certain transactions with our affiliates;
- 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 organizational documents or the organizational documents of a subsidiary 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;
- Change our, or permit a subsidiary to change its, 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.

As a result of these covenants, we are limited in the manner in which we conduct our business, and we may be unable to engage in favorable business activities or finance future operations or capital needs.

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 contained in our existing Credit Agreement could result in an event of default under such agreements, which, if not cured or waived, could have a material, adverse effect on our business, financial condition, and profitability. In the event of any default under our existing debt agreement, 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 the collateral granted to them to secure that indebtedness. If the indebtedness under our existing debt agreements were to be accelerated, there can be no assurance that our assets would be sufficient to repay such indebtedness in full.

Our charges to earnings resulting from acquisition, restructuring, and integration costs may materially, adversely affect the market value of our common stock.

We account for the completion of our acquisitions using the purchase method of accounting. We allocate the total estimated purchase prices to net tangible assets, amortizable intangible assets and indefinite-lived intangible assets, and based on their fair values as of the date of completion of the acquisitions, record the excess of the purchase price over those fair values as goodwill. Our financial results, including earnings per share, could be adversely affected by a number of financial adjustments required in purchase accounting including the following:

- We will incur additional amortization expense over the estimated useful lives of some of the intangible assets acquired in connection with acquisitions during such estimated useful lives;
- We will incur additional depreciation expense as a result of recording purchased tangible assets;
- To the extent the value of goodwill or intangible assets becomes impaired, we may be required to incur material charges relating to the impairment of those assets;
- Cost of sales may increase temporarily following an acquisition as a result of acquired inventory being recorded at its fair market value;
- Earnings may be affected by changes in estimates of future contingent consideration to be paid when an earn-out is part of the consideration; or
- Earnings may be affected by transaction and integration costs, which are expensed immediately.

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, representing 30% of revenues in both the three months ended September 30, 2019 and 2018. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows, if we are unable to:

- Source sufficient quantities of some tissue types from human donors or address potential excess supply of other tissue types. We rely primarily upon the efforts of third-party procurement organizations, tissue banks (most of which are not-for-profit), and others 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 in tissue preservation services, as we may be unable to capitalize on our clinical advantage or our competitors may have advantages over us in terms of cost structure, pricing, back office automation, marketing, and sourcing tissue; or
- Mitigate sufficiently the risk that processed tissue cannot be sterilized and hence carries an inherent risk of infection or disease transmission; there is no assurance that our quality controls will be adequate to mitigate such risk.

In addition, U.S. and foreign governments and regulatory agencies have adopted restrictive laws, regulations, and rules that apply to our tissue preservation services. These include but are not limited to:

- National Organ Transplant Act, which prohibits the acquisition or transfer of human organs for valuable consideration for use in human transplantation, but allows for the payment of reasonable expenses associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of human organs; and
- U.S. Department of Labor, Occupational Safety and Health Administration, and U.S. Environmental Protection Agency requirements for prevention of occupational exposure to infectious agents and hazardous chemicals and protection of the environment.

Any of these laws, regulations, and rules or others could change, our interpretation of them could be challenged by U.S., state, or foreign governments and regulatory agencies, or these governments and regulatory agencies could adopt more restrictive laws or regulations in the future regarding tissue preservation services that could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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

BioGlue® Surgical Adhesive ("BioGlue") is a significant source of our revenues, representing 23% and 24% of revenues in the three months ended September 30, 2019 and 2018, respectively. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

- Our ability to achieve anticipated BioGlue revenue in the U.S. and in international markets outside the U.S.;
- BioGlue is a mature product, our U.S. Patent for BioGlue expired in mid-2012, and our patents in most of the rest of the world for BioGlue expired in mid-2013. Other companies may use the inventions disclosed in the expired patents to develop and make competing products;
- Some companies have launched competitive products and others may pursue regulatory approval for competitive products in the future. These companies may have greater financial, technical, manufacturing, and marketing resources than we do and may be better established in their markets;
- We may be unable to obtain regulatory approvals to commercialize BioGlue in certain countries other than the U.S. at the same rate as our competitors or at all. We also may not be able to capitalize on new regulatory approvals we obtain for BioGlue in countries other than the U.S., including approvals for new indications;
- BioGlue contains a bovine blood protein. Animal-based products are subject to increased scrutiny from the public and regulators, who may have concerns about the use of animal-based products or concerns about the transmission of disease from animals to humans. These concerns could lead to additional regulations or product bans in certain countries;
- Changes to components in the BioGlue product, including in the delivery system, require regulatory approval, which, if delayed, could cause prolonged disruptions to our ability to supply BioGlue; and
- On June 13, 2019 our European Notified Body for BioGlue, Lloyd's Register Quality Assurance Limited, which is headquartered in the U.K., informed us that it will no longer provide Notified Body services to companies in European Economic Area ("EEA") effective September 2019. On July 5, 2019 the U.K. Medicines and Healthcare Products Regulatory Agency ("MHRA") granted us a one year grace period to transfer BioGlue (and PhotoFix) to a new Notified Body. We are currently in the process of transferring to a new Notified Body for BioGlue (and PhotoFix) in the EEA. If we are delayed or unsuccessful in transferring to a new Notified Body for BioGlue (and PhotoFix) in the EEA, if the scheduled exit of the U.K. from the European Union, or "Brexit," occurs and undermines the validity of the MHRA's one-year grace period, 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 the situation is resolved.

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

JOTEC is now a significant source of our revenues, representing 23% of revenues in both the three months ended September 30, 2019 and 2018. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

- Our ability to achieve anticipated JOTEC revenue in international markets outside the U.S.;
- Our ability to meet demand for JOTEC products as we seek to expand our business globally;

- 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;
- Our ability to develop innovative and in-demand products in the aortic surgery space; and
- Our ability to contend with enhanced regulatory requirements and enforcement activities.

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

On-X is a significant source of our revenues, representing 19% and 18% of revenues in the three months ended September 30, 2019 and 2018, respectively. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

- Our ability to achieve anticipated On-X revenue in the U.S. and in international markets outside the U.S.;
- Our ability to capitalize on the FDA's approved reduced International Normalized Ratio ("INR") indication;
- 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;
- Our ability to manage the risks associated with less favorable contract terms for On-X products on consignment at hospitals with more bargaining power;
- Clinical trial data or changes in technology that may impact the market for mechanical heart valves, such as transcatheter aortic valve replacement, or "TAVR" devices;
- Enhanced regulatory enforcement activities or failure to receive renewed certifications that could cause interruption in our ability to sell On-X products in certain markets; and
- Our ability to execute and complete the FDA mandated post-approval study to assess the occurrence of adverse events with the On-X Aortic Prosthetic Heart Valve when targeted at an INR level of 1.8 (1.5-2.0 range) during a 5-year follow-up.

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

The manufacture and sale of medical devices and processing, preservation, and distribution of human tissues are highly complex and subject to significant quality and regulatory risks in the U.S. and internationally. Any of the following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

- Our products and tissues may be recalled or placed on hold by us, the FDA, or other regulatory bodies;
- Our products and tissues allegedly have caused, and may in the future cause, injury to patients, which has exposed, and could in the future expose, us to product and tissue processing liability claims, and such claims could lead to additional regulatory scrutiny and inspections;
- Our manufacturing and tissue processing operations are subject to regulatory scrutiny and inspections, including by the FDA and foreign regulatory agencies, and these agencies could require us to change or modify our manufacturing operations, processes, and procedures or take other adverse action. For example, in January 2013 we received a warning letter from the FDA related to the manufacture of our products and our processing, preservation, and distribution of human tissue, as well as a subsequent 2014 Form 483, after a FDA re-inspection related to the warning letter that included observations concerning design and process validations, environmental monitoring, product controls and handling, corrective and preventive actions, and employee training. After an FDA re-inspection in the first quarter of 2015, the FDA closed out the warning letter issued in 2013;
- Regulatory agencies could reclassify, reevaluate, or suspend our clearances and approvals, or fail or decline to timely issue or reissue our clearances and approvals, that are necessary to sell our products and distribute tissues;
- Local and international regulatory and quality laws and standards are subject to change, which could adversely affect our clearances and approvals to sell our products and distribute tissues; and
- Adverse publicity associated with our products or processed tissues or our industry could lead to a decreased use of our products or tissues, additional regulatory scrutiny, and/or product or tissue processing liability lawsuits.

Further, on May 25, 2017, the European Union adopted a new Medical Device Regulation (MDR 2017/745) ("MDR"), which takes effect on May 26, 2020. Among other changes, MDR places more stringent requirements on manufacturers and European Notified Bodies regarding product classifications, pre- and post-market clinical studies, and other regulatory requirements for product clearances and approvals. These changes could result in product reclassifications and the imposition of other regulatory requirements that could delay, impede, or prevent our ability to commercialize existing, improved, or new products in the EEA. In addition, we or our Notified Bodies (or both) might be unable to timely meet the requirements of MDR. If either of the foregoing were to occur, it could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

At the same time, European Notified Bodies have begun engaging in more rigorous regulatory enforcement activities and may continue to do so. For example, our Notified Body for the On-X product line temporarily suspended the CE Mark for the On-X ascending aortic prosthesis ("AAP") in the EEA. See the risk factor below entitled "Our revenues for the On-X AAP in Europe may continue to be adversely affected by regulatory enforcement activities regarding the On-X AAP's CE Mark" for further discussion. Further, in anticipation of MDR, Notified Bodies will no longer review routine submissions unless they are submitted in accordance with MDR. Our inability to timely adapt to these new requirements of our Notified Bodies could adversely impact our clearances and approvals, which could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

We may not realize all the anticipated benefits of our agreements with Endospan.

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 (the "Nexus Product") in certain countries in Europe for a fixed distribution fee of $9 million; a loan agreement ("Endospan Loan") for a secured loan from CryoLife to Endospan in an amount up to $15 million, funded over three tranches of $5 million each upon the completion of certain milestones (the first tranche of which was paid in September 2019); and a security purchase option agreement providing CryoLife the option to purchase all the then outstanding securities of Endospan from Endospan's existing securityholders for a price between $350 million and $450 million before or upon FDA approval of the Nexus Product, for which option CryoLife paid to Endospan $1 million.

Our ability to realize the anticipated business opportunities, growth prospects, synergies, and other benefits of the Endospan Transaction depends on a number of factors including:

- The continued growth of the global market for stent grafts used in endovascular repair of aortic disease;
- Our ability to introduce and drive adoption of the Nexus Product in the European market;
- Our ability to foster cross-selling opportunities between the JOTEC product portfolio and the Nexus Product;
- Our ability to leverage our global infrastructure to sell the Nexus Product, including in the markets in which JOTEC is already direct;
- Endospan's ability to comply with the Endospan Loan, as well as other debt obligations, and avoid an event of default;
- Endospan's ability to successfully commercialize the Nexus Product in markets outside of Europe;
- Endospan's ability to meet demand for the Nexus Product;
- Endospan's ability to meet quality and regulatory requirements;
- Endospan's ability to manage any intellectual property risks and uncertainties associated with the Nexus Product;
- Endospan's ability to obtain FDA approval of the Nexus Product; and
- Our ability to manage the unforeseen risks and uncertainties related to the Nexus Product.

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, which could materially, adversely impact our business, financial condition, profitability, and cash flows. These benefits may not be achieved within the anticipated time frame or at all. Any of these factors could negatively impact our earnings per share and negatively impact the price of our common stock.

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

We own patents, patent applications, and licenses relating to our technologies, which we believe provide us with important competitive advantages. In addition, we have certain proprietary technologies and methods that we believe provide us with important competitive advantages. We cannot be certain 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. Furthermore, competitors may independently develop similar technologies either before or after our patents expire, or duplicate our technologies, or design around the patented aspects of such technologies.

Our technologies, products, or services could infringe patents or other rights owned by others, or others could infringe our patents. If we become involved in a patent dispute, the costs of the dispute could be expensive, and if we were to lose or decide to settle the dispute, the amounts or effects of the settlement or award by a tribunal could be costly. For example, in 2015 we resolved a patent infringement case with Medafor related to technology we licensed from Starch Medical, Inc. ("SMI"). The settlement of that patent infringement case resulted in the continuation of an injunction prohibiting us from marketing, selling, or distributing PerClot in the U.S. until February 8, 2019. We incurred substantial attorneys' fees and costs in pursuing and defending that case, and only a portion of those fees and costs are subject to recovery through indemnification. Should we be forced to sue a potential infringer, if we are unsuccessful in prohibiting infringements of our patents, should the validity of our patents be successfully challenged by others, or if we are sued by another party for alleged infringement (whether we ultimately prevail or not), our revenues, financial condition, profitability, and cash flows could be materially, adversely affected.

We also have obtained licenses from third parties for certain patents and patent application rights, including rights related to our PerClot technologies. These licenses allow us to use intellectual property rights owned by or licensed to these third parties. We do not control the maintenance, prosecution, enforcement, or strategy for many of these patents or patent application rights and as such are dependent in part on the owners of the intellectual property rights to maintain their viability. Their failure to do so could significantly impair our ability to exploit those technologies.

Our revenues for the On-X AAP in Europe may continue to be adversely affected by regulatory enforcement activities regarding the On-X AAP's CE Mark.

On November 22, 2016, we received a letter from G-Med, which acts as our Notified Body for the On-X product line, indicating that it was temporarily suspending the CE Mark for the On-X AAP in the EEA, due to an allegedly untimely and allegedly deficient plan by us to address certain technical documentation issues found by G-Med during a review and renewal of the design examination certificate for the On-X AAP. On July 26, 2017, we received a letter from G-Med indicating that it was continuing the suspension of the CE Mark for the AAP product for a period of up to 18 months pending further assessment. We have since withdrawn our application from G-Med for certification of the AAP product and are currently pursuing another pathway to CE Mark for the AAP. Failure to obtain CE Mark for the On-X AAP in the EEA could have a material, adverse effect on EEA revenues for the remainder of 2019 and beyond.

Our investment in PerClot is subject to significant risks, including our ability to fully realize our investment by obtaining FDA approval and to successfully commercialize PerClot in the U.S. either directly or indirectly.

In 2010 and 2011, we entered into various agreements with SMI pursuant to which, among other things, we (i) may distribute PerClot in certain international markets and are licensed to manufacture PerClot in the U.S.; (ii) acquired some technology to assist in the production of a potentially key component in PerClot; and (iii) obtained the exclusive right to pursue, obtain, and maintain FDA Pre-Market Approval ("PMA") for PerClot. We are currently conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S., and we completed enrollment in January 2019. We anticipate submission to the FDA in early 2020. There is no guarantee, however, that we will obtain FDA approval when anticipated or at all. The estimated timing of regulatory approval for PerClot is based on factors beyond our control, including but not limited to, unforeseen scheduling difficulties and unfavorable results at various stages in the PMA application process. We may also decide to delay or terminate our pursuit of U.S. regulatory approval for PerClot at any time due to changing conditions at CryoLife, in the marketplace, or in the economy in general.

Further, even if we receive FDA PMA for PerClot, we may be unsuccessful in selling PerClot in the U.S. By the time we secure approvals, competitors may have substantial market share or significant market protections due to contracts, among other things. We may also be unsuccessful in selling in countries other than the U.S. due, in part, to a proliferation in other countries of multiple generic competitors, SMI's breach of its contractual obligations, or the lack of adequate intellectual property protection or enforcement. Any of these occurrences could materially, adversely affect our future revenues, financial condition, profitability, and cash flows.

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

In October 2014 the FDA convened an advisory committee meeting to consider the FDA's recommendation to re-classify more than minimally manipulated ("MMM") allograft heart valves from an unclassified medical device to a Class III medical device. The class of MMM allograft heart valves includes our CryoValve SGPV. At the meeting, a majority of the advisory committee panel recommended to the FDA that MMM allograft heart valves be re-classified as a Class III product. We expect that the FDA will issue a proposal for reclassification of MMM allograft heart valves, which will be subject to a public comment period before finalization. After publication of the reclassification rule, we expect to have thirty months to submit for an FDA PMA, after which the FDA will determine if, and for how long, we may continue to provide these tissues to customers. To date, the FDA has not issued a proposed reclassification for MMM allograft heart valves.

We have continued to process and ship our CryoValve SGPV tissues. If the FDA ultimately classifies our CryoValve SGPV as a Class III medical device, we anticipate requesting a meeting with the FDA to determine the specific requirements to file for and obtain a PMA, and we will determine an appropriate course of action in light of those requirements. 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, this could materially, adversely affect our revenues, financial condition, profitability, and/or cash flows in future periods. In addition, we could decide that the requirements for obtaining a PMA make continued processing of the CryoValve SGPV too onerous, leading us to discontinue distribution of these tissues.

Our key growth areas may not generate anticipated benefits.

Our strategic plan is focused on four growth areas, primarily in the cardiac and vascular surgery segment, which are expected to drive our business in the near term. These growth areas and their key elements are described below:

- *New Products* – Drive growth through new products, including Endospan and JOTEC products;
- *New Indications* – Drive growth by broadening the reach of some of our products and services, including the JOTEC, On-X, and BioGlue products, and preserved cardiac and vascular tissues, with new or expanded approvals and indications in the U.S. or in international markets;
- *Global Expansion* – Drive growth by expanding our current products and services into new markets, including emerging markets, and developing new direct sales territories overseas; and
- *Business Development* – Drive growth through business development by selectively pursuing potential acquisitions, licensing, or distribution rights of companies or technologies that complement our existing products, services, and infrastructure and expand our footprint in the cardiac and vascular surgery space, as we did with the recent distribution agreement with Endospan and the acquisitions of JOTEC and On-X; and licensing of products developed internally with non-cardiac or non-vascular indications. To the extent we identify new non-core products or additional applications for our core products, we may attempt to license these products to corporate partners for further development or seek funding from outside sources to continue commercial development.

Although we continue to implement these strategies, we cannot be certain that they will ultimately drive business expansion and enhance shareholder value.

We may not be successful in obtaining necessary clinical results and regulatory approvals for products and services in development, and our new products and services may not achieve market acceptance.

Our growth and profitability will depend, in part, upon our ability to complete development of, and successfully introduce, new products and services, or expand upon existing indications, which requires that we invest significant time and resources to obtain required regulatory approvals, including significant investment of time and resources into clinical trials. Although we have conducted clinical studies on certain products and services under development, which indicate that such products and services may be effective in a particular application, we cannot be certain that we will be able to successfully execute on these clinical trials or that the results we obtain from clinical studies will be sufficient for us to obtain any required regulatory approvals or clearances. In addition, we must complete various post-market clinical studies to satisfy various regulatory and reimbursement requirements. These post-market clinical studies also require significant time and resources, and we cannot be certain that we will be able to successfully execute them or that the results we obtain will satisfy post-market regulatory and reimbursement requirements.

We are currently engaged in several clinical trials and post-market clinical studies for our products, and we also have begun efforts to initiate future U.S. clinical trials for certain JOTEC products. Each of these trials or studies is subject to the risks outlined herein.

We cannot give assurance that the relevant regulatory agencies will clear or approve these, 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 applicable market or achieve market acceptance. We may encounter delays or rejections during any stage of the regulatory approval process if clinical or other data fails to demonstrate satisfactorily compliance with, or if the service or product fails to meet, the regulatory agency's requirements for safety, efficacy, and quality, or the regulatory agency otherwise has concerns about our quality or regulatory compliance. Regulatory requirements for safety, efficacy, quality, and the conduct of clinical trials and post-market clinical studies may become more stringent due to changes in applicable laws, regulatory agency policies, or the adoption of new regulations. Clinical trials and post-market clinical studies may also be delayed or halted due to the following, among other factors:

- Unanticipated side effects;
- Lack of funding;
- Inability to locate or recruit clinical investigators;
- Inability to locate, recruit, and qualify sufficient numbers of patients;
- Redesign of clinical trial or post-market clinical study programs;
- Inability to manufacture or acquire sufficient quantities of the products, tissues, or any other components required for clinical trials or post-market clinical study programs;
- Changes in development focus; or
- Disclosure of trial results by competitors.

Our ability to complete the development of any of our products and services is subject to all of the risks associated with the commercialization of new products and services based on innovative technologies. Such risks include unanticipated technical or other problems, manufacturing, or processing difficulties, and the possibility that we have allocated insufficient funds to complete such development. Consequently, we may not be able to successfully introduce and market our products or services, or we may not be able to do so on a timely basis. These products and services may not meet price or performance objectives and may not prove to be as effective as competing products and services.

If we are unable to successfully complete the development of a product, service, or application, or if we determine for financial, technical, competitive, or other reasons 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 revenues, financial condition, profitability, and cash flows. 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. The introduction of new products or services may require significant physician training and years of clinical evidence derived from follow-up studies on human patients in order to gain acceptance in the medical community.

All of these could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

We are subject to a variety of risks as we seek to expand our business globally.

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

- Difficulties and costs associated with staffing, establishing and maintaining internal controls, managing foreign operations, including foreign distributor relationships, and developing direct sales operations in key foreign countries;
- Expanded compliance obligations, including obligations associated with the Foreign Corrupt Practices Act, the U.K. Bribery Law, local anti-corruption laws, Office of Foreign Asset Control administered sanction programs, and the European Union's General Data Protection Regulation;
- Broader exposure to corruption;
- Overlapping and potentially conflicting international legal and regulatory requirements, as well as unexpected changes in international legal and regulatory requirements or reimbursement policies and programs;
- Longer accounts receivable collection cycles in certain foreign countries and additional cost of collection of those receivables;

- Diminished protection for intellectual property and the presence of a growing number of generic or smaller competitors in some countries;
- Changes in currency exchange rates, particularly fluctuations in the Euro as compared to the U.S. Dollar;
- Differing local product preferences and product requirements;
- Differing local labor and employment laws, including those related to terminations, unionization, and the formation of works councils or other similar employee organizations;
- Adverse economic or political changes or political instability;
- Potential trade restrictions, exchange controls, and import and export licensing requirements including tariffs;
- Potential adverse tax consequences of overlapping tax structures; and
- Potential adverse financial consequences resulting from the scheduled exit of the U.K. from the European Union, or "Brexit," including a potential disruption of sales into the U.K.

Our failure to adequately address these risks could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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 selectively pursue the potential acquisition, licensing, or distribution rights of companies or technologies that complement our existing products, services, and infrastructure. In connection with one or more of the acquisition transactions, we may:

- Issue additional equity securities that would dilute our stockholders' ownership interest in us;
- Use cash that we may need in the future to operate our business;
- Incur debt, including on terms that could be unfavorable to us or debt that we might be unable to repay;
- Structure the transaction in a manner that has unfavorable tax consequences, such as a stock purchase that does not permit a step-up in the tax basis for the assets acquired;
- Be unable to realize the anticipated benefits, such as increased revenues, cost savings, or synergies from additional sales;
- Be unable to integrate, upgrade, or replace the purchasing, accounting, financial, sales, billing, employee benefits, payroll, and regulatory compliance functions of an acquisition target;
- Be unable to secure or retain the services of key employees related to the acquisition;
- Be unable to succeed in the marketplace with the acquisition; or
- Assume material unknown liabilities associated with the acquired business.

As an example of these risks, in December 2017 we acquired JOTEC, which we financed by incurring further debt, using cash on hand, and issuing additional equity securities. This acquisition poses many of the same risks as set forth above.

Any of the above risks, should they occur, could materially, adversely affect our revenues, financial condition, profitability, and cash flows, including the inability to recover our investment or cause a write-down or write-off of such investment, associated goodwill, or assets.

We are heavily dependent on our suppliers to provide quality materials and supplies.

The materials and supplies used in our product manufacturing and our tissue processing are subject to stringent quality standards and requirements, and many of these materials and supplies are subject to significant regulatory oversight and action. If materials or supplies used in our processes fail to meet these standards and requirements or are subject to recall or other quality action, an outcome could be the rejection or recall of our products or tissues and/or the immediate expense of the costs of the manufacturing or preservation. In addition, if these materials and 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, whether by government order, natural disaster, or other reason, or if the related suppliers are otherwise unable or unwilling to supply us, there may not be sufficient materials or supplies available for purchase to allow us to manufacture our products or process tissues. Any of these occurrences or actions could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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

Some of the materials, supplies, and services that are key components of our product manufacturing or our 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, during the third quarter of 2019, we determined that we will not have a supply of handpieces for at least most of the fourth quarter of 2019 until the FDA approves our supplier's change in manufacturing location, pending resolution of several observations the FDA raised during a manufacturing site change reinspection. We do not believe these observations relate to quality or safety. We will not have any handpieces available to ship until our supplier resolves these issues with the FDA. We currently anticipate resumption of supply by the first quarter of 2020.

We also conduct nearly all our operations at three facilities: Austin, Texas for our On-X product line, Hechingen, Germany for our JOTEC product line, and Kennesaw, Georgia for all our other products. If one of these facilities ceases operations temporarily or permanently, due to natural disaster or other reason, our business could be substantially disrupted.

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

The market for our products and services is intensely competitive and significantly affected by new product introductions and activities of other industry participants. We face intense competition from other companies engaged in the following lines of business:

- The sale of endovascular and surgical stents;
- The sale of mechanical, synthetic, and animal-based tissue valves for implantation;
- The sale of synthetic and animal-based patches for implantation;
- The sale of surgical adhesives, surgical sealants, and hemostatic agents; and
- The processing and preservation of human tissue.

A significant percentage of market revenues from these products was generated by Baxter International, Inc.; Ethicon (a Johnson & Johnson Company); Medtronic, Inc.; Abbott Laboratories; LivaNova PLC; Edwards Lifesciences Corp.; Bard, a subsidiary of Becton, Dickinson, and Company; Integra Life Sciences Holdings; LifeNet; Admedus, Inc.; Aziyo Biologics; Cook Medical; Gore & Associates; Terumo Corp.; Endologix; Antegraft, Inc.; LeMaitre Vascular, Inc.; Maquet, Inc.; Vascutek; Novadaq Technologies, Inc.; Pfizer, Inc.; and BioCer Entwicklungs-GmbH. Several of our competitors enjoy competitive advantages over us, including:

- Greater financial and other resources for product research and development, sales and marketing, acquisitions, and patent litigation;
- Enhanced experience in, and resources for, launching, marketing, distributing, and selling products;
- Greater name recognition as well as more recognizable trademarks for products similar to the products that we sell;
- More established record of obtaining and maintaining FDA and other regulatory clearances or approvals for products and product enhancements;
- More established relationships with healthcare providers and payors;
- Lower cost of goods sold or preservation costs;
- Advanced systems for back office automation, product development, and manufacturing, which may provide certain cost advantages; and
- Larger direct sales forces and more established distribution networks.

Our competitors may develop services, products, or processes with significant advantages over the products, services and processes that we offer or are seeking to develop, and our products and tissues may not be able to compete successfully. If we are unable to successfully market and sell innovative and in-demand products and services, our competitors may gain competitive advantages that may be difficult to overcome. In addition, consolidation among our competitors may make it more difficult for us to compete effectively. If we fail to compete effectively, this could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

We are dependent on our key personnel.

Our business and future operating results depend in significant part upon the continued contributions of our key personnel, including qualified personnel with medical device and tissue processing experience, and senior management with experience in the medical device or tissue processing space, many of whom would be difficult to replace. Our business and future operating results, including production at our manufacturing and tissue processing facilities, also depend in significant part on our ability to attract and retain qualified management, operations, processing, marketing, sales, and support personnel for our operations. Our main facilities are in Kennesaw, Georgia; Austin, Texas; and Hechingen, Germany, where the local supply of qualified personnel in the medical device and tissue processing industries is limited. Competition for such personnel is intense, and we cannot ensure that we will be successful in attracting and retaining such personnel. If we lose any key employees, if any of our key employees fail to perform adequately, or if we are unable to attract and retain skilled employees as needed, this could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

Future tax reform regulations could have a material, adverse impact on us.

The December 2017 tax reform legislation known as H.R. 1, commonly referred to as the "Tax Cuts and Jobs Act" ("the Tax Act"), made significant changes to U.S. federal income tax law. In response, the U.S. Treasury Department issued multiple significant proposed regulation packages to further interpret certain provisions of the Tax Act. As of this interim period, certain significant proposed regulation packages have not yet been finalized. It is possible that when released in final form, these regulations packages could have a material tax impact on us. In addition, we continue to await responses from various state taxing jurisdictions on the impact of the Tax Act on their local taxing regimes. We will continue to monitor and account for the future impacts of federal regulatory and state guidance in the interim period in which such guidance is issued.

Our operating results may fluctuate significantly on a quarterly or annual basis as a result of a variety of factors, many of which are outside our control.

Fluctuations in our quarterly and annual financial results have resulted and will continue to result from numerous factors, including:

- Changes in demand for the products we sell;
- Increased product and price competition, due to the announcement or introduction of new products by our competitors, market conditions, the regulatory landscape, or other factors;
- Changes in the mix of products we sell;
- Availability of materials and supplies, including donated tissue used in preservation services;
- Our pricing strategy with respect to different product lines;
- Strategic actions by us, such as acquisitions of businesses, products, or technologies;
- Unanticipated costs and expenses;
- Effects of domestic and foreign economic conditions and exchange rates on our industry and/or customers;
- The divestiture or discontinuation of a product line or other revenue generating activity;
- The relocation and integration of manufacturing operations and other strategic restructuring;
- Regulatory actions that may necessitate recalls of our products or warning letters that negatively affect the markets for our products;
- Failure of government and private health plans to adequately and timely reimburse the users of our products or changes in reimbursement policies;
- Costs incurred by us in connection with the termination of contractual and other relationships, including distributorships;
- Our ability to collect outstanding accounts receivable in selected countries outside of the U.S.;
- The expiration or utilization of deferred tax assets such as net operating loss carryforwards;
- Market reception of our new or improved product offerings; and
- The loss of any significant customer, especially in regard to any product that has a limited customer base.

We have based our current and future expense levels largely on our investment plans and estimates of future events, although some of our expense levels are, to a large extent, fixed. We may be unable to adjust spending in a timely manner to compensate for any unexpected revenue shortfall. Accordingly, any significant shortfall in revenue relative to our planned expenditures would have an immediate, adverse effect on our business, results of operations, and financial condition. Further, as a strategic response to changes in the competitive environment, we may from time to time make certain pricing, service, or marketing decisions that could have a material, adverse effect on our business, results of operations, and financial condition. Due to the foregoing factors, some of which are not within our control, the price of our common stock may fluctuate substantially. If our quarterly operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly. We believe the quarterly comparisons of our financial results are not always meaningful and should not be relied upon as an indication of our future performance.

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

We rely upon a combination of sophisticated information technology systems and traditional recordkeeping to operate our business. In the ordinary course of business, we collect, store, and transmit large amounts of confidential information (including, but not limited to, personal information, intellectual property and, in some instances, patient data). We have also outsourced elements of our operations to third parties, including elements of our information technology infrastructure and, as a result, we manage a number of independent vendor relationships with third parties who may or could have access to our confidential information. Our information technology and information security systems and records are potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors. Our information technology and information security systems are also potentially vulnerable to malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. While we have invested significantly in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. For example, although we have taken security precautions and are assessing additional precautions to provide greater data security, certain data may be vulnerable to loss in a catastrophic event. We have only limited cyber-insurance coverage that will not cover a number of the events described above and this insurance is subject to deductibles and coverage limitations, and we may not be able to maintain this insurance. We thus have no insurance for most of the claims that could be raised and, for those where we have coverage, those claims could exceed the limits of our coverage. Any interruption or breach in our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result 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.

The implementation of the General Data Protection Regulation in the European Union in May 2018 could adversely affect our business.

The European Union's General Data Protection Regulation ("GDPR") took effect in May 2018. GDPR includes significant new requirements for companies that receive or process the personal data of residents of the European Union (including company employees), which increase our operating costs and require significant management time and energy. GDPR also includes significant penalties for noncompliance. Although our personal data practices, policies, and procedures are intended to comply with GDPR, there can be no assurance that regulatory or enforcement authorities will view these 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 GDPR related government enforcement activities may be costly to comply with, result in negative publicity, and subject us to significant penalties, any of which could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

Consolidation in the healthcare industry could have an adverse effect on our revenues and results of operations.

Many healthcare industry companies, including health care systems, are consolidating to create new companies with greater market power. As the healthcare industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions. If we are forced to reduce our prices because of consolidation in the healthcare industry, our revenues would decrease and our financial condition, profitability, and/or cash flows would suffer.

The success of some of our products and preservation services depends upon relationships with healthcare professionals.

If we fail to maintain our working relationships with healthcare professionals, many of our products and preservation services may not be developed and marketed to appropriately meet the needs and expectations of the professionals who use and support our products and preservation services or the patients who receive them.

The research, development, marketing, and sales of many of our new and improved products and preservation services are dependent upon us maintaining working relationships with healthcare professionals. We rely on these professionals to provide us with considerable knowledge and experience regarding our products and preservation services. Healthcare professionals assist us as researchers, marketing and training consultants, product consultants, and speakers. If we are unable to maintain our relationships with these professionals and do not continue to receive their advice and input, the development and commercialization of our products and preservation services could suffer, which could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

We may be subject to fines, penalties, injunctions, 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 specific approved uses. Generally, unless the products are approved or cleared by the FDA for the alternative uses, the FDA contends that 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 the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales, marketing, and/or support activities, though designed to comply with all FDA requirements, constitute the promotion of our products for an unapproved use in violation of the Federal Food, Drug, and Cosmetic Act. We also face the risk that the FDA or other governmental authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs, and other activities. 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. There is also a possibility that we could be enjoined from selling some or all of our products for any unapproved use. In addition, as a result of an enforcement action against us or our executive officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid.

Our acquired federal tax net operating loss and general business credit carryforwards will be limited or may expire, which could result in greater future income tax expense and adversely impact future cash flows.

Our federal tax net operating loss and general business credit carryforwards include acquired net operating loss carryforwards. Such acquired net operating loss carryforwards will be limited in future periods due to a change in control of our former subsidiaries Hemosphere and Cardiogenesis, as mandated by Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"). We believe that our acquisitions of these companies each constituted a change in control, and that prior to our acquisition, Hemosphere had experienced other equity ownership changes that should be considered a change in control. We also acquired net operating loss carryforwards in certain foreign jurisdictions with the acquisition of JOTEC, but we do not believe these carryforwards will be limited in any material way due to a change of control provision. The deferred tax assets recorded on our Consolidated Balance Sheets exclude amounts that we expect will not be realizable due to these changes in control. A portion of the acquired net operating loss carryforwards is related to state income taxes for which we believe it is more likely than not that these deferred tax assets will not be realized. Therefore, we recorded a valuation allowance against these state net operating loss carryforwards. Limitations on our federal tax net operating loss and general business credit carryforwards could result in greater future income tax expense and adversely impact future cash flows.

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 changing interpretations. Possible sanctions for violation of these healthcare compliance laws include monetary fines, civil and criminal penalties, exclusion from government healthcare programs, and forfeiture of amounts collected in violation of such prohibitions. Any government investigation or a finding of a violation of these laws, despite our compliance efforts, could result in a material, adverse effect on our business, financial condition, and profitability.

We have entered into consulting agreements, speaker agreements, research agreements, and product development agreements with healthcare professionals or healthcare organizations, including some who may order our products or make decisions to use them. While these transactions were structured with the intention of complying with all applicable compliance laws, it is possible that regulatory or enforcement agencies or courts may in the future view these transactions as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties.

We have also adopted the AdvaMed Code of Conduct and the MedTech Europe Code of Ethical Business Practice into our Code of Business Conduct, which governs our relationships with healthcare professionals, including our payment of travel and lodging expenses, research and educational grant procedures, and sponsorship of third-party conferences. In addition, we conduct training sessions on these principles. There can be no assurance, however, that regulatory or enforcement authorities will view these 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. Because our strategy relies on the involvement of healthcare professionals or healthcare organizations who consult with us on the design of our products, perform clinical research on our behalf, or educate the market about the efficacy and uses of our products, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with healthcare professionals or healthcare organizations, who refer or order our products, to be in violation of applicable laws and determine that we would be unable to achieve compliance with such applicable laws. This could harm our reputation and the reputations of the healthcare professionals or healthcare organizations we engage to provide services on our behalf. In addition, the cost of noncompliance with these laws could be substantial since we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from government funded healthcare programs, including Medicare and Medicaid, for noncompliance.

The scope and enforcement of all of these laws is uncertain and subject to rapid change, especially in light of the scarcity of applicable precedent and regulations. There can be no assurance that regulatory or enforcement authorities will not investigate or challenge our current or future activities under these laws. Any investigation or challenge could have a material, adverse effect on our business, financial condition, and profitability. Any regulatory or enforcement review of us, regardless of the outcome, would 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.

Healthcare policy changes, including U.S. healthcare reform legislation signed in 2010, 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 federal government, state governments, regulators, and third-party payors to control these costs and, more generally, to reform the U.S. healthcare system. Some of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of some or all of these proposals could have a material, adverse effect on our financial condition and profitability.

The Patient Protection and Affordable Care Act ("ACA") and the Health Care and Education Affordability Reconciliation Act of 2010 imposed significant new taxes on medical device manufacturers in the form of a 2.3% excise tax on all U.S. medical device sales that commenced in January 2013. While this tax was suspended for 2016, 2017, 2018, and 2019, the excise tax will be levied in 2020 unless Congress passes another suspension. If Congress does not pass a suspension, the excise tax could adversely affect our business and profitability.

Efforts to repeal and replace the ACA altogether have been ongoing since the 2016 election, but it is unclear if these efforts will be successful. On January 20, 2017 President Trump issued an executive order titled "Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal." In addition, as part of the Tax Act, the "individual mandate," which required individuals to purchase insurance, was repealed. The impact of the executive order and the repeal of the individual mandate, as well as the future of the ACA itself, remain unclear. Further, candidates for the 2020 presidential election have put forward numerous healthcare reform proposals, including "Medicare for All." These proposals may affect aspects of our business. We cannot predict what further reform proposals, if any, will be adopted, when they will be adopted, or what impact they may have on us. Any changes that lower reimbursement for our products or reduce medical procedure volumes, however, could adversely affect our business and profitability.

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 product sales are made to customers in other countries who must convert local currencies into U.S. Dollars 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 existing insurance coverage may be insufficient, and we may be unable to obtain insurance in the future.

Our products and tissues allegedly have caused, and may in the future cause, injury to patients using our products or tissues, and we have been, and may be, exposed to product and tissue processing liability claims. 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. In addition, our product and tissue processing liability insurance policies do not include coverage for any punitive damages. Although we have insurance for product and tissue processing liabilities, securities, property, and general liabilities, it is possible that:

- We could be exposed to product and tissue processing liability claims and security claims greater than the amount that we have insured;
- We may be unable to obtain future insurance policies in an amount sufficient to cover our anticipated claims at a reasonable cost or at all; or
- Because we are not insured against all potential losses, uninsured losses due to natural disasters or other catastrophes could adversely impact our business.

Any product liability claim, with or without merit, could result in an increase in our product insurance rates or our inability to secure coverage on reasonable terms, if at all. Even in the absence of a claim, our insurance rates may rise in the future due to market, industry, or other factors. Any product liability claim, even a meritless or unsuccessful one, would be time-consuming and expensive to defend and could result in the diversion of our management's attention from our business and result in adverse publicity, withdrawal of clinical trial participants, injury to our reputation, and loss of revenue.

If we are unsuccessful in arranging acceptable settlements of future product or tissue processing liability claims or future securities class action or derivative claims, we may not have sufficient insurance coverage and liquid assets to meet these obligations. If we are unable to obtain satisfactory insurance coverage in the future, we may be subject to additional future exposure from product or tissue processing liability or securities claims. Additionally, if one or more claims with respect to which we may become, in the future, a defendant should result in a substantial verdict rendered in favor of the plaintiff(s), such verdict(s) could exceed our available insurance coverage and liquid assets. If we are unable to meet required future cash payments to resolve any outstanding or any future claims, this will materially, adversely affect our financial condition, profitability, and cash flows. Further, although we have an estimated reserve for our unreported product and tissue processing liability claims for which we do expect that we will obtain recovery under our insurance policies, these costs could exceed our current estimates. Finally, our facilities could be materially damaged by tornadoes, flooding, other natural disasters, or catastrophic circumstances, for which we are not fully covered by business interruption and disaster insurance, and, even with such coverage, we could suffer substantial losses in our inventory and operational capacity, along with a potential adverse impact on our customers and opportunity costs for which our insurance would not compensate us.

Any of these events could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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 frequently propose to involve themselves in the governance, strategic direction, and operations of a company. We may in the future become subject to such shareholder activism and demands. Such demands may disrupt our business and divert the attention of our management and employees, and any perceived uncertainties as to our future direction resulting from such a situation could result in the loss of potential business opportunities, be exploited by our competitors, cause concern to our current or potential customers, and make it more difficult to attract and retain qualified personnel and business partners, all of which could adversely affect our business. In addition, actions of activist shareholders may cause significant fluctuations in our stock price based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

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 if the market price of our common stock has increased when they sell shares of our common stock that they own. Future dividends, if any, will be authorized by our Board of Directors and declared by us based upon a variety of factors deemed relevant by our directors, including, among other things, our financial condition, liquidity, earnings projections, and business prospects. In addition, restrictions in our credit facility limit our ability to pay future dividends. We can provide no assurance of our ability to pay cash dividends in the future.

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 restricting persons who may call shareholder meetings and allowing 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.

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

(c) The following table provides information about purchases by us during the quarter ended September 30, 2019 of equity securities that are registered by us pursuant to Section 12 of the Securities Exchange Act of 1934:

Period	Total Number of Common Shares and Common Stock Units Purchased	Average Price Paid per Common Share	Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs	Dollar Value of Common Shares That May Yet Be Purchased Under the Plans or Programs
07/01/19 - 07/31/19	253	$ 30.25	--	$ --
08/01/19 - 08/31/19	1,912	26.61	--	--
09/01/19 - 09/30/19	--	--	--	--
Total	**2,165**	27.04	--	

The common shares purchased during the quarter ended September 30, 2019 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.

In October of 2019 the Compensation Committee of our Board of Directors amended our Clawback Policy to require the Company to recoup excess performance-based cash or equity incentive compensation received by current or former officers in the completed three fiscal years immediately preceding the date on which the Company is required to prepare a material accounting restatement as a result of noncompliance with any financial reporting requirement under the federal securities laws, unless the cost of recovery exceeds the amount to be recovered.

Item 6. Exhibits.

The exhibit index can be found below.

Exhibit Number	Description
3.1	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, 2019.)
3.2	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.)
4.1	Form of Certificate for our Common Stock. (Incorporated herein by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.)
10.1*†	Loan Agreement, dated September 11, 2019, by and between CryoLife, Inc., as lender, and Endospan Ltd., as borrower.
10.2*†	Exclusive Distribution Agreement, dated September 11, 2019, by and between JOTEC GmbH, as distributor, and Endospan Ltd., as manufacturer.
31.1*	Certification by J. Patrick Mackin pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32**	Certification Pursuant To 18 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

* 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	/s/ D. ASHLEY LEE
J. PATRICK MACKIN Chairman, President, and Chief Executive Officer (Principal Executive Officer)	D. ASHLEY LEE Executive Vice President, Chief Operating Officer, and Chief Financial Officer (Principal Financial and Accounting Officer)
October 31, 2019	
DATE	

LOAN AGREEMENT

This Loan Agreement (the "**Agreement**") is made and entered into as of the 11th day of September 2019 (the "**Effective Date**"), by and between CryoLife, Inc., a Florida corporation (the "**Lender**"); and Endospan Ltd., an Israeli private limited liability company, registered number 514172931 (the "**Borrower**").

WHEREAS, the Borrower is engaged in the research, development, manufacture, marketing and sale of a product known as the Nexus™ Aortic Arch Stent Graft System (the "**Product**"), and requires funding to finance its efforts to obtain approval from the U.S. Food and Drug Administration (the "**FDA**") of the Product as a medical device indicated for the endovascular treatment of thoracic aortic diseases involving the aortic arch with proximal landing zone in ascending aorta and the Brachiocephalic artery or for other indications("**FDA Approval**");

WHEREAS, concurrently herewith, a Securities Purchase Option Agreement is being entered into by and among the Lender, the Borrower and the Securityholders (the "**SPA**"), the Borrower has asked the Lender for a loan in the principal amount of up to USD fifteen million ($15,000,000) (the "**Principal Amount**"), to be used primarily for the purpose of obtaining FDA Approval and for working capital needs for purposes of commercializing the Product within the territory described in Exhibit B to the Distribution Agreement; and

WHEREAS, subject to the Borrower and the securityholders thereof entering into the SPA, the Lender agrees to provide the Borrower the Loan, all subject to the terms and conditions in this Agreement.

NOW, THEREFORE, the Lender and the Borrower (each a "**Party**" and collectively the "**Parties**") hereby agree as follows:

1. INTERPRETATION

1.1. The preamble and exhibits to this Agreement constitute an integral part hereof.

1.2. Section headings and references to headings are intended solely for convenience purposes and are to be disregarded in construing this Agreement.

1.3. Any capitalized terms otherwise not defined in this Agreement shall have the meaning ascribed thereto in the SPA.

1.4. References to "**Distribution Agreement**" in this Agreement shall refer to that certain Distribution Agreement being entered into contemporaneously herewith between Borrower and JOTEC GmbH, which is an affiliate of Lender, and references to "**Distributor**" shall refer to JOTEC GmbH or its permitted assignee under the Distribution Agreement.

2. THE LOAN

2.1. The Lender shall provide the Principal Amount to the Borrower in three equal tranches of USD five million ($5,000,000) each (each, a "**Tranche**") as follows (in each case subject to the conditions precedent set forth in Section 5):

2.1.1. the first Tranche shall be provided by the Lender to the Borrower within the later of (i) 14 Business Days of the Effective Date; or (ii) such time as the conditions set forth in Section 5 below have been fulfilled;

2.1.2. the second Tranche shall be provided by the Lender to the Borrower within 14 Business Days of the later of (i) receipt of a written notice sent by the Borrower to the Lender that the Product received IDE Approval together with a copy of such IDE Approval; or (ii) such time as the conditions set forth in Section 5 below have

been fulfilled; and

2.1.3. the third Tranche shall be provided by the Lender to the Borrower within the later of (i) 14 Business Days of receipt of a written notice sent by the Borrower to the Lender that the Borrower has achieved the Clinical Trial Threshold; or (ii) such time as the conditions set forth in Section 5 below have been fulfilled.

Notwithstanding the foregoing, if there is an event, development or circumstance occurring or in existence that has resulted in, or could reasonably be expected to have, a Company Material Adverse Effect, the Lender shall have an additional 30 days from receipt of written notice from the Company under 2.1.2 or 2.1.3 to determine whether the condition under Section 5.2.2 has been satisfied and may delay funding on any Tranche during such 30-day period.

For the purpose of this Agreement:

"**IDE Approval**" means approval by the FDA that the Product received Investigational Device Exemption.

"**Clinical Trial Threshold**" means the enrolment of at least 50% of the required number of patients in the primary arm, as set forth in the applicable clinical trial protocol, in the FDA approved clinical trial for the Product.

2.2. The Lender shall make available to the Borrower each Tranche by way of wire transfer to the Borrower's bank account as detailed in **Exhibit A**.

2.3. In the event the Distribution Agreement is terminated pursuant to circumstances giving rise to the Termination Fee (as defined in the Distribution Agreement, the "**Termination Fee**"), the Principal Amount under this Agreement shall automatically be increased by an amount equal to the unpaid portion of the Termination Fee.

2.4. Each Tranche shall bear simple interest at a rate equal to 5% per annum commencing on the date of receipt of the applicable Tranche and until the earlier of full repayment thereof or Cancellation (as defined below) thereof, in accordance with the terms hereof (the "**Interest**"). The Interest shall be computed on the basis of a 360-day year, comprised of twelve months counting 30 days each. For periods of indebtedness of less than one month the Interest shall be calculated *pro rata* to the actual number of days of the month then elapsed.

3. REPAYMENT & CANCELLATION

3.1. The then-outstanding Principal Amount, any unpaid Interest thereon and all other obligations owing under the Loan Documents (collectively the "**Loan Amount**") shall be due and repaid by the Borrower to the Lender on the first anniversary of the closing of the Acquisition (the "**Maturity Date**"); *provided, however*, that in the event that (i) the Lender does not deliver to the Borrower an Exercise Notice during the Option Period, or (ii) the Acquisition can otherwise no longer be consummated under the terms of the SPA, then Borrower's obligation to repay the Loan Amount shall be cancelled, deemed fully discharged, and the Borrower shall not have any further duties or obligations with respect to the repayment thereof to the Lender (the "**Cancellation**"); *provided further*, that the Cancellation shall not occur if there is an Event of Default then in existence; and *provided, further*, in the event that the Principal Amount is increased pursuant to Section 2.3 to include the unpaid portion of the Termination Fee, the portion of the Principal Amount attributable to the unpaid Termination Fee shall be excluded from the portion of the Loan Amount cancelled in the Cancellation and instead shall be due and payable on the date determined pursuant to the Distribution Agreement. For the avoidance of doubt, upon Borrower's payment of the Termination Fee or all portions thereof that are due pursuant to the Distribution Agreement and that have been added to the Principal Amount pursuant to Section 2.3 of this Agreement, such added amounts shall be deducted from the Principal Amount and shall no longer be recoverable from Borrower by Lender.

3.2. The Borrower shall not be entitled to prepay, and except as required in 3.1 above or 8.1 below, be obligated to repay the Principal Amount (in whole or in part) at any time prior to the Maturity Date.

3.3. Simultaneously with the closing of the Acquisition, the Borrower shall pay to the Lender any and all unpaid Interest accrued on the then outstanding Principal Amount.

3.4. Any payments to be made by the Borrower to the Lender hereunder shall be paid by way of a wire transfer to the Lender's bank account in US dollars.

3.5. The Borrower shall pay any and all amounts due hereunder without setoff, deduction, counterclaim or defense of any kind.

4. SECURITY

In order to secure the observance and performance of all the Borrower's obligations hereunder, the Borrower shall grant the Lender a fixed and floating charge and security interest over all of the Borrower's right, title and interest in and to the Collateral (as defined in the Debenture) (the "**Lender Security Interest**"), provided however that, the Lender Security Interest shall rank junior to and shall be subordinate to only that certain security interest in favour of Japan Lifeline Co., Ltd ("**JLL**") arising under that certain Loan Agreement by and between the Borrower and JLL, dated October 24, 2018, and the Loan Documents (as defined in the Loan Documents), including the Security Agreement by and between the Borrower and JLL dated October 24, 2018 securing up to $10 million in obligations (the "**JLL Security Agreement**" and the "**JLL Security Interest**" as applicable) (collectively, such loan documents are referred to as the "**JLL Loan Documents**"). For the avoidance of doubt, Borrower agrees that (i) the Lender Security Interest shall rank junior to the JLL Security Interest and Borrower's payment obligations to JLL solely with respect to a maximum principal amount of up $10,000,000.00 and only with respect to collateral subject to the JLL Security Interest (such limitations, the "**Senior Cap**"), and (ii) the Collateral shall exclude up to NIS 500,000 held by Borrower in a deposit account subject to that certain registered first ranking fixed charge and a first ranking floating charge, in favor of Mizrahi-Tefahot Bank Ltd. (the "**Mizrahi-Tefahot Lien**"). As to all other Collateral (as defined in the Debenture), the Lender Security Interest shall be a first priority lien.

5. CONDITIONS PRECEDENT

5.1. The effectiveness of this Agreement shall be subject to the fulfilment of the following conditions:

5.1.1. The Borrower shall have executed and delivered to the Lender the Debenture in the form attached hereto as **Exhibit B** (the "**Debenture**").

5.1.2. The Lender, Borrower, and JLL have executed a Subordination Agreement, substantially in the forms attached hereto as **Exhibit C** (the "**Subordination Agreement**"), which includes JLL's written consent to the creation of the Lender Security Interest.

5.1.3. The Borrower shall have delivered to the Lender, a copy of the executed filings and exhibits thereto to be submitted to the Israeli Companies Registrar, requesting the registration of the Lender Security Interest (the "**Submission**").

5.2. The obligation of the Lender to provide any Tranche shall be subject to the fulfilment of the following conditions:

5.2.1. At the time of and immediately after giving effect to the provision of such Tranche, no Default shall have occurred and be continuing. As used in this Agreement, the term "**Default**" means any event or condition which constitutes an Event of Default or which upon notice, lapse of time or both would, unless cured or waived, become

an Event of Default.

5.2.2. At the time of and immediately after giving effect to the provision of such Tranche, the Company has not caused an event, development or circumstance to occur or exist that has resulted in, or could reasonably be expected to have, a Company Material Adverse Effect.

5.2.3. The representations and warranties of the Borrower set forth in this Agreement and in the other Loan Documents shall be true and correct on and as of the date of the provision of such Tranche, except to the extent any such representations and warranties are expressly limited to an earlier date, in which case, on and as of the date of the provision of such Tranche, such representations and warranties shall continue to be true and correct as of such specified earlier date. As used in this Agreement, the term "**Loan Documents**" means this Agreement, the Debenture, and all other instruments and documents heretofore or hereafter executed or delivered to or in favour of the Lender in connection herewith and the transactions contemplated by this Agreement.

5.2.4. The provision of such Tranche would not conflict with, or cause the Lender to violate or exceed, any applicable governmental requirement, and no litigation shall be pending or threatened, which does or, with respect to any threatened litigation, seeks to, enjoin, prohibit or restrain, the provision of such Tranche or the consummation of the transactions contemplated by this Agreement or any other Loan Document.

5.2.5. The receipt by the Lender of a budget, in form and substance satisfactory to the Lender, detailing the anticipated use of proceeds of such Tranche, which use of proceeds shall comply with Section 7.1.

5.2.6. The receipt by the Lender of a borrowing request not less than ten (10) Business Days prior to the requested funding date executed by the chief executive officer of the Borrower unconditionally certifying as to the matters set forth in this Section 5.2.

5.2.7. The Agreement has not been terminated.

6. REPRESENTATIONS AND WARRANTIES OF THE BORROWER

The Borrower hereby represents and warrants to the Lender, that on the Effective Date, as follows:

6.1. The Borrower is duly organized and in good standing under the laws of the State of Israel and has the power to own its properties and to carry on its business as now conducted and as proposed to be conducted.

6.2. The execution and performance by the Borrower of this Agreement and the other Loan Documents (a) are within the Borrower's power and authority, (b) have been duly authorized by all necessary corporate approvals and requirements of the Borrower, and (c) do not or will not, conflict with or breach or constitute default of any agreement, contract or other instrument to which the Borrower is party, or any law, regulation, order, judgment, writ, injunction, license or permit, applicable to the Borrower.

6.3. The execution by the Borrower of this Agreement and the other Loan Documents will result in valid and legally binding obligations of the Borrower, enforceable against the Borrower in accordance with the terms and provisions hereof and thereof. No third party consents or authorizations are required on the part of the Borrower in connection with the consummation of the transactions contemplated by this Agreement or the other Loan Documents or its

obligations hereunder or thereunder, save for the JLL Consent.

6.4. The Collateral is free and clear from any restrictions, covenants, mortgages, pledges, liens, encumbrances, attachments, assignments, title retentions or other third party rights or security interests (an "**Encumbrance**"), other than the JLL Security Interest up to the Senior Cap.

6.5. The Borrower does not have any debts or liabilities beyond its ability to pay as they become due, and the Borrower has not and is not contemplating filing for bankruptcy, liquidation, insolvency or for relief under the provisions of any applicable insolvency laws, nor is the Borrower in any situation that would reasonably cause it to file for bankruptcy, liquidation, insolvency or relief under any applicable insolvency laws. No liquidator or receiver has been appointed on behalf of, or for, the Borrower.

7. COVENANTS

7.1. The Borrower shall use the Principal Amount primarily for purpose of obtaining the FDA Approval and for working capital needs for purposes of commercializing the Nexus Product within the Territory described in Exhibit B to the Distribution Agreement.

7.2. Prior to the full repayment of the Loan Amount or Cancellation (as applicable) and for as long as any amount is outstanding and owed by the Borrower to the Lender hereunder, the Borrower shall maintain sufficient insurance coverage and shall not, without the prior written consent of the Lender:

7.2.1. Except as permitted under the Debenture, transfer, sell, assign, gift or grant a license with respect of, any of the Collateral; provided, however, that as long as no Event of Default has occurred, Borrower will be permitted to sell, lease, or grant non-exclusive licenses of such assets in the ordinary course of business of Borrower; or

7.2.2. except for the JLL Security Interest, the lien on up to NIS 500,000 in the deposit account subject to the Mizrahi-Tefahot Lien, and as set forth in the Debenture, create, register, assume or permit to subsist any Encumbrance over the Collateral; or

7.2.3. except for the repayment of the existing Loan from JLL, repay any loans or debts, other than in the ordinary course of business; or

7.2.4. make or pay any distribution or dividend to its shareholders; or

7.2.5. take any action prohibited under, or fail to take any action required under, Section 9.1 ("Preservation of Business") or Section 9.2 ("Exclusivity") of the SPA.

7.3. The Borrower will furnish to the Lender:

7.3.1. As soon as available, but in any event not later than one hundred and twenty (120) days after the end of each fiscal year of the Borrower, its audited consolidated balance sheet and related statements of operations, stockholders' equity and cash flows as of the end of and for such year, setting forth in each case in comparative form the figures for the previous fiscal year, audited and certified by an independent public accounting firm which is one of the "big four" Israeli accounting firms to the effect that such consolidated financial statements present fairly in all material respects the financial condition and results of operations of the Borrower and its consolidated subsidiaries on a consolidated basis in accordance with Accepted Accounting Principles consistently applied.

7.3.2. As soon as available, but in any event not later than forty-five (45) days after the end of each fiscal quarter of each fiscal year of the Borrower, its consolidated balance sheet and related statements of operations, stockholders' equity and cash

flows as of the end of and for such fiscal quarter and the then elapsed portion of the fiscal year, setting forth in each case in comparative form the figures for the corresponding period or periods of (or, in the case of the balance sheet, as of the end of) the previous fiscal year, all certified by one of its financial officers as presenting fairly in all material respects the financial condition and results of operations of the Borrower and its consolidated subsidiaries on a consolidated basis in accordance with Accepted Accounting Principles consistently applied, subject to normal year-end audit adjustments and the absence of footnotes.

7.3.3. Concurrently with any delivery of financial statements under Section 7.3.1 or 7.3.2, a certificate of a financial officer (i) certifying as to whether a Default has occurred and, if a Default has occurred, specifying the details thereof and any action taken or proposed to be taken with respect thereto, and (ii) stating whether any change in Accepted Accounting Principles or in the application thereof has occurred since the date of the audited financial statements referred to in Section 7.3.1 and, if any such change has occurred, specifying the effect of such change on the financial statements accompanying such certificate.

7.3.4. As soon as available, but not later than sixty (60) days after the end of each fiscal year of the Borrower, an annual operating plan for the Borrower and its consolidated subsidiaries, approved by the Board, for the then current fiscal year, which will include a statement of all of the material assumptions on which such plan is based, will include balance sheets and a budget in each case on a quarterly basis for the then current fiscal year and will integrate sales, gross profits, operating expenses, operating profit and cash flow projections (and in the case of cash flow projections, representing management's good faith estimates of future financial performance based on historical performance).

8. DEFAULT

8.1. The Loan Amount will automatically and immediately become due and payable by the Borrower to the Lender upon the occurrence of any of the following events ("**Event of Default**"):

8.1.1. the failure by the Borrower to make any payment on the Loan Amount when due pursuant to the Loan Documents;

8.1.2. any other material breach by the Borrower of any of its representations, obligations, covenants or undertakings under this Agreement, the Debenture, or the other Loan Documents or the JLL Loan Documents (but solely if such breach as resulted in the acceleration of obligations thereunder); provided however that if such breach is capable of remedy (as determined by Lender in its reasonable discretion), the Borrower shall have 45 days after the Lender's written notice thereof to remedy such breach;

8.1.3. any breach by the Borrower of the restrictions set forth in Article 85 of Borrower's Restated Articles, which in the case of Article 85.4 of the Borrower's Restated Articles must be a material breach; provided however that if such breach is under Article 85.4 of the Borrower's Restated Articles, the Borrower shall have 45 days after the Lender's written notice thereof to remedy such breach;

8.1.4. (a) any liquidation or dissolution of the Borrower, (b) the execution by the Borrower of a general assignment for the benefit of creditors, (c) the voluntary filing by the Borrower of any petition in liquidation, insolvency or bankruptcy proceedings, (d) the filing against the Borrower of any petition in liquidation, insolvency or bankruptcy proceedings or for relief and the continuation of such petition without dismissal for a period of 30 days or more, I the temporary or permanent appointment of a receiver, trustee or liquidator which is not permanently

removed or otherwise permanently dismissed within 30 days thereafter, to take possession of a substantial portion of the property or assets of the Borrower, (f) the levy of an Encumbrance or the institution of execution proceedings against all or a substantial part of all of the Borrower's assets, (g) consummation of an initial public offering of the Borrower's securities, or (h) the Company ceases to further develop the Nexus Product or pursue the FDA Approval; or

8.2. The Borrower shall notify the Lender within 24 hours of any Event of Default.

8.3. At any time after the occurrence and during the continuance of an Event of Default the Lender shall be entitled, but not obligated, to immediately enforce its remedies under the Debenture or any other Loan Document, in whole or in part (subject to the Subordination Agreement), and to use the proceeds obtained therefrom to repay the Loan Amount.

8.4. The Borrower hereby, to the fullest extent permitted by law, irrevocably and absolutely waives any demand and/or claim against the Lender, relating to, arising out of or connected to the enforcement of the Lender's remedies under the Debenture or any other Loan Document, to the extent such actions are in compliance with the terms of this Agreement, including in respect of the timing of such enforcement or realization.

8.5. The Borrower shall promptly reimburse the Lender for all fees, expenses and other sums paid to attorneys and other consultants thereof, whose engagement is required to enforce the Lender's rights under this Agreement, the Debenture or any other Loan Document.

9. MISCELLANEOUS

9.1. This Agreement will inure to the benefit of and be binding on the respective successors and assigns of the Borrower. Notwithstanding the foregoing, neither Party may assign its rights or obligations under this Agreement, except that Lender shall be permitted to assign its rights and obligations under this Agreement pursuant to a written agreement delivered with prior notice to Borrower (i) to an Affiliate of Lender, (ii) to an acquirer of all or substantially all of Lender's assets, or (iii) as a collateral assignment to the Financing Sources.

9.2. Lenders' rights and remedies under this Agreement and the other Loan Documents shall be cumulative and are not exclusive of any rights or remedies provided by law. Nothing in this Agreement shall be deemed to limit the Lender's right to any remedies available under applicable laws or otherwise.

9.3. This Agreement, taken together with the Debenture, the SPA and the Distribution Agreement, constitutes the full and entire agreement, and understandings between the Parties with respect to the subject matter hereof and supersedes any and all prior agreements and understandings between the Parties concerning the subject matter hereof.

9.4. If any provision of this Agreement is held by a court of competent jurisdiction to be unenforceable under applicable law, then such provision shall be amended to the maximum extent required to render it valid, legal and enforceable (or deleted if no such amendment is feasible), and such amendment or deletion shall not affect the enforceability of the other provisions hereof.

9.5. This Agreement may be executed in any number of counterparts, and by the different parties on separate counterparts, each of which, when so executed and delivered, will be deemed to be an original, but all the counterparts will together constitute one and the same instrument.

9.6. The Agreement may not be amended or waived except by an instrument in writing signed by both Parties.

9.7. Notice as required in this Agreement shall be delivered to the address provided in, and shall be effective as of the date specified in, Section 13.1 of the SPA, as such address may be changed from time to time pursuant to Section 13.1 of the SPA.

9.8. This Agreement shall be governed by and construed in accordance with the laws of the State

of Israel, and the competent courts of Tel Aviv-Jaffa shall have exclusive jurisdiction over all matters relating to or arising from this Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement:

Creditor:		Borrower:	
CryoLife, Inc.		**Endospan Ltd.**	
By:	/s/ J. Patrick Mackin	By:	/s/ Kevin Mayberry
Name:	J. Patrick Mackin	Name:	Kevin Mayberry
Title:	Chairman, President and CEO	Title:	Chief Executive Officer

Exhibit A

Borrower Bank Information

[*See Attached*.]

[PERSONAL INFORMATION HAS BEEN REDACTED]

Exhibit B

Form of Debenture

[*See Attached*.]

DEBENTURE

This Debenture (this "**Debenture**") is made and executed on this the 11th day of September 2019, by and between CryoLife, Inc., a Florida corporation (the "**Creditor**") and Endospan Ltd., an Israeli private limited liability company, registered number 514172931 (the "**Borrower**").

WHEREAS, The Borrower and Creditor entered into a certain Loan Agreement dated September 11, 2019, as may be amended and/or restated from time to time (the "**Loan Agreement**"); and

WHEREAS, as a condition for extending a loan under the Loan Agreement, the Creditor requested a security interest to secure the Borrower's obligations thereunder; and

WHEREAS, the Borrower hereby agrees to pledge the Collateral (as defined below) by way of a first ranking fixed charge and a first ranking floating charge in favor of the Creditor, subordinate only to the security interest granted to Japan Lifeline Co., Ltd., a Japanese corporation ("**JLL**"), pursuant to that certain Subordination Agreement, dated of even date herewith (the "**Subordination Agreement**") between JLL and Creditor, subject to the Senior Cap (as defined in the Loan Agreement), and only with respect to collateral subject to the JLL Security Interest. As to all other collateral, the security interest granted to Creditor under this Debenture shall be a first priority lien.

NOW, THEREFORE, IT IS AGREED AS FOLLOWS:

1. Definitions

1.1. The preamble and exhibits to this Agreement constitute an integral part hereof.

1.2. Section headings and references to headings are intended solely for convenience purposes and are to be disregarded in construing this Agreement.

1.3. All capitalized terms used in this Debenture (including in the preamble hereto) and not otherwise defined in this Debenture shall bear the meanings ascribed to such terms in the Loan Agreement.

1.4. For the purpose of this Debenture, "**Mizrahi-Tefahot Lien**" shall mean a registered first ranking fixed charge and a first ranking floating charge, in favor of Mizrahi-Tefahot Bank Ltd., with respect to the Borrower's deposit account in the amount of NIS 500,000.

2. The Pledge

2.1. As continuing security to secure the obligations of the Borrower under and in connection with the Loan Agreement, including without limitation, the full and punctual payment of the then outstanding Principal Amount, any Interest and all other obligations owing to the Creditor under the Loan Documents (collectively, the "**Secured Sums**"), the Borrower hereby absolutely and unconditionally charges and pledges, by way of a first ranking fixed charge and a first ranking floating charge, all of its rights, title and interest in and to the Collateral in favor of the Creditor (the "**Pledge**"), subordinate only to the JLL Security Interest and only with respect to collateral subject to the JLL Security Interest.

"**Collateral**" means all of the tangible and intangible assets of the Company, whether now owned or hereafter acquired, whether now existing or hereafter created, developed or arising, and wherever located, including without limitation the Nexus Assets, Intellectual Property Rights, Accounts Receivable and Contracts (each as defined in the SPA), and all

inventory, monies, receivables, proceeds, insurance proceeds, equipment, approvals, causes in action, claims and products, excluding up to NIS 500,000 in Borrower's deposit account so long as such funds remain subject to the Mizrahi-Tafahot Lien.

3. <u>Declarations and Undertakings of the Borrower</u>

Without derogating from any representations and/or warranties of the Borrower under the Loan Agreement, the Borrower hereby represents, declares and undertakes as follows:

3.1. The Collateral is exclusively owned by the Borrower, and save for the assets that are subject to the JLL Security Interest (subject to the Senior Cap) and the Mizrahi-Tefahot Lien (which is limited to Borrower's deposit account in an amount not to exceed NIS 500,000), is free and clear of any Encumbrances (save for non-exclusive licenses in the ordinary course of business), and shall remain free and clear of any Encumbrances, until the earlier of repayment in full of the Secured Sums or the Cancellation.

3.2. The Borrower shall not pledge or charge or permit any Encumbrances to subsist or be registered on the Collateral or any part thereof, in any manner whatsoever, whereby the rights thereunder shall rank prior to, *pari passu* with, or subordinated to the rights given to the Creditor under this Debenture, other than the JLL Security Interest (subject to the Senior Cap) and the Mizrahi-Tefahot Lien (which, for the avoidance of doubt, shall not exceed NIS 500,000).

3.3. The Borrower shall defend the Creditor's rights in the Pledge and Collateral against all claims actions and demands of all other persons at any time claiming any interest in the Collateral. The Borrower shall be responsible towards the Creditor, without any limitations and/or reservations, for any defects in the proprietary rights of the Borrower in the Collateral.

3.4. This Debenture, and all of the Borrower's obligations and undertakings pursuant to or in connection herewith, are lawful, valid, effective and binding on the Borrower and enforceable for all intents and purposes, and there is no impediment and/or encumbrance and/or limitation to the creation and/or to the enforcement of the Pledge.

3.5. The Borrower shall sign and execute any document reasonably required by the Creditor in order to more fully evidence the Creditor's rights hereunder and in respect of the Collateral, and to do or cause to be done all things necessary to perfect, protect and continue the Creditor's security interest in the Pledge and maintain the Pledge granted in this Debenture as a valid, effective and duly perfected lien on the Collateral. Without derogating from the generality of the foregoing, the Borrower shall immediately following the Effective Date, and in no event later than 7 days thereafter, register the Pledge with the Israeli Companies Registrar.

3.6. The Borrower shall, except in the ordinary course of the Borrower's business, keep the Collateral (and the records pertaining thereto) at such locations as are acceptable to the Creditor. Upon Creditor's request, but in no event more than once per each 6 months period, Borrower will deliver to the Creditor, in the form satisfactory to the Creditor, a schedule of real properties and locations relating to the Borrower's operations, including without limitation all real property owned, leased or rented by the Borrower and all other properties where the Collateral and any records thereof are or may be located, including the names and addresses of the Borrower's applicable bank or other accounts, safes and safe deposit boxes.

3.7. The Borrower shall procure and maintain all reasonable risks insurances, and upon request of the Creditor, deliver to the Creditor the relevant policies or certificates of insurance in form satisfactory to the Creditor together with loss payee (in the case of property insurance)

or additional insured (in the case of liability insurance) endorsements in favor of the Creditor, and shall not cancel such policies without at least thirty days' prior written notice to the Creditor.

3.8. The Borrower shall not, (i) except in the ordinary course of the Borrower's business and consistent with past practices, directly or indirectly, sell, assign, gift, grant a license with respect of, or transfer in any manner whatsoever, (ii) except in the ordinary course of the Borrower's business and consistent with past practices, undertake (whether orally or in writting) to sell, assign, gift, grant a license with respect of or transfer in any manner whatsoever, the Collateral, or (iii) undertake (whether orally or in writting) to sell, assign, gift, grant a license with respect of or transfer in any manner whatsoever the rights of the Borrower under this Debenture or any part thereof, to any third party.

3.9. The Borrower shall notify the Creditor immediately upon becoming aware of any imposition of any attachment, the issue of any execution proceedings or of any application for the appointment of a receiver or any other officer over or with respect to the Collateral or any part thereof. The Borrower shall further immediately notify the authority which levied such attachment or issued such execution proceedings or requested the application for the appointment of such receiver or officer, and the third party who initiated or applied for such action or any part thereof, of the Pledge, and to take, at its own expense, any and all the steps necessary for the discharge of such attachment, execution proceedings or appointment of receiver or officer, as the case may be.

3.10. The Borrower shall promptly notify the Creditor in writing prior to any (1) change in Borrower's name; (2) change in Borrower's assumed business name(s); (3) change in the directors of the Borrower, Borrower's Chief Executive Officer, or any officer of Borrower that leads Borrower's research and development, quality, clinical, or sales functions; (4) change in the Borrower's principal office address.

3.11. The Borrower shall keep and maintain, and cause others to keep and maintain, the Collateral in good order and condition, except for reasonable wear and tear, at all times while this Debenture remains in effect.

3.12. The Borrower hereby irrevocably appoints the Creditor as its power of attorney and authorises the Creditor to effect in good faith in the Borrower's name, in its place and at its reasonable expense, any of the acts required by the Borrower in accordance with this Debenture, and the Borrower hereby irrevocably authorises the Creditor to execute any necessary document, obligation or instrument reasonably required by the Creditor for the purpose of implementing such actions, including without limtation making all filings with the Israeli Companies Registrar to perfect the Pledge and the Creditor's security interest in the Collateral; provided however that the grant of such authorization shall not exempt the Borrower from fulfilling each and every one of its undertakings under this Debenture and shall not obligate the Creditor to utilize such authorization, in whole or in part.

4. <u>Independent Collateral</u>

4.1. The Pledge is independent of all pledges, collateral or securities which the Creditor may hereafter receive from or for the Borrower and shall not affect or be affected thereby, and shall serve as a continuing security, remaining in full force and effect until repayment or Cancellation in full of solely the Secured Sums.

4.2. After the full payment or Cancellation of the Secured Sums, and within 7 days from the date the Borrower sent to the Creditor a written request to receive confirmation thereof, the Creditor shall confirm to the Borrower in writing that this Debenture is null and void.

5. Event of Default and Exercise of Pledge

5.1. Subject to the Subordination Agreement, upon the occurrence of any Event of Default, or event which is or is likely to materially adversely affect the enforcement of the Pledge, the Creditor shall be entitled, without further notice (other than as required under the Loan Agreement), and in addition to all other applicable rights and remedies at law or in equity, to take any and all steps and actions as it sees fit to protect and/or exercise its rights under this Debenture and to collect the Secured Sums from the Borrower, and to realize the Collateral, and to use the proceeds thereof for the repayment of the Secured Sums, without being under the obligation to first realise other guaranties or take any further action, including pursuing any judicial proceedings, including:

5.1.1. Creditor may require Borrower to deliver and transfer to the Creditor all or any portion of the Collateral and any and all certificates of title and other documents relating thereto. The Creditor shall have full power to enter upon the property of the Borrower to take possession of and remove the Collateral.

5.1.2. The Creditor may appoint a receiver, trustee, manager or other officer on its behalf (the "**Receiver**"). The Receiver shall be the agent of the Creditor and shall have all the powers of the Creditor hereunder or under law. The Creditor, either itself or through the Receiver, may collect and transfer the Collateral into the Creditor's own name or that of the Creditor's nominee and receive the payments, income, and revenues therefrom and hold the same as security for the Secured Sums or apply it to payment of the Secured Sums in such order of preference as the Creditor or Receiver may determine. The Creditor may demand, collect, receipt for, settle, compromise, adjust, sue for, foreclose, or realize the Collateral as the Creditor may determine. For these purposes, the Creditor may, on behalf of and in the name of the Borrower, receive, open and dispose of mail addressed to the Borrower; change any address to which mail and payments are to be sent; and endorse notes, checks, drafts, money orders, documents of title, instruments and items pertaining to payment of the Secured Sums. To facilitate collection, the Creditor may notify account debtors and obligors on any Collateral to make payments directly to the Creditor. The Creditor's right to the appointment of a Receiver shall exist whether or not the apparent value of the Collateral exceeds the Secured Sums by a substantial amount. Employment by Creditor shall not disqualify a person from serving as a Receiver.

5.1.3. The Creditor (and/or Receiver) shall be authorized to accelerate all payments due under the Loan Agreement, and seize the Collateral, hold it and take any and all actions and exercise any and all rights derived from and/or associated therewith as if it were the owner thereof.

6. Miscellaneous

6.1. The Borrower shall bear (and hold harmless the Creditor in connection with) all reasonable expenses (including any reasonable fees of the lawyers of the Creditor) in connection with any claim filed by the Creditor (or on their behalf) for sums due on account of the Secured Sums.

6.2. A waiver by the Creditor in favour of the Borrower in respect of a prior breach of, or non-compliance with, any one or more of its obligations towards the Creditor, whether such obligation be contained in this Debenture or the Loan Agreement or otherwise, shall not be construed as a justification or an agreement by the Creditor to allow another breach or for non-compliance; and the abstention by the Creditor from the exercise of any right granted to it under this Debenture or the Loan Agreement shall not be construed as a

forbearance or waiver of such right. No waiver by the Creditor shall bind the Creditor unless made in writing.

6.3. This Debenture will inure to the benefit of and be binding on the respective heirs, legal representatives, successors and permitted assigns of the Borrower. Notwithstanding the foregoing, neither Party may assign its rights or obligations under this Debenture except as permitted by the Loan Agreement.

6.4. All issues related to notices with regard to this Debenture will be made in accordance with the Loan Agreement.

6.5. This Debenture shall be governed by and construed in accordance with the laws of the State of Israel, and the competent courts of Tel Aviv-Jaffa shall have exclusive jurisdiction over all matters relating to or arising herefrom, provided however that to the extent that any of the Collateral is located in any jurisdiction outside the State of Israel, the Creditor shall be entitled to seek equitable or injunctive relief in any such jurisdiction.

6.6. If any provision of this Debenture is held by a court of competent jurisdiction to be unenforceable under applicable law, then such provision shall be amended to the maximum extent required to render it valid, legal and enforceable (or deleted if no such amendment is feasible), and such amendment or deletion shall not affect the enforceability of the other provisions hereof.

6.7. This Debenture is intended to add and not to derogate from the provisions set forth in the Loan Agreement. If and to the extent a contradiction exists between the provisions set forth in the Loan Agreement and any of the provisions hereof, the provisions set forth in the Loan Agreement shall prevail, provided however that the foregoing shall apply only if a specific matter is expressly addressed both in this Debenture and in the Loan Agreement, and in the event that it is reasonably possible to construe the provisions as complementary rather than contradictory, the interpretation thereof as complementary shall prevail.

IN WITNESS WHEREOF the Borrower and Creditor have signed this Debenture the day and year first above written.

	Creditor:		Borrower:
	CryoLife, Inc.		**Endospan Ltd.**
By:	_____	By:	_____
Name:	_____	Name:	_____
Title:	_____	Title:	_____

Exhibit C

Form of Subordination Agreement

[*See Attached*.]

SUBORDINATION AGREEMENT

This Subordination Agreement (this "**Agreement**") is effective as of September 11, 2019, (the "Effective Date") by and among **Japan Lifeline Co., Ltd.**, a Japanese corporation ("**JLL**"), Endospan Ltd., a company organized under the laws of the State of Israel ("**Borrower**"), and CryoLife, Inc., a Florida corporation (the "**Lender**"). Each JLL, Borrower, and Lender is referred to as a "**Party**" and collectively as the "**Parties**".

Recitals

A. Borrower has obtained a certain loan from JLL in an aggregate amount of USD $10,000,000, which is secured by assets and property of Borrower, pursuant to that certain Loan Agreement by and between the Borrower and JLL, dated October 24, 2018, including the Security Agreement by and between the Borrower and JLL dated October 24, 2018 (together, the "**JLL Agreement**");

B. Borrower has asked Lender for a loan in the principal amount of up to USD $15,000,000 to be extended under that certain Loan Agreement between Borrower and the Lender, dated September 11, 2019 (the "**Loan**" and "**Loan Agreement**", respectively), which principal amount (plus all other obligations of Borrower thereunder) are to be secured by assets and property of Borrower pursuant to that certain debenture, dated September 11, 2019 (the "**Debenture**"), between Borrower and Lender, in subordination to the security interest Borrower previously granted to JLL; and

C. In order to facilitate the provision of the Loan from Lender to Borrower, (a) Lender is willing to subordinate: (i) all of Borrower's indebtedness and obligations to Lender (including, without limitation, principal, premium (if any), interest, fees, charges, expenses, costs, professional fees and expenses, and reimbursement obligations) (the "**Subordinated Debt**") to all of Borrower's indebtedness and obligations to JLL (collectively, the "**Senior Debt**") including but not limited to, USD $10,000,000 plus interest and other obligations owing to JLL with respect to such principal and interest pursuant to the JLL Agreement (including any amendment to, extension or modification of the Senior Debt) and any arising debt to JLL in the future (the "**JLL Cap**"); and (ii) all of Lender' security interests, if any, to all of JLL's security interests in Borrower's property up to the JLL Cap, and (b) JLL gives its consent to the creation, perfection and registration of subordinated security in favor of Lender.

NOW, THEREFORE, THE PARTIES AGREE AS FOLLOWS:

1. The Lender subordinates to JLL any security interest or lien that Lender may have in any property of Borrower, if any, up to the JLL Cap. Notwithstanding the respective dates of attachment or perfection of the security interests of Lender and the security interests of JLL, all now existing and hereafter arising security interests of JLL in any property of Borrower and all proceeds thereof (the "**Collateral**"), including, without limitation, the "Collateral", as defined in the Debenture and as referred to under the Loan Agreement, in each case up to the JLL Cap, shall at all times be senior to the security interests of the Lender, if any. All Subordinated Debt is subordinated in right of payment to the Senior Debt.

2. JLL hereby (a) acknowledges and consents to (i) Borrower granting to Lender a security interest in the Collateral to secure the Subordinated Debt, (ii) Lender filing any and all financing statements and other documents as deemed necessary by Lender in order to perfect

Lender's security interest in the Collateral, and (iii) the entering into of the Loan Agreement and all documents in connection therewith by Borrower; (b) acknowledges and agrees that the Subordinated Debt, the entering into of the Loan Agreement and all documents in connection therewith by Borrower, and the security interest granted by Borrower to Lender in the Collateral shall be permitted under the provisions of the JLL Agreement (notwithstanding any provision of the JLL Agreement to the contrary), and (c) acknowledges that Borrower and Lender have agreed that Borrower will not modify or extend the Senior Debt or incur any other indebtedness from JLL without prior written notice to the Lender, whereas in each case, prior to any further indebtedness from JLL or Lender to Borrower, JLL and Lender shall decide the seniority of such further debts in written agreement. In addition, to the extent necessary to give effect to the limitations on the subordination to JLL's security interest provided in this Agreement and avoid any conflict with the Security Agreement by and between the Borrower and JLL dated October 24, 2018, Borrower and JLL each agree that the JLL Agreement is hereby amended to provide that (i) the Loan and Debenture constitute "Permitted Indebtedness" and the security interest granted pursuant to the Debenture constitutes a "Permitted Lien" under the JLL Agreement, as applicable, and (ii) JLL's prior right of payment is limited to the JLL Cap and JLL's first priority security interest under the JLL Agreement is limited to the JLL Cap and the collateral subject to the JLL Agreement.

3. The Lender hereby acknowledges, agrees and covenants that (a) Lender shall not contest, challenge or dispute the validity, attachment, perfection, priority or enforceability of JLL's security interest in the Collateral, or the validity, priority or enforceability of the Senior Debt up to the JLL Cap, but only with respect to Collateral subject to the security interest granted to JLL pursuant to the Senior Debt, and (b) Lender will not demand or receive from Borrower or from any other person all or any part of the Subordinated Debt, by way of payment, prepayment, setoff, lawsuit or otherwise, nor will Lender exercise any remedy with respect to any property of Borrower, including the Collateral nor will Lender accelerate the Subordinated Debt, or commence, or cause to commence, prosecute or participate in any administrative, legal or equitable action against Borrower with respect to the Subordinated Debt.

4. Nothing in the foregoing paragraph shall prohibit or restrict (i) the conversion or deemed conversion of all or any part of the Subordinated Debt into equity securities of Borrower (which conversion shall not require any notice to or consent of JLL), and (ii) any payment by Borrower to Lender other than with respect to the Subordinated Debt. Furthermore, notwithstanding the foregoing paragraph, the Lender: (i) may file a proof of claim or statement of interest with respect to the Subordinated Debt in any insolvency or liquidation proceeding commenced by or against the Borrower; (ii) shall be entitled to file any necessary responsive or defensive pleadings in opposition to any motion, claim, adversary proceeding or other pleading made by any party objecting to or otherwise seeking the disallowance of the claims of the Lender, in each case not otherwise in contravention of the terms of this Agreement; (iii) may take any action and exercise any rights and remedies available to unsecured creditors except as prohibited by this Agreement; (iv) may vote on any plan of reorganization that is not inconsistent with the terms of this Agreement; (v) may make a cash bid on all or any portion of the assets of the Borrower in any foreclosure proceeding or action, not otherwise in contravention of the terms of this Agreement; (vi) may enforce the terms of any subordination agreement with respect to any indebtedness subordinated to the Subordinated Debt not in contravention of the terms of this Agreement; (vii) may take any action to the extent necessary to prevent the running of any applicable statute of limitation or similar restriction on claims, or to assert a compulsory cross-claim or counterclaim against the Borrower and (viii) may take any action to seek and obtain specific performance or injunctive relief to compel the Borrower to comply with (or not violate or breach) an obligation

under the Loan Documents (as defined in the Loan Agreement), so long as it is not accompanied by a claim for monetary damages or collection action.

5. This Agreement shall bind and inure to the benefit of any successors of JLL and/or the Lender. Notwithstanding the foregoing, neither party may assign its rights or obligations under this Agreement without a prior written consent of the other party.

6. This Agreement shall remain effective until the Senior Debt has been fully repaid, unless terminated earlier by mutual consent of both JLL and Lender.

7. Each party hereof hereby agrees to execute such documents and/or take such further action as JLL may at any time or times reasonably request in order to carry out the provisions and intent of this Agreement, including, without limitation, ratifications and confirmations of this Agreement from time to time hereafter, as and when requested by JLL.

8. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without giving effect to conflicts of laws principles. All disputes arising out of or in connection with this Agreement, shall be finally settled by arbitration in New York, New York, U.S.A, except in connection with disputes that involve equitable or injunctive relieve, and nothing herein shall prevent any party from seeking injunctive relief through a court of law. For any action, suit, or proceeding of any kind which arises out of or by reason of this Agreement and is not subject to arbitration pursuant to the prior sentence, Lender and JLL submit to the exclusive jurisdiction of the competent courts located in the State of New York, U.S.A, however all parties exclusively waive any and all the rights to trial by jury. Any arbitration shall be held in accordance with the Rules of Arbitration of the International Center for Dispute Resolution (ICDR) and shall be conducted in the English language. The arbitrator's decision shall be final and binding on the parties and judgement upon the arbitrator's decision may be entered and enforced in any court of competent jurisdiction.

9. This Agreement represents the entire agreement with respect to the subject matter hereof, and supersedes all prior negotiations, agreements and commitments.

10. In the event of any legal action to enforce the rights of a party under this Agreement, the party prevailing in such action shall be entitled, in addition to such other relief as may be granted, all reasonable costs and expenses, including reasonable attorneys' fees, incurred in such action.

[*Signature page follows*]

IN WITNESS WHEREOF, the undersigned have executed this Agreement (which may be executed in three counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument) as of the Effective Date.

"JLL"

JAPAN LIFELINE CO., LTD.

By: _____

Name: _____

Title: _____

"Borrower"

ENDOSPAN LIMITED

By: _____

Name: _____

Title: _____

"Lender"

CRYOLIFE, INC.

By:_____

Name:_____

Title:_____

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

EXCLUSIVE DISTRIBUTION AGREEMENT

This Exclusive Distribution Agreement is dated September 11, 2019 (the "**Agreement**"), and is between JOTEC GmbH, a wholly-owned subsidiary of CryoLife, Inc., located at Lotzenäcker 23, 72379 Hechingen, Germany ("**Distributor**") and Endospan, Ltd., located at Maskit St. 4 Herzlia Business Park, Herzlia, Israel 46733 (the "**Company**").

RECITALS

a) Concurrently with this Agreement, Company is entering into a Securities Purchase Option Agreement with Distributor's parent company, CryoLife, Inc. ("**Buyer**"), which agreement provides Buyer the option to acquire Company (either directly or through an affiliate) (the "**Option Agreement**"), and Company is entering into a Loan Agreement with Buyer (the "**Loan Agreement**"). Capitalized terms used but not defined in this Agreement shall have the meaning ascribed to each such term in the Option Agreement.

b) The parties desire that Company appoint Distributor to act as Company's exclusive distributor of the Nexus Stent Graft System and all accessories and ancillary products, as well as any improvements or modifications, as listed in Exhibit A (the "**Products**" or "**Product**") within the territory described in Exhibit B (the "**Territory**").

c) The parties further desire that this appointment becomes effective on the date of this Agreement (the "**Effective Date**").

AGREEMENT

Accordingly, the Parties agree as follows:

1. APPOINTMENT.

1.1. Appointment; Consideration. Company hereby appoints Distributor to act as Company's exclusive distributor of Products in the Territory under the terms and conditions of this Agreement. Company shall not have or appoint any other distributors for the Products in the Territory (including any of Company's Affiliates), and Company itself shall not distribute or sell Products in the Territory. In consideration of this appointment, Distributor or Buyer shall pay Company a fixed amount of Nine Million US Dollars ($9,000,000) (the "**Distribution Fee**") within fourteen (14) business days of the Effective Date. To the extent permitted by law, Distributor undertakes that neither it nor any of its Affiliates shall, without the Company's prior written consent, make any sales of Products to any customers outside the Territory. "**Affiliate**" means any other entity Controlling, Controlled by, or under common Control with such party. "**Control**" means holding fifty percent (50%) or more of the voting rights in the general meeting of the shareholders of a company or in the equivalent body of a different entity.

1.2. Term. The term of this Agreement begins on the Effective Date and ends ninety (90) days following the earlier of (i) the date on which the acquisition contemplated by the Option Agreement can no longer be consummated under its terms or (ii) the date on which the Option Agreement is terminated under its terms (the "**Term**"), unless (a) the Agreement has been terminated earlier under Section 10, "Expiration & Termination"; (b) the Distributor has exercised the Buyer Option, in which case the Term will end upon the Closing Date, as defined in the Option Agreement; or (c) the Agreement is otherwise extended by mutual written agreement of the parties.

1.3. Sub-Distributors. Distributor may appoint sub-distributors for Products within the Territory. In the event that Distributor appoints a sub-distributor, Distributor and sub-distributor shall enter into a written agreement under similar terms and conditions to this Agreement. Distributor is liable for the compliance of its sub-distributors with the terms and conditions of their agreements with Distributor. Without derogating from the above, Distributor shall promptly inform Company of any material misalignment between the terms and conditions of an agreement with any sub-distributor and the terms and conditions of this Agreement.

1.4. Competitive Products. Neither Distributor nor any of its Affiliates shall, directly or indirectly, inside the Territory, market, promote, distribute, sell, provide, or support products that are competitive with the Products. The parties acknowledge that Distributor may address the minimally invasive treatment of thoracic aortic aneurysms and dissections through Distributor's E-xtra Design product made according to the specifications of a surgeon, provided that Distributor shall not make any such product for zone 0 of the aortic arch. The parties further acknowledge that Distributor may continue to market, promote, distribute, sell, provide, or support open surgical products for the treatment of thoracic aortic aneurysms and dissections, including but not limited to polyester grafts, the On-X Ascending Aortic Prosthesis (AAP), and the E-vita Open Plus and in each case, any modifications, improvements, or next generation equivalents thereto. Company shall not directly or indirectly, inside the Territory, market, promote, distribute, sell, provide, or support any other stent grafts for the minimally invasive treatment of thoracic aortic aneurysms and dissections for zone 0 or zone 1 of the aortic arch.

1.5 New Products. Company shall provide Distributor a right of first offer and negotiation to distribute or sell in the Territory additional endovascular products and any improvements or modifications to those additional endovascular products (in each instance, including accessories and ancillary products), and Company shall provide Distributor written notice of its intent to commercialize any such products at least one hundred and eighty (180) days before commercializing such product in the Territory or offering such commercialization rights to any third party. If Company exercises its right under this Section 1.5, the parties shall negotiate in good faith to reach an agreement for the distribution of such products within ninety (90) days of Company's written notice. If the parties are unable to reach an agreement in good faith within the ninety (90) day period, Company may negotiate and enter into agreements with third parties for the distribution and/or sale of such products in the Territory or any part thereof.

2. PRODUCT PURCHASES.

2.1 Product Prices. The prices for Products are listed in Exhibit A (the "**Prices**" or "**Price**") and will remain in effect until December 31, 2020. Thereafter, such Prices will be subject to adjustment as provided in Exhibit A.

2.2 Purchase Orders. Distributor shall submit a written purchase order to Company for the purchase of any Products (each, a "**Purchase Order**"). Distributor shall include in any Purchase Order the (a) Product, (b) Price, (c) article code, (d) quantity, (e) desired delivery schedule, (f) shipping destination, (g) shipping instructions, if any, and (h) invoice destination. To the extent that there is a conflict between the terms of any Purchase Order and the terms of this Agreement, the terms of this Agreement shall prevail, unless the parties expressly agree otherwise in writing.

2.3 Acceptance of Purchase Orders. Company shall accept a Purchase Order, provided that Company may reject in good faith a Purchase Order if the Purchase Order does not comply with Section 2.2, "Purchase Orders," does not comply with Company's applicable lead time requirements as set forth in Exhibit C (the "**Lead Time Schedule**"), or the Products ordered exceed Distributor's Minimum Purchase Amount, as defined in Section 2.10, "Minimum Purchase Amount," for the applicable period. Company shall provide Distributor written notice of Company's acceptance or rejection of a Purchase Order within ten (10) business days of receipt of the Purchase Order. If Company rejects a Purchase Order for a reason permitted under this Section 2.3, Company shall provide the reason for the rejection and provide Distributor with a reasonable opportunity to cure the stated non-compliance. If Company does not reject a Purchase Order within ten (10) business days of receipt of the Purchase Order, the Purchase Order is deemed accepted. In the event that Company does not timely fulfill a Purchase Order that Company has an obligation to accept or otherwise has accepted under this Section 2.3, Company shall, in its sole discretion, pay Distributor or issue a credit to Distributor in an amount equal to fifty percent (50%) of the total of the Prices of the Products (i.e., the transfer price hereunder) that Company is unable to fulfill from such Purchase Order. Except for Distributor's rights to terminate for cause under Section 10.2, "Termination for Cause," and to obtain the Termination Fee under Section 10.6, "Expiration and Termination," the remedy under this Section 2.3 is Distributor's sole remedy for Company's failure to timely fulfill a Purchase Order.

2.4 Shipping; Delivery. Any shipment under this Agreement is Free Carrier (FCA) from Herzliya, Israel (the "**Shipping Point**"). Distributor shall bear all costs of moving the Products from the Shipping Point to the destination. Distributor may designate a shipper. Company shall deliver a Product with the following minimum shelf life at the time of delivery: twelve (12) months if the labeled maximum shelf life at the time of delivery is one (1) year; or seventy five percent (75%) of the labeled maximum shelf life if the labeled maximum shelf life at the time of delivery is three (3) years. In the event that Company delivers a Product to Distributor with less than twelve (12) months of shelf life remaining and the labeled maximum shelf at the time of delivery is one (1) year, Company shall at its own expense exchange such Product if the Product shelf life has been reached before it is sold by Distributor. Subject to Section 2.3, "Acceptance of Purchase Orders," Company shall deliver Products within the desired delivery schedule.

2.5 Partial Shipments. Company may make partial shipments of Products listed in a Purchase Order. Any partial shipment constitutes an independent transaction for which payment is due under the terms of this Agreement.

2.6 Title & Risk of Loss. Title to and risk of loss of Products transfers from Company to Distributor at the Shipping Point.

2.7 Payment. Company shall submit an Invoice to Distributor upon shipment of each Product ordered under this Agreement (each, an "**Invoice**"). To the extent that there is a conflict between the terms of any Invoice and the terms of this Agreement, the terms of this Agreement shall prevail, unless the parties expressly agree otherwise in writing. Payment terms are net sixty (60) days.

2.8 Inspection & Rejection of Products. Distributor shall inspect Products upon their receipt. Distributor may reject any defective or non-conforming Product within thirty (30) days of receipt. If Distributor rejects a Product, Distributor shall notify Company in writing of its rejection of the Product and request a Return Goods Authorization ("**RGA**") number. Company shall provide a RGA number within ten (10) business days of receipt of the request. Within ten (10) business days of receipt of the RGA number, Distributor shall ship to Company the rejected Product, freight collected, with the RGA number displayed on the shipping container. Company shall issue a credit for the value of Distributor's fully-landed purchase price for the rejected Product, to the extent confirmed by the Company to be defective or non-conforming, within fifteen (15) business days of receipt thereof by the Company.

2.9 Product Warranty

2.9.1. Product Warranty. Company hereby represents and warrants that any Product sold under this Agreement and any replacement Product (a) is free and clear of any liens, security interests, or encumbrances of any nature; (b) has been designed, manufactured, labeled, packaged, stored, exported, and sold by Company in accordance with all applicable laws, regulations, rules, and restrictions; and (c) is free from defects in material and workmanship under normal conditions of storage, handling, and use from delivery of the Product until the Product expiration date (the "**Warranty Period**")(together, the "**Product Warranty**").

2.9.2. Limitations. The Product Warranty does not apply to the following situations after delivery of the Product from Company to Distributor: (i) normal wear and tear; (ii) storage inconsistent with Company's instructions for use of the Product; (iii) improper or negligent handling or (attempted) modification of the Product by Distributor or a third party; and (iv) improper or negligent use of the Product, including any use inconsistent with Company's instructions for use or any use of the Product in combination with any third-party products where such use is not approved by Company.

2.9.3. Breach. Distributor shall notify Company in writing within thirty (30) days of the discovery of any breach of the Product Warranty and request a RGA number. Company shall provide a RGA number within ten (10) business days of receipt of the request. Within ten (10) business days of receipt of the RGA number, Distributor shall ship to Company the affected Product, freight collected, with the RGA number displayed on the shipping container. Company shall, in its sole discretion, either replace the affected Product or issue a credit for the value of Distributor's fully-landed purchase price for the affected Product within fifteen (15) business days of receipt.

2.9.4. Expiration. Any claim for breach of the Product Warranty will lapse upon the sooner of (i) the expiry of the Warranty Period or (ii) sixty (60) days following the discovery of the breach of the Product Warranty.

2.9.5. Third Parties. The Product Warranty extends solely for the benefit of Distributor. No person has the authority to bind the Company to any representation or warranty, and there are no product warranties that extend beyond the Product Warranty.

2.10. Minimum Purchase Amount. Distributor and Company shall agree in writing upon a reasonable minimum purchase amount in Euros for Distributor for the Product in the Territory for each calendar year during the Term (the "**Minimum Purchase Amount**"). The initial Minimum Purchase Amount is set forth in Exhibit E. For each subsequent calendar year during the Term, the Minimum Purchase Amount for that upcoming calendar year will increase automatically by ten

percent (10%) from the previous calendar year unless the parties agree otherwise in writing. Distributor shall purchase Products in sufficient quantities to meet or exceed the Minimum Purchase Amount for the applicable year, provided that Distributor will have no obligation to meet the Minimum Purchase Amount if the Product is unavailable for more than sixty (60) consecutive days or a total of seventy-five (75) days during the applicable year. In the event that Distributor does not meet or exceed the Minimum Purchase Amount for a calendar year, Distributor shall make a payment to Company in an amount equal to fifty percent (50%) of the shortfall amount within sixty (60) days of the end of that calendar year. The remedy under this Section 2.10 is Company's sole remedy for Distributor's failure to meet or exceed the Minimum Purchase Amount. For the avoidance of doubt, a Purchase Order submitted in any calendar year counts towards the Minimum Purchase Amount for that calendar year unless Distributor cancels such Purchase Order.

2.11. Tenders. Company acknowledges that Distributor and its sub-distributors will enter into binding agreements with public-sector customers for the sale of Products in the Territory (each, a "**Tender**") and that the term of such Tenders may extend beyond the expiration or termination of this Agreement. Company shall continue to sell Products to Distributor through the expiration of any Tender and any renewal thereof.

2.12. Sample Products. Company shall sell Distributor non-sterile samples of Products, to be used solely for marketing and training purposes, at a price [omitted].

3. ADDITIONAL DISTRIBUTOR OBLIGATIONS.

Distributor shall undertake the obligations in this Section 3 at its own expense.

3.1 Best Efforts. Distributor shall use its best efforts to market, promote, distribute, sell, and support the Products in the Territory for approved uses. Distributor shall use its best efforts to distribute or sell all Products on a first-in first-out (FIFO) basis. Before each calendar year, Distributor shall provide to Company a marketing plan for Products in the Territory, including but not limited to Distributor's plans for advertising Products in relevant trade publications, participating in relevant trade shows, conducting workshops and trainings, and proctoring cases (the "**Plan**"). Company may provide comments on the Plan to Distributor, which Distributor will consider in good faith. The parties shall meet to discuss the Plan once per calendar year.

3.2 Facilities. Distributor shall maintain adequate facilities in the Territory.

3.3 Personnel. Distributor shall assign or hire a sufficient number of personnel in the Territory to market, promote, distribute, sell, and support Products. Distributor shall assign or hire such personnel who, in Distributor's good faith determination, are skilled and have the relevant experience and expertise.

3.4 Training. Distributor shall provide adequate Product training to all applicable personnel, agents, and sub-distributors, as well as to the personnel of Distributor's direct customers who handle the Products. Distributor shall provide physician proctors or clinical specialists (each, a "**Specialist**") to support all new users of Products until Distributor confirms that each such new user is prepared to conduct a case alone. Each Specialist shall complete a training program before supporting any case in the Territory. The parties shall cooperate in good faith to update any Product-training programs or materials as necessary during the Term.

3.5 Customer Support. Distributor shall provide post-market support to its direct customers in accordance with Company's instructions and as required by applicable law.

3.6 Trademarks. Distributor shall only use Company's trademarks, service marks, trade names, or other identifying markings (together, "**Trademarks**") within the scope of this Agreement. Distributor shall not register Trademarks or similar trademarks, service marks, trade names, or other identifying markings inside or outside the Territory. Distributor may indicate on its website that it is an authorized distributor of Products for Company.

3.7 Promotional Materials. Distributor shall only use brochures, catalogues, leaflets, samples, and other promotional materials that have been approved by or obtained from Company (together, "**Promotional Materials**"). Distributor shall maintain an adequate inventory of Promotional Materials. Distributor may at its own expense (a) prepare accurate translations of Promotional Materials in the official language(s) of the Territory and (b) add Distributor-identifying information to Promotional Materials, provided that this information does not obscure Company's Trademarks. Distributor shall not make any other changes to the Promotional Materials without Company's prior written consent. Upon Company's request, Distributor shall provide to Company copies of Promotional Materials used by the Distributor and its sub-distributors.

3.8 Rolling Forecast. Before each calendar quarter or on a more frequent basis if the parties agree otherwise in writing, Distributor shall provide to Company a non-binding forecast of Product purchases for at least the next four calendar quarters.

3.9 Company Visits. Upon Company's request, Distributor shall provide to Company reasonable cooperation in planning and participating in any Company visit to the Territory.

3.10 Records. Distributor shall permanently maintain complete and accurate records of all Products sold by Distributor and its Affiliates, and shall require its sub-distributors to maintain such records, including but not limited to the names and addresses of all direct customers and the specific Products sold to each. Distributor shall also maintain for a minimum rolling period of six (6) years complete, accurate, and sufficient records of all payments and transactions made by Distributor in connection with this Agreement and all steps taken by Distributor to comply with Section 5, "Compliance with Laws."

3.11 Company Inspections & Audits. Upon Company's good faith request, Distributor shall permit Company to inspect Distributor's relevant facilities or audit Distributor's relevant electronic and paper books, records, files, databases, and documents, in person or remotely, to determine Distributor's compliance with this Agreement. Company shall provide to Distributor at least sixty (60) days prior written notice of any such inspection or audit and conduct the inspection or audit during normal business hours, provided that (a) no notice is required if Company reasonably suspects a breach of Section 5, "Compliance with Laws" and (b) lesser notice is required if exigent circumstances warrant an inspection or audit sooner. Distributor shall provide to Company reasonable assistance in facilitating any such investigation or audit, including but not limited to making personnel available, providing in-person or remote access, permitting copying, and promptly completing and returning to Company any requests for information provided by Company to Distributor. Company shall not exercise its rights under this Section 3.11 more than twice per calendar year absent exigent circumstances. Distributor shall ensure that similar inspection and audit rights apply to Distributor's sub-distributors of the Products. The parties acknowledge that any inspection or audit of Distributor's sub-distributor will be coordinated by Distributor.

3.12 Insurance. Distributor shall, at all times throughout the Term and with respect to the Term, maintain adequate insurance for its activities and liabilities under this Agreement. Distributor shall provide to Company a copy of any certificates of insurance upon the execution of this Agreement and thereafter upon Company's request. Distributor shall, without derogating from the above, promptly inform Company of any change in its insurance coverage required by this paragraph.

3.13 Non-Solicitation. Distributor and its Affiliates shall not directly or indirectly solicit for hire any of Company's current personnel during the Term and for two (2) years following the termination or expiration of this Agreement, provided that Distributor and its Affiliates may engage in such solicitation if Buyer or an Affiliate of Buyer acquires Company.

3.14. Local Licenses, Registrations, & Approvals. To the extent required by law in any country within the Territory and not otherwise an obligation of Company under Section 4.4, "Licenses, Registrations, & Approvals," Distributor or its sub-distributors shall obtain, maintain, and comply with any required local license, registration, or approval to import, market, promote, distribute, sell, and support Products in the Territory (collectively, "**Local Approvals**"). To the extent permitted by law, Distributor or its sub-distributors shall obtain any Local Approvals in Company's name. In the event that a Local Approval cannot be obtained in Company's name, to the extent permitted by law, Distributor hereby agrees, and shall bind its sub-distributors to agree, to register such approvals in the name of the Distributor or the sub-distributor, as required by law, and to transfer the Local Approvals to Company upon the expiration or termination of this Agreement. In the event that a Local Approval is required by law to be obtained in the name of a sub-distributor, any such Local Approval shall be subject to the Company's written consent, which consent shall not be unreasonably withheld or delayed. Distributor shall promptly notify Company in writing if Distributor becomes aware of any circumstances that could potentially jeopardize the Local Approvals.

3.15 Quality Agreement. Distributor shall abide by the requirements of the Quality Agreement as set forth in Exhibit E.

4. ADDITIONAL COMPANY OBLIGATIONS.

Company shall undertake the obligations in this Section 4 at its own expense.

4.1 Product Information; Response to Inquiries. Company shall provide to Distributor information regarding the technical aspects of Products and their use. Company shall promptly respond to all inquiries from Distributor regarding matters under this Agreement.

4.2 Potential Customers. Company shall promptly provide Distributor any information that Company receives regarding potential customers for Products within the Territory.

4.3 Training. Company shall provide to Distributor adequate Product training in accordance with its training policy. Each party shall pay its own travel expenses for any such training. The party hosting the training shall organize the training and pay any expenses, including but not limited to expenses for adequate training space, necessary equipment, and amenities.

4.4 Licenses, Registrations & Approvals. Company shall obtain, maintain, and comply with any required license, registration, or approval to design, manufacture, label, package, store, export,

market, promote, distribute, sell, and provide Products for distribution or sale by Distributor in the Territory, including but not limited to CE Mark for the Product (collectively, "**Approvals**"). Company shall promptly notify Distributor in writing of any circumstances that could potentially affect the Approvals. Further, Company shall notify Distributor in writing ninety (90) days before making any change to the Products that could potentially affect the Approvals.

4.5 Records. Company shall permanently maintain complete and accurate records of all Products sold to Distributor. Company shall also maintain for a minimum rolling period of six (6) years complete, accurate, and sufficient records of all payments and transactions made by Company in connection with this Agreement and all steps taken by Company to comply with Section 5, "Compliance with Laws."

4.6 Distributor Inspections & Audits. Upon Distributor's good faith request, Company shall permit Distributor to inspect Company's relevant facilities or audit Company's relevant electronic and paper books, records, files, databases, and documents, in person or remotely, to determine Company's compliance with this Agreement. Distributor shall provide to Company at least sixty (60) days prior written notice of any such inspection or audit and conduct the inspection or audit during normal business hours, provided that (a) no notice is required if Company reasonably suspects a breach of Section 5, "Compliance with Laws" and (b) lesser notice is required if exigent circumstances warrant an inspection or audit sooner. Company shall provide to Distributor reasonable assistance in facilitating any such investigation or audit, including but not limited to making personnel available, providing in-person or remote access, permitting copying, and promptly completing and returning to Distributor any requests for information provided by Distributor to Company. Distributor shall not exercise its rights under this Section 3.11 more than twice per calendar year absent exigent circumstances.

4.7 Insurance. Company shall, at all times throughout the Term and with respect to the Term, maintain adequate insurance for its activities and liabilities under this Agreement. Company shall provide to Distributor a copy of any certificates of insurance upon the execution of this Agreement and thereafter upon Distributor's request. Company shall, without derogating from the above, promptly inform Distributor of any change in its insurance coverage required by this paragraph.

4.8 Non-Solicitation. Company and its Affiliates shall not directly or indirectly solicit for hire any of Distributor's current personnel during the Term and for two (2) years following the termination or expiration of this Agreement, provided that Company and its Affiliates may engage in such solicitation if Buyer or an Affiliate of Buyer acquires Company.

4.9 Quality Agreement. Company shall abide by the requirements of the Quality Agreement as set forth in Exhibit E.

5. COMPLIANCE WITH LAWS.

5.1 General. The parties shall comply with all laws, regulations, rules, and restrictions applicable to the design, manufacture, labeling, packaging, storage, importing/exporting, marketing, promotion, distribution, sale, provision, and support of Products under this Agreement (collectively, "**Applicable Laws**"), and with all applicable requirements of competent regulatory authorities. Except for routine matters involving the Local Approvals, Distributor shall promptly inform Company of any communication with a competent regulatory authority regarding this Agreement, and shall coordinate all Distributor responses to such authorities with Company. In the event a

change in Applicable Laws materially affects this Agreement, the party learning of the change shall promptly inform the other party, and the parties shall cooperate in good faith to determine a solution.

5.2 GDPR. The parties acknowledge that the European Union's General Data Protection Regulation 2016/679 ("**GDPR**") governs the processing of personal data of citizens of the European Union. To the extent applicable, the parties shall enter into a data transfer agreement under terms and conditions substantially similar to those contained in the standard contractual clauses promulgated by the European Commission or expressly required by the GDPR.

6. FORCE MAJEURE.

6.1 Definition. "**Force Majeure**" means any event or condition, not existing as of the Effective Date, not reasonably foreseeable as of the Effective Date, and not within the control of either party, that prevents in whole or in material part the performance of a party of its obligations under this Agreement, including but not limited to riots, civil or military disturbances, war, epidemics, fire, flood, hurricane, typhoon, earthquake, lightning, and explosion. For the avoidance of doubt, Force Majeure does not include the suspension or withdraw of the Approvals, labor strikes or work stoppage disruptions, or supply chain interruptions.

6.2 Effect. Neither party is liable to the other party for any failure or delay in performing any obligation under this Agreement (except the obligation to make payments when and as due) if the failure or delay is directly or indirectly caused by Force Majeure.

6.3 Procedure. The party claiming Force Majeure shall give the other party written notice of the cause within fourteen (14) days of the event and shall exercise reasonable diligence to remove the cause and resume performance.

7. LIMITATIONS OF LIABILITY; DISCLAIMER OF WARRANTIES.

7.1 NO PARTY OR ANY OF ITS AFFILIATES IS LIABLE FOR ANY LOSS OF PROFITS (ACTUAL OR ANTICIPATED), LOSS OF REVENUE, LOSS OF ANTICIPATED SAVINGS, LOSS OF GOODWILL, OR FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, OR SPECIAL LOSS OR DAMAGE, IN EACH CASE ARISING FROM THIS AGREEMENT EXCEPT (A) AS REQUIRED BY LAW; (B) FOR SUCH DAMAGES PAID OR DUE AND PAYABLE FOR A THIRD PARTY CLAIM; (C) FOR A BREACH OF SECTION 1.1, "APPOINTMENT; CONSIDERATION"; AND (D) FOR A BREACH OF SECTION 1.4, "COMPETITIVE PRODUCTS."

7.2 EXCEPT FOR THOSE EXPRESSLY STATED IN THIS AGREEMENT, THE PARTIES HEREBY DISCLAIM ALL WARRANTIES, CONDITIONS, TERMS, UNDERTAKINGS, AND OBLIGATIONS IMPLIED BY STATUTE, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, COMMON LAW OR OTHERWISE, TO THE FULLEST EXTENT PERMITTED BY LAW.

8. INDEMNIFICATION.

8.1 Company. Subject to Section 7, "Limitations of Liability; Disclaimer of Warranties," Company shall indemnify and hold harmless Distributor and its Affiliates and their respective officers, directors, employees, and agents (the "**Distributor Indemnified Parties**") against any damages,

losses, liabilities, claims, actions, settlements, costs, charges, judgments, and expenses (including but not limited to interest, penalties, fines and reasonable attorneys' fees) (together, "**Damages**"), arising from or relating to (a) any claim for death or personal injury allegedly caused in whole or in part by Company's design, manufacture, labeling/warning, packaging, storage, marketing or promotion of the Product (b) any claim for infringement, misappropriation, or other violation of any third party's intellectual property; (c) any recalls or field actions regarding the Product; (d) any negligent or intentional acts or omissions of Company or its Affiliates; and (e) any breach of Company's obligations under this Agreement or of any applicable law; provided that Company will have no obligation to indemnify and hold harmless the Distributor Indemnified Parties for Damages for which Distributor has an indemnification obligation under Section 8.2. For the avoidance of doubt, if both parties are liable for the same transaction or occurrence and both parties have an indemnification obligation under this Agreement therefrom, the Damages will be apportioned between the parties relative to their respective liability.

8.2 Distributor. Subject to Section 7, "Limitations of Liability; Disclaimer of Warranties," Distributor shall indemnify and hold harmless Company and its Affiliates and their respective officers, directors, employees, and agents (the "**Company Indemnified Parties**") against any Damages arising from or relating to (a) any negligent or intentional acts or omissions of Distributor, its Affiliates, or its sub-distributors; or (b) any breach of Distributor's obligations under this Agreement or of any applicable law; provided that Distributor will have no obligation to indemnify and hold harmless the Company Indemnified Parties for Damages for which Company has an indemnification obligation under Section 8.1. For the avoidance of doubt, if both parties are liable for the same transaction or occurrence and both parties have an indemnification obligation under this Agreement therefrom, the Damages will be apportioned between the parties relative to their respective liability.

8.3 Procedure. In each case, the party requiring indemnification and holding harmless (the "**Indemnified Party**") shall promptly notify the party providing indemnification (the "**Indemnifying Party**") in writing of any claim against Indemnified Party to which any such indemnification might apply, provided that the failure to give such notice shall not affect the Indemnified Party's rights to indemnification except to the extent that the Indemnifying Party is actually prejudiced as a result of the delay. If Indemnifying Party chooses adequate counsel and makes adequate provision to compensate Indemnified Party in the event of an adverse result, Indemnifying Party may control the defense of any action, provided Indemnified Party is allowed to participate at its own expense and if in the written opinion of counsel to the Indemnified Party (a) there are affirmative defenses available to the Indemnified Party that are different from or in addition to those available to the Indemnifying Party or that the Indemnifying Party is unable to assert or (b) there exists a conflict of interest between the Indemnifying Party and the Indemnified Party that would limit the Indemnifying Party's ability to protect the Indemnified Party's interests, the reasonable legal fees and expenses of separate counsel to the Indemnified Party will be deemed to constitute attorney fees within the scope of Damages subject to indemnification under this Agreement. The Indemnifying Party may enter into a settlement agreement involving solely the payment of money damages for which the Indemnifying Party is obligated to indemnify the Indemnified Party and that does not result in the Indemnified Party's becoming subject to injunctive or other equitable relief, without the Indemnified Party's consent, provided that the Indemnifying Party shall provide reasonable evidence of its ability to pay the agreed-upon damages and any Damages owed to Indemnified Party and shall have obtained the written, unqualified release of the Indemnified Party. Any other settlement agreement requires the Indemnified Party's written consent, which will not be unreasonably withheld.

8.4 Intellectual Property Remedies. In addition to any other remedies under this Section 8, in the event that the Product is enjoined or a court of competent jurisdiction otherwise determines that the Product infringes, misappropriates, or violates a third party's intellectual property, Company shall at its own expense and discretion (a) procure the right to continue using such third-party intellectual property in a manner consistent with this Agreement; or (b) modify the Product so that it no longer infringes, misappropriates, or violates such third-party intellectual property; or (c) remove the Products and refund the aggregate payments paid therefor by Distributor, less a reasonable sum for use and damage, if any. Subject to Section 8.3, "Procedure," Company may control the defense of any action alleging infringement of any third-party patents or trademarks by Products. Distributor shall ensure that its written agreements with any sub-distributors permit Company to control such a defense.

9. INTELLECTUAL PROPERTY & CONFIDENTIALITY.

9.1 Intellectual Property.

9.1.1 Acknowledgement. Distributor acknowledges Company's exclusive right, title, and interest in certain patents, trademarks, trade names, copyrights, and trade secrets, including but not limited to emblems, designs, models, know-how, and methods of presentation, regarding Products in the Territory or elsewhere (the "**Intellectual Property**").

9.1.2 No Challenge or Impairment. Distributor shall not do or cause to be done anything that directly or indirectly challenges or impairs the Intellectual Property.

9.1.3 License. During the Term, Company hereby grants Distributor an exclusive, royalty-free, sub-licensable license under the Intellectual Property solely to import, use, market, promote, distribute, offer for sale, and sell the Products in the Territory for approved uses.

9.1.4 No Vested Rights; Assignment. Except as set forth in this Section 9, Distributor does not acquire any right, title, or interest in the Intellectual Property by Distributor's performance of its duties and obligations under this Agreement, and Distributor shall not describe or represent itself to others as having any such right, title, or interest. Distributor hereby assigns to Company any right, title, or interest Distributor obtains in the Intellectual Property by operation of law, regulation, or rule in the Territory.

9.1.5 Notice of Infringement; Protection of Intellectual Property. Distributor shall immediately notify in writing Company of any infringement or potential infringement of the Intellectual Property in the Territory, and Distributor shall provide to Company reasonable cooperation in taking action against any such infringement. Distributor shall not take any action against an alleged infringer without Company's prior written consent.

9.2 Confidential Information.

9.2.1 Acknowledgement. Each party (the "**Receiving Party**") acknowledges that it will obtain certain non-public, confidential, and proprietary information (the "**Disclosed Information**") from the other party (the "**Disclosing Party**") during the Term. Disclosed Information includes information, data, files, documents, or other materials, of or related to the Disclosing Party or its Affiliates, that is disclosed to, or obtained or accessed by the Receiving Party, whether in tangible or intangible form, whether in writing, orally, electronically, visually, or in any other form or medium,

and whether marked as "confidential" or not, including but not limited to (a) information about the terms and conditions of this Agreement; (b) unpatented inventions, ideas, methods, and discoveries, trade secrets, know-how, unpublished patent applications, and other confidential intellectual property; (c) scientific, technical, engineering, financial, business, or economic information, including patterns, plans, compilations, devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes; (d) business plans, forecasts, strategies, manufacturing capabilities, and other information that would be reasonably considered non-public, confidential, or proprietary given the nature of the information and the Disclosing Party's businesses; and (e) all derivative materials, notes, analyses, summaries, and other materials prepared by or for Receiving Party that contain, are based on, or otherwise reflect, to any degree, any of the foregoing. Disclosed Information does not include information that (a) was available to or in the Receiving Party's possession on a non-confidential basis prior to disclosure under this Agreement; (b) is or later becomes public knowledge by publication or otherwise through no breach of this Agreement by the Receiving Party; (c) is properly acquired by the Receiving Party from a third-party under no disclosure restriction with the legal right to such information; (d) is required to be disclosed by a governmental or judicial authority with jurisdiction over the Receiving Party; or (e) the Receiving Party can demonstrate by written records was independently developed without reference to or reliance upon the Disclosed Information.

9.2.2 Non-disclosure; Non-Use. Receiving Party shall limit the disclosure of the Disclosed Information to its directors, officers, employees, and agents as necessary for the performance of this Agreement. Receiving Party shall not otherwise disclose the Disclosed Information without Disclosing Party's prior written consent. Receiving Party shall not, directly or indirectly, use Disclosed Information except as required for the performance of this Agreement. Receiving Party shall take all reasonable steps, including but not limited to the insertion of relevant clauses in contracts, to prevent the unauthorized disclosure or use of any Disclosed Information by Receiving Party or Receiving Party's directors, officers, employees, agents, or sub-distributors and to protect the Disclosed Information from damage, theft, loss, or perusal by unauthorized persons. Receiving Party is independently liable to Disclosing Party for any unauthorized disclosure or use of Disclosed Information by Receiving Party's directors, officers, employees, agents, or sub-distributors.

9.2.3 No Vested Rights; Assignment. Receiving Party does not acquire any right, title, or interest in the Disclosed Information by Receiving Party's performance of its duties and obligations under this Agreement, and Receiving Party shall not describe or represent itself to others as having any such right, title, or interest.

9.2.4 Right to Equitable Relief. Disclosing Party acknowledges that breach of this Section 9.2 may cause harm to Receiving Party for which damages are not an adequate remedy, and Disclosing Party shall therefore be entitled to equitable relief in addition to all other remedies available at law.

10. EXPIRATION & TERMINATION.

10.1 Expiration. This Agreement expires on the last day of the Term unless it is terminated earlier under this Section 10.

10.2 Termination for Cause.

10.2.1 Either Party. Either party may terminate this Agreement immediately for cause by providing the other party with written notice under the following circumstances:

a) for the other party's material breach of a duty or obligation under this Agreement, including but not limited to a series of repeated breaches that together constitute a material breach (a "**Material Breach**"), provided that the party seeking termination has provided the other party with thirty (30) days prior written notice of the Material Breach and the Material Breach remains uncured;

b) for the other party's breach of a material obligation under Section 5, "Compliance with Laws";

c) for the other party's petition in bankruptcy, insolvency, receivership, winding up of assets, or nationalization; or

d) for a Force Majeure event applicable to the other party lasting more than six (6) months.

10.2.2 Distributor. Distributor may terminate this Agreement immediately for cause by providing Company with written notice under the following circumstances:

a) for the inability of Company to deliver sixty percent (60%) or more of the pro rata portion of the units required for Distributor to meet its Minimum Purchase Amount over a cumulative six (6) months in any twelve (12) month period, subject to Distributor having issued Purchase Orders for such Products in accordance with the terms of this Agreement;

b) for the suspension of the Approvals lasting six (6) months or more or for the withdrawal of the Approvals;

c) for a temporary injunction of the Product lasting six (6) months or more or for a permanent injunction of the Product, unless such injunction resulted solely from an act or omission of Distributor, its Affiliates, or their sub-distributors; and

d) for a recall of the Product in the Territory that results in the inability to distribute the Product in the Territory over a cumulative six (6) months in any twelve (12) month period, unless such recall resulted solely from an act or omission of Distributor, its Affiliates, or their sub-distributors.

10.2.3 Company. Company may terminate this Agreement immediately for cause by providing Distributor with written notice for Distributor's failure to pay for three (3) months or more any shortfall amount required to be paid pursuant to Section 2.10, "Minimum Purchase Amount."

10.3 Termination for Convenience. Distributor may terminate this Agreement without cause by providing Company with one hundred and eighty (180) days prior written notice.

10.4 Effect of Expiration or Termination.

10.4.1 Company. Upon the expiration or termination of this Agreement, Company may appoint a new distributor (or distributors) or market, promote, distribute, sell, provide, or support Products directly in the Territory, and, at its own expense, shall:

a) not use or disclose to third parties Distributor's Disclosed Information that is not in the public domain or that is only in the public domain because of Company's breach of an obligation under this Agreement;

b) continue to indemnify Distributor regarding all matters for which this Agreement requires indemnification and ensure that its insurance coverage remains in effect; and

c) continue to perform any duty or obligation under this Agreement that either expressly or impliedly survives the expiration or termination of this Agreement, including but not limited to the provisions of Section 9, "Intellectual Property & Confidentiality."

10.4.2 Distributor. Upon the expiration or termination of this Agreement, subject to Sections 2.11, "Tenders," and Section 10.5, "Inventory," Distributor, at its own expense, shall:

a) return to Company or destroy all Promotional Materials obtained from Company;

b) continue to make any payments due to Company;

c) cease marketing, promoting, distributing, selling, providing, or supporting all Products in the Territory, and provide written notice to any of Distributor's Affiliates and sub-distributors in the Territory to do the same;

d) provide to Company a list of all Tenders and any related information in format and detail reasonably requested by the Company;

e) cease using all Intellectual Property;

f) remove all references to Company from Distributor's website;

g) not use or disclose to third parties Company's Intellectual Property and Disclosed Information that is not in the public domain or that is only in the public domain because of Distributor's breach of an obligation under this Agreement;

h) continue to indemnify Company regarding all matters for which this Agreement requires indemnification and ensure that its insurance coverage remains in effect; and

i) continue to perform any duty or obligation under this Agreement that either expressly or impliedly survives the expiration or termination of this Agreement, including but not limited to the provisions of Section 9, "Intellectual Property & Confidentiality."

10.4.3. Buyer Option and Loan Agreement. The parties acknowledge that to the extent Distributor terminates this Agreement for cause under Section 10.2 or for convenience under Section 10.3, upon such termination, the Buyer Option is terminated and the Loan Agreement is extinguished, as set forth in those agreements.

10.5 Inventory. Upon the expiration of this Agreement, Distributor may continue distributing and selling its remaining inventory of salable Products (the "**Remaining Inventory**") until the Remaining Inventory is depleted or the Product shelf life has been reached; or offer to sell its Remaining Inventory to Company. Upon the termination of this Agreement by Distributor for cause, Distributor in its sole discretion may sell all or a portion of its Remaining Inventory to Company, in

which case Company or its designee shall buy such Remaining Inventory for Distributor's fully-landed purchase price, or continue distributing and selling all or a portion of the Remaining Inventory until the Remaining Inventory is depleted or the Product shelf life has been reached. Upon the termination of this Agreement by Company for cause or by Distributor for convenience, subject to Section 2.11, "Tenders," Company in its sole discretion may buy all or a portion of the Remaining Inventory (or permit its designee to do so), in which case Distributor shall sell such Remaining Inventory for Distributor's fully-landed purchase price, or allow Distributor to continue distributing and selling all or a portion of the Remaining Inventory until the Remaining Inventory is depleted or the Product shelf life has been reached.

10.6 Termination Fee. In the event that this Agreement is terminated by Distributor under Section 10.2, "Termination for Cause", except for a termination for uncured Material Breach under 10.2.1(a) or Force Majeure under 10.2.1(d), within one hundred and eighty days (180) days of the termination date, Company shall pay Distributor a fixed amount in US dollars according to the following formula: Distributor and its Affiliates' total cash outlay to Company (the Distribution Fee *plus* the Fee, as defined in the Option Agreement, *plus* any tranches paid out under the Loan Agreement) *minus* accumulated Distributor Gross Margins (as defined in Exhibit A) for sales of Products under this Agreement (the "**Termination Fee**"). In the event that this Agreement is terminated by Distributor under Section 10.2, "Termination for Cause," except for a termination for uncured Material Breach under 10.2.1(a) or Force Majeure under 10.2.1(d), subject to Section 2.3, "Acceptance of Purchase Orders," Section 2.9, "Product Warranty," and Section 8, "Indemnification," the Termination Fee under this Section 10.6 is Distributor and its Affiliates' sole remedy under this Agreement for the actions, omissions, and/or circumstances giving rise to the termination of this Agreement.

11. GENERAL.

11.1 Authority. The parties represent and warrant that they have the full power and authority to enter into this Agreement and that they can do so without violating or conflicting with any laws or other agreements to which they are a party.

11.2 Entire Agreement. This Agreement, including its Exhibits and any attachments, constitutes the final, exclusive agreement between the parties on the matters contained in this Agreement, except to the extent the Option Agreement and the Loan Agreement are referenced herein. Except as provided in the Option Agreement and the Loan Agreement, all earlier and contemporaneous negotiations and agreements between the parties on the matters contained in this Agreement are expressly merged into and superseded by this Agreement. To the extent that there is a conflict between the terms of any Exhibit and the terms of this Agreement, the terms of this Agreement shall prevail.

11.3 Amendments. The parties may amend this Agreement only by the parties' written agreement that identifies itself as an amendment to this Agreement.

11.4 Notice.

11.4.1 Written Notice; Permitted Delivery Methods. Each party giving or making any notice, request, demand, or other communication (each, a "**Notice**") under this Agreement shall give the Notice in writing and use one of the following delivery methods in addition to electronic mail:

(a) Personal delivery
(b) Registered or Certified Mail (in each case, return receipt requested and postage prepaid)
(c) Internationally recognized overnight courier (with all fees prepaid)

11.4.2 Addressees and Addresses. Any party giving a Notice to the other party shall address the Notice to the person and address listed below (the "**Addressee**"):

Distributor	**Company**
Legal Department Attn: General Counsel	Kevin Mayberry, CEO
1655 Roberts Blvd., NW Kennesaw, GA 30144 U.S.A.	Maskit St. 4 Herzlia Business Park, Herzlia, Israel 46733
[omitted]	[omitted]

11.4.3 Effectiveness of a Notice. Notice is effective upon receipt, provided that the party giving the Notice has complied with Sections 11.4.1 and 11.4.2 above.

11.5 Independent Contractor. Distributor is operating at all times under this Agreement as an independent contractor, and nothing in this Agreement will be construed to create an employer and employee, principal and agent, joint venture, partnership, or fiduciary relationship between the parties.

11.6 Assignment and Delegation. Company shall not assign any right or delegate any performance under this Agreement without Distributor's prior written consent.

11.7 Successors and Assigns. This Agreement binds and benefits the parties and their respective permitted successors and assigns.

11.8 Waiver. No failure or delay by any party in exercising its rights, powers, or privileges under this Agreement, nor any single or partial exercise, will operate as a waiver of that party's rights, power, or privileges under this Agreement.

11.9 Severability. If any provision of this Agreement is determined to be illegal or unenforceable, the remaining provisions of this Agreement remain in full force, if the essential provisions of this Agreement for each party remain legal and enforceable.

11.10 Construction. The headings in this Agreement are for convenience only and do not form a part of the terms and conditions of this Agreement.

11.11 Choice of Law. The laws of Delaware, U.S.A. (without regard to its conflict of law principles) govern all matters arising from or relating to this Agreement. The state or federal courts of Delaware, U.S.A. will have exclusive jurisdiction over any dispute arising from or relating to this Agreement. Each party knowingly, voluntarily, and intentionally waives its right to a trial by jury in any legal proceeding arising from or relating to this Agreement. This waiver applies to any legal proceeding, whether sounding in contract, tort, or otherwise. Each party acknowledges that it has received the advice of competent counsel.

[Remainder of page intentionally blank. Signature page(s) follow.]

Each party is signing this Exclusive Distribution Agreement on the date stated below that party's signature.

Distributor:	**Company:**
JOTEC GmbH	**Endospan, Ltd.**
By: /s/ Thomas Bogenshütz	**By:** /s/ Kevin Mayberry
Name: Thomas Bogenschütz **Title:** General Manager, JOTEC GmbH and Senior Vice President EMEA, CryoLife, Inc. **Date:** September 11, 2019	**Name**: Kevin Mayberry **Title:** Chief Executive Officer **Date:** September 11, 2019

EXHIBIT A
PRODUCTS AND PRICES

[Omitted]

EXHIBIT B
TERRITORY

[Omitted]

EXHIBIT C
LEAD TIME SCHEDULE

[Omitted]

EXHIBIT D
INITIAL MINIMUM PURCHASE AMOUNT

[Omitted]

EXHIBIT E
QUALITY AGREEMENT

1. Purpose. This Quality Agreement outlines the responsibilities of Distributor and Company regarding quality assurance for Products in the field.

2. Scope. To the extent there is a conflict between the terms of this Quality Agreement and the terms of any other agreement between the parties, the terms of this Quality Agreement prevail.

3. Product Storage & Handling.

3.1 Instructions for Use. The parties shall comply with all instructions for use of Products, including but not limited to instructions for storage, handling, and transportation of Products, and the parties shall require their agents and sub-distributors to comply with all such instructions for use. Distributor shall also inform its direct customers of the instructions for use of Products. The parties shall maintain records of their efforts to comply with all instructions for use of Products, including but not limited to records of temperature and environmental conditions at its Product storage facilities.

3.2 Distributor Information. Distributor shall indicate on the Product or in a document accompanying the Product the Distributor's name, trade name or trademark, and address, provided that this information does not obscure Company's information.

4. Traceability. Distributor shall establish and maintain a process to ensure traceability of Products, including, at a minimum, the ability of Distributor to trace Products by customer, customer address, and batch, lot, or serial number. Distributor shall permanently maintain traceability records.

5. Complaints, Incidents & Nonconformities. Distributor shall immediately notify Company, in writing, of any complaint, incident, or nonconformity with regulation regarding a Product or Products, including but not limited to any failure or change in the characteristics or performance of a Product or any inaccuracies in the labeling or instructions for use of a Product. In each case, Distributor shall provide to Company the Product batch, lot, or serial number and a detailed description of the complaint, incident, or nonconformity. Distributor shall maintain a register of all such complaints, incidents, and nonconformities.

6. Investigations. Company shall investigate any complaints or incidents. Distributor shall use its best efforts to assist Company in any such investigation and shall only perform investigative functions under the direct instructions of Company.

7. Recalls, Field Safety Notices & Field Safety Corrective Actions. Company shall investigate and consult with Distributor to determine whether any recall, field safety notice (each a "**FSN**"), or field safety corrective action (each a "**FSCA**") is warranted. Distributor shall use its best efforts to assist Company in any such recall, FSN, or FSCA, including but not limited to notifying direct customers and retrieving Products, as applicable. Distributor shall have procedures for any such Company-directed activities and shall maintain a register of all such actions.

8. Reporting. Company shall appoint an EC Representative and ensure that it fulfills any reporting requirements regarding Product complaints or incidents.

9. Inspection & Audits. Either party may perform inspections or audits as set forth in the Distribution Agreement to determine the other party's compliance with this Quality Agreement.

10. MDR. Distributor shall abide by the European Union's Medical Device Regulation 2017/745 ("**MDR**"), including but not limited to Article 13 "General obligations of importers" and Article 14 "General obligations of distributors." To the extent that there is a conflict between the terms of this Agreement and the terms of the MDR, the terms of the MDR prevail.

Exhibit 31.1

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: October 31, 2019

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

Exhibit 31.2

I, David Ashley Lee, certify that:

1. I have reviewed this quarterly report on Form 10-Q of 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: October 31, 2019

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

Exhibit 32

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of CryoLife, Inc. (the "Company") on Form 10-Q for the quarter ending September 30, 2019, 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, to his knowledge:

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

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

/s/ J. PATRICK MACKIN
J. PATRICK MACKIN
Chairman, President, and
Chief Executive Officer
October 31, 2019

/s/ D. ASHLEY LEE
D. ASHLEY LEE
Executive Vice President,
Chief Operating Officer, and Chief Financial Officer
October 31, 2019