

CRYOLIFE INC
Form 10-Q
November 01, 2018

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, 2018**

OR

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

For the transition period from _____ to _____

Commission file number: 1-13165

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

Florida
(State or other jurisdiction of
incorporation or organization)

59-2417093
(I.R.S. Employer
Identification No.)

1655 Roberts Boulevard, NW, Kennesaw, Georgia
(Address of principal executive offices)

30144
(Zip Code)

(770) 419-3355

(Registrant's telephone number, including area code)

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

Edgar Filing: CRYOLIFE INC - Form 10-Q

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes No

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

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

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

Class	Outstanding at October 26, 2018
Common Stock, \$.01 par value	36,967,506 shares

Part I FINANCIAL INFORMATION**Item 1. Financial Statements.****CRYOLIFE, INC. AND SUBSIDIARIES****SUMMARY CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)****(IN THOUSANDS, EXCEPT PER SHARE DATA)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(Unaudited)		(Unaudited)	
Revenues:				
Products	\$ 45,152	\$ 27,029	\$ 138,063	\$ 84,519
Preservation services	19,446	16,970	56,979	52,357
Total revenues	64,598	43,999	195,042	136,876
Cost of products and preservation services:				
Products	12,459	6,220	40,166	21,196
Preservation services	9,425	7,917	27,083	23,401
Total cost of products and preservation services	21,884	14,137	67,249	44,597
Gross margin	42,714	29,862	127,793	92,279
Operating expenses:				
General, administrative, and marketing	32,871	24,756	104,946	71,016
Research and development	5,225	4,277	16,314	13,098
Total operating expenses	38,096	29,033	121,260	84,114
Operating income	4,618	829	6,533	8,165
Interest expense	4,104	851	11,863	2,486
Interest income	(52)	(64)	(141)	(159)
Other (income) expense, net	(1,542)	21	(257)	(70)

Income (loss) before income taxes	2,108	21	(4,932)	5,908
Income tax expense (benefit)	543	(1,304)	(2,868)	(803)
Net income (loss)	\$ 1,565	\$ 1,325	\$ (2,064)	\$ 6,711
Income (loss) per common share:				
Basic	\$ 0.04	\$ 0.04	\$ (0.06)	\$ 0.20
Diluted	\$ 0.04	\$ 0.04	\$ (0.06)	\$ 0.19
Weighted-average common shares outstanding:				
Basic	36,526	32,887	36,331	32,665
Diluted	37,610	34,057	36,331	33,851
Net income (loss)	\$ 1,565	\$ 1,325	\$ (2,064)	\$ 6,711
Other comprehensive income (loss):				
Foreign currency translation adjustments	(514)	217	(540)	582
Comprehensive income (loss)	\$ 1,051	\$ 1,542	\$ (7,204)	\$ 7,293

See accompanying Notes to Summary Consolidated Financial Statements.

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

	September 30, 2018	December 31, 2017
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 34,558	\$ 39,977
Restricted securities	753	776
Trade receivables, net	48,882	47,525
Other receivables	3,974	3,916
Inventories	46,149	46,684
Deferred preservation costs	33,509	35,671
Prepaid expenses and other	6,127	4,731
Total current assets	173,952	179,280
Property and equipment, net	32,072	33,579
Goodwill	188,118	188,305
Acquired technology, net	121,254	130,359
Other intangibles, net	42,184	49,071
Other	12,115	9,099
Total assets	\$ 569,695	\$ 589,693
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 5,941	\$ 9,767
Accrued compensation	8,628	10,208
Current portion of long-term debt	1,266	718
Taxes payable	924	4,020
Accrued expenses and other	13,990	18,227
Total current liabilities	30,749	42,940
Long-term debt	216,579	218,236
Deferred income taxes	26,116	30,431
Other	19,444	21,028
Total liabilities	292,888	312,635

Commitments and contingencies**Shareholders equity:**

Preferred stock	--	--
Common stock (issued shares of 38,445 in 2018 and 37,618 in 2017)	384	376
Additional paid-in capital	258,555	249,935
Retained earnings	35,742	37,609
Accumulated other comprehensive (loss) income	(3,283)	1,857
Treasury stock at cost (shares of 1,484 in 2018 and 1,387 in 2017)	(14,591)	(12,719)
Total shareholders equity	276,807	277,058
Total liabilities and shareholders equity	\$ 569,695	\$ 589,693

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,	
	2018	2017
	(Unaudited)	
Net cash flows from operating activities:		
Net (loss) income	\$ (2,064)	\$ 6,711
Adjustments to reconcile net (loss) income to net cash from operating activities:		
Depreciation and amortization	13,636	6,683
Non-cash compensation	4,685	5,652
Other non-cash adjustments to (loss) income	(1,330)	879
Changes in operating assets and liabilities:		
Receivables	(2,310)	(4,303)
Inventories and deferred preservation costs	1,697	(6,901)
Prepaid expenses and other assets	(2,481)	(3,040)
Accounts payable, accrued expenses, and other liabilities	(12,473)	(855)
Net cash flows (used in) provided by operating activities	(640)	4,826
Net cash flows from investing activities:		
Proceeds from sale of business component	--	740
Capital expenditures	(4,275)	(5,384)
Other	(722)	(67)
Net cash flows used in investing activities	(4,997)	(4,711)
Net cash flows from financing activities:		
Repayment of term loan	(2,098)	(3,916)
Proceeds from exercise of stock options and issuance of common stock	3,793	2,599
Redemption and repurchase of stock to cover tax withholdings	(2,085)	(1,600)
Other	(888)	(3)
Net cash flows used in financing activities	(1,278)	(2,920)
Effect of exchange rate changes on cash, cash equivalents, and restricted securities	1,473	477

Decrease in cash, cash equivalents, and restricted securities	(5,442)	(2,328)
Cash, cash equivalents, and restricted securities beginning of period	40,753	57,341
Cash, cash equivalents, and restricted securities end of period	\$ 35,311	\$ 55,013

See accompanying Notes to Summary Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

NOTES TO SUMMARY CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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, 2017 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, 2018 and 2017 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, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. 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, 2017 filed with the SEC on March 9, 2018.

New Accounting Standards

Recently Adopted

As of January 1, 2018 we adopted Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers* and the additional related ASUs (ASC 606). These standards provide guidance on recognizing revenue, including a five-step model to determine when revenue recognition is appropriate. ASC 606 provides that we recognize revenue to depict the transfer of control of promised goods or services to our customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. We used the modified retrospective method applied to those contracts that were not substantially completed as of January 1, 2018. As a result of the adoption, we recorded an immaterial adjustment to increase retained earnings to recognize the impact of contract assets under the new revenue recognition guidance. See Note 11 for further discussion of revenue recognition.

In August 2016 the Financial Accounting Standards Board (FASB) issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* (ASU 2016-18). ASU 2016-18 is intended to address diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The guidance requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. We adopted ASU 2016-18 as of January 1, 2018 and disclosure revisions have been made for the periods presented on the Summary Consolidated Statement of Cash Flows.

Not Yet Effective

In February 2016 the FASB amended its Accounting Standards Codification (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 leases (with the exception of short-term leases) at the commencement date and recognize expenses on their income statements similar to the current Topic 840, *Leases*. It is effective for fiscal years and interim periods beginning after December 15, 2018, and early adoption is permitted. We have identified contracts with potential leasing arrangements, entered leases into a tracking software, and are currently evaluating the impact the adoption of this standard will have on our financial position, results of operations, and cash flows.

2. Financial Instruments

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

September 30, 2018	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 1,237	\$ --	\$ --	\$ 1,237
Restricted securities:				
Money market funds	753	--	--	753
Total assets	\$ 1,990	\$ --	\$ --	\$ 1,990

December 31, 2017	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 372	\$ --	\$ --	\$ 372
Restricted securities:				
Money market funds	776	--	--	776
Total assets	\$ 1,148	\$ --	\$ --	\$ 1,148

We used prices quoted from our investment advisors to determine the Level 1 valuation of our investments in money market funds.

3. Cash Equivalents and Restricted Securities

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

September 30, 2018	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	\$ 1,237	\$ --	\$ 1,237
Restricted securities:			
Money market funds	753	--	753
December 31, 2017	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	\$ 372	\$ --	\$ 372
Restricted securities:			
Money market funds	776	--	776

As of September 30, 2018 and December 31, 2017 \$753,000 and \$776,000, respectively, of our money market funds were designated as short-term restricted securities due to a contractual commitment to hold the securities as pledged collateral relating primarily to international tax obligations.

Edgar Filing: CRYOLIFE INC - Form 10-Q

There were no gross realized gains or losses on cash equivalents in the three and nine months ended September 30, 2018 and 2017. As of September 30, 2018 \$231,000 of our restricted securities had a maturity date within three months and \$522,000 of our restricted securities had a maturity date between three months and one year. As of December 31, 2017 \$537,000 of our restricted securities had a maturity date within three months and \$239,000 had a maturity date between three months and one year.

4. Acquisition of JOTEC

Overview

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 a contract value of approximately \$225.0 million, subject to certain adjustments. JOTEC is being operated as a wholly-owned subsidiary of CryoLife. In connection with the closing of the JOTEC Acquisition, CryoLife entered into a senior secured credit facility in an aggregate principal amount of \$255.0 million, which includes a \$225.0 million term loan and a \$30.0 million revolving credit facility. See Note 8 for further discussion of the senior secured credit facility.

Accounting for the Transaction

We have updated our preliminary analysis of the purchase price of the JOTEC Acquisition to \$222.2 million, including debt and cash acquired as determined on the date of closing, consisting of \$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 the closing. This purchase price reflects an additional payment related to a working capital true-up calculated and paid to the sellers as defined in the purchase agreement. Upon closing of the JOTEC Acquisition, \$22.5 million was paid into an escrow account for any amounts payable for indemnification claims or other payment obligations. Our preliminary allocation of the \$222.2 million purchase consideration was allocated to JOTEC's tangible and identifiable intangible assets acquired and liabilities assumed, based on their estimated fair values as of December 1, 2017. Goodwill was preliminarily recorded based on the amount by which the purchase price exceeded the fair value of the net assets acquired and is not deductible for tax purposes. Goodwill from this transaction has been allocated to our Medical Devices segment. The estimated allocation of assets acquired and liabilities assumed is based on the information available to us. As we complete our valuation procedures, if new information regarding these values is received that would result in a material adjustment to the values recorded, we will recognize the adjustment, which may include the recognition of additional expenses, impairments, or other allocation adjustments, in the period this determination is made. As of September 30, 2018 goodwill increased by \$3.2 million resulting from adjustments made during the measurement period, primarily related to certain intangible assets.

The preliminary purchase price allocation as of December 1, 2017, reflecting the measurement period adjustments is as follows (in thousands):

	Opening Balance Sheet
Cash and cash equivalents	\$ 4,130
Receivables	13,392
Inventories	17,393
Intangible assets	111,711
Property and equipment, net	13,051
Goodwill	112,431
Other assets	4,281
Debt acquired	(3,808)
Liabilities assumed	(50,424)
Total purchase price	\$ 222,157

We incurred transaction and integration costs of \$1.8 million and \$6.1 million for the three and nine months ended September 30, 2018 related to the JOTEC Acquisition, which included, among other costs, expenses related to the termination of international distribution agreements, severance costs, and legal, other professional, and consulting costs. These costs were expensed as incurred and were primarily recorded as general, administrative, and marketing expenses on our Summary Consolidated Statements of Operations and Comprehensive Income (Loss).

Pro Forma Results - Unaudited

JOTEC revenues were \$4.1 million and the net loss was \$1.5 million from the date of the JOTEC Acquisition through December 31, 2017. Our unaudited pro forma results of operations for the years ended December 31, 2017 and 2016, assuming the JOTEC Acquisition had occurred as of January 1, 2016, are presented for comparative purposes below. These amounts are based on available information from the results of operations of JOTEC prior to the acquisition date and are not necessarily indicative of what the results of operations would have been had the JOTEC Acquisition been completed on January 1, 2016. Differences between the

preliminary and final purchase price allocation could have an impact on the pro forma financial information presented below and that impact could be material. This unaudited pro forma information does not project operating results post JOTEC Acquisition.

A summary of this unaudited pro forma information is as follows (in thousands, except per share amounts):

	Twelve Months Ended December 31,	
	2017	2016
Total revenues	\$ 236,209	\$ 224,896
Net loss	(736)	(1,966)
Pro forma loss per common share - basic	\$ (0.02)	\$ (0.06)
Pro forma loss per common share - diluted	\$ (0.02)	\$ (0.06)

Pro forma net loss was calculated using a normalized tax rate of approximately 38%.

5. Inventories and Deferred Preservation Costs

Inventories at September 30, 2018 and December 31, 2017 were comprised of the following (in thousands):

	September 30, 2018	December 31, 2017
Raw materials and supplies	\$ 16,858	\$ 16,328
Work-in-process	4,093	5,504
Finished goods	25,198	24,852
Total inventories	\$ 46,149	\$ 46,684

Deferred preservation costs at September 30, 2018 and December 31, 2017 were comprised of the following (in thousands):

	September 30, 2018	December 31, 2017
Cardiac tissues	\$ 16,077	\$ 16,988
Vascular tissues	17,432	18,683
Total deferred preservation costs	\$ 33,509	\$ 35,671

To facilitate patient support and access, we maintain consignment inventory of our On-X Life Technologies Holdings, Inc. (On-X) heart valves at domestic and international hospital locations and JOTEC products at international hospital locations. We retain title to this consignment inventory and it is included in finished goods inventory until the device

is implanted, at which time we invoice the hospital. As of September 30, 2018 we had \$10.6 million in consignment inventory, with approximately 58% in domestic locations and 42% in foreign locations. As of December 31, 2017 we had \$9.3 million in consignment inventory with approximately 58% in domestic locations and 42% in foreign locations.

6. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

As of September 30, 2018 and December 31, 2017 the carrying values of our indefinite lived intangible assets were as follows (in thousands):

	September 30, 2018	December 31, 2017
Goodwill	\$ 188,118	\$ 188,305
In-process R&D	9,485	13,954
Procurement contracts and agreements	2,013	2,013
Trademarks	841	841

Based on our experience with similar agreements, we believe that our acquired procurement contracts and agreements have indefinite useful lives, as we expect to continue to renew these contracts for the foreseeable future. We believe that our trademarks have indefinite useful lives as we currently anticipate that our trademarks will contribute to our cash flows indefinitely.

We monitor the phases of development of all 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. All 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.

As of September 30, 2018 and December 31, 2017 our entire goodwill balance was related to our Medical Devices segment.

	Medical Devices Segment
Balance as of December 31, 2017	\$ 188,305
JOTEC Acquisition measurement period adjustments	3,177
Revaluation of goodwill denominated in foreign currency	(3,364)
Balance as of September 30, 2018	\$ 188,118

Definite Lived Intangible Assets

As of September 30, 2018 and December 31, 2017 the gross carrying values, accumulated amortization, and approximate amortization period of our definite lived intangible assets were as follows (in thousands):

	Gross Value	Accumulated Amortization	Amortization Period	
September 30, 2018				
Acquired technology	\$ 136,061	\$ 14,807	11	22 Years
Customer lists and relationships	31,191	4,702	13	22 Years
Distribution and manufacturing rights and know-how	4,059	2,035	11	15 Years
Patents	3,621	2,918		17 Years
Other	2,096	1,467	3	5 Years
December 31, 2017				
Acquired technology	\$ 139,045	\$ 8,686	11	22 Years
Customer lists and relationships	32,419	3,552	13	23 Years
Distribution and manufacturing rights and know-how	4,059	1,820	11	15 Years
Patents	3,612	2,819		17 Years
Other	1,439	1,075	3	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 Income (Loss) (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Amortization expense	\$ 2,707	\$ 1,140	\$ 8,195	\$ 3,423

As of September 30, 2018 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	Remainder of 2018	2019	2020	2021	2022	2023	Total
Amortization expense	\$ 2,597	\$ 10,386	\$ 10,222	\$ 10,202	\$ 9,673	\$ 9,287	\$ 52,367

7. Income Taxes

Income Tax Expense

Our effective income tax rate was an expense of 26% and a benefit of 58% for the three and nine months ended September 30, 2018, respectively. Our effective income tax rate for the three months ended September 30, 2017 was not meaningful due to the impact of the value of tax adjustments as compared to the low amount of income before taxes. Our effective income tax rate was a benefit of 14% for the nine months ended September 30, 2017 due to the impact of the value of tax adjustments. Our income tax rate for the three and nine months ended September 30, 2018 was affected by excess tax benefit deductions related to stock compensation, which increased the year-to-date income tax benefits by approximately \$1.4 million, and losses in high rate jurisdictions. These factors were partially offset by the effects of non-deductible operating expenses and executive compensation expenses.

Our income tax rate for the three and nine months ended September 30, 2017 was favorably affected by excess tax benefits, primarily related to the exercise of non-qualified stock options and the vesting of stock awards, which decreased income tax expense by approximately \$1.1 million and \$2.7 million, respectively.

On December 22, 2017 the U.S. enacted tax reform legislation known as the H.R. 1, commonly referred to as the Tax Cuts and Jobs Act (the Tax Act), resulting in significant modifications to existing law. We have elected to follow the guidance in SEC Staff Accounting Bulletin 118 (SAB 118), which provides additional clarification regarding the application of ASC Topic 740, *Income Taxes* (ASC 740) in situations where we do not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of the Tax Act for the reporting period in which the Tax Act was enacted. SAB 118 provides for a measurement period beginning in the reporting period that includes the Tax Act's enactment date and ending when we have obtained, prepared, and analyzed the information needed in order to complete the accounting requirements, but the measurement period cannot extend beyond one year from the enactment date.

As of September 30, 2018 we have not fully completed our accounting for the income tax effects of all elements of the Tax Act, but we have completed our analysis of the 2017 repatriation transition tax. Our final transition tax calculation was not materially different from the provisional nominal tax benefit recorded at December 31, 2017. For elements of the Tax Act for which our analysis is not yet complete, we made reasonable estimates of the effects and recorded provisional adjustments. If we were not yet able to make reasonable estimates of the impact of certain elements, we have not recorded any adjustments related to those elements and have continued accounting for them in accordance with ASC 740 based on the tax laws in effect before the Tax Act.

For our calendar year beginning in 2018, we are subject to several provisions of the Tax Act including computations under Global Intangible Low Taxed Income (GILTI), Foreign Derived Intangible Income (FDII), Base Erosion and Anti-Abuse Tax (BEAT), and Internal Revenue Code Section 163(j) interest limitation (Interest Limitation) rules. Based on preliminary information and analysis, we have recorded a provisional estimate for a FDII deduction of \$565,000 in our effective tax rate for the nine months ended September 30, 2018. We estimate the Interest Limitation will apply, but not affect our 2018 tax rate. We are not subject to BEAT at this time based on revenue trends. We will continue to refine our provisional estimates for our computations of the GILTI, FDII, and Interest Limitation rules as we gather additional information.

We currently estimate that other provisions of the Tax Act generally will not materially impact our 2018 effective rate, other than the potential impact of changes to the deductibility of meals and entertainment and executive compensation. We continue to gather new information on the interpretation of these new law changes and refine our provisional estimates.

As we complete our analysis of the Tax Act, further collect and analyze data, interpret any additional guidance issued by the U.S. Treasury Department, the Internal Revenue Service, and other standard-setting bodies, we may adjust our provisional amounts. Those adjustments may materially impact our provision for income taxes.

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 due to operating losses. We acquired significant deferred tax assets, primarily net operating loss carryforwards, from our acquisitions of JOTEC 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 2018 tax year. We recorded significant deferred tax liabilities in 2017 related to the intangible assets acquired in the JOTEC Acquisition.

As of September 30, 2018 we maintained a total of \$2.5 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and had a net deferred tax liability of \$22.7 million. As of December 31, 2017 we had a total of \$2.5 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax liability of \$28.8 million.

8. 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 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.

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 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, 2018 the aggregate interest rate was 6.39% per annum. We are obligated to pay an unused commitment fee equal to 0.50% of the un-utilized portion of the *Revolving Credit Facility* and are obligated to pay other customary fees for a credit facility of this size and type.

In October 2018 we finalized an amendment to the *Credit Agreement* to reprice, resulting in a reduction in the interest rate margin over LIBOR on the *Term Loan Facility*. Under the amendment to the *Credit Agreement*, the interest rates will be revised to a floating annual rate equal to either base rate, plus a margin of 2.25%, or LIBOR, plus a margin of 3.25%.

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, 2018 and December 31, 2017 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 GmbH obtained two loans from Sparkasse Zollernalb, which we assumed in the acquisition, and are government sponsored by the Kreditanstalt für Wiederaufbau Bank (KFW). Both KFW loans have a term of 9 years and one loan bears an interest rate of 2.45% and the second loan bears an interest rate of 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, 2018	December 31, 2017
Term loan balance	\$ 223,313	\$ 225,000
2.45% Sparkasse Zollernalb (KFW Loan 1)	1,401	1,657
1.40% Sparkasse Zollernalb (KFW Loan 2)	1,989	2,312
Total loan balance	226,703	228,969
Less unamortized loan origination costs	(8,858)	(10,015)
Net borrowings	217,845	218,954
Less short-term loan balance	(1,266)	(718)
Long-term loan balance	\$ 216,579	\$ 218,236

Interest Expense

Interest expense was \$4.1 million and \$11.9 million for the three and nine months ended September 30, 2018, respectively, as compared to \$851,000 and \$2.5 million for the three and nine months ended September 30, 2017, respectively. Interest expense for the three and nine months ended September 30, 2018 and 2017 included interest on debt and uncertain tax positions. The increase in interest expense in 2018 was due to the interest on borrowings under the \$225.0 million secured term loan facility that we entered into in December 2017 to finance, in part, the JOTEC Acquisition.

9. Commitments and Contingencies**Liability Claims**

Our estimated unreported loss liability was \$1.9 million and \$1.8 million as of September 30, 2018 and December 31, 2017, respectively. As of September 30, 2018 and December 31, 2017, the related recoverable insurance amounts were \$773,000 and \$692,000, 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, 2018 could have been as high as \$3.1 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 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. Assuming enrollment proceeds as anticipated, we could receive Premarket Approval (PMA) from the U.S. Food and Drug Administration (FDA) in mid-year of 2020.

As of September 30, 2018 we had \$1.5 million in prepaid royalties, \$2.4 million in intangible assets, net, and \$1.4 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.

10. Shareholders Equity

Common Shares Issued

In December 2017 we issued 2,682,754 shares of CryoLife common stock, as part of the consideration for the acquisition of JOTEC. The stock had a value of \$53.1 million as determined on the date of the closing. See Note 4 for further discussion of the JOTEC Acquisition.

11. Revenue Recognition

Contracts with Customers

We have adopted ASC 606, *Revenue from Contracts with Customers* effective January 1, 2018 using the modified retrospective method applied to those contracts which were not substantially completed as of January 1, 2018. These standards provide guidance on recognizing revenue, including a five-step model to determine when revenue recognition is appropriate. The standard requires that an entity recognize revenue to depict the transfer of control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Revenues for 2018 are reported under ASC 606, while prior period amounts are not adjusted and continue to be reported under ASC 605, *Revenue Recognition*.

We routinely enter into contracts with customers that include general commercial terms and conditions, notification requirements for price increases, shipping terms and in most cases prices for the products and services that we offer. These agreements, however, do not obligate us to provide goods or services to the customer, and there is no consideration promised to us at the onset of these arrangements. For customers without separate agreements, we have a standard list price established by geography and by currency for all products and services, and our invoices contain standard terms and conditions that are applicable to those customers where a separate agreement is not controlling. Our performance obligations are established when a customer submits a purchase order notification (in writing, electronically or verbally) for goods and services, and we accept the order. We identify performance obligations as the delivery of the requested product or service in appropriate quantities and to the location specified in the customer's contract and/or purchase order. We generally recognize revenue upon the satisfaction of these criteria when control of the product or service has been transferred to the customer at which time we have an unconditional right to receive payment. Our prices are fixed and are not affected by contingent events that could impact the transaction price. We do not offer price concessions and do not accept payment that is less than the price stated when we accept the purchase order, except in rare credit related circumstances. We do not have any material performance obligations where we are acting as an agent for another entity.

Revenues for products, including: BioGlue® Surgical Adhesive, On-X products, JOTEC products, PerClot, PhotoFix™ and other medical devices, are typically recognized at the time the product is shipped, at which time the title passes

to the customer, and there are no further performance obligations. Revenues from consignment are recognized when the medical device is implanted. We recognize revenues for preservation services when services are completed and tissue is shipped to the customer.

Our E-xtra DESIGN ENGINEERING products are specifically designed to meet specifications of a particular patient, and therefore, do not create an asset with an alternative use. We evaluate open orders for these products each reporting period, and when material we recognize the revenue and related contract asset based on the amount of payment we believe we are entitled to at that time.

In certain limited circumstances, CardioGenesis cardiac laser consoles are provided to a customer for their use without transfer of title for evaluation purposes. We have determined that a portion of the revenue for the handpieces purchased during these evaluations constitutes revenue associated with the use of the laser console, but these are immaterial to reported revenues.

Sources of Revenue

We have identified the following revenues disaggregated by revenue source:

1. Domestic Hospitals – direct sales of products and preservation services.
2. International Hospitals – direct sales of products and preservation services.
3. 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.
4. 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, 2018 and 2017 the sources of revenue were as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
	(Unaudited)		(Unaudited)	
Domestic hospitals	\$ 34,924	\$ 30,720	\$ 103,606	\$ 95,327
International hospitals	19,001	5,158	56,440	12,291
International distributors	9,083	6,632	30,482	24,128
CardioGenesis cardiac laser therapy	1,590	1,489	4,514	5,130
Total sources of revenue	\$ 64,598	\$ 43,999	\$ 195,042	\$ 136,876

Also see segment and geographic 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.

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, 2018 are not material.

Warranty

Our general product warranties do not extend beyond an assurance that the product or services delivered will be consistent with stated specifications and do not include separate performance obligations. Warranties included with our CardioGenesis cardiac laser products provide for annual maintenance services, which are priced separately and are recognized as revenues at the stand-alone price over the service period, whether invoiced separately or recognized based on our allocation of the transaction price.

Significant Judgments in the Application of the Guidance in ASC 606

There are no significant judgments associated with the satisfaction of our performance obligations. We generally satisfy performance obligations upon delivery of the product or service to the customer. This is consistent with the time in which the customer obtains control of the products or service. Performance obligations are also generally settled quickly after the purchase order acceptance, other than as identified for the E-xtra DESIGN ENGINEERING product, therefore, the value of unsatisfied performance obligations at the end of any reporting period is generally immaterial.

For performance obligations provided through our E-xtra DESIGN ENGINEERING product line, we determine the value of our enforceable right to payment based on the timing required and costs incurred for design services and manufacture of the in-process device in relation to the total inputs required to complete the device.

We consider variable consideration in establishing the transaction price. Forms of variable consideration potentially applicable to our arrangements include sales returns, rebates, volume-based bonuses, and prompt pay discounts. We use historical information along with an analysis of the expected value to properly calculate and to consider the need to constrain estimates of variable consideration. Such amounts are included as a reduction to revenue from the sale of products and services in the periods in which the related revenue is recognized and adjusted in future periods as necessary.

Commissions and Contract Costs

Sales commissions are earned upon completion of each performance obligation, and therefore, are expensed when incurred. These costs are included in general, administrative, and marketing expenses in the Summary Consolidated Statements of Operations and Comprehensive Income (Loss). We generally do not incur incremental charges associated with securing agreements with customers which would require capitalization and recovery over the life of the agreement.

Practical Expedients

Our payment terms for sales direct to customers are substantially less than the one-year collection period that falls within the practical expedient in the determination of whether a significant financing component exists.

Shipping and Handling Charges

Fees charged to customers for shipping and handling of products and tissues are included in product revenues and preservation services revenues. The costs for shipping and handling of products and tissues are included as a component of cost of products and cost of preservation services.

Taxes Collected from Customers

Taxes collected on the value of transaction revenue are excluded from product and services revenues and cost of sales and are accrued in current liabilities until remitted to governmental authorities.

Effective Date and Transition Disclosures

Adoption of the new standards related to revenue recognition did not have a material impact on our consolidated financial statements and is not expected to have a material impact in future periods. During our evaluation of the impact of adopting the new revenue standard, which included a detailed review of performance obligations for all material revenue streams, we identified two noteworthy items:

Certain distributor agreements have historically included inventory buyback provisions under defined change of business conditions. Transactions under these terms would not qualify as a completed revenue transaction until sale through to the end customer, resulting in a revenue deferral until the proper criteria were satisfied. These agreements were modified or replaced to remove the buyback provisions effective on or before January 1, 2018 which eliminated any retrospective adjustment requirements.

Certain JOTEC products discussed above are manufactured to order, have no alternative use, and contain an enforceable right to receive payment for the performance completed. These factors qualify the transactions for revenue recognition over time. Upon adoption of the new standard, we evaluated all appropriate contracts in

progress to determine the value of unbilled revenues representing outstanding contract assets. We recorded an immaterial cumulative effect adjustment to recognize the impact of contract assets.

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), performance stock awards (PSAs), 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, 2018 the Compensation Committee of our Board of Directors (the Committee) authorized awards from approved stock incentive plans of RSUs to certain employees and RSAs and PSUs to certain Company officers, which, assuming that performance under the PSUs were to be achieved at target levels, together totaled 317,000 shares and had an aggregate grant date market value of \$7.1 million. The PSUs granted in 2018 represent the right to receive from 60% to 150% of the target number of shares of common stock. The performance component of PSU awards granted in 2018 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 2018 calendar year. We currently believe that achievement of the performance component is probable, and we reevaluate this likelihood on a quarterly basis.

During the nine months ended September 30, 2017 the Committee authorized awards from approved stock incentive plans of RSUs to certain employees and RSAs and PSUs to certain Company officers, which, including PSUs at target levels, together totaled 384,000 shares of common stock and had an aggregate grant date market value of \$6.3 million. The PSUs granted in 2017 represented the right to receive from 60% to 150% of the target number of shares of common stock. The performance component of PSU awards granted in 2017 was based on attaining specified levels of adjusted EBITDA, adjusted inventory levels, and trade accounts receivable days sales outstanding, each as defined in the PSU grant documents, for the 2017 calendar year. The PSUs granted in 2017 earned 100% of the target number of shares.

The Committee authorized, from approved stock incentive plans, grants of stock options to purchase a total of 219,000 and 260,000 shares to certain Company officers during the nine months ended September 30, 2018 and 2017, respectively. The exercise prices of the options were equal to the closing stock prices on their respective grant dates.

Employees purchased common stock totaling 46,000 and 82,000 shares in the three and nine months ended September 30, 2018, respectively, and 47,000 and 93,000 shares in the three and nine months ended September 30, 2017, respectively, through the ESPP.

Stock Compensation Expense

The following weighted-average assumptions were used to determine the fair value of options:

	Three Months Ended September 30, 2018		Nine Months Ended September 30, 2018	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	N/A	0.5 Years	5.0 Years	0.5 Years
Expected stock price volatility	N/A	0.32	0.40	0.35
Risk-free interest rate	N/A	2.11%	2.64%	1.53%

	Three Months Ended September 30, 2017		Nine Months Ended September 30, 2017	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	N/A	0.5 Years	5.0 Years	0.5 Years
Expected stock price volatility	N/A	0.32	0.40	0.35
Risk-free interest rate	N/A	2.11%	2.64%	1.53%

Expected life of options	N/A	0.5 Years	4.8 Years	0.5 Years
Expected stock price volatility	N/A	0.43	0.40	0.35
Risk-free interest rate	N/A	1.14%	1.87%	0.62%

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,	
	2018	2017	2018	2017
RSA, PSA, RSU, and PSU expense	\$ 1,281	\$ 1,448	\$ 3,750	\$ 4,326
Stock option and ESPP option expense	412	519	1,301	1,614
Total stock compensation expense	\$ 1,693	\$ 1,967	\$ 5,051	\$ 5,940

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. The total stock compensation expense also included expenses related to PSAs during the three

and nine months ended September 30, 2017. We have not granted any other PSAs and there is no unrecognized compensation expense for PSAs. 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 \$125,000 and \$363,000 in the three and nine months ended September 30, 2018, respectively, and \$111,000 and \$288,000 in the three and nine months ended September 30, 2017, respectively, of the stock compensation expense into our inventory costs and deferred preservation costs.

As of September 30, 2018 we had total unrecognized compensation costs of \$7.9 million related to RSUs, RSAs, and PSUs and \$2.2 million related to unvested stock options. As of September 30, 2018 this expense is expected to be recognized over a weighted-average period of 1.9 years for RSUs, 1.7 years for stock options, 1.2 years for RSAs, and 1.0 years for PSUs.

13. Income (Loss) Per Common Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
<u>Basic income (loss) per common share</u>				
Net income (loss)	\$ 1,565	\$ 1,325	\$ (2,064)	\$ 6,711
Net (income) loss allocated to participating securities	(15)	(22)	20	(126)
Net income (loss) allocated to common shareholders	\$ 1,550	\$ 1,303	\$ (2,044)	\$ 6,585
Basic weighted-average common shares outstanding	36,526	32,887	36,331	32,665
Basic income (loss) per common share	\$ 0.04	\$ 0.04	\$ (0.06)	\$ 0.20
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
<u>Diluted income (loss) per common share</u>				
Net income (loss)	\$ 1,565	\$ 1,325	\$ (2,064)	\$ 6,711
Net (income) loss allocated to participating securities	(14)	(22)	20	(122)
Net income (loss) allocated to common shareholders	\$ 1,551	\$ 1,303	\$ (2,044)	\$ 6,589

Basic weighted-average common shares outstanding	36,526	32,887	36,331	32,665
Effect of dilutive stock options and awards	1,084	1,170	--	1,186
Diluted weighted-average common shares outstanding	37,610	34,057	36,331	33,851
Diluted income (loss) per common share	\$ 0.04	\$ 0.04	\$ (0.06)	\$ 0.19

We excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares because the inclusion of these stock options would be antidilutive to income (loss) per common share. 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. For the three and nine months ended September 30, 2017 stock options to purchase a weighted-average 264,000 shares and 215,000 shares, respectively, were antidilutive and excluded from the calculation of diluted weighted-average common shares outstanding.

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; BioFoam® Surgical Matrix; JOTEC products, since the JOTEC Acquisition; 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,	
	2018	2017	2018	2017
Revenues:				
Medical devices	\$ 45,152	\$ 27,029	\$ 138,063	\$ 84,519
Preservation services	19,446	16,970	56,979	52,357
Total revenues	64,598	43,999	195,042	136,876
Cost of products and preservation services:				
Medical devices	12,459	6,220	40,166	21,196
Preservation services	9,425	7,917	27,083	23,401
Total cost of products and preservation services	21,884	14,137	67,249	44,597
Gross margin:				
Medical devices	32,693	20,809	97,897	63,323
Preservation services	10,021	9,053	29,896	28,956
Total gross margin	\$ 42,714	\$ 29,862	\$ 127,793	\$ 92,279

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Products:				
BioGlue and BioFoam	\$ 15,646	\$ 15,730	\$ 48,685	\$ 48,094
JOTEC	15,004	--	46,669	--
On-X	11,298	8,326	33,495	27,048
CardioGenesis cardiac laser therapy	1,590	1,489	4,514	5,130
PerClot	882	886	2,822	2,641
PhotoFix	732	598	1,878	1,606
Total products	45,152	27,029	138,063	84,519

Edgar Filing: CRYOLIFE INC - Form 10-Q

Preservation services:

Cardiac tissue	9,502	7,932	26,660	23,911
Vascular tissue	9,944	9,038	30,319	28,446

Total preservation services	19,446	16,970	56,979	52,357
------------------------------------	---------------	---------------	---------------	---------------

Total revenues	\$ 64,598	\$ 43,999	\$ 195,042	\$ 136,876
-----------------------	------------------	------------------	-------------------	-------------------

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, 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 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 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 belief that the JOTEC products will achieve double-digit growth over the next five years;

Our expectation that our expanded sales force will take market share and drive market expansion, including opening additional hospitals to using JOTEC products, based on the technologically and clinically advanced benefits of JOTEC products;

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 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 2018 tax year;

Our estimate that the Interest Limitation will apply, but not affect our 2018 tax rate; 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, 2017 and elsewhere throughout that report and other risks, 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); On-X Life Technologies Holdings, Inc. (On-X) mechanical heart valves and surgical products; JOTEC GmbH (JOTEC) endovascular 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 \$64.6 million in the three months ended September 30, 2018, a 47% increase from the quarter ended September 30, 2017 primarily due to revenues from JOTEC. See the Results of Operations section below for additional analysis of the three and nine months ended September 30, 2018.

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, 2017. 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, 2018 in any of our Critical Accounting Policies from those contained in our Form 10-K for the year ended December 31, 2017.

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 as a Percentage of Total Revenues for the			
	Revenues for the Three Months Ended September 30,		Three Months Ended September 30,	
	2018	2017	2018	2017
Products:				
BioGlue and BioFoam	\$ 15,646	\$ 15,730	24%	36%
JOTEC	15,004	--	23%	--%
On-X	11,298	8,326	18%	19%
CardioGenesis cardiac laser therapy	1,590	1,489	3%	3%
PerClot	882	886	1%	2%
PhotoFix	732	598	1%	1%
Total products	45,152	27,029	70%	61%
Preservation services:				
Cardiac tissue	9,502	7,932	15%	18%
Vascular tissue	9,944	9,038	15%	21%
Total preservation services	19,446	16,970	30%	39%
Total	\$ 64,598	\$ 43,999	100%	100%

	Revenues as a Percentage of Total Revenues for the			
	Revenues for the Nine Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Products:				
BioGlue and BioFoam	\$ 48,685	\$ 48,094	25%	35%
JOTEC	46,669	--	24%	--%
On-X	33,495	27,048	17%	20%
CardioGenesis cardiac laser therapy	4,514	5,130	3%	4%

Edgar Filing: CRYOLIFE INC - Form 10-Q

PerClot	2,822	2,641	1%	2%
PhotoFix	1,878	1,606	1%	1%
Total products	138,063	84,519	71%	62%
Preservation services:				
Cardiac tissue	26,660	23,911	14%	17%
Vascular tissue	30,319	28,446	15%	21%
Total preservation services	56,979	52,357	29%	38%
Total	\$ 195,042	\$ 136,876	100%	100%

Revenues increased 47% and 42% for the three and nine months ended September 30, 2018, respectively, as compared to the three and nine months ended September 30, 2017. The increase in revenues for the three and nine months ended September 30, 2018 was primarily due to revenues from JOTEC, which we acquired in December 2017, in addition to increases in On-X product revenues and preservation services revenues. A detailed discussion of the changes in product revenues and preservation services revenues for the three and nine months ended September 30, 2018 is presented below.

Products

Revenues from products increased 67% and 63% for the three and nine months ended September 30, 2018, respectively, as compared to the three and nine months ended September 30, 2017. The increase was primarily due to the acquisition of JOTEC in

December 2017 as well as an increase in revenues from the sale of On-X products. A detailed discussion of the changes in product revenues for BioGlue and BioFoam[®] Surgical Matrix; 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 Zloty, Swiss Francs, Brazilian Real, and Canadian Dollars which are subject to exchange rate fluctuations. For the three months ended September 30, 2018 compared to the three months ended September 30, 2017, the U.S. Dollar strengthened in comparison to these currencies, resulting in revenue decreases when these foreign currency denominated transactions were translated into U.S. Dollars. For the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, the U.S. Dollar weakened in comparison to the major currencies, resulting in revenue increases when these foreign currency denominated transactions were translated into U.S. Dollars. The impact on the results of operations was not material in either period. 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 and BioFoam

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, decreased 1% for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017. This decrease was primarily due to a decrease in average sales prices, which decreased revenues by 2%, partially offset by a 1% increase in volume of units sold.

Revenues from the sale of surgical sealants increased 1% for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017. This increase was primarily due to the favorable effect of foreign currency exchange, which increased revenues by 2%, partially offset by a 1% decrease in the average sales prices.

Revenues in the U.S., Canada, and the European Economic Area, Middle East, and Africa (EMEA) markets increased during these periods but were offset by a reduction in revenues to certain Asia Pacific and Latin American distributors due to changes in their buying patterns.

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 54% of total BioGlue revenues for both the three and nine months ended September 30, 2018, and 52% and 54% of total BioGlue revenues for the three and nine months ended September 30, 2017, respectively. BioFoam revenues accounted for less than 1% of surgical sealant revenues for both the three and nine months ended September 30, 2018 and 2017. BioFoam is approved for sale in certain international markets.

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. JOTEC products are distributed in a variety of international markets.

JOTEC post-acquisition revenues for the three and nine months ended September 30, 2018 increased 32% and 28%, respectively, when compared to JOTEC pre-acquisition revenues for the three and nine months ended September 30,

2017. Excluding the effects for foreign exchange, revenues for the three and nine months ended September 30, 2018 increased 33% and 19%, respectively, as compared to the JOTEC pre-acquisition revenues for the three and nine months ended September 30, 2017, primarily due to an increase in unit shipments.

We believe that the JOTEC products will achieve double-digit growth over the next five years due to the selling efforts of our larger, realigned international sales force as they undertake additional training and become more experienced in selling JOTEC products. We expect this larger sales force will take market share and drive market expansion, including opening additional hospitals to using JOTEC products, based on the technologically and clinically advanced benefits of JOTEC products.

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). On-X product revenues also include revenues from the distribution of CarbonAid ζ O diffusion catheters and from the sale of Chord-X ePTFE sutures for mitral chordal replacement. On-X products are distributed in both domestic and international

markets. On-X also generates revenue from pyrolytic carbon coating products produced for other medical device manufacturers (OEM).

On-X product revenues, excluding OEM, increased 36% for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017. This increase was primarily due to a 57% increase in volume of units sold, which increased revenues by 41%, partially offset by a decrease in average sales prices, which decreased revenues by 5%.

On-X product revenues, excluding OEM, increased 24% for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017. This increase was primarily due to a 30% increase in volume of units sold, which increased revenues by 22%, an increase in average sales prices, which increased revenues by 1%, and the favorable effect of foreign currency exchange, which increased revenues by 1%.

The volume increase of On-X products for the three and nine months ended September 30, 2018 was primarily due to an increase in volume in EMEA, the U.S., and Canada, after establishing a direct market in Canada in July 2017.

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 increased 7% for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017. The increase in the three months ended September 30, 2018 was primarily due to a 7% increase in unit shipments of handpieces.

Revenues from cardiac laser therapy decreased 12% for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017. The decrease in revenues for the nine months ended September 30, 2018 was primarily due to a 7% decrease in unit shipments of handpieces and the effect of the sale of one laser console for the nine months ended September 30, 2018, as compared to the sale of two laser consoles for the nine months ended September 30, 2017.

The major contributing factors to the decrease in handpiece revenues included the de-emphasis on this product line since 2016, when the On-X product line was acquired and the corresponding realignment of our sales force. Cardiac laser therapy is generally used adjunctively with cardiac bypass surgery by a limited number of physicians who perform these procedures, although there has been a slight growth in the number of performing physicians in recent months. Revenues from laser console sales are difficult to predict and can vary significantly from quarter to quarter.

PerClot

Revenues from the sale of PerClot remained flat for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017. The key factors affecting revenues during this period included an increase in the volume of grams sold, which increased revenues by 9%, offset by a reduction in the average sales price, which decreased revenues by 8%, and an unfavorable effect of foreign currency exchange, which decreased revenues by 1%.

Revenues from the sale of PerClot increased 7% for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017. This increase was primarily due to an increase in the volume of grams sold, which increased revenues by 8% and the favorable effect of foreign currency exchange, which increased revenues by 4%, partially offset by a decrease in average sales prices, which decreased revenues by 5%.

The volume increase for the three and nine months ended September 30, 2018 was primarily due to an increase in sales of PerClot in EMEA. The decrease in average selling prices for the three and nine months ended September 30, 2018 was primarily due to price reductions to certain customers in Europe as a result of pricing pressures from

competitive products.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Assuming enrollment proceeds as anticipated, we could receive Premarket Approval (PMA) from the U.S. Food and Drug Administration (FDA) in mid-year of 2020.

PhotoFix

PhotoFix revenues increased 22% and 17% for the three and nine months ended September 30, 2018, respectively, as compared to the three and nine months ended September 30, 2017. These increases were primarily due to an increase in units sold, which increased revenues by 22% and 16%, respectively. The increase in units sold 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.

Preservation Services

Revenues from preservation services increased 15% and 9% for the three and nine months ended September 30, 2018, respectively, as compared to the three and nine months ended September 30, 2017.

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 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. See further discussion below of specific items affecting cardiac and vascular preservation services revenues for the three and nine months ended September 30, 2018.

Cardiac Preservation Services

Revenues from cardiac preservation services, consisting of revenues from the distribution of heart valves and cardiac patch tissues, increased 20% for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017. The increase in the three months ended September 30, 2018 was primarily due to a 21% increase in unit shipments of cardiac tissues, which increased revenues by 21%, partially offset by a decrease in average service fees, which decreased revenues by 1%.

Revenues from cardiac preservation services increased 11% for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017. The increase in the nine months ended September 30, 2018 was primarily due to a 17% increase in unit shipments of cardiac tissues, which increased revenues by 12%, partially offset by a decrease in average service fees, which decreased revenues by 1%.

The increase in cardiac volume for the three and nine months ended September 30, 2018 was primarily due to an increase in the volume of cardiac valve shipments and a smaller increase in cardiac patch shipments. Factors contributing to this increase included major hurricanes in 2017, which reduced revenues in 2017, current health trends, and the availability of tissues for processing.

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.

Vascular Preservation Services

Revenues from vascular preservation services increased 10% for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017. This increase was primarily due to a 16% increase in vascular tissue shipments, which increased revenues by 13%, partially offset by a decrease in average service fees, which decreased revenues by 3%.

Revenues from vascular preservation services increased 7% for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017. This increase was primarily due to a 12% increase in vascular tissue shipments, which increased revenues by 10%, partially offset by a decrease in average service fees, which decreased revenues by 3%.

The increase in vascular volume for the three and nine months ended September 30, 2018 was primarily due to increases in saphenous vein and femoral artery shipments. Factors contributing to this increase included major

hurricanes in 2017, which reduced revenues in 2017, and the availability of tissues for processing. The decrease in average service fees for the three and nine months ended September 30, 2018 was primarily driven by fee differences due to physical characteristics of vascular tissues and the routine negotiation of pricing contracts with certain customers.

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 in revenue volume. These tissues are primarily distributed in domestic markets.

Cost of Products and Preservation Services

Cost of Products

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of products	\$ 12,459	\$ 6,220	\$ 40,166	\$ 21,196

Cost of products increased 100% and 89% for the three and nine months ended September 30, 2018, respectively, as compared to the three and nine months ended September 30, 2017. Cost of products for the three and nine months ended September 30, 2018 and 2017 included costs related to BioGlue, BioFoam, On-X, CardioGenesis cardiac laser therapy, PerClot, and PhotoFix. Cost of products for the three and nine months ended September 30, 2018 also included costs related to JOTEC.

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. Cost of products for the three and nine months ended September 30, 2017 included \$32,000 and \$2.1 million, respectively, in inventory basis step-up expense, primarily related to costs for On-X products repurchased from previous international and domestic distributors in excess of the unit cost to manufacture the inventory.

The increase in cost of products for the three and nine months ended September 30, 2018 was primarily due to an increase in revenues related to JOTEC, which we acquired in December 2017, and an increase of acquisition inventory basis step-up expense, as compared to the prior year period as discussed above.

Cost of Preservation Services

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of preservation services	\$ 9,425	\$ 7,917	\$ 27,083	\$ 23,401

Cost of preservation services increased 19% and 16% for the three and nine months ended September 30, 2018, as compared to the three and nine months ended September 30, 2017. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services increased in the three months ended September 30, 2018 primarily due to a 19% increase in the unit shipment of tissues. Cost of preservation services increased in the nine months ended September 30, 2018 primarily due to a 15% increase in the unit shipment of tissues and a 1% increase in the per unit cost of processing tissues.

Gross Margin

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Gross margin	\$ 42,714	\$ 29,862	\$ 127,793	\$ 92,279
Gross margin as a percentage of total revenues	66%	68%	66%	67%

Gross margin increased 43% and 38% for the three and nine months ended September 30, 2018, respectively, as compared to the three and nine months ended September 30, 2017, primarily due to increases in JOTEC and On-X product revenues. Gross margin as a percentage of total revenues decreased in the three and nine months ended September 30, 2018, as compared to the three and nine months ended September 30, 2017, primarily due to lower margins on JOTEC revenues, after the impact of purchase accounting adjustments, in comparison to our other product revenues. This decrease was partially offset by the overall growth in other medical device product revenues, primarily On-X, in relation to total revenues. The gross margins of medical device products are generally higher than the margins on preservation services.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
General, administrative, and marketing expenses	\$ 32,871	\$ 24,756	\$ 104,946	\$ 71,016
General, administrative, and marketing expenses as a percentage of total revenues	51%	56%	54%	52%

General, administrative, and marketing expenses increased 33% and 48% for the three and nine months ended September 30, 2018, respectively, as compared to the three and nine months ended September 30, 2017. The increase in general, administrative, and marketing expenses for the three and nine months ended September 30, 2018 was primarily due to the addition of JOTEC's general, administrative, and marketing expenses, as well as an increase in business development and integration expenses, and higher expenses to support our increasing revenue base and employee headcount. General, administrative, and marketing expenses for the three and nine months ended September 30, 2018 included \$1.9 million and \$6.9 million, respectively, in business development and integration expenses, primarily related to the JOTEC Acquisition, as compared to \$3.0 million and \$4.4 million for the three and nine months ended September 30, 2017, respectively.

Research and Development Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development expenses	\$ 5,225	\$ 4,277	\$ 16,314	\$ 13,098
Research and development expenses as a percentage of total revenues	8%	10%	8%	10%

Research and development expenses increased 22% and 25% for the three and nine months ended September 30, 2018, respectively, as compared to the three and nine months ended September 30, 2017. 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, BioGlue, and PhotoFix products. Research and development spending in the three and nine months ended September 30, 2017 was primarily focused on 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, NeoPatchTM, On-X, and BioGlue products.

Interest Expense

Interest expense was \$4.1 million and \$11.9 million for the three and nine months ended September 30, 2018, respectively, as compared to \$851,000 and \$2.5 million for the three and nine months ended September 30, 2017, respectively. Interest expense in the three and nine months ended September 30, 2018 and 2017 included interest on debt and uncertain tax positions. The increase in interest expense in 2018 was due to the interest on borrowings under the \$225.0 million secured term loan facility (the Term Loan Facility) we entered into in December 2017 to finance, in part, the JOTEC Acquisition.

Other (Income) Expense, Net

Other income was \$1.5 million and \$257,000 for the three and nine months ended September 30, 2018, respectively, as compared to other expense of \$21,000 and other income of \$70,000 for the three and nine months ended September 30, 2017, respectively. Other income and other expense primarily includes the realized effect of foreign currency gains and losses, which have increased since the acquisition of JOTEC. In the three and nine months ended September 30, 2018, other income also included a \$2.7 million gain resulting from a cash settlement related to claims against the representative of the former shareholders of On-X.

Earnings

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Income (loss) before income taxes	\$ 2,108	\$ 21	\$ (4,932)	\$ 5,908
Income tax expense (benefit)	543	(1,304)	(2,868)	(803)
Net income (loss)	\$ 1,565	\$ 1,325	\$ (2,064)	\$ 6,711
Diluted income (loss) per common share	\$ 0.04	\$ 0.04	\$ (0.06)	\$ 0.19
Diluted weighted-average common shares outstanding	37,610	34,057	36,331	33,851

Income before income taxes increased in the three months ended September 30, 2018, as compared to the three months ended September 30, 2017 primarily due to an increase in income from operations and a \$2.7 million gain resulting from a cash settlement related to claims against the representative of the former shareholders of On-X, partially offset by an increase in interest expense due to the interest on borrowings under the Term Loan Facility. We experienced a loss before income taxes for the nine months ended September 30, 2018, as compared to income before income taxes for the nine months ended September 30, 2017. The loss before income taxes for the nine months ended September 30, 2018 was primarily due to an increase in business development and integration expenses including expenses related to the JOTEC inventory fair value adjustment, partially offset by a \$2.7 million gain resulting from a cash settlement related to claims against the representative of the former shareholders of On-X. We have experienced an increase in operating expenses due to the addition of JOTEC's general, administrative, and marketing expenses, higher expenses to support our increasing revenue base and employee headcount, and an increase in interest expense due to the interest on borrowings under the Term Loan Facility.

Our effective income tax rate was an expense of 26% and a benefit of 58% for the three and nine months ended September 30, 2018, respectively. Our effective tax rate for the three months ended September 30, 2017 was not meaningful due to the impact of the value of tax adjustments as compared to the low amount of income before taxes. Our effective income tax rate was a benefit of 14% for the nine months ended September 30, 2017, due to the impact of the value of tax adjustments. Our income tax rate for the three and nine months ended September 30, 2018 was affected by excess tax benefit deductions related to stock compensation, which increased the year-to-date income tax benefits by approximately \$1.4 million, and losses in high rate jurisdictions. These factors were partially offset by the effects of non-deductible operating expenses and executive compensation expenses.

Our income tax rate for the three and nine months ended September 30, 2017 was favorably affected by excess tax benefits, primarily related to the exercise of non-qualified stock options and the vesting of stock awards, which decreased income tax expense by approximately \$1.1 million and \$2.7 million, respectively.

On December 22, 2017 the U.S. enacted tax reform legislation known as the H.R. 1, commonly referred to as the Tax Cuts and Jobs Act (the Tax Act), resulting in significant modifications to existing law. We have elected to follow the guidance in SEC Staff Accounting Bulletin 118 (SAB 118), which provides additional clarification regarding the application of Accounting Standards Codification (ASC) Topic 740, *Income Taxes* (ASC 740) in situations where we

do not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of the Tax Act for the reporting period in which the Tax Act was enacted. SAB 118 provides for a measurement period beginning in the reporting period that includes the Tax Act's enactment date and ending when we have obtained, prepared, and analyzed the information needed in order to complete the accounting requirements. The measurement period, however, cannot extend beyond one year from the enactment date.

As of September 30, 2018 we have not fully completed our accounting for the income tax effects of all elements of the Tax Act, but we have completed our analysis of the 2017 repatriation transition tax. Our final transition tax calculation was not materially different from the provisional nominal tax benefit recorded at December 31, 2017. For elements of the Tax Act for which our analysis is not complete, we made reasonable estimates of the effects and recorded provisional adjustments. If we were not yet able to make reasonable estimates of the impact of certain elements, we have not recorded any adjustments related to those elements and have continued accounting for them in accordance with ASC 740 based on the tax laws in effect before the Tax Act.

For our calendar year beginning in 2018, we are subject to several provisions of the Tax Act including computations under Global Intangible Low Taxed Income (GILTI), Foreign Derived Intangible Income (FDII), Base Erosion and Anti-Abuse Tax (BEAT), and Internal Revenue Code Section 163(j) interest limitation (Interest Limitation) rules. Based on preliminary information and analysis, we have recorded a provisional estimate for a FDII deduction of \$565,000 in our effective tax rate for the nine months ended September 30, 2018. We estimate the Interest Limitation will apply, but not affect our 2018 tax rate. We are not subject to BEAT at this time based on revenue trends. We will continue to refine our provisional estimates for our computations of the GILTI, FDII, and Interest Limitation rules, as we gather additional information.

We currently estimate that other provisions of the Tax Act generally will not materially impact our 2018 effective rate, other than the potential impact of changes to the deductibility of meals and entertainment and executive compensation. We continue to gather new information on the interpretation of these new law changes and refine our provisional estimates.

As we complete our analysis of the Tax Act, further collect and analyze data, interpret any additional guidance issued by the U.S. Treasury Department, the Internal Revenue Service, and other standard-setting bodies, we may adjust our provisional amounts. Those adjustments may materially impact our provision for income taxes.

Net income per common share increased for the three months ended September 30, 2018, as compared to the three months ended September 30, 2017. The increase for the three months ended September 30, 2018 was primarily due to the income before income taxes, partially offset by an income tax expense, as discussed above. Net (loss) income and diluted (loss) income per common share decreased for the nine months ended September 30, 2018, as compared to the nine months ended September 30, 2017, primarily due to the loss before income taxes, partially offset by an income tax benefit, as discussed above.

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 further believe that demand for BioGlue in Japan may continue to be lowest in the second quarter of each year due to distributor ordering patterns driven by the slower summer holiday season in Japan, although this trend could vary somewhat from year to year. 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 subsequent to the JOTEC Acquisition including the distributor to direct strategy and the European sales force realignment.

We do not believe the demand for CardioGenesis cardiac laser therapy is seasonal, as our data does not indicate a significant trend.

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

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, 2018 net working capital (current assets of \$174.0 million less current liabilities of \$30.7 million) was \$143.3 million, with a current ratio (current assets divided by current liabilities) of 6 to 1, compared to net working capital of \$136.4 million and a current ratio of 4 to 1 at December 31, 2017.

Overall Liquidity and Capital Resources

Our primary cash requirements for the nine months ended September 30, 2018 were general working capital needs, interest and principal payments under our debt agreement, business development and integration expenses, capital expenditures for facilities and equipment, and to a lesser extent repurchases of stock to cover tax withholdings. We funded our cash requirements through our existing cash reserves, proceeds from stock option exercises, and the cash settlement received related to claims against the representative of the former shareholders of On-X.

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. 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 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.

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. As of September 30, 2018 the remaining availability on our revolving credit facility was \$30.0 million.

In October 2018 we finalized an amendment to the Credit Agreement to reprice, resulting in a reduction in the interest rate margin over LIBOR on the Term Loan Facility. Under the amendment to the Credit Agreement, the interest rates will be revised to a floating annual rate equal to either the base rate plus a margin of 2.25% or LIBOR plus a margin of 3.25%.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Assuming enrollment proceeds as anticipated, we could receive PMA from the FDA in mid-year of 2020. See also Part II, Item 1A, Risk Factors Risks Relating To Our Business Our investment in PerClot is subject to significant risks, and our ability to fully realize our investment is dependent on our ability to obtain FDA approval and to successfully commercialize PerClot in the U.S. either directly or indirectly.

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 2018 tax year.

As of September 30, 2018 approximately 36% of our cash and cash equivalents were held in foreign jurisdictions.

Net Cash Flows from Operating Activities

Net cash used in operating activities was \$640,000 for the nine months ended September 30, 2018, as compared to net cash provided by operating activities of \$4.8 million for the nine months ended September 30, 2017. The current year cash used in operating activities was largely a result of increased business development costs, primarily related to the JOTEC Acquisition and interest payments under our debt agreement.

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 for changes in operating assets and liabilities from the prior year end. For the nine months ended September 30, 2018 these non-cash items included \$13.6 million in depreciation and amortization expenses and \$4.7 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, 2018 these changes included an unfavorable adjustment of \$12.5 million due to the

timing differences between recording accounts payable, accrued expenses, and other liabilities and the payment of cash, \$2.3 million due to the timing difference between recording receivables and the receipt of cash, and \$2.5 million due to increases in prepaid expenses and other assets, partially offset by \$1.7 million due to decreases in inventory balances and deferred preservation costs.

Net Cash Flows from Investing Activities

Net cash used in investing activities was \$5.0 million for the nine months ended September 30, 2018, as compared to \$4.7 million for the nine months ended September 30, 2017 primarily due to capital expenditures in both years.

Net Cash Flows from Financing Activities

Net cash used in financing activities was \$1.3 million for the nine months ended September 30, 2018, as compared to \$2.9 million for the nine months ended September 30, 2017. The current year cash used was primarily due to \$2.1 million in principal payments on debt and \$2.1 million for repurchases of common stock to cover tax withholdings, partially offset by \$3.8 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, 2018 were as follows (in thousands):

	Total	Remainder of 2018	2019	2020	2021	2022	Thereafter
Long-term debt obligations	\$ 226,703	\$ 648	\$ 2,797	\$ 2,797	\$ 2,797	\$ 2,797	\$ 214,867
Interest payments	75,578	3,299	12,552	12,416	12,279	12,141	22,891
Operating leases	22,131	1,271	6,077	5,237	4,266	1,806	3,474
Capital leases	7,749	210	866	695	648	592	4,738
Research obligations	3,785	1,616	1,613	262	159	135	--
Purchase commitments	3,901	1,700	1,915	158	64	64	--
Contingent payments	1,000	--	--	1,000	--	--	--
Total contractual obligations	\$ 340,847	\$ 8,744	\$ 25,820	\$ 22,565	\$ 20,213	\$ 17,535	\$ 245,970

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 operating and capital 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.

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

Our purchase commitments include obligations from agreements with suppliers, one of which is the minimum purchase requirements for PerClot under a distribution agreement with Starch Medical, Inc. (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 2019, based on the assumption that we will not terminate the distribution agreement before its target date for receiving FDA approval for PerClot in mid-year of 2020. However, if we do not obtain FDA approval for PerClot and 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 contingent payments obligation includes payments that we may make if certain U.S. regulatory approvals and certain commercial milestones are achieved related to our transaction with SMI for PerClot.

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 \$4.0 million, as no specific assessments have been made by any taxing authorities.

Capital Expenditures

Capital expenditures were \$4.3 million and \$5.4 million for the nine months ended September 30, 2018 and 2017, respectively. Capital expenditures in the nine months ended September 30, 2018 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 \$34.6 million as of September 30, 2018 and interest paid on the outstanding balances, if any, of our variable rate Revolving Credit Facility and \$223.3 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, 2018, affecting our cash and cash equivalents, restricted cash and securities, \$223.3 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 Zloty, Canadian Dollars, and Brazilian Reals and a portion of our general, administrative, and marketing expenses are denominated in Euros, British Pounds, Swiss Francs, Polish Zloty, 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, we could recognize a reduction in revenues or an increase in expenses related to a change in exchange rates.

An additional 10% adverse change in exchange rates from the exchange rates in effect on September 30, 2018, affecting our balances denominated in foreign currencies, would not have had a material effect on our financial position, results of operations, or cash flows. An additional 10% adverse change in exchange rates from the weighted-average exchange rates experienced by us for the nine months ended September 30, 2018, affecting our revenue and expense transactions denominated in foreign currencies, would not have had a material effect on our financial position, results of operations, or cash flows.

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, 2018, 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.

As disclosed above, 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. We are currently in the process of integrating the JOTEC operations, evaluating their internal controls, and implementing CryoLife's internal control structure over these operations.

Part II - OTHER INFORMATION

Item 1. Legal Proceedings.

There are no material pending legal proceedings to which we or any of our subsidiaries is a party or of which any of our property is the subject. We reference herein the quarterly report for the quarter ending June 30, 2018, which reports upon our settlement of our indemnification claims against the representative of the former shareholders of On-X Life Technologies Holdings, Inc. (On-X) and the related litigation previously disclosed.

Item 1A. Risk Factors.

Risks Relating To Our Business

We may not realize all of 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 successfully integrate the JOTEC business with ours, including integrating the combined European sales force;

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 the Company's, 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 implementation costs, which are expensed immediately.

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 approximately 24% and 36% of revenues in the three months ended September 30, 2018 and 2017, respectively. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

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 increasingly subject to 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; and

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.

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 the three months ended September 30, 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 compete effectively with our major competitors, as they may have advantages over us in terms of cost structure, 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 enforcement activities.

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% and 39% of revenues in the three months ended September 30, 2018 and 2017, respectively. 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;

Process donated tissue cost effectively or at all due to factors such as employee turnover, ineffective or inefficient operations, or an insufficiently skilled workforce;

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, (NOTA), 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 On-X and are subject to a variety of risks affecting them.

On-X is a significant source of our revenues, representing 18% and 19% of revenues in the three months ended September 30, 2018 and 2017, respectively. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

Our ability to achieve anticipated On-X revenue in international markets outside the U.S.;

Our ability to capitalize on the U.S. Food and Drug Administration (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, 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;

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 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 ascending aortic prosthesis (AAP) in the European Economic Area (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 2018 and beyond.

Our investment in PerClot is subject to significant risks, and our ability to fully realize our investment is dependent on our ability to obtain 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 Starch Medical, Inc. (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 assuming enrollment proceeds as anticipated, we could receive PMA from the FDA in mid-year of 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, the pace of enrollment in the pivotal clinical trial and the approval process may be delayed because of unforeseen scheduling difficulties and unfavorable results at various stages in the pivotal clinical trial or the 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.

PerClot sold in the EEA has a CE Mark that is owned by a third party, and that expired in the second quarter of 2018. If that CE Mark is not timely renewed, we may be unable to purchase additional PerClot to distribute in the EEA and other countries that recognize the CE Mark after our distributors' inventories of approved PerClot are depleted, which could materially, adversely affect our future revenues.

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 infeasible, necessitating that we 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 JOTEC and On-X 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 acquisitions of JOTEC and On-X; and licensing of products developed internally with

non-cardiac 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.

As noted above, we are currently engaged in an Investigational Device Exemption clinical trial for PerClot, as well as clinical trials in China for BioGlue and in the U.S. for the On-X valve. We also anticipate commencing efforts in 2018 to initiate future U.S. clinical trials for certain JOTEC products. Each of these trials 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, in a timely basis, if ever, or that the new 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 may become more stringent due to changes in applicable laws, regulatory agency policies, or the adoption of new regulations. Clinical trials 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 programs;

Inability to manufacture or acquire sufficient quantities of the products, tissues, or any other components required for clinical trials;

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, and Office of Foreign Asset Control administered sanction programs;

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 British Pound and Euro as compared to the U.S. Dollar, including any fluctuations in exchange rates due to the exit of the U.K. from the European Union;

Differing local product preferences and product requirements;

Adverse economic or political changes or political instability;

Potential trade restrictions, exchange controls, and import and export licensing requirements including tariffs; and

Potential adverse tax consequences of overlapping tax structures.

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 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 or the related suppliers and/or their facilities are shut down temporarily or permanently, whether by government order, natural disaster, or otherwise, 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 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. We also conduct substantially all of 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.

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. 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;

Regulatory agencies could reclassify, reevaluate, or suspend our clearances and approvals to sell our products and distribute tissues;

European Notified Bodies have recently engaged 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 AAP in the EEA. See the risk factor above 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;

The European Union has adopted a new Medical Device Regulation (MDR 2017/745), which could result in product reclassifications or more stringent commercialization requirements that adversely impact our clearances and approvals; 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.

As another example of these risks, 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 re-inspection by the FDA 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. Nevertheless, any future adverse action from the FDA, or other regulatory bodies, may decrease demand for our products or tissues or cause us to write down our inventories or deferred preservation costs and could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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 mechanical, synthetic, and animal-based tissue valves for implantation;

The sale of endovascular and surgical stents;

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, Ethicon (a Johnson & Johnson Company), Medtronic, Inc., Abbott Laboratories, LivaNova PLC, Edwards Life Sciences Corp., BD, Integra Life Sciences Holdings, LifeNet, Admedus, Inc., Aziyo Biologics, Cook Medical, Gore, Terumo Corp., Endologix, Antegraft, Inc., LeMaitre, 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.

Tax reform could have a material adverse effect on us.

The December 2017 tax reform legislation known as the H.R. 1, commonly referred to as the Tax Cuts and Jobs Act (the Tax Act) made significant changes to federal income tax law including, among other things, reducing the statutory corporate income tax rate to 21% from 35% and changing the U.S. taxation of our non-U.S. business activities. We may be adversely affected by these changes in U.S. tax laws and regulations, and it is possible that governmental authorities in the U.S. and/or other countries could further amend tax laws that would adversely affect us. In addition, we are required to evaluate the impact of the Tax Act on our operations and financial statements, and to the extent we initially do so inaccurately, we may not provide investors or the public with advance notice of any adverse effect. Currently, we have accounted for the effects of the Tax Act using reasonable estimates based on currently available information and our interpretations thereof. This accounting may change due to, among other things, changes in interpretations we have made and the issuance of new tax or accounting guidance.

Certain changes in tax law implemented by the Tax Act will be partially effective in the current 2018 fiscal year and fully effective in the 2019 fiscal year. The primary impacts to us include repeal of the alternative minimum tax regime, decrease of the corporate income tax rate structure, net operating loss limitations, and changes to the limits on executive compensation deductions. These changes will have a material impact to the value of deferred tax assets and liabilities, and our future taxable income and effective tax rate. Although we currently anticipate the enacted changes in the corporate tax rate and calculation of taxable income will have a favorable effect on our financial condition, profitability, and/or cash flows, we are still analyzing the Tax Act with our professional advisers and we are still awaiting guidance from the U.S. Department of Treasury. Until such analysis is complete and verified, and until we receive additional guidance, the full impact of the Tax Act on us in future periods is uncertain, and no assurances can be made by us that it will not have any negative impacts on us.

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 EEA in May 2018 could adversely affect our business.

The European Commission has approved a data protection regulation, known as the General Data Protection Regulation (GDPR), which 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. 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 or reductions for medical devices that incorporate components produced by us. 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.

Our sales are affected by challenging domestic and international economic and geopolitical conditions and their constraining effect on hospital budgets, and demand for our products and tissue preservation services could decrease in the future, which could materially, adversely affect our business.

The demand for our products and tissue preservation services can fluctuate from time to time. In challenging economic environments, hospitals attempt to control costs by reducing spending on consumable and capital items, which can result in reduced demand for some of our products and services. If demand for our products or tissue preservation services decreases significantly in the future, our revenues, profitability, and cash flows would likely decrease, possibly materially. In addition, the manufacturing throughput of our products and the processing throughput of our preservation services would necessarily decrease, which would likely adversely impact our margins and, therefore, our profitability, possibly materially. Further, if demand for our products and/or tissue preservation services materially decreases in the future, we may not be able to ship our products and/or tissues before they expire, which would cause us to write down our inventories and/or deferred preservation costs.

Our sales may also be affected by challenging economic and geopolitical conditions in countries around the world, in addition to the U.S., particularly in countries where we have significant BioGlue, On-X product, or JOTEC product sales or where BioGlue, On-X products, or JOTEC products are still in a growth phase. These factors could materially, adversely affect our revenues, financial condition, and profitability.

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.

If healthcare providers are not adequately reimbursed for procedures conducted with our products, or if reimbursement policies change adversely, we may not be successful in marketing and selling our products or preservation services.

Most of our customers, and the healthcare providers to whom our customers supply medical devices, rely on third-party payors, including government programs and private health insurance plans, to reimburse some or all of the cost of the procedures in which medical devices that incorporate components we manufacture or assemble are used. Healthcare providers, facilities, and government agencies are unlikely to purchase our products or implant our tissues if they are not adequately reimbursed for these procedures. Unless a sufficient amount of peer-reviewed clinical data about our products and preservation services has been published, third-party payors, including insurance companies and government agencies, may refuse to provide reimbursement. The continuing efforts of governmental authorities, insurance companies, and other payors of healthcare costs to contain or reduce these costs could lead to patients being unable to obtain approval for payment from these third-party payors. Furthermore, even if reimbursement is provided, it may not be adequate to fully compensate the clinicians or hospitals. Some third-party payors may impose restrictions on the procedures for which they will provide reimbursement. If healthcare providers cannot obtain sufficient reimbursement from third-party payors for our products or preservation services or the screenings conducted with our products, we may not achieve significant market acceptance. Acceptance of our products in international markets will depend upon the availability of adequate reimbursement or funding within prevailing healthcare payment systems. Reimbursement, funding, and healthcare payment systems vary significantly by country. We may not obtain approvals for reimbursement in a timely manner or at all.

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, (FDCA) 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 the acquisition of On-X that are limited under Section 382. We believe, however, that such net operating loss carryforwards from On-X will be fully realizable prior to expiration. 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 federal and state anti-kickback, false claims privacy, 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 federal anti-kickback, self-referral, false claims, privacy, and transparency laws, and similar laws, often referred to collectively as healthcare compliance laws. Healthcare compliance laws are broad, can be ambiguous, and are complex, and even minor inadvertent violations can give rise to claims that the relevant law has been violated. Possible sanctions for violation of these healthcare compliance laws include monetary fines, civil and criminal penalties, exclusion from federal and state healthcare programs, including Medicare, Medicaid, Veterans Administration health programs, workers compensation programs, and TRICARE (the healthcare system administered by or on behalf of the U.S. Department of Defense for uniformed services beneficiaries, including active duty and their dependents and retirees and their dependents), and forfeiture of amounts collected in violation of such prohibitions. Any government investigation or a finding of a violation of these laws could result in a material, adverse effect on our business, financial condition, and profitability.

Anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation, or receipt of any form of remuneration in return for the referral of an individual or the ordering or recommending of the use of a product or service for which payment may be made by Medicare, Medicaid, or other government-sponsored healthcare programs. We have entered into consulting agreements, speaker agreements, research agreements, and product development agreements with healthcare professionals, 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 laws, including state anti-referral laws and other applicable anti-kickback 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 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 have conducted 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 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, 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 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 federally funded healthcare programs, including Medicare and Medicaid, for noncompliance.

The Federal False Claims Act (FCA) imposes civil liability on any person or entity that submits, or causes the submission of, a false or fraudulent claim to the U.S. Government. Damages under the FCA can be significant and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity with knowledge of past or present fraud against the federal government to sue on behalf of the government to recover the civil penalties

and treble damages. The U.S. Department of Justice (DOJ) on behalf of the government has previously alleged that the marketing and promotional practices of pharmaceutical and medical device manufacturers, including the off-label promotion of products or the payment of prohibited kickbacks to doctors, violated the FCA, resulting in the submission of improper claims to federal and state healthcare entitlement programs such as Medicaid. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts, and entered into corporate integrity agreements that require, among other things, substantial reporting, and remedial actions going forward.

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 federal or state 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 state or federal 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 makers 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 and 2017, and just recently suspended again for 2018 and 2019 the excise tax may be reinstated.

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. There are many programs and requirements for which the details have not yet been fully established or the consequences are not fully understood. 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.

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;

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;

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.

Continued fluctuation of foreign currencies relative to the U.S. Dollar could materially, adversely affect our business.

The majority of our foreign product and tissue processing revenues are denominated in Euros and British Pounds 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 and British Pounds 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.

If we experience decreasing prices for our goods and services and we are unable to reduce our expenses, our results of operations will suffer.

We may experience decreasing prices for our goods and services due to pricing pressure experienced by our customers from managed care organizations and other third-party payors, increased market power of our customers as the medical device industry

consolidates, and increased competition among medical engineering and manufacturing services providers. If the prices for our goods and services decrease and we are unable to reduce our expenses, our results of operations will be adversely affected.

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.

We 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.

Furthermore, competitors may independently develop similar technologies, or duplicate our technologies, or design around the patented aspects of such technologies. In addition, 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 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 may be subject to damages resulting from claims that we, our employees, or our independent contractors have wrongfully used or disclosed alleged trade secrets of others.

Some of our employees were previously employed at other medical device or tissue companies. We may also hire additional employees who are currently employed at other medical device or tissue companies, including our competitors. Additionally, consultants or other independent agents with which we may contract may be or have been in a contractual arrangement with one or more of our competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or independent contractors have used or disclosed any party's trade secrets or other proprietary information. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to us. If we fail to defend such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to market existing or new products, which could severely harm our business.

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 the 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, 2018 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
07/01/18 - 07/31/18	292	\$ 29.65		\$
08/01/18 - 08/31/18	1,401	32.75		
09/01/18 - 09/30/18	6,446	34.00		
Total	8,139	33.63		

The common shares purchased during the quarter ended September 30, 2018 were tendered to us in payment of taxes on stock compensation and were not part of a publicly announced plan or program.

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

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibit index can be found below.

Exhibit Number	Description
2.1	<u>Agreement and Plan of Merger, dated as of December 22, 2015, by and among CryoLife, Inc., On-X Life Technologies Holdings, Inc., Cast Acquisition Corporation, Fortis Advisors LLC and each of the security holders who becomes a party thereto. (Incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed January 25, 2016.)</u>
2.2	<u>Securities Purchase Agreement, dated as of October 10, 2017, by and among CryoLife, Inc., CryoLife Germany HoldCo GmbH, Jolly Buyer Acquisition GmbH, JOTEC AG, each of the security holders identified therein, and Lars Sunnanväder as the representative of such security holders. (Incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed October 11, 2017.)</u>
3.1	<u>Amended and Restated Articles of Incorporation of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed November 23, 2015.)</u>
3.2	<u>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.)</u>
4.1	<u>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.)</u>
4.2	<u>Form of Indenture for Senior Debt Securities (Incorporated herein by reference to Exhibit 4.7 to the Registrant's Registration Statement on Form S-3 filed August 5, 2015 (No. 333-206119).)</u>
4.3	<u>Form of Subordinated Indenture for Subordinated Debt Securities (Incorporated herein by reference to Exhibit 4.9 to the Registrant's Registration Statement on Form S-3 filed August 5, 2015 (No. 333-206119).)</u>
10.1	<u>CryoLife, Inc. 2009 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009.)</u>
10.1(a)	<u>Amended and Restated CryoLife, Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 99.1 to the Registrant's Form S-8 filed June 22, 2012.)</u>
10.1(b)	<u>First Amendment to the Amended and Restated CryoLife, Inc. 2009 Stock Incentive Plan, dated July 24, 2012. (Incorporated herein by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)</u>
10.1(c)	<u>Second Amended and Restated CryoLife Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Appendix B to the Registrant's Definitive Proxy Statement filed April 8, 2014.)</u>
10.1(d)	<u>Form of Non-Qualified Stock Option Grant Agreement pursuant to the CryoLife, Inc. 2009 Employee Stock Incentive Plan entered into with each Named Executive Officer. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.)</u>
10.2	<u>CryoLife, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.3 to Registrant's Quarterly Report on Form 10-Q filed July 28, 2015.)</u>

Edgar Filing: CRYOLIFE INC - Form 10-Q

- 10.2(a) First Amendment to CryoLife, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Appendix B to the Registrant's Definitive Proxy Statement filed March 8, 2017.)
- 10.2(b) Form of 2018 Performance Share Award Agreement pursuant to the CryoLife, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.2(b) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)
- 10.2(c) Form of 2018 Officer Restricted Stock Award Agreement pursuant to the CryoLife, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.2(c) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)
- 10.2(d) Form of 2018 Non-Employee Director Restricted Stock Award Agreement pursuant to the CryoLife, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.2(d) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)

Exhibit Number	Description
10.2(e)	<u>Form of 2018 Grant of Non-Qualified Stock Option pursuant to the CryoLife, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.2(e) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)</u>
10.3	<u>CryoLife, Inc. Employee Stock Purchase Plan. (Incorporated herein by reference to Appendix A to the Registrant's Definitive Proxy Statement filed April 10, 1996.)</u>
10.3(a)	<u>First Amendment to the CryoLife, Inc. Employee Stock Purchase Plan. (Incorporated herein by reference to the Registrant's Definitive Proxy Statement filed May 20, 2010.)</u>
10.4	<u>CryoLife, Inc. Executive Deferred Compensation Plan. (Incorporated herein by reference to Exhibit 10.52 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2010.)</u>
10.5	<u>Summary of 2017 Compensation Arrangements with Non-Employee Directors. (Incorporated by reference to Exhibit 10.8(b) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2017.)</u>
10.6	<u>Employment Agreement between CryoLife, Inc. and J. Patrick Mackin, dated as of July 7, 2014. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed July 11, 2014.)</u>
10.7	<u>Stock Option Grant Agreement by and between CryoLife, Inc. and J. Patrick Mackin, dated September 2, 2014. (Incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed October 28, 2014.)</u>
10.8	<u>Form of Indemnification Agreement for Non-Employee Directors and Certain Officers. (Incorporated herein by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed March 23, 2017.)</u>
10.9	<u>Change of Control Severance Agreement between CryoLife, Inc. and John E. Davis, dated November 21, 2016. (Incorporated herein by reference to Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)</u>
10.10	<u>Change of Control Severance Agreement between CryoLife, Inc. and Jean F. Holloway, dated November 21, 2016 (Incorporated herein by reference to Exhibit 10.3 to Registrant's Current Report on Form 8-K filed November 22, 2016.)</u>
10.11	<u>Change of Control Severance Agreement between CryoLife, Inc. and D. Ashley Lee, dated November 21, 2016 (Incorporated herein by reference to Exhibit 10.4 to Registrant's Current Report on Form 8-K filed November 22, 2016.)</u>
10.12	<u>Change of Control Severance Agreement between CryoLife, Inc. and James McDermid, dated November 21, 2016. (Incorporated herein by reference to Exhibit 10.12 to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)</u>
10.13	<u>Lease Agreement between CryoLife, Inc. and The H.N. and Frances C. Berger Foundation, successor in interest to Amlis Land Development I Limited Partnership, dated April 18, 1995. (Incorporated herein by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2007.)</u>
10.13 (a)	<u>First Amendment to Lease Agreement between CryoLife, Inc. and The H.N. and Frances C. Berger Foundation, successor in interest to Amlis Land Development I Limited Partnership, dated August 6, 1999. (Incorporated herein by reference to Exhibit 10.16(a) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999.)</u>
10.13 (b)	

Restatement and Amendment to Funding Agreement between CryoLife, Inc. and The H.N. and Frances C. Berger Foundation, successor in interest to Amlil Land Development I Limited Partnership, dated August 6, 1999. (Incorporated herein by reference to Exhibit 10.16(b) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)

- 10.13 (c) Second Amendment to Lease Agreement between CryoLife, Inc. and The H.N. and Frances C. Berger Foundation, successor in interest to P&L Barrett, L.P., dated May 10, 2010. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010.)
- 10.14++ Lease Agreement between On-X Life Technologies, Inc. and 1300 E. Anderson Lane, Ltd., dated March 2, 2009. (Incorporated herein by reference to Exhibit 10.14 to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)

Exhibit Number	Description
10.14 (a)++	<u>First Amendment to Lease Agreement between On-X Life Technologies, Inc. and 1300 E. Anderson Lane, Ltd., dated November 15, 2012. (Incorporated herein by reference to Exhibit 10.14(a) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)</u>
10.14 (b)++	<u>Second Amendment to Lease Agreement between On-X Life Technologies, Inc. and 1300 E. Anderson Lane, Ltd., dated January 29, 2015. (Incorporated herein by reference to Exhibit 10.14(b) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)</u>
10.14 (c)++	<u>Third Amendment to Lease Agreement between On-X Life Technologies, Inc. and 1300 E. Anderson Lane, Ltd., dated January 29, 2015. (Incorporated herein by reference to Exhibit 10.14(c) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)</u>
10.15	<u>Lease Agreement between JOTEC GmbH and Lars Sunnaväder for Lotzenäcker 23, dated October 27, 2017 and November 2, 2017. (Incorporated herein by reference to Exhibit 10.15 to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)</u>
10.15(a)	<u>First Amendment to Lease Agreement between JOTEC GmbH and Lars Sunnaväder for Lotzenäcker 23, dated December 28, 2017 and January 1, 2018. (Incorporated herein by reference to Exhibit 10.15(a) to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)</u>
10.16++	<u>Lease Agreement between JOTEC GmbH and Lars Sunnaväder for Lotzenäcker 25, dated October 27, 2017 and November 2, 2017. (Incorporated herein by reference to Exhibit 10.16 to the Registrant's Quarterly Report on Form 10-Q filed May 4, 2018.)</u>
10.16(a)++	<u>First Amendment to Lease Agreement between JOTEC GmbH and Lars Sunnaväder for Lotzenäcker 25, dated April 27, 2018. (Incorporated herein by reference to Exhibit 10.16(a) to the Registrant's Quarterly Report on Form 10-Q filed August 7, 2018.)</u>
10.17	<u>Credit and Guaranty Agreement, dated as of December 1, 2017, by and among CryoLife, Inc., CryoLife International, Inc., On-X Life Technologies Holdings, Inc., On-X Life Technologies, Inc., AuraZyme Pharmaceuticals, Inc., the financial institutions party thereto from time to time as lenders, and Deutsche Bank AG New York Branch, as administrative agent and collateral agent. (Incorporated herein by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed December 1, 2017.)</u>
21.1	<u>Subsidiaries of CryoLife, Inc. (Incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2017.)</u>
31.1*	<u>Certification by J. Patrick Mackin pursuant to section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2*	<u>Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.</u>
32**	<u>Certification Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant To Section 906 Of The Sarbanes-Oxley Act Of 2002</u>
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.

Indicates management contract or compensatory plan or arrangement.

+ The Registrant has requested confidential treatment for certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

++ The Registrant has been granted confidential treatment for certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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)

November 1, 2018

DATE