

Edgar Filing: CRYOLIFE INC - Form 10-Q/A

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

Explanatory Note

This Amendment No. 1 to our Quarterly Report on Form 10-Q (the "Form 10-Q/A") amends our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 previously filed on November 1, 2018 (the "Original Filing"). We are filing this Form 10-Q/A solely to typographically correct the amount of foreign currency translation adjustments included in the Original Filing under Other comprehensive income (loss) for the nine months ended September 30, 2018. The correct dollar amount of the foreign currency translation adjustments for such period is (5,140), rather than (540). The total Comprehensive income (loss) for that period was correct as initially filed. No other values on the Summary Consolidated Statements of Operations and Comprehensive Income (Loss) are affected.

Pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, as amended, this Form 10-Q/A also contains new certifications pursuant to Sections 302 and 906 of the Sarbanes-Oxley Act of 2002, which are attached hereto.

Except as described above, no other changes have been made to the Original Filing, and this Form 10-Q/A does not modify, amend, or update in any way, any of the financial or other information contained in the Original Filing. This Form 10-Q/A does not reflect events that may have occurred subsequent to the filing date of the Original Filing.

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	(5,140)	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		
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		
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/A

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/A

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;

Edgar Filing: CRYOLIFE INC - Form 10-Q/A

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.

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/A

- 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 Amlí 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 Amlí 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)	

Edgar Filing: CRYOLIFE INC - Form 10-Q/A

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.

*** Previously Filed

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 19, 2018

DATE