CRYOLIFE INC
Form 10-Q
May 02, 2019
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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 **March 31, 2019**

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

(770) 419-3355

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be

submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes No

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	CRY	New York Stock Exchange

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

Class	Outstanding at April 26, 2019
Common Stock, $.01 par value	37,335,737

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Part I FINANCIAL INFORMATION

Item 1. Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME

(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Three Months Ended March 31,	
	2019	**2018**
	(Unaudited)	
Revenues:		
Products	$ 48,401	$ 43,598
Preservation services	19,104	18,350
Total revenues	**67,505**	**61,948**
Cost of products and preservation services:		
Products	13,826	14,157
Preservation services	9,406	8,563
Total cost of products and preservation services	**23,232**	**22,720**
Gross margin	**44,273**	**39,228**
Operating expenses:		
General, administrative, and marketing	36,520	37,348
Research and development	5,548	5,370
Total operating expenses	**42,068**	**42,718**
Operating income (loss)	**2,205**	**(3,490)**
Interest expense	3,894	3,656
Interest income	(116)	(59)

Other expense (income), net		77		(181)
Loss before income taxes		**(1,650)**		**(6,906)**
Income tax benefit		(1,353)		(3,051)
Net loss	**$**	**(297)**	**$**	**(3,855)**
Loss per common share:				
Basic	**$**	**(0.01)**	**$**	**(0.11)**
Diluted	**$**	**(0.01)**	**$**	**(0.11)**
Weighted-average common shares outstanding:				
Basic		36,778		36,146
Diluted		36,778		36,146
Net loss	**$**	**(297)**	**$**	**(3,855)**
Other comprehensive (loss) income:				
Foreign currency translation adjustments		(3,781)		7,139
Comprehensive (loss) income	**$**	**(4,078)**	**$**	**3,284**

See accompanying Notes to Summary Consolidated Financial Statements.

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CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS)

	March 31, 2019	December 31, 2018
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 40,344	$ 41,489
Restricted securities	731	747
Receivables, net	54,313	51,432
Inventories	44,124	45,478
Deferred preservation costs	32,635	33,174
Prepaid expenses and other	6,505	6,848
Total current assets	**178,652**	**179,168**
Property and equipment, net	30,254	31,028
Operating lease right-of-use assets, net	22,961	--
Goodwill	186,706	188,781
Acquired technology, net	114,479	118,184
Trademarks and other intangibles, net	41,333	41,897
Deferred income taxes	4,086	4,111
Other	8,457	7,922
Total assets	**$ 586,928**	**$ 571,091**
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 5,425	$ 7,547
Accrued compensation	9,168	10,733
Current maturities of long-term debt	1,153	1,160
Current maturities of operating leases	4,982	--
Taxes payable	1,721	2,250
Accrued expenses and other	13,974	12,833
Total current liabilities	**36,423**	**34,523**

Long-term debt	215,260	215,721
Non-current maturities of operating leases	19,902	--
Deferred income taxes	26,331	27,267
Other	16,390	18,513
Total liabilities	**314,306**	**296,024**
Commitments and contingencies		
Shareholders equity:		
Preferred stock	--	--
Common stock (issued shares of 38,756 in 2019 and 38,463 in 2018)	388	385
Additional paid-in capital	261,991	260,361
Retained earnings	34,687	34,984
Accumulated other comprehensive loss	(9,853)	(6,072)
Treasury stock at cost (shares of 1,484 in 2019 and 1,484 in 2018)	(14,591)	(14,591)
Total shareholders equity	**272,622**	**275,067**
Total liabilities and shareholders equity	**$ 586,928**	**$ 571,091**

See accompanying Notes to Summary Consolidated Financial Statements.

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CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

	Three Months Ended March 31,	
	2019	**2018**
	(Unaudited)	
Net cash flows from operating activities:		
Net loss	$ (297)	$ (3,855)
Adjustments to reconcile net loss to net cash from operating activities:		
Depreciation and amortization	4,351	4,376
Non-cash compensation	1,850	1,248
Deferred income taxes	(424)	(1,283)
Other non-cash adjustments to loss	737	810
Changes in operating assets and liabilities:		
Receivables	(3,292)	(3,346)
Inventories and deferred preservation costs	1,396	2,954
Prepaid expenses and other assets	627	(215)
Accounts payable, accrued expenses, and other liabilities	(3,787)	(10,416)
Net cash flows provided by (used in) operating activities	**1,161**	**(9,727)**
Net cash flows from investing activities:		
Capital expenditures	(1,194)	(2,116)
Other	(233)	(3)
Net cash flows used in investing activities	**(1,427)**	**(2,119)**
Net cash flows from financing activities:		
Repayment of term loan	(696)	(707)
Proceeds from exercise of stock options and issuance of common stock	2,029	606
Redemption and repurchase of stock to cover tax withholdings	(2,376)	(1,512)
Other	(172)	(341)
Net cash flows used in financing activities	**(1,215)**	**(1,954)**

Effect of exchange rate changes on cash		320		439
Decrease in cash, cash equivalents, and restricted securities		**(1,161)**		**(13,361)**
Cash, cash equivalents, and restricted securities beginning of period		42,236		40,753
Cash, cash equivalents, and restricted securities end of period	**$**	**41,075**	**$**	**27,392**

See accompanying Notes to Summary Consolidated Financial Statements.

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CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

(IN THOUSANDS)

	Common Stock		Additional Paid In Capital	Retained Earnings	Accumulated Other Comprehensive Income	Treasury Stock		Total Shareholders Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2017	**37,618**	**$ 376**	**$ 249,935**	**$ 37,609**	**$ 1,857**	**(1,386)**	**$ (12,719)**	**$ 277,058**
Cumulative effect of ASC 606 Adjustment	--	--	--	215	--	--	--	215
Net loss	--	--	--	(3,855)	--	--	--	(3,855)
Other comprehensive income:								
Foreign currency translation income	--	--	--	--	7,139	--	--	7,139
Comprehensive income								3,284
Equity compensation	225	1	1,353	--	--	--	--	1,354
Exercise of options	317	4	1,886	--	--	(98)	(1,872)	18
Employee stock purchase plan	37	--	588	--	--	--	--	588
Redemption and repurchase of stock to cover tax withholdings	(82)	--	(1,511)	--	--	--	--	(1,511)

Balance at March 31, 2018	**38,115**	**$ 381**	**$ 252,251**	**$ 33,969**	**$ 8,996**	**(1,484)**	**$ (14,591)**	**$ 281,006**

	Common Stock		Additional Paid In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Total Shareholders Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2018	**38,463**	**$ 385**	**$ 260,361**	**$ 34,984**	**$ (6,072)**	**(1,484)**	**$ (14,591)**	**$ 275,067**
Net loss	--	--	--	(297)	--	--	--	(297)
Other comprehensive loss:								
Foreign currency translation loss	--	--	--	--	(3,781)	--	--	(3,781)
Comprehensive loss								(4,078)
Equity compensation	205	2	1,978	--	--	--	--	1,980
Exercise of options	145	1	1,450	--	--	--	--	1,451
Employee stock purchase plan	25	--	578	--	--	--	--	578
Redemption and repurchase of stock to cover tax withholdings	(82)	--	(2,376)	--	--	--	--	(2,376)
Balance at March 31, 2019	**38,756**	**$ 388**	**$ 261,991**	**$ 34,687**	**$ (9,853)**	**(1,484)**	**$ (14,591)**	**$ 272,622**

See accompanying Notes to Consolidated Financial Statements.

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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, 2018 has been derived from audited financial statements. The accompanying unaudited summary consolidated financial statements as of, and for the three months ended, March 31, 2019 and 2018 have been prepared in accordance with (i) accounting principles generally accepted in the U.S. for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U.S. Securities and Exchange Commission (SEC). Accordingly, such statements do not include all of the information and disclosures required by accounting principles generally accepted in the U.S. for a complete presentation of financial statements. In the opinion of management, all adjustments (including those of a normal, recurring nature) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019. These summary consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in CryoLife s Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on February 26, 2019.

New Accounting Standards

Recently Adopted

As of January 1, 2019 we adopted the new Accounting Standards Codification (ASC) Topic 842, *Leases* (ASC 842). The final guidance requires lessees to recognize a right-of-use asset and a lease liability for all leases (with the exception of short-term leases) at the commencement date and recognize expenses on their income statements similar to the current Topic 840, *Leases*. We used the modified retrospective approach, which allows application of the standard at the adoption date rather than at the beginning of the earliest comparative period presented. The adoption of this standard resulted in the recognition of operating lease agreements with a net present value of $22.7 million and corresponding right-of-use assets obtained in the same amount at January 1, 2019. See Note 7 for further discussion of leases.

Not Yet Effective

In June 2016, the Financial Accounting Standards Board (FASB) issued ASC Update No. 2016-13, *Financial Instruments Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments.* The purpose of Update No. 2016-13 is to replace the current incurred loss impairment methodology for financial assets measured at amortized cost with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information, including forecasted information, to develop credit loss estimates. Update No. 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those annual periods and early adoption is permitted. We are in the process of evaluating the effect that the adoption of this standard will have on our financial position and results of operations.

2. Financial Instruments

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

March 31, 2019	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market funds	$ 1,450	$ --	$ --	$ 1,450
Restricted securities:				
Money market funds	731	--	--	731
Total assets	**$ 2,181**	**$ --**	**$ --**	**$ 2,181**

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

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

3. Cash Equivalents and Restricted Securities

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

March 31, 2019	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	$ 1,450	$ --	$ 1,450
Restricted securities:			
Money market funds	731	--	731

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

As of March 31, 2019 and December 31, 2018 $731,000 and $747,000, respectively, all of our money market funds were designated as short-term restricted securities due to a contractual commitment to hold the securities as pledged collateral relating primarily to international tax obligations.

There were no gross realized gains or losses on cash equivalents in the three months ended March 31, 2019 and 2018. As of March 31, 2019 $731,000 of our restricted securities had a maturity date within three months. As of December 31, 2018 $512,000 of our restricted securities had a maturity date within three months and $235,000 had a maturity date between three months and one year.

4. Inventories and Deferred Preservation Costs

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

	March 31,	December 31,

	2019	2018
Raw materials and supplies	$ 16,762	$ 17,381
Work-in-process	4,487	3,858
Finished goods	22,875	24,239
Total inventories	**$ 44,124**	**$ 45,478**

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

	March 31, 2019	December 31, 2018
Cardiac tissues	$ 16,223	$ 15,972
Vascular tissues	16,412	17,202
Total deferred preservation costs	**$ 32,635**	**$ 33,174**

We maintain consignment inventory of our On-X Life Technologies Holdings, Inc. (On-X) heart valves at domestic hospital locations and On-X heart valves and JOTEC products at international hospital locations to facilitate usage. We retain title to this consignment inventory until the device is implanted, at which time we invoice the hospital and recognize revenue. As of March 31, 2019 we had $11.3 million in consignment inventory, with approximately 54% in domestic locations and 46% in foreign locations. As of December 31, 2018 we had $11.2 million in consignment inventory, with approximately 55% in domestic locations and 45% in foreign locations.

5. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

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

	March 31, 2019	December 31, 2018
Goodwill	$ 186,706	$ 188,781
In-process R&D	9,206	9,382
Procurement contracts and agreements	2,013	2,013
Trademarks	844	844

We monitor the phases of development of our acquired in-process R&D projects, including the risks associated with further development and the amount and timing of benefits expected to be derived from the completed projects. Incremental costs associated with development are charged to expense as incurred. Capitalized costs are amortized over the estimated useful life of the developed asset once completed. Our in-process R&D projects are reviewed for impairment annually or more frequently if events or changes in circumstances indicate that the asset might be impaired.

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

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

		Medical Devices Segment
Balance as of December 31, 2018	$	188,781
Revaluation of goodwill denominated in foreign currency		(2,075)
Balance as of March 31, 2019	**$**	**186,706**

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Definite Lived Intangible Assets

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

March 31, 2019	Gross Value	Accumulated Amortization	Amortization Period
Acquired technology	$ 133,187	$ 18,708	11 22 Years
Customer lists and relationships	31,131	5,444	13 22 Years
Distribution and manufacturing rights and know-how	4,059	2,179	11 15 Years
Patents	3,622	2,979	17 Years
Other	1,350	290	3 5 Years

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

Amortization Expense

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

	Three Months Ended March 31, 2019	2018
Amortization expense	$ 2,579	$ 2,735

As of March 31, 2019 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	Remainder of 2019	2020	2021	2022	2023	2024	Total
Amortization expense	$ 7,727	$ 10,151	$ 10,129	$ 9,583	$ 9,173	$ 8,948	$ 55,711

6. Income Taxes

Income Tax Expense

Our effective income tax rate was a benefit of 82% and 44% for the three months ended March 31, 2019 and 2018, respectively. Our income tax rate for the three months ended March 31, 2019 increased primarily due to excess tax benefit deductions related to stock compensation. The income tax rate was favorably impacted by the research and

development tax credit and losses in high rate jurisdictions, partially offset by unfavorable impacts of non-deductible operating expenses and executive compensation expenses.

Our income tax rate for the three months ended March 31, 2018 was favorably impacted by losses in high rate jurisdictions and excess tax benefit deductions related to stock compensation, partially offset by unfavorable impacts of non-deductible operating expenses and executive compensation expenses.

Deferred Income Taxes

We generate deferred tax assets primarily as a result of write-downs of inventory and deferred preservation costs, accruals for product and tissue processing liability claims, investment and asset impairments, and operating losses. We

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acquired significant deferred tax assets, primarily net operating loss carryforwards, from our acquisitions of JOTEC GmbH (JOTEC) and its subsidiaries in 2017, On-X in 2016, Hemosphere, Inc. in 2012, and Cardiogenesis Corporation in 2011. We believe utilization of these net operating losses will not have a material impact on income taxes for the 2019 tax year.

As of March 31, 2019 we maintained a total of $3.4 million in valuation allowances against deferred tax assets, primarily related to state net operating loss carryforwards, and had a net deferred tax liability of $22.2 million. As of December 31, 2018 we had a total of $3.4 million in valuation allowances against deferred tax assets, primarily related to state net operating loss carryforwards, and a net deferred tax liability of $23.2 million.

7. Leases

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

The adoption of this standard resulted in the recognition of operating lease agreements with a net present value of $22.7 million, and corresponding right-of-use assets obtained in the same amount, at January 1, 2019. The leases were recognized with a weighted average discount rate of 5.5% and a weighted average remaining lease term of six years. In addition, deferred rent obligations of approximately $2.4 million recognized under prior lease rules were offset against the corresponding right-of-use asset and will be reflected in amortization over the remaining life of the lease.

Our operating and finance lease liabilities result from the lease of land and buildings that comprise our corporate headquarters, various manufacturing facilities and related space, leases on company vehicles, and leases on a variety of office and other equipment. Our leases do not include terms or conditions which would result in variable lease payments other than for small office equipment leases with an additional charge for volume of usage. These incremental payments are excluded from our calculation of lease liability and the related right-of-use asset.

Our leases have remaining lease terms of one year up to 11 years, some of which have options to extend the leases for up to 29 years and one lease contains a termination option with a two-year notice requirement. We do not include option terms in the determination of lease liabilities and the related right-of-use assets until we determine the exercise of the option is reasonably certain. Our leases do not contain residual value guarantee provisions or other restrictions or financial covenant provisions. The adoption of the new leasing standard had no significant impact on covenants or other provisions of our current term and revolver loan facility agreements.

We exercised judgment in the adoption of the new leasing standard, including the determination of whether a financial arrangement includes a lease and in determining the appropriate discount rates to be applied to leases based on our general collateralized credit standing and the geographical market considerations impacting lease rates across all locations. When available, we use the implicit discount rate in the lease contract to discount lease payments to present value. If an implicit discount rate is not available in the lease contract, we used our incremental borrowing rate. We have elected the package of practical expedients permitted under the transition guidance of the new leasing standard which includes a provision which allows us to carry forward the historical lease classification of identified leasing arrangements and not reassess (i) classification for any existing leases, (ii) whether any expired or existing agreements are or contain a lease, or (iii) whether any initial direct costs qualified for capitalization. We have also elected the

practical expedients that allow us to omit leases with initial terms of 12 months or less from our balance sheet, which are expensed on a straight-line basis over the life of the lease. We have elected not to separate lease and non-lease components for future leases.

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

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

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

Operating leases:		**March 31, 2019**
Operating lease right-of-use assets	$	24,160
Accumulated amortization		(1,199)
Operating lease right-of-use assets, net	**$**	**22,961**
Current maturities of operating leases	$	4,982
Non-current maturities of operating lease		19,902
Total operating lease liabilities	**$**	**24,884**
Finance leases:		
Property and equipment, at cost	$	7,530
Accumulated amortization		(1,075)
Property and equipment, net	**$**	**6,455**
Current maturities of finance leases	$	678
Non-current maturities of finance leases		5,690
Total finance lease liabilities	**$**	**6,368**
Weighted average remaining lease term (in years):		
Operating leases		6.2
Finance leases		11.2
Weighted average discount rate:		
Operating leases		5.5%
Finance leases		2.0%

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

	Three Months Ended March 31, 2019

Amortization of property and equipment	$	211
Interest expense on finance leases		32
Total finance lease expense		**243**
Operating lease expense		1,550
Sublease income		(228)
Total lease expense	**$**	**1,565**

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

Cash paid for amounts included in the measurement of lease liabilities:		**Three Months Ended March 31, 2019**
Operating cash flows for finance leases	$	32
Operating cash flows for operating leases		1,636
Financing cash flows for finance leases		172

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

	Finance Leases	Operating Leases	Sublease Income
Remainder of 2019	$ 627	$ 4,396	$ 684
2020	675	6,046	921
2021	628	5,607	930
2022	575	3,343	380
2023	575	2,321	--
Thereafter	4,023	7,382	--
Total minimum lease payments	$ 7,103	$ 29,095	$ 2,915
Less amount representing interest	(735)	(4,211)	
Present value of net minimum lease payments	6,368	24,884	
Less current maturities	(678)	(4,982)	
Lease liabilities, less current maturities	**$ 5,690**	**$ 19,902**	

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 previously announced acquisition of JOTEC and its subsidiaries (the JOTEC Acquisition), (ii) pay certain fees and expenses related to the JOTEC Acquisition and the Credit Agreement, and (iii) pay the outstanding balance of our prior credit facility. The Revolving Credit Facility is undrawn following the JOTEC Acquisition and may be used for working capital, capital expenditures, acquisitions permitted under the Credit Agreement, and other general corporate purposes pursuant to the terms of the Credit Agreement.

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

In October 2018 we finalized an amendment to the Credit Agreement to reprice interest rates, resulting in a reduction in the interest rate margins over base rates on the Term Loan Facility. The loan under the Term Loan Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of 2.25%, or LIBOR, plus a margin of 3.25%. Prior to the repricing, the optional floating annual rate was equal to either the base rate plus a margin of 3.00%, or LIBOR, plus a margin of 4.00%. The loan under the Revolving Credit Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of between 3.00% and 3.25%, depending on our consolidated leverage ratio, or LIBOR, plus a margin of between 4.00% and 4.25%, depending on our consolidated leverage ratio. While a payment or bankruptcy event of default exists, we are obligated to pay a per annum default rate of interest of 2.00% in excess of the interest rate otherwise payable with respect to the overdue principal amount of any loans outstanding and overdue interest payments and other overdue fees and amounts. As of March 31, 2019 the aggregate interest rate was 5.85% per annum. We are obligated to pay an unused commitment fee equal to 0.50% of the unutilized portion of the revolving loans. In addition, we are also obligated to pay other customary fees for a credit facility of this size and type.

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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 March 31, 2019 and December 31, 2018 there were no outstanding balances on our Revolving Credit Facility and the remaining availability was $30.0 million.

Government Supported Bank Debt

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

Loan Balances

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

	March 31, 2019	December 31, 2018
Term loan balance	$ 222,187	$ 222,750
2.45% Sparkasse Zollernalb (KFW Loan 1)	1,206	1,318
1.40% Sparkasse Zollernalb (KFW Loan 2)	1,683	1,885
Total loan balance	225,076	225,953
Less unamortized loan origination costs	(8,663)	(9,072)
Net borrowings	216,413	216,881
Less short-term loan balance	(1,153)	(1,160)
Long-term loan balance	**$ 215,260**	**$ 215,721**

Interest Expense

Interest expense was $3.9 million for the three months ended March 31, 2019, as compared to $3.7 million for the three months ended March 31, 2018. Interest expense includes interest on debt and uncertain tax positions in both periods.

9. Commitments and Contingencies

Liability Claims

Our estimated unreported loss liability was $1.8 million and $1.7 million as of March 31, 2019 and December 31, 2018, respectively. As of March 31, 2019 and December 31, 2018, the related recoverable insurance amounts were $853,000 and $693,000, respectively. We accrue our estimate of unreported product and tissue processing liability claims as a component of other long-term liabilities and record the related recoverable insurance amount as a component of other long-term assets, as appropriate. Further analysis indicated that the estimated liability as of March 31, 2019 could have been as high as $3.6 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

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Employment Agreements

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

PerClot Technology

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

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

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

As of March 31, 2019 we had $1.5 million in prepaid royalties, $2.3 million in intangible assets, net, and $1.3 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. Revenue Recognition

Sources of Revenue

We have identified the following revenues disaggregated by revenue source:

Domestic Hospitals direct sales of products and preservation services.
International Hospitals direct sales of products and preservation services.
International Distributors generally these contracts specify a geographic area that the distributor will service, terms and conditions of the relationship, and purchase targets for the next calendar year.
CardioGenesis Cardiac Laser Console Trials and Sales CardioGenesis cardiac trialed laser consoles are delivered under separate agreements.

For the three months ended March 31, 2019 and 2018 the sources of revenue were as follows (in thousands):

	Three Months Ended March 31,	
	2019	**2018**
	(Unaudited)	
Domestic hospitals	$ 35,611	$ 33,543
International hospitals	20,570	19,008
International distributors	9,610	8,052
CardioGenesis cardiac laser therapy	1,714	1,345
Total sources of revenue	**$ 67,505**	**$ 61,948**

Also see segment and geographic disaggregation information in Note 13 below.

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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 March 31, 2019 and 2018 were not material.

11. Stock Compensation

Overview

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

Equity Grants

During the three months ended March 31, 2019 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 453,000 shares and had an aggregate grant date market value of $13.4 million. Two types of PSUs were granted in 2019, one with a short-term performance component and the other with a long-term performance component. If performance thresholds are met, the short-term PSUs granted in 2019 represent the right to receive up to 150% of the target number of shares of common stock. The performance component of the short-term PSU awards granted in 2019 is based on attaining specified levels of adjusted earnings before interest, taxes, depreciation, and amortization, (EBITDA), as defined in the PSU grant documents, for the 2019 calendar year. If performance thresholds are met, the long-term PSUs granted in 2019 represent the right to receive up to 288% of the target number of shares of common stock. The performance component of the long-term PSU awards granted in 2019 is based on attaining specified levels of adjusted revenue growth and gross margin, as defined in the PSU grant document, for the years 2019 through 2023. We currently believe that achievement of the performance component for both types of PSUs is probable, and we reevaluate this likelihood on a quarterly basis.

During the three months ended March 31, 2018 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 273,000 shares of common stock and had an aggregate grant date market value of $5.9 million. The PSUs granted in 2018 represented the right to receive up to 150% of the target number of shares of common stock based on meeting performance thresholds. The performance component of PSU awards granted in 2018 was based on attaining specified levels of adjusted EBITDA, as defined in the PSU grant documents, for the 2018 calendar year. The PSUs granted in 2018 earned 80% of the target number of shares.

The Committee authorized, from approved stock incentive plans, grants of stock options to purchase a total of 169,000 and 219,000 shares to certain Company officers during the three months ended March 31, 2019 and 2018, respectively. The exercise prices of the options were equal to the closing stock prices on their respective grant dates.

Employees purchased common stock totaling 24,000 shares and 36,000 shares in the three months ended March 31, 2019 and 2018, respectively, through the ESPP.

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Stock Compensation Expense

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

	Three Months Ended March 31, 2019		Three Months Ended March 31, 2018	
	Stock Options	**ESPP Options**	**Stock Options**	**ESPP Options**
Expected life of options	5.0 Years	0.5 Years	5.0 Years	0.5 Years
Expected stock price volatility	0.40	0.39	0.40	0.35
Risk-free interest rate	2.54%	2.56%	2.64%	1.53%

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 March 31,	
	2019	**2018**
RSA, RSU, and PSU expense	$ 1,510	$ 948
Stock option and ESPP option expense	471	406
Total stock compensation expense	**$ 1,981**	**$ 1,354**

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, RSUs, PSUs, and stock options issued in each respective year, as well as those issued in prior periods that continue to vest during the period, and compensation related to the ESPP. These amounts were recorded as stock compensation expense and were subject to our normal allocation of expenses to inventory costs and deferred preservation costs. We capitalized $132,000 in the three months ended March 31, 2019 and $106,000 in the three months ended March 31, 2018, of the stock compensation expense into our inventory costs and deferred preservation costs.

As of March 31, 2019 we had total unrecognized compensation costs of $18.0 million related to RSAs, RSUs, and PSUs and $3.4 million related to unvested stock options. As of March 31, 2019 this expense is expected to be recognized over a weighted-average period of 3.1 years for PSUs, 2.2 years for stock options, 1.9 years for RSUs, and 1.6 years for RSAs.

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12. Loss Per Common Share

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

	Three Months Ended March 31,	
Basic loss per common share	**2019**	**2018**
Net loss	$ (297)	$ (3,855)
Net loss allocated to participating securities	2	38
Net loss allocated to common shareholders	**$ (295)**	**$ (3,817)**
Basic weighted-average common shares outstanding	**36,778**	**36,146**
Basic loss per common share	**$ (0.01)**	**$ (0.11)**

	Three Months Ended March 31,	
Diluted loss per common share	**2019**	**2018**
Net loss	$ (297)	$ (3,855)
Net loss allocated to participating securities	2	38
Net loss allocated to common shareholders	**$ (295)**	**$ (3,817)**
Basic weighted-average common shares outstanding	36,778	36,146
Effect of dilutive stock options and awards	--	--
Diluted weighted-average common shares outstanding	**36,778**	**36,146**
Diluted loss per common share	**$ (0.01)**	**$ (0.11)**

We excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares because the inclusion of these stock options would be antidilutive to loss per common share. Accordingly, for the three months ended March 31, 2019 and 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.

13. Segment Information

We have two reportable segments organized according to our products and services: Medical Devices and Preservation Services. The Medical Devices segment includes external revenues from product sales of BioGlue, JOTEC products, On-X products, CardioGenesis cardiac laser therapy, PerClot, and PhotoFix. The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues. There are no intersegment revenues.

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

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

	Three Months Ended March 31,	
	2019	**2018**
Revenues:		
Medical devices	$ 48,401	$ 43,598
Preservation services	19,104	18,350
Total revenues	**67,505**	**61,948**
Cost of products and preservation services:		
Medical devices	13,826	14,157
Preservation services	9,406	8,563
Total cost of products and preservation services	**23,232**	**22,720**
Gross margin:		
Medical devices	34,575	29,441
Preservation services	9,698	9,787
Total gross margin	**$ 44,273**	**$ 39,228**

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

	Three Months Ended March 31,	
	2019	**2018**
Products:		
BioGlue	$ 17,222	$ 15,970
JOTEC	15,954	14,460
On-X	11,731	10,309
CardioGenesis cardiac laser therapy	1,714	1,346
PerClot	1,050	972
PhotoFix	730	541
Total products	**48,401**	**43,598**
Preservation services:		

Cardiac tissue	8,930	8,103
Vascular tissue	10,174	10,247
Total preservation services	**19,104**	**18,350**
Total revenues	**$ 67,505**	**$ 61,948**

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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, antic future, assume, and other similar expressions generally identify forward-looking statements. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements, which are made as of the date of this Form 10-Q.

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

- Our belief that our distributors may delay or reduce purchases of products in U.S. Dollars depending on the relative price of goods in their local currencies;
- Our belief regarding the international growth opportunity that would be provided by obtaining regulatory approval for BioGlue in China;
- Our plans, costs, and expected timeline regarding regulatory approval for PerClot in the U.S. and additional international markets and the distribution of PerClot in those markets after the requisite regulatory approvals are obtained;
- Our belief that revenues for preservation services, particularly revenues for certain high-demand cardiac tissues, can vary from quarter to quarter and year to year due to a variety of factors including: quantity and type of incoming tissues, yields of tissue through the preservation process, timing of receipt of donor information, timing of the release of tissues to an implantable status, demand for certain tissue types due to the number and type of procedures being performed, and pressures from competing products or services;
- Our beliefs regarding the seasonal nature of the demand for some of our products and services and the reasons for such seasonality, if any;
- Our belief that our cash from operations and existing cash and cash equivalents will enable us to meet our current operational liquidity needs for at least the next twelve months, our expectations regarding future cash requirements, and the impact that our cash requirements might have on our cash flows for the next twelve months;
- Our expectation regarding the impact on cash flows of undertaking significant business development activities and the potential need to obtain additional borrowing capacity or financing;
- Our belief that the utilization of net operating loss carryforwards from our acquisitions of JOTEC, On-X, Hemosphere, Inc., and Cardiogenesis Corporation will not have a material impact on income taxes for the 2019 tax year; and
- Other statements regarding future plans and strategies, anticipated events, or trends.

These and other forward-looking statements reflect the views of management at the time such statements are made based on certain assumptions and analyses made by us in light of our experience and our perception of historical trends, current conditions, and expected future developments as well as other factors we believe are appropriate in the circumstances and are subject to a number of risks, uncertainties, estimates, and assumptions. Whether actual results and developments will conform with our expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from our expectations, including, without limitation, in addition to those specified in the text surrounding such statements, the risks described under Part II, Item 1A, Risks Factors in

this Form 10-Q and elsewhere throughout this report, the risks described under in Part I, Item 1A, Risks Factors in our Annual Report on Form 10-K for the year ended December 31, 2018 and elsewhere throughout that report, and other risks, 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.

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PART I - FINANCIAL INFORMATION

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

Overview

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

We reported quarterly revenues of $67.5 million in the three months ended March 31, 2019, a 9% increase from the quarter ended March 31, 2018 primarily due to an increase in revenues from JOTEC, On-X, and BioGlue products, and from preservation services. See the Results of Operations section below for additional analysis of the three months ended March 31, 2019.

Critical Accounting Policies

A summary of our significant accounting policies is included in Note 1 of the Notes to Consolidated Financial Statements contained in our Form 10-K for the year ended December 31, 2018. Management believes that the consistent application of these policies enables us to provide users of the financial statements with useful and reliable information about our operating results and financial condition. The summary consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S., which require us to make estimates and assumptions. We did not experience any significant changes during the quarter ended March 31, 2019 in any of our Critical Accounting Policies from those contained in our Form 10-K for the year ended December 31, 2018.

New Accounting Pronouncements

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

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Results of Operations

(Tables in thousands)

Revenues

	Revenues for the Three Months Ended March 31,		Percent Change From Prior Year	Revenues as a Percentage of Total Revenues for the Three Months Ended March 31,	
	2019	**2018**		**2019**	**2018**
Products:					
BioGlue	$ 17,222	$ 15,970	8%	26%	26%
JOTEC	15,954	14,460	10%	24%	23%
On-X	11,731	10,309	14%	17%	17%
CardioGenesis cardiac laser therapy	1,714	1,346	27%	3%	2%
PerClot	1,050	972	8%	1%	1%
PhotoFix	730	541	35%	1%	1%
Total products	**48,401**	**43,598**	**11%**	**72%**	**70%**
Preservation services:					
Cardiac tissue	8,930	8,103	10%	13%	13%
Vascular tissue	10,174	10,247	-1%	15%	17%
Total preservation services	**19,104**	**18,350**	**4%**	**28%**	**30%**
Total	**$ 67,505**	**$ 61,948**	**9%**	**100%**	**100%**

Revenues increased 9% for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018. The increase in revenues for the three months ended March 31, 2019 was primarily due to increases in JOTEC, On-X, and BioGlue product revenues, as well as preservation services revenues. Excluding the effects for foreign exchange, revenues increased 11% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. A detailed discussion of the changes in product revenues and preservation services revenues for the three months ended March 31, 2019 is presented below.

Products

Revenues from products increased 11% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. The increase was primarily due to the increase in revenues from the sale of JOTEC, On-X, and BioGlue products. A detailed discussion of the changes in product revenues for BioGlue, JOTEC, On-X, CardioGenesis cardiac laser therapy, PerClot, and PhotoFix is presented below.

Sales of certain products through our direct sales force and distributors across Europe and various other countries are denominated in a variety of currencies, with a concentration in Euros but also including British Pounds, Polish Zloty, Swiss Francs, Brazilian Real, and Canadian Dollars which are subject to exchange rate fluctuations. For the three months ended March 31, 2019 as compared to the three months ended March 31, 2018, the U.S. Dollar strengthened in comparison to the major currencies, resulting in revenue decreases when these foreign currency denominated transactions were translated into U.S. Dollars. 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

Revenues from the sale of BioGlue increased 8% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. This increase was primarily due to a 12% increase in the volume of milliliters sold, which increased revenues by 13%, partially offset by a decrease in average sales prices, which decreased revenues by 3%, and the impact of foreign exchange rates, which decreased revenues by 2%. Excluding the effects for foreign exchange, revenues increased 10% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018.

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Revenues for BioGlue increased in the first quarter of 2019 compared to the first quarter of 2018 in all markets worldwide with the largest growth in Asia Pacific and Latin America primarily due to changes in distributor buying patterns in those markets.

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

Domestic revenues from BioGlue accounted for 53% and 57% of total BioGlue revenues for the three months ended March 31, 2019 and 2018, respectively.

JOTEC

The JOTEC catalogue of products are used in endovascular and open vascular surgery as well as for the treatment of complex aortic arch and thoracic aortic disease.

JOTEC revenues increased 10% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. This increase was primarily due to a 31% increase in volume of units sold, which increased revenues by 20%, partially offset by a decrease in average sales prices, which decreased revenues by 3%, and the impact of foreign exchange rates, which decreased revenues by 7%. Excluding the effects for foreign exchange, revenues increased 18% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018.

Revenues for JOTEC increased in the first quarter of 2019 compared to the first quarter of 2018 in the European Economic Area, Middle East, and Africa (EMEA), Asia Pacific, and Latin America with the largest growth in the EMEA due to growth in both direct and distributor markets. The decrease in average sales prices was primarily due to an increase in the percentage of sales in indirect markets, which have lower average sales prices than the direct markets.

On-X

The On-X catalogue of products includes the On-X prosthetic aortic and mitral heart valves and the On-X ascending aortic prosthesis (AAP). On-X product revenues also include revenues from the distribution of CarbonAid CO_2 diffusion catheters and from the sale of Chord-X ePTFE sutures for mitral chordal replacement. On-X also generates revenue from pyrolytic carbon coating products produced for other medical device manufacturers (OEM).

On-X product revenues, excluding OEM, increased 14% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. This increase was primarily due to a 12% increase in volume of units sold, which increased revenues by 14%, and an increase in average sales prices, which increased revenues by 1%, partially offset by the impact of foreign exchange rates, which decreased revenues by 1%.

The volume increase of On-X products for the three months ended March 31, 2019 was primarily due to an increase in volume in North America as a result of increases in market share, as well as an increase in volume in EMEA primarily due to increases of shipments in direct markets. On-X OEM sales accounted for less than 1% of product revenues for both the three months ended March 31, 2019 and 2018.

CardioGenesis Cardiac Laser Therapy

Revenues from our CardioGenesis cardiac laser therapy product line consist primarily of sales of handpieces and, in certain periods, the sale of laser consoles. Revenues from cardiac laser therapy increased 27% for the three months

ended March 31, 2019, as compared to the three months ended March 31, 2018. The increase in the three months ended March 31, 2019 was primarily due to a 30% increase in unit shipments of handpieces, which increased revenues by 30%, partially offset by a decrease in average sales prices, which decreased revenues by 7%. The remainder of the increase is due to an increase in service fees.

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

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PerClot

Revenues from the sale of PerClot increased 8% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. The increase in the three months ended March 31, 2019 was primarily due to an increase in average sales prices, which increased revenues by 21%, partially offset by a decrease in the volume of grams sold, which decreased revenues by 10% and the impact of foreign exchange rates, which decreased revenues by 3%.

The increase in average selling prices for the three months ended March 31, 2019 was in both indirect and direct markets. The decrease in volume for the three months ended March 31, 2019 was primarily due to a decrease in sales of PerClot in EMEA.

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

PhotoFix

PhotoFix revenues increased 35% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. The revenue increase was primarily due to an increase in units sold, which increased revenues by 35%, 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. In addition, we introduced smaller PhotoFix sizes in 2018 which is contributing to the volume increases.

Preservation Services

Revenues from preservation services increased 4% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018.

We continue to evaluate modifications to our tissue processing procedures in an effort to improve tissue processing throughput, reduce costs, and maintain quality across our tissue processing business. Preservation services revenues, particularly revenues for certain high-demand cardiac tissues, can vary from quarter to quarter and year to year due to a variety of factors including: quantity and type of incoming tissues, yields of tissue through the preservation process, timing of receipt of donor information, timing of the release of tissues 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 months ended March 31, 2019.

Cardiac Preservation Services

Revenues from cardiac preservation services, consisting of revenues from the distribution of heart valves and cardiac patch tissues, increased 10% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. The increase in the three months ended March 31, 2019 was primarily due to a 13% 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 2%.

The increase in cardiac volume for the three months ended March 31, 2019 was primarily due to an increase in the volume of cardiac valve shipments and, to a lesser extent, cardiac patch shipments. The decrease in average service

fees was primarily due to fee differences related to physical characteristics of these tissues and the routine negotiation of pricing contracts with certain customers.

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 decreased 1% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. This decrease was primarily due to a decrease in average service fees, which decreased revenues by 3%, partially offset by a 2% increase in vascular tissue shipments, which increased revenues by 2%.

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The decrease in average service fees for the three months ended March 31, 2019 was primarily driven by fee differences due to physical characteristics of vascular tissues, the routine negotiation of pricing contracts with certain customers, as well as competitive pricing pressures. The increase in vascular volume for the three months ended March 31, 2019 was primarily due to increases in saphenous vein and aortoiliac shipments.

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 March 31,	
	2019	**2018**
Cost of products	$ 13,826	$ 14,157

Cost of products decreased 2% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. Cost of products for the three months ended March 31, 2019 and 2018 included costs related to BioGlue, JOTEC, On-X, CardioGenesis cardiac laser therapy, PerClot, and PhotoFix.

Cost of products for the three months ended March 31, 2018 included $1.5 million in inventory basis step-up expense, primarily related to the JOTEC inventory fair value adjustment recorded in purchase accounting.

The decrease in cost of products for the three months ended March 31, 2019 was primarily due to a decrease of acquisition inventory basis step-up expense, as compared to the prior year period as discussed above, partially offset by increases in unit shipments.

Cost of Preservation Services

	Three Months Ended March 31,	
	2019	**2018**
Cost of preservation services	$ 9,406	$ 8,563

Cost of preservation services increased 10% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services increased in the three months ended March 31, 2019 primarily due to an increase in the unit shipment of tissues and a small increase in the unit cost of tissue.

Gross Margin

	Three Months Ended March 31,	
	2019	**2018**
Gross margin	$ 44,273	$ 39,228
Gross margin as a percentage of total revenues	66%	63%

Gross margin increased 13% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018, primarily due to increases in JOTEC, On-X, and BioGlue product revenues. Gross margin as a percentage of total revenues increased in the three months ended March 31, 2019, as compared to the three months ended March 31, 2018, primarily due to the additional costs in 2018 for the inventory fair value adjustment recorded in purchase accounting for the JOTEC acquisition.

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Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended March 31,	
	2019	2018
General, administrative, and marketing expenses	$ 36,520	$ 37,348
General, administrative, and marketing expenses as a percentage of total revenues	54%	60%

General, administrative, and marketing expenses decreased 2% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. The decrease in general, administrative, and marketing expenses for the three months ended March 31, 2019 was primarily due to decreased business development and integration expenses primarily related to the JOTEC Acquisition, offset by higher expenses to support our increased revenue base and employee headcount. General, administrative, and marketing expenses for the three months ended March 31, 2019 included $1.1 million in business development and integration expenses, as compared to $3.8 million for the three months ended March 31, 2018, primarily related to the JOTEC Acquisition.

Research and Development Expenses

	Three Months Ended March 31,	
	2019	2018
Research and development expenses	$ 5,548	$ 5,370
Research and development expenses as a percentage of total revenues	8%	9%

Research and development expenses increased 3% for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. Research and development spending in the three months ended March 31, 2019 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 JOTEC and On-X products. Research and development spending in the three months ended March 31, 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.

Interest Expense

Interest expense was $3.9 million for the three months ended March 31, 2019, as compared to $3.7 million for the three months ended March 31, 2018. Interest expense in the three months ended March 31, 2019 and 2018 included interest on debt and uncertain tax positions.

Other Expense (Income), Net

Other expense was $77,000 for the three months ended March 31, 2019, as compared to other income of $181,000 for the three months ended March 31, 2018. Other income and other expense primarily includes the realized effect of foreign currency gains and losses.

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Earnings

	Three Months Ended March 31,	
	2019	**2018**
Loss before income taxes	$ (1,650)	$ (6,906)
Income tax benefit	(1,353)	(3,051)
Net loss	**$ (297)**	**$ (3,855)**
Diluted loss per common share	**$ (0.01)**	**$ (0.11)**
Diluted weighted-average common shares outstanding	**36,778**	**36,146**

Loss before income taxes decreased 76% in the three months ended March 31, 2019, as compared to the three months ended March 31, 2018 primarily due to a decrease in integration and business development expenses and inventory basis step-up expense related to the JOTEC Acquisition.

Our effective income tax rate was a benefit of 82% and 44% for the three months ended March 31, 2019 and 2018, respectively. Our income tax rate for the three months ended March 31, 2019 increased primarily due to excess tax benefit deductions related to stock compensation. The income tax rate was favorably impacted by the research and development tax credit and losses in high rate jurisdictions, partially offset by unfavorable impacts of non-deductible operating expenses and executive compensation expenses.

Our income tax rate for the three months ended March 31, 2018 was favorably impacted by losses in high rate jurisdictions and excess tax benefit deductions related to stock compensation, partially offset by unfavorable impacts of non-deductible operating expenses and executive compensation expenses.

Net loss and diluted loss per common share decreased for the three months ended March 31, 2019, as compared to the three months ended March 31, 2018. The decrease for the three months ended March 31, 2019 was primarily due to the decrease in the loss before income taxes, 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.

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Liquidity and Capital Resources

Net Working Capital

As of March 31, 2019 net working capital (current assets of $178.7 million less current liabilities of $36.4 million) was $142.3 million, with a current ratio (current assets divided by current liabilities) of 5 to 1, compared to net working capital of $144.7 million and a current ratio of 5 to 1 at December 31, 2018.

Overall Liquidity and Capital Resources

Our primary cash requirements for the three months ended March 31, 2019 were general working capital needs, interest and principal payments under our debt agreement, repurchases of stock to cover tax withholdings, business development and integration expenses, and capital expenditures for facilities and equipment. We funded our cash requirements through our existing cash reserves and proceeds from stock option exercises.

We believe our cash from operations and existing cash and cash equivalents will enable us to meet our current operational liquidity needs for at least the next twelve months. Our future cash requirements are expected to include interest and principal payments under our debt agreement, expenditures for clinical trials, additional research and development expenditures, general working capital needs, capital expenditures, and other corporate purposes and may include cash to fund business development activities. These items may have a significant effect on our future cash flows during the next twelve months. Subject to the terms of our credit facility, considering our revolving credit availability and other obligations, we may seek additional borrowing capacity or financing, pursuant to our current or any future shelf registration statement, for general corporate purposes or to fund other future cash requirements. If we undertake any further significant business development activity, we may need to finance such activities by drawing down monies under our credit agreement, discussed below, obtaining additional debt financing, or using a registration statement to sell equities. There can be no assurance that we will be able to obtain any additional debt or equity financing at the time needed or that such financing will be available on terms that are favorable or acceptable to us.

Significant Sources and Uses of Liquidity

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

On December 1, 2017 CryoLife borrowed the entire $225.0 million Term Loan Facility. The proceeds of the Term Loan Facility were used along with cash on hand and shares of CryoLife common stock to (i) fund the JOTEC Acquisition, (ii) pay certain fees and expenses related to the JOTEC Acquisition and the Credit Agreement, and (iii) pay the outstanding balance of our prior credit facility.

In October 2018 we finalized an amendment to the Credit Agreement to reprice interest rates, resulting in a reduction in the interest rate margins over base rates on the Term Loan Facility. The loan under the Term Loan Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of 2.25%, or LIBOR, plus a margin of 3.25%. Prior to the repricing, the optional floating annual rate was equal to either the base rate, plus a margin of 3.00%, or LIBOR, plus a margin of 4.00%. The loan under the Revolving Credit Facility bears interest, at

our option, at a floating annual rate equal to either the base rate, plus a margin of between 3.00% and 3.25%, depending on our consolidated leverage ratio, or LIBOR, plus a margin of between 4.00% and 4.25%, depending on our consolidated leverage ratio. While a payment or bankruptcy event of default exists, we are obligated to pay a per annum default rate of interest of 2.00% in excess of the interest rate otherwise payable with respect to the overdue principal amount of any loans outstanding and overdue interest payments and other overdue fees and amounts. As of March 31, 2019 the remaining availability on our revolving credit facility was $30.0 million.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Enrollment was completed in January 2019. We anticipate PMA submission to the FDA in early 2020. See also Part II, Item 1A, Risk Factors Risks Relating To Our Business Our investment in PerClot is subject to significant risks, including our

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ability to fully realize our investment by obtaining 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 2019 tax year.

As of March 31, 2019 approximately 17% of our cash and cash equivalents were held in foreign jurisdictions.

Net Cash Flows from Operating Activities

Net cash provided by operating activities was $1.2 million for the three months ended March 31, 2019, as compared to net cash used in operating activities of $9.7 million for the three months ended March 31, 2018. The prior year cash used in operating activities was largely a result of increased integration and business development costs resulting in a higher net loss, primarily related to the JOTEC Acquisition. These expenses made up a large portion of the $10.4 million unfavorable adjustment due to the timing differences between recording accounts payable, accrued expenses, and other liabilities and the payment of cash.

We use the indirect method to prepare our cash flow statement and, accordingly, the operating cash flows are based on our net loss, 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 three months ended March 31, 2019 these non-cash items included $4.4 million in depreciation and amortization expenses and $1.9 million in non-cash compensation.

Our working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the three months ended March 31, 2019 these changes included unfavorable adjustments of $3.3 million due to the timing difference between recording receivables and the receipt of cash and $3.8 million due to timing differences between recording accounts payable, accrued expenses, and other liabilities and the payment of cash, partially offset by $1.4 million due to decreases in inventory balances and deferred preservation costs.

Net Cash Flows from Investing Activities

Net cash used in investing activities was $1.4 million for the three months ended March 31, 2019, as compared to $2.1 million for the three months ended March 31, 2018 primarily due to capital expenditures in both years.

Net Cash Flows from Financing Activities

Net cash used in financing activities was $1.2 million for the three months ended March 31, 2019, as compared to $2.0 million for the three months ended March 31, 2018. The current year cash used was primarily due to $2.4 million for repurchases of common stock to cover tax withholdings and $696,000 in principal payments on debt, partially offset by $2.0 million in proceeds from the exercise of options and issuance of common stock.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

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Scheduled Contractual Obligations and Future Payments

Scheduled contractual obligations and the related future payments as of March 31, 2019 were as follows (in thousands):

	Total	Remainder of 2019	2020	2021	2022	2023	Thereafter
Long-term debt obligations	$ 225,262	$ 2,085	$ 2,781	$ 2,781	$ 2,781	$ 2,781	$ 212,053
Interest on long-term debt	71,753	9,757	12,886	12,744	12,603	12,461	11,302
Operating leases	29,095	4,396	6,046	5,607	3,343	2,321	7,382
Purchase commitments	8,539	6,150	1,975	243	138	18	15
Finance leases	7,103	627	675	628	575	575	4,023
Research obligations	4,043	1,807	760	531	466	325	154
Contingent payments	1,000	--	--	1,000	--	--	--
Total contractual obligations	**$ 346,795**	**$ 24,822**	**$ 25,123**	**$ 23,534**	**$ 19,906**	**$ 18,481**	**$ 234,929**

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 finance lease obligations result from the lease of land and buildings that comprise our corporate headquarters and our various manufacturing facilities, leases related to additional manufacturing, office, and warehouse space, leases on Company vehicles, and leases on a variety of office equipment and other equipment. The operating and finance lease obligations in this schedule are based on actual payments which includes both interest and lease liability.

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 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.

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

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 $4.3 million, as no specific assessments have been made by any taxing authorities.

Capital Expenditures

Capital expenditures were $1.2 million and $2.1 million for the three months ended March 31, 2019 and 2018, respectively. Capital expenditures in the three months ended March 31, 2019 were primarily related to the routine purchases of manufacturing and tissue processing equipment, leasehold improvements needed to support our business, computer software, and computer and office equipment.

Risks and Uncertainties

See the risks identified in Part II, Item 1A of this Form 10-Q.

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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 $40.3 million as of March 31, 2019 and interest paid on the outstanding balances, if any, of our variable rate Revolving Credit Facility and $225.0 million secured Term Loan Facility. A 10% adverse change in interest rates, as compared to the rates experienced by us in the three months ended March 31, 2019, affecting our cash and cash equivalents, restricted cash and securities, $225.0 million secured Term Loan Facility, and Revolving Credit Facility would not have a material effect on our financial position, results of operations, or cash flows.

Foreign Currency Exchange Rate Risk

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

We have revenues and expenses that are denominated in foreign currencies. Specifically, a portion of our international BioGlue, On-X, PerClot, and JOTEC revenues are denominated in Euros, British Pounds, Swiss Francs, Polish 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 March 31, 2019, 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 three months ended March 31, 2019, 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

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with the participation of the CEO and CFO, as of March 31, 2019, the CEO and CFO have concluded that our Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by us in our periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission s rules and forms.

Part II - OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we are involved in legal proceedings concerning matters arising from the conduct of our business activities. We regularly evaluate the status of legal proceedings in which we are involved in order to assess whether a loss is probable or whether there is a reasonable possibility that a loss or additional loss may have been incurred and to determine if accruals are appropriate. We further evaluate each legal proceeding to assess whether an estimate of possible loss or range of loss can be made.

Based on current knowledge, we do not believe that there are any pending matters that could potentially have a material adverse effect on our business, financial condition, results of operations, or cash flows. We are, however, engaged in various legal actions in the normal course of business. There can be no assurances in light of the inherent uncertainties involved in any potential legal proceedings, some of which are beyond our control, and an adverse outcome in any legal proceeding could be material to our results of operations or cash flows for any particular reporting period.

Item 1A. Risk Factors.

Risks Relating To Our Business

We may not realize all 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.

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Many of these factors are outside of our control and any one of them could result in increased costs, decreased revenues, and diversion of management s time and energy, which could materially, adversely impact our business, financial condition, profitability, and cash flows. These benefits may not be achieved within the anticipated time frame or at all. Any of these factors could negatively impact our earnings per share, decrease or delay the expected accretive effect of the acquisition, and negatively impact the price of our common stock. In addition, if we fail to realize the anticipated benefits of the acquisition, we could experience an interruption or loss of momentum in our existing business activities, which could adversely affect our revenues, financial condition, profitability, and cash flows.

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

Our current and future levels of indebtedness could:

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

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

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

- Incur or guarantee additional debt;
- Pay dividends on or make distributions in respect of our share capital, including repurchasing or redeeming capital stock or make other restricted payments, including restricted junior payments;
- Enter into agreements that restrict our subsidiaries ability to pay dividends to us, repay debt owed to us or our subsidiaries, or make loans or advances to us or our other subsidiaries;
- Comply with certain financial ratios set forth in the agreement;
- Enter into any transaction or merger or consolidation, liquidation, winding-up, or dissolution; convey, sell, lease, exchange, transfer or otherwise dispose of all or any part of our business, assets or property; or sell, assign, or otherwise dispose of any capital stock of any subsidiary;
- Create liens on certain assets;
- Enter into certain transactions with our affiliates;
- Enter into certain rate swap transactions, basis swaps, credit derivative transactions, and other similar transactions, whether relating to interest rates, commodities, investments, securities, currencies, or any other relevant measure, or transactions of any kind subject to any form of master purchase agreement governed by

the International Swaps and Derivatives Association, Inc., any International Foreign Exchange Master Agreement, or any other master agreement;

Amend, supplement, waive, or otherwise modify our organizational documents or the organizational documents of a subsidiary in a manner that would be materially, adverse to the interests of the lenders, or change or amend the terms of documentation regarding junior financing in a manner that would be materially adverse to the interests of the lenders;

Change our, or permit a subsidiary to change its, fiscal year without notice to the administrative agent under the agreement;

Enter into agreements which restrict our ability to incur liens;

Engage in any line of business substantially different from that in which we are currently engaged; and

Make certain investments, including strategic acquisitions or joint ventures.

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

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

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

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

If we are unable to repay those amounts, the holders of our secured indebtedness could proceed against the collateral granted to them to secure that indebtedness. If the indebtedness under our existing debt agreements were to be accelerated, there can be no assurance that our assets would be sufficient to repay such indebtedness in full.

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

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

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

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

Tissue preservation services are a significant source of our revenues, representing 28% and 30% of revenues in the three months ended March 31, 2019 and 2018, 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;

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.

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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 BioGlue and are subject to a variety of risks affecting them.

BioGlue® Surgical Adhesive (BioGlue) is a significant source of our revenues, representing approximately 26% of revenues in the both the three months ended March 31, 2019 and 2018. 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 subject to increased scrutiny from the public and regulators, who may have concerns about the use of animal-based products or concerns about the transmission of disease from animals to humans. These concerns could lead to additional regulations or product bans in certain countries;
- Changes to components in the BioGlue product, including in the delivery system, require regulatory approval, which if delayed, could cause prolonged disruptions to our ability to supply BioGlue; and
- Our European Notified Body for BioGlue, Lloyd s Register Quality Assurance Limited (LRQA), is headquartered in the U.K. If the U.K. withdraws from the European Union so called Brexit without an agreement, and if LRQA is unsuccessful in qualifying a subsidiary in the European Economic Area (EEA) or if we are unable to timely update our BioGlue labels to reflect this newly qualified subsidiary in the EEA, we may be unable to sell BioGlue in the EEA until the situation is resolved.

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

JOTEC is now a significant source of our revenues, representing 24% and 23% of revenues in the three months ended March 31, 2019 and 2018, respectively. 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.

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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 17% of revenues in both the three months ended March 31, 2019 and 2018. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

- Our ability to achieve anticipated On-X revenue in the U.S. and in international markets outside the U.S.;
- Our ability to capitalize on the 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 products and tissues are highly regulated and subject to significant quality and regulatory risks.

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

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

Adverse publicity associated with our products or processed tissues or our industry could lead to a decreased use of our products or tissues, additional regulatory scrutiny, and/or product or tissue processing liability lawsuits.

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

At the same time, European Notified Bodies have begun engaging in more rigorous regulatory enforcement activities and may continue to do so. For example, our Notified Body for the On-X product line temporarily suspended the CE Mark for the On-X ascending aortic prosthesis (AAP) in the EEA. See the risk factor below entitled Our revenues for the On-X

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AAP in Europe may continue to be adversely affected by regulatory enforcement activities regarding the On-X AAP s CE Mark for further discussion. Further, in anticipation of MDR, Notified Bodies have begun establishing deadlines in 2019 after which they will no longer review routine submissions unless they are submitted in accordance with MDR. Our inability to timely adapt to these new requirements of our Notified Bodies could adversely impact our clearances and approvals, which could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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

We own patents, patent applications, and licenses relating to our technologies, which we believe provide us with important competitive advantages. In addition, we have certain proprietary technologies and methods that we believe provide us with important competitive advantages. We cannot be certain that our pending patent applications will issue as patents or that no one will challenge the validity or enforceability of any patent that we own or license. Furthermore, competitors may independently develop similar technologies, or duplicate our technologies, or design around the patented aspects of such technologies.

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

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

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

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

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

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

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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 too onerous, leading us to discontinue distribution of these tissues.

Our key growth areas may not generate anticipated benefits.

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

New Products Drive growth through new products, including 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 or non-vascular indications. To the extent we identify new non-core products or additional applications for our core products, we may attempt to license these products to corporate partners for further development or seek funding from outside sources to continue commercial development.

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

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

Our growth and profitability will depend, in part, upon our ability to complete development of, and successfully introduce, new products and services, or expand upon existing indications, which requires that we invest significant time and

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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 have begun efforts 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, on 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.

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

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

- Difficulties and costs associated with staffing, establishing and maintaining internal controls, managing foreign operations, including foreign distributor relationships, and developing direct sales operations in key foreign countries;
- Expanded compliance obligations, including obligations associated with the Foreign Corrupt Practices Act, the U.K. Bribery Law, local anti-corruption laws, Office of Foreign Asset Control administered sanction programs, and the European Union s General Data Protection Regulation;
- Broader exposure to corruption;
- Overlapping and potentially conflicting international legal and regulatory requirements, as well as unexpected changes in international legal and regulatory requirements or reimbursement policies and programs;
- Longer accounts receivable collection cycles in certain foreign countries and additional cost of collection of those receivables;
- Diminished protection for intellectual property and the presence of a growing number of generic or smaller competitors in some countries;
- Changes in currency exchange rates, particularly fluctuations in the Euro as compared to the U.S. Dollar;
- Differing local product preferences and product requirements;
- Differing local labor and employment laws, including those related to terminations, unionization, and the formation of works councils or other similar employee organizations;
- Adverse economic or political changes or political instability;
- Potential trade restrictions, exchange controls, and import and export licensing requirements including tariffs;
- Potential adverse tax consequences of overlapping tax structures; and
- Potential adverse financial consequences resulting from the scheduled exit of the U.K. from the European Union, or Brexit, including a potential disruption of sales into the U.K.

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

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

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

- Issue additional equity securities that would dilute our stockholders ownership interest in us;
- Use cash that we may need in the future to operate our business;
- Incur debt, including on terms that could be unfavorable to us or debt that we might be unable to repay;
- Structure the transaction in a manner that has unfavorable tax consequences, such as a stock purchase that does not permit a step-up in the tax basis for the assets acquired;

- Be unable to realize the anticipated benefits, such as increased revenues, cost savings, or synergies from additional sales;
- Be unable to integrate, upgrade, or replace the purchasing, accounting, financial, sales, billing, employee benefits, payroll, and regulatory compliance functions of an acquisition target;
- Be unable to secure or retain the services of key employees related to the acquisition;
- Be unable to succeed in the marketplace with the acquisition; or
- Assume material unknown liabilities associated with the acquired business.

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

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

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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 if those suppliers and/or their facilities refuse to supply us or cease operations temporarily or permanently, we could be forced to cease product manufacturing or tissue processing until the suppliers resume operations, until alternative suppliers could be identified and qualified, or permanently if the suppliers do not resume operations and no alternative suppliers could be identified and qualified. We could also be forced to purchase alternative materials, supplies, or services with unfavorable terms due to diminished bargaining power. We also conduct nearly all our operations at three facilities: Austin, Texas for our On-X product line, Hechingen, Germany for our JOTEC product line, and Kennesaw, Georgia for all our other products. If one of these facilities ceases operations temporarily or permanently, due to natural disaster or other reason, our business could be substantially disrupted.

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

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

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

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

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

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

We are dependent on our key personnel.

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

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

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

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

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

- Changes in demand for the products we sell;
- Increased product and price competition, due to the announcement or introduction of new products by our competitors, market conditions, the regulatory landscape, or other factors;
- Changes in the mix of products we sell;
- Availability of materials and supplies, including donated tissue used in preservation services;
- Our pricing strategy with respect to different product lines;
- Strategic actions by us, such as acquisitions of businesses, products, or technologies;
- Unanticipated costs and expenses;

Effects of domestic and foreign economic conditions and exchange rates on our industry and/or customers;
The divestiture or discontinuation of a product line or other revenue generating activity;
The relocation and integration of manufacturing operations and other strategic restructuring;
Regulatory actions that may necessitate recalls of our products or warning letters that negatively affect the markets for our products;
Failure of government and private health plans to adequately and timely reimburse the users of our products or changes in reimbursement policies;
Costs incurred by us in connection with the termination of contractual and other relationships, including distributorships;
Our ability to collect outstanding accounts receivable in selected countries outside of the U.S.;
The expiration or utilization of deferred tax assets such as net operating loss carryforwards;
Market reception of our new or improved product offerings; and
The loss of any significant customer, especially in regard to any product that has a limited customer base.

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

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

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

The implementation of the General Data Protection Regulation in the 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. Although our personal data practices are intended to comply with GDPR, there can be no assurance that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws, or that one or more of our employees or agents will not disregard the rules we have established. Any GDPR related government enforcement activities may be costly to comply with, result in negative publicity, and

subject us to significant penalties, any of which could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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

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

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

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

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

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

Our business and future growth depend on the continued use of our products for specific approved uses. Generally, unless the products are approved or cleared by the FDA for the alternative uses, the FDA contends that we may not make claims about the safety or effectiveness of our products, or promote them, for such uses. Such limitations present a risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales, marketing, and/or support activities, though designed to comply with all FDA requirements, constitute the promotion of our products for an unapproved use in violation of the Federal Food, Drug, and Cosmetic Act, (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 certain foreign jurisdictions with the acquisition of JOTEC, but we do not believe these carryforwards will be limited in any material way due to a change of control provision. The deferred tax assets recorded on our Consolidated Balance Sheets exclude amounts that we expect will not be realizable due to these changes in control. A portion of the acquired net operating loss carryforwards is related to state income taxes for which we believe it is more likely than not that these deferred tax assets will not be realized. Therefore, we recorded a valuation allowance against these state net

operating loss carryforwards. Limitations on our federal tax net operating loss and general business credit carryforwards could result in greater future income tax expense and adversely impact future cash flows.

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

Our relationships with physicians, hospitals, and other healthcare providers are subject to scrutiny under various U.S. and international, bribery, anti-kickback, false claims, privacy, transparency, and similar laws, often referred to collectively as healthcare compliance laws. Healthcare compliance laws are broad, sometimes ambiguous, complex, and subject to changing interpretations. Possible sanctions for violation of these healthcare compliance laws include monetary fines, civil and criminal penalties, exclusion from government healthcare programs, and forfeiture of amounts collected in violation of such prohibitions. Any government investigation or a finding of a violation of these laws, despite our compliance efforts, could result in a material, adverse effect on our business, financial condition, and profitability.

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

We have also adopted the AdvaMed Code of Conduct and the MedTech Europe Code of Ethical Business Practice into our Code of Business Conduct, which governs our relationships with healthcare professionals, including our payment of travel and lodging expenses, research and educational grant procedures, and sponsorship of third-party conferences. In addition, we conduct training sessions on these principles. There can be no assurance, however, that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws or that one or more of our employees or agents will not disregard the rules we have established. Because our strategy relies on the involvement of healthcare professionals or healthcare organizations who consult with us on the design of our products, perform clinical research on our behalf, or educate the market about the efficacy and uses of our products, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with healthcare professionals or healthcare organizations, who refer or order our products, to be in violation of applicable laws and determine that we would be unable to achieve compliance with such applicable laws. This could harm our reputation and the reputations of the healthcare professionals or healthcare organizations we engage to provide services on our behalf. In addition, the cost of noncompliance with these laws could be substantial since we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from government funded healthcare programs, including Medicare and Medicaid, for noncompliance.

The scope and enforcement of all of these laws is uncertain and subject to rapid change, especially in light of the scarcity of applicable precedent and regulations. There can be no assurance that regulatory or enforcement authorities will not investigate or challenge our current or future activities under these laws. Any investigation or challenge could have a material, adverse effect on our business, financial condition, and profitability. Any regulatory or enforcement review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in or interpretations of these laws, whether these changes will be retroactive or will have effect on a going-forward basis only.

Healthcare policy changes, including U.S. healthcare reform legislation signed in 2010, may have a material, adverse effect on us.

In response to perceived increases in healthcare costs in recent years, there have been and continue to be proposals by the federal government, state governments, regulators, and third-party payors to control these costs and, more generally, to reform the U.S. healthcare system. Some of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of some or all of these proposals could have a material, adverse effect on our financial condition and profitability.

The Patient Protection and Affordable Care Act (ACA) and the Health Care and Education Affordability Reconciliation Act of 2010 imposed significant new taxes on medical device 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. Further, candidates for the 2020 presidential election have put forward numerous healthcare reform proposals, including Medicare for All. These proposals may affect aspects of our business. We cannot predict what further reform proposals, if any, will be adopted, when they will be adopted, or what impact they may have on us. Any changes that lower reimbursement for our products or reduce medical procedure volumes, however, could adversely affect our business and profitability.

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

The majority of our foreign product revenues are denominated in Euros and, as such, are sensitive to changes in exchange rates. In addition, a portion of our dollar-denominated product sales are made to customers in other countries who

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must convert local currencies into U.S. Dollars in order to purchase these products. We also have balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency transactions and balances are sensitive to changes in exchange rates. Fluctuations in exchange rates of Euros or other local currencies in relation to the U.S. Dollar could materially reduce our future revenues as compared to the comparable prior periods. Should this occur, it could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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

Our products and tissues allegedly have caused, and may in the future cause, injury to patients using our products or tissues, and we have been, and may be, exposed to product and tissue processing liability claims. We maintain claims-made insurance policies to mitigate our financial exposure to product and tissue processing liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. In addition, our product and tissue processing liability insurance policies do not include coverage for any punitive damages. Although we have insurance for product and tissue processing liabilities, securities, property, and general liabilities, it is possible that:

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

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

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

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

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

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

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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.

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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 March 31, 2019 of equity securities that are registered by us pursuant to Section 12 of the Securities Exchange Act of 1934:

Period	Total Number of Common Shares and Common 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
01/01/19 - 01/31/19	--	$ --	--	$ --
02/01/19 - 02/28/19	27,902	28.88	--	--
03/01/19 - 03/31/19	53,588	29.32	--	--
Total	**81,490**	**29.17**	**--**	

The common shares purchased during the quarter ended March 31, 2019 were tendered to us in payment of taxes on stock compensation and were not part of a publicly announced plan or program.

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

Item 3. Defaults Upon Senior Securities.
None.

Item 4. Mine Safety Disclosures.
Not applicable.

Item 5. Other Information.
None.

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Item 6. Exhibits.

The exhibit index can be found below.

Exhibit Number	Description
3.1	Amended and Restated Articles of Incorporation of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed November 23, 2015.)
3.2	Amended and Restated By-Laws of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K filed February 22, 2018.)
4.1	Form of Certificate for our Common Stock. (Incorporated herein by reference to Exhibit 4.2 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1997.)
31.1*	Certification by J. Patrick Mackin pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32**	Certification Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant To Section 906 Of The Sarbanes-Oxley Act Of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Furnished herewith.

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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
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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)
May 2, 2019	

DATE	