**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, 2020**

OR

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

For the transition period from _____ to _____

Commission file number: 1-13165

# CRYOLIFE INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

| Class | Outstanding at April 24, 2020 |
|---|---|
| Common Stock, $0.01 par value | 37,740,425 |

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**Part I – FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

**CryoLife, Inc. and Subsidiaries**
**Summary Consolidated Statements of Operations and Comprehensive Loss**
*In Thousands, Except Per Share Data*
**(Unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| **Revenues:** | | |
| Products | $ 46,420 | $ 48,401 |
| Preservation services | 20,009 | 19,104 |
| **Total revenues** | **66,429** | **67,505** |
| | | |
| **Cost of products and preservation services:** | | |
| Products | 13,040 | 13,826 |
| Preservation services | 9,218 | 9,406 |
| **Total cost of products and preservation services** | **22,258** | **23,232** |
| | | |
| **Gross margin** | **44,171** | **44,273** |
| | | |
| **Operating expenses:** | | |
| General, administrative, and marketing | 39,002 | 36,520 |
| Research and development | 6,356 | 5,548 |
| **Total operating expenses** | **45,358** | **42,068** |
| | | |
| **Operating (loss) income** | **(1,187)** | **2,205** |
| | | |
| Interest expense | 3,388 | 3,894 |
| Interest income | (102) | (116) |
| Other expense, net | 3,662 | 77 |
| | | |
| **Loss before income taxes** | **(8,135)** | **(1,650)** |
| Income tax benefit | (1,470) | (1,353) |
| | | |
| **Net loss** | $ **(6,665)** | $ **(297)** |
| | | |
| **Loss per common share:** | | |
| **Basic** | $ **(0.18)** | $ **(0.01)** |
| **Diluted** | $ **(0.18)** | $ **(0.01)** |
| | | |
| **Weighted-average common shares outstanding:** | | |
| Basic | 37,390 | 36,778 |
| Diluted | 37,390 | 36,778 |
| | | |
| **Net loss** | $ **(6,665)** | $ **(297)** |
| **Other comprehensive loss:** | | |
| Foreign currency translation adjustments | (4,463) | (3,781) |
| **Comprehensive loss** | $ **(11,128)** | $ **(4,078)** |

See accompanying Notes to Summary Consolidated Financial Statements.

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

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| | (Unaudited) | |
| **ASSETS** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 63,383 | $ 33,766 |
| Restricted securities | 494 | 528 |
| Trade receivables, net | 48,723 | 52,940 |
| Other receivables | 2,951 | 2,921 |
| Inventories | 54,300 | 53,071 |
| Deferred preservation costs | 32,918 | 32,551 |
| Prepaid expenses and other | 11,313 | 11,613 |
| **Total current assets** | **214,082** | **187,390** |
| | | |
| Property and equipment, net | 31,878 | 32,150 |
| Operating lease right-of-use assets, net | 20,423 | 21,994 |
| Goodwill | 184,014 | 186,697 |
| Acquired technology, net | 111,136 | 115,415 |
| Other intangibles, net | 41,242 | 42,319 |
| Deferred income taxes | 4,769 | 5,481 |
| Other assets | 13,489 | 14,208 |
| **Total assets** | **$ 621,033** | **$ 605,654** |
| | | |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| **Current liabilities:** | | |
| Accounts payable | $ 10,453 | $ 9,796 |
| Accrued compensation | 9,783 | 12,260 |
| Accrued procurement fees | 4,030 | 4,362 |
| Current maturities of operating leases | 5,442 | 5,487 |
| Current portion of long-term debt | 1,155 | 1,164 |
| Taxes payable | 2,692 | 2,984 |
| Accrued expenses and other | 10,130 | 9,142 |
| **Total current liabilities** | **43,685** | **45,195** |
| | | |
| Long-term debt | 244,227 | 214,571 |
| Deferred income taxes | 24,268 | 25,844 |
| Non-current maturities of operating leases | 16,411 | 17,918 |
| Deferred compensation liability | 4,084 | 4,434 |
| Other | 11,749 | 11,996 |
| **Total liabilities** | **$ 344,424** | **$ 319,958** |
| | | |
| **Commitments and contingencies** | | |
| | | |
| **Shareholders' equity:** | | |
| Preferred stock | -- | -- |
| Common stock (issued shares of 39,219 in 2020 and 39,018 in 2019) | 392 | 390 |
| Additional paid-in capital | 273,821 | 271,782 |
| Retained earnings | 30,039 | 36,704 |
| Accumulated other comprehensive loss | (13,052) | (8,589) |
| Treasury stock at cost (shares of 1,484 in each of 2020 and 2019) | (14,591) | (14,591) |
| **Total shareholders' equity** | **276,609** | **285,696** |
| | | |
| **Total liabilities and shareholders' equity** | **$ 621,033** | **$ 605,654** |

See accompanying Notes to Summary Consolidated Financial Statements.

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| **Net cash flows from operating activities:** | | |
| Net loss | $ (6,665) | $ (297) |
| | | |
| Adjustments to reconcile net loss to net cash from operating activities: | | |
| Depreciation and amortization | 4,898 | 4,351 |
| Non-cash compensation | 2,564 | 1,850 |
| Deferred income taxes | (265) | (424) |
| Other non-cash adjustments to net loss | 2,927 | 737 |
| | | |
| Changes in operating assets and liabilities: | | |
| Receivables | 3,557 | (3,292) |
| Inventories and deferred preservation costs | (2,874) | 1,396 |
| Prepaid expenses and other assets | 982 | 627 |
| Accounts payable, accrued expenses, and other liabilities | (2,489) | (3,787) |
| **Net cash flows provided by operating activities** | **2,635** | **1,161** |
| | | |
| **Net cash flows from investing activities:** | | |
| Capital expenditures | (2,539) | (1,194) |
| Other | (364) | (233) |
| **Net cash flows used in investing activities** | **(2,903)** | **(1,427)** |
| | | |
| **Net cash flows from financing activities:** | | |
| Proceeds from revolving line of credit | 30,000 | -- |
| Repayment of term loan | (691) | (696) |
| Proceeds from exercise of stock options and issuance of common stock | 1,064 | 2,029 |
| Redemption and repurchase of stock to cover tax withholdings | (1,712) | (2,376) |
| Other | (146) | (172) |
| **Net cash flows provided by (used in) financing activities** | **28,515** | **(1,215)** |
| | | |
| Effect of exchange rate changes on cash, cash equivalents, and restricted securities | 1,336 | 320 |
| **Increase (decrease) in cash, cash equivalents, and restricted securities** | **29,583** | **(1,161)** |
| | | |
| Cash, cash equivalents, and restricted securities beginning of period | 34,294 | 42,236 |
| **Cash, cash equivalents, and restricted securities end of period** | **$ 63,877** | **$ 41,075** |

See accompanying Notes to Summary Consolidated Financial Statements

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

| | Common Stock | | Additional Paid-In Capital | Retained Earnings | Accumulated Other Comprehensive Loss | Treasury Stock | | Total Shareholders' Equity |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | | | | Shares | Amount | |
| **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 adjustment | -- | -- | -- | -- | (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** |

| | 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, 2019** | **39,018** | **390** | **271,782** | **36,704** | **(8,589)** | **(1,484)** | **(14,591)** | **285,696** |
| Net loss | | -- | -- | (6,665) | -- | -- | -- | (6,665) |
| Other comprehensive loss: | | | | | | | | |
| Foreign currency translation adjustment | -- | -- | -- | -- | (4,463) | -- | -- | (4,463) |
| Comprehensive loss | | | | | | | | (11,128) |
| Equity compensation | 208 | 2 | 2,687 | -- | -- | -- | -- | 2,689 |
| Exercise of options | 33 | -- | 376 | -- | -- | -- | -- | 376 |
| Employee stock purchase plan | 30 | -- | 688 | -- | -- | -- | -- | 688 |
| Redemption and repurchase of stock to cover tax withholdings | (70) | -- | (1,712) | -- | -- | -- | -- | (1,712) |
| **Balance at March 31, 2020** | **39,219** | **$ 392** | **$ 273,821** | **$ 30,039** | **$ (13,052)** | **(1,484)** | **$ (14,591)** | **$ 276,609** |

See accompanying Notes to Consolidated Financial Statements

**CryoLife, Inc. and Subsidiaries**
**Notes to Summary Consolidated Financial Statements**
**(Unaudited)**

## 1. Basis of Presentation

***Overview***

The accompanying summary consolidated financial statements include the accounts of CryoLife, Inc. and its subsidiaries ("CryoLife," the "Company," "we," or "us"). All significant intercompany accounts and transactions have been eliminated in consolidation. The accompanying Summary Consolidated Balance Sheet as of December 31, 2019 has been derived from audited financial statements. The accompanying unaudited summary consolidated financial statements as of, and for the three months ended, March 31, 2020 and 2019 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 the information and disclosures that are required by accounting principles generally accepted in the U.S. for a complete presentation of financial statements. In the opinion of management, all adjustments (including those of a normal, recurring nature) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020. These summary consolidated financial statements should be read in conjunction with the consolidated financial statements and notes included in CryoLife's Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on February 19, 2020.

***New Accounting Standards***

*Recently Adopted*

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* ("ASU 2016-13"). 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. The Company adopted this new guidance on January 1, 2020. The adoption of ASU 2016-13 did not result in a material effect on the Company's financial condition, results of operations, or cash flows.

## 2. Agreements with Endospan

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

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

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

***Loan Agreement***

CryoLife and Endospan also entered into a loan agreement ("Endospan Loan"), dated September 11, 2019, in which CryoLife agreed to provide Endospan a secured loan of up to $15.0 million to be funded in three tranches of $5.0 million each.

The first tranche of the Endospan Loan was funded upon execution of the agreement in September 2019. The second tranche is required to be funded generally under the same terms as the first tranche, upon certification of Investigational Device Exemption (“IDE”) approval from the FDA of NEXUS, and the third tranche is required to be funded upon certification of enrollment of at least 50% of the required number of patients in the primary arm of the FDA approved clinical trial for NEXUS, in each case subject to Endospan’s continued compliance with the Endospan Loan and certain other conditions. If a termination fee becomes payable by Endospan under the Endospan Distribution Agreement, it will be added to the amount payable to CryoLife under the Endospan Loan.

***Variable Interest Entity***

We consolidate the results of a variable interest entity ("VIE") when it is determined that we are the primary beneficiary. Based on our evaluation of Endospan and the related agreements with Endospan, we determined that Endospan is a VIE. Although the arrangement with Endospan resulted in our holding a variable interest, it did not empower us to direct those activities of Endospan that most significantly impact the VIE economic performance. Therefore, we are not the primary beneficiary, and we have not consolidated Endospan into our financial results. Our payments to Endospan in September 2019 totaled $15.0 million which included a $9.0 million distribution fee, a $1.0 million securities purchase option, and $5.0 million for the first tranche of the Endospan Loan. No additional amounts have been paid to Endospan under these agreements during the three months ended March 31, 2020. Our payments to date, including any loans, guarantees, and other subordinated financial support related to this VIE, totaled $15.0 million as of March 31, 2020, representing our maximum exposure to loss and were not individually significant to our consolidated financial statements.

***Valuation***

The agreements with Endospan were entered into concurrently and had certain terms that are interrelated. In our evaluation of the initial relative fair value of each of the Endospan agreements to determine the amount to record, we utilized discounted cash flows to estimate the fair market value for the Endospan Loan and for the Endospan Distribution Agreement. We estimated the fair value of the Endospan Option Agreement utilizing the Monte Carlo simulation. Inputs in our valuation of the Endospan agreements included cash payments and anticipated payments based on the executed agreements with Endospan, projected discounted cash flows in connection with the Endospan transaction, our expected internal rate of return and discount rates, and our assessed probability and timing of receipt of certification that certain approvals and milestones in obtaining FDA approval. Based on the initial fair value of the Endospan Loan and the relative fair values of the Endospan Distribution Agreement and Endospan Option Agreement, we recorded the Endospan Loan value of $358,000 and the Endospan Option Agreement of $4.8 million in Other long-term assets in the Summary Consolidated Balance Sheets as of March 31, 2020 and December 31, 2019. We recorded the Endospan Distribution Agreement of $8.5 million and $9.8 million in Other intangibles, net in the Summary Consolidated Balance Sheets as of March 31, 2020 and December 31, 2019, respectively.

We elected the fair value option for recording the Endospan Loan. We assess the fair value of the Endospan Loan based on quantitative and qualitative characteristics, and adjust the amount recorded to its current fair market value at each reporting period. We performed an assessment of the fair value of the Endospan Loan as of March 31, 2020 and concluded that an adjustment to the fair value as a result of this assessment was not material.

**3. Financial Instruments**

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

| **March 31, 2020** | **Level 1** | **Level 2** | **Level 3** | **Total** |
|---|---|---|---|---|
| Cash equivalents: | | | | |
| Money market funds | $ 1,478 | $ -- | $ -- | $ 1,478 |
| Restricted securities: | | | | |
| Money market funds | 494 | -- | -- | 494 |
| Endospan Loan | -- | -- | 358 | 358 |
| **Total assets** | **$ 1,972** | **$ --** | **$ 358** | **$ 2,330** |

| December 31, 2019 | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| Cash equivalents: | | | | |
| Money market funds | $ 1,472 | $ -- | $ -- | $ 1,472 |
| Restricted securities: | | | | |
| Money market funds | 528 | -- | -- | 528 |
| Endospan Loan | -- | -- | 358 | 358 |
| **Total assets** | **$ 2,000** | **$ --** | **$ 358** | **$ 2,358** |

We used prices quoted from our investment advisors to determine the Level 1 valuation of our investments in money market funds. We recorded the Endospan Loan, classified as Level 3, as a result of an agreement with Endospan in September 2019. See Note 2 for further discussion of the Endospan Loan. Changes in fair value of Level 3 assets are listed in the table below (in thousands):

| | Endospan Loan |
|---|---|
| Balance as of December 31, 2019 | $ 358 |
| Change in valuation of Endospan Loan | -- |
| Balance as of March 31, 2020 | **$ 358** |

## 4. Cash Equivalents and Restricted Securities

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

| March 31, 2020 | Cost Basis | Unrealized Holding Gains | Estimated Market Value |
|---|---|---|---|
| Cash equivalents: | | | |
| Money market funds | $ 1,478 | $ -- | $ 1,478 |
| Restricted securities: | | | |
| Money market funds | 494 | -- | 494 |
| **Total** | $ 1,972 | $ -- | $ 1,972 |

| December 31, 2019 | Cost Basis | Unrealized Holding Gains | Estimated Market Value |
|---|---|---|---|
| Cash equivalents: | | | |
| Money market funds | $ 1,472 | $ -- | $ 1,472 |
| Restricted securities: | | | |
| Money market funds | 528 | -- | 528 |
| **Total** | $ 2,000 | $ -- | $ 2,000 |

As of March 31, 2020 and December 31, 2019 all money market funds were designated as short-term restricted securities due to a contractual commitment to hold the securities as pledged collateral relating primarily to international tax obligations.

There were no gross realized gains or losses on cash equivalents and restricted securities in the three months ended March 31, 2020 and 2019. As of March 31, 2020 $494,000 of our restricted securities had a maturity date within three months. As of December 31, 2019 $528,000 of our restricted securities had a maturity date within three months.

**5. Inventories and Deferred Preservation Costs**

Inventories at March 31, 2020 and December 31, 2019 were comprised of the following (in thousands):

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| Raw materials and supplies | $ 22,414 | $ 21,180 |
| Work-in-process | 6,059 | 5,127 |
| Finished goods | 25,827 | 26,764 |
| **Total inventories** | **$ 54,300** | **$ 53,071** |

Deferred preservation costs at March 31, 2020 and December 31, 2019 were comprised of the following (in thousands):

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| Cardiac tissues | $ 15,477 | $ 15,365 |
| Vascular tissues | 17,441 | 17,186 |
| **Total deferred preservation costs** | **$ 32,918** | **$ 32,551** |

To facilitate product usage, we maintain consignment inventory of our On-X heart valves at domestic hospital locations and both On-X heart valves and JOTEC products at international hospital locations. We retain title and control over this consignment inventory until the device is implanted, at which time we invoice the hospital and recognize revenue. As of March 31, 2020 we had $12.0 million in consignment inventory, with approximately 50% in domestic locations and 50% in international locations. As of December 31, 2019 we had $12.0 million in consignment inventory, with approximately 51% in domestic locations and 49% in international locations.

**6. Goodwill and Other Intangible Assets**

***Indefinite Lived Intangible Assets***

As of March 31, 2020 and December 31, 2019 the carrying values of our indefinite lived intangible assets were as follows (in thousands):

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| Goodwill | $ 184,014 | $ 186,697 |
| In-process R&D | 2,136 | 2,190 |
| Procurement contracts and agreements | 2,013 | 2,013 |
| Trademarks | 765 | 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.

We evaluate our goodwill and non-amortizing intangible assets for impairment on an annual basis during the fourth quarter of the year, and, if necessary, during interim periods if factors indicate that an impairment review is warranted. As of March 31, 2020 we concluded that our assessment of current factors do not indicate that goodwill or non-amortizing intangible assets are more likely than not to be impaired. We will continue to evaluate the recoverability of these non-amortizing intangible assets in future periods as necessary.

As of March 31, 2020 and December 31, 2019 our entire goodwill balance was related to our Medical Devices segment.

| | Medical Devices Segment |
|---|---|
| Balance as of December 31, 2019 | $ 186,697 |
| Revaluation of goodwill denominated in foreign currency | (2,683) |
| **Balance as of March 31, 2020** | **$ 184,014** |

***Definite Lived Intangible Assets***

As of March 31, 2020 and December 31, 2019 the gross carrying values, accumulated amortization, and approximate amortization period of our definite lived intangible assets were as follows (in thousands):

| March 31, 2020 | Gross Carrying Value | Accumulated Amortization | Amortization Period |
|---|---|---|---|
| Acquired technology | $ 137,676 | $ 26,540 | 11 – 22 Years |
| Customer lists and relationships | 31,082 | 6,954 | 13 – 22 Years |
| Distribution and manufacturing rights and know-how | 13,585 | 3,508 | 5 – 15 Years |
| Patents | 3,745 | 3,090 | 17 Years |
| Other | 2,135 | 667 | 3 – 10 Years |

| December 31, 2019 | Gross Carrying Value | Accumulated Amortization | Amortization Period |
|---|---|---|---|
| Acquired technology | $ 140,193 | $ 24,778 | 11 – 22 Years |
| Customer lists and relationships | 31,131 | 6,581 | 13 – 22 Years |
| Distribution and manufacturing rights and know-how | 13,826 | 3,005 | 5 – 15 Years |
| Patents | 3,664 | 3,074 | 17 Years |
| Other | 1,919 | 608 | 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 (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2020 | 2019 |
| Amortization expense | $ 3,033 | $ 2,579 |

As of March 31, 2020 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

| | Remainder of 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | Total |
|---|---|---|---|---|---|---|---|
| Amortization expense | $ 9,057 | $ 12,208 | $ 11,662 | $ 11,153 | $ 10,927 | $ 8,993 | $ 64,000 |

**7. Income Taxes**

***Income Tax Expense***

Our effective income tax rate was a benefit of 18% and 82% for the three months ended March 31, 2020 and 2019, respectively. The change in the tax rate for the three months ended March 31, 2020 is primarily due to a change in pre-tax book loss, as well as a reduction in the excess tax benefit related to stock compensation for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019.

The income tax rate for the three months ended March 31, 2020 was impacted by excess tax benefit deductions related to stock compensation, which increased income tax benefits by approximately $250,000. These factors were partially offset by unfavorable impacts of non-deductible operating expenses and executive compensation expenses.

The income tax rate for the three months ended March 31, 2019 was impacted by excess tax benefit deductions related to stock compensation, the research and development tax credit, and losses in high rate jurisdictions. These factors were partially offset by impacts of non-deductible operating expenses and executive compensation expenses.

***Deferred Income Taxes***

We generate deferred tax assets primarily as a result of write-downs of inventory and deferred preservation costs, accruals for product and tissue processing liability claims, investment and asset impairments, and operating losses. We acquired significant deferred tax assets, primarily net operating loss carryforwards, from our acquisitions of JOTEC and its subsidiaries in 2017, On-X in 2016, Hemosphere, Inc. in 2012, and Cardiogenesis Corporation in 2011. We believe utilization of these net operating losses will not have a material impact on income taxes for the 2020 tax year.

As of March 31, 2020 we maintained a total of $3.4 million in valuation allowances against deferred tax assets, primarily related to state and foreign net operating loss carryforwards, and a net deferred tax liability of $19.5 million. As of December 31, 2019 we maintained a total of $3.2 million in valuation allowances against deferred tax assets, primarily related to state and foreign net operating loss carryforwards, and a net deferred tax liability of $20.4 million.

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

In response to the novel coronavirus disease ("COVID-19") pandemic, the US government enacted the CARES Act on March 27, 2020. The CARES Act provides various forms of relief and assistance to US businesses. The Company recorded a reduction to income taxes payable and deferred tax assets of approximately $1.3 million for the anticipated change to the 2019 Section 163(j) interest expense deduction limitation. The Company will continue to analyze the impacts of the CARES Act as interpretations are published.

**8. Leases**

We have operating and finance lease obligations resulting from the lease of land and buildings that comprise our corporate headquarters and various manufacturing facilities; leases related to additional manufacturing, office, and warehouse space; leases on Company vehicles; and leases on a variety of office and other equipment.

We sublease, on an operating lease basis, two unused office space facilities near our corporate office. Total annual sub-lease rental income for these facilities is approximately $905,000.

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

| **Operating leases:** | **March 31, 2020** | **December 31, 2019** |
|---|---|---|
| Operating lease right-of-use assets | $ 26,714 | $ 27,007 |
| Accumulated amortization | (6,291) | (5,013) |
| **Operating lease right-of-use assets, net** | **$ 20,423** | **$ 21,994** |
| | | |
| Current maturities of operating leases | $ 5,442 | $ 5,487 |
| Non-current maturities of operating lease | 16,411 | 17,918 |
| **Total operating lease liabilities** | **$ 21,853** | **$ 23,405** |
| | | |
| **Finance leases:** | | |
| Property and equipment, at cost | $ 6,984 | $ 7,161 |
| Accumulated amortization | (1,408) | (1,279) |
| **Property and equipment, net** | **$ 5,576** | **$ 5,882** |
| | | |
| Current maturities of finance leases | $ 569 | $ 597 |
| Non-current maturities of finance leases | 5,147 | 5,415 |
| **Total finance lease liabilities** | **$ 5,716** | **$ 6,012** |
| | | |
| **Weighted average remaining lease term (in years):** | | |
| Operating leases | 6.5 | 5.5 |
| Finance leases | 10.4 | 10.6 |
| | | |
| **Weighted average discount rate:** | | |
| Operating leases | 4.3% | 5.4% |
| Finance leases | 2.0% | 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 are as follows (in thousands):

| | **Three Months Ended March 31, 2020** | **Three Months Ended March 31, 2019** |
|---|---|---|
| Amortization of property and equipment | $ 162 | $ 211 |
| Interest expense on finance leases | 29 | 32 |
| **Total finance lease expense** | **191** | **243** |
| Operating lease expense | 1,748 | 1,550 |
| Sublease income | (226) | (228) |
| **Total lease expense** | **$ 1,713** | **$ 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, 2020** | **Three Months Ended March 31, 2019** |
|---|---|---|
| Operating cash flows for finance leases | $ 29 | $ 32 |
| Operating cash flows for operating leases | 1,745 | 1,636 |
| Financing cash flows for finance leases | 147 | 172 |

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

| | Finance Leases | Operating Leases | Sublease Income |
|---|---|---|---|
| Remainder of 2020 | $ 519 | $ 4,833 | $ 679 |
| 2021 | 642 | 6,289 | 905 |
| 2022 | 598 | 3,834 | 306 |
| 2023 | 597 | 2,547 | -- |
| 2024 | 595 | 2,539 | -- |
| Thereafter | 3,380 | 4,919 | -- |
| Total minimum lease payments | $ 6,331 | $ 24,961 | $ 1,890 |
| Less amount representing interest | (615) | (3,108) | |
| Present value of net minimum lease payments | 5,716 | 21,853 | |
| Less current maturities | (569) | (5,442) | |
| **Lease liabilities, less current maturities** | **$ 5,147** | **$ 16,411** | |

**9. Debt**

***Credit Agreement***

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

On December 1, 2017 we borrowed the entire $225.0 million Term Loan Facility. The proceeds of the Term Loan Facility were used along with cash on hand and shares of CryoLife common stock to (i) fund the acquisition of JOTEC and its subsidiaries (the "JOTEC Acquisition"), (ii) pay certain fees and expenses related to the JOTEC Acquisition and the Credit Agreement, and (iii) pay the outstanding balance of our prior credit facility. The Revolving Credit Facility 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 event of default 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, 2020 the aggregate interest rate was 4.70% per annum. We are obligated to pay an unused commitment fee equal to 0.50% of the unutilized portion of the revolving loans. In addition, we are also obligated to pay other customary fees for a credit facility of this size and type.

The Credit Agreement contains certain customary affirmative and negative covenants, including covenants that limit our ability and the ability of our subsidiaries to, among other things, grant liens, incur debt, dispose of assets, make loans and investments, make acquisitions, make certain restricted payments (including cash dividends), merge or consolidate, change business or accounting or reporting practices, in each case subject to customary exceptions for a credit facility of this size and type.

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.

In March 2020 as a precautionary measure to increase cash and maintain maximum financial flexibility during the current uncertainty in global markets resulting from the COVID-19 pandemic, we borrowed the entire amount available under our $30.0 million Revolving Credit Facility at an aggregate interest rate of 5.20%. Under the terms of the Credit Agreement at the time of borrowing and as of March 31, 2020, because the principal amount of loans outstanding under the Revolving Credit Facility was in excess of 25% of the entire amount of the Revolving Credit Facility on the last day of the fiscal quarter ending March 31, 2020, the Credit Agreement required us to comply with a maximum first lien net leverage ratio of 5.25x bank EBITDA as of the end of such fiscal quarter and any subsequent fiscal quarter if the principal amount of the loans remains in excess of such threshold as of the last day of such fiscal quarter. A breach of the 5.25x leverage ratio would become an event of default only to the extent that this leverage level occurs when the Revolving Credit Facility balance exceeds 25%, or $7.5 million, at the end of a test period.

See “Subsequent Events” included in Part I, Item 1 of this form 10-Q for a discussion of an amendment of the Credit Agreement affecting the Revolving Credit Facility and the maximum first lien net leverage ratio covenant.

***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, 2020 | December 31, 2019 |
|---|---|---|
| Term loan balance | $ 219,938 | $ 220,500 |
| Revolving credit facility | 30,000 | -- |
| 2.45% Sparkasse Zollernalb (KFW Loan 1) | 974 | 1,061 |
| 1.40% Sparkasse Zollernalb (KFW Loan 2) | 1,506 | 1,615 |
| Total loan balance | 252,418 | 223,176 |
| Less unamortized loan origination costs | (7,036) | (7,441) |
| Net borrowings | 245,382 | 215,735 |
| Less short-term loan balance | (1,155) | (1,164) |
| Long-term loan balance | $ 244,227 | $ 214,571 |

***Interest Expense***

Interest expense was $3.4 million for the three months ended March 31, 2020, as compared to $3.9 million for the three months ended March 31, 2019. Interest expense includes interest on debt and uncertain tax positions in both periods.

**10. Commitments and Contingencies**

***Liability Claims***

Our estimated unreported loss liability was $1.9 million as of March 31, 2020 and December 31, 2019. As of March 31, 2020 and December 31, 2019, the related recoverable insurance amounts were $962,000 and $935,000, 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, 2020 could have been as high as $3.7 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

***Employment Agreements***

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

***PerClot Technology***

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

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

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

As of March 31, 2020 we had $1.5 million in prepaid royalties, $2.0 million in intangible assets, net, and $1.2 million in property and equipment, net, on our Summary Consolidated Balance Sheets related to the PerClot product line. If we do not ultimately pursue or receive FDA approval to commercialize PerClot in the U.S., these assets could be materially impaired in future periods.

**11. Revenue Recognition**

***Sources of Revenue***

We have identified the following revenues disaggregated by revenue source:

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

For the three months ended March 31, 2020 and 2019 the sources of revenue were as follows (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2020 | 2019 |
| | (Unaudited) | |
| Domestic hospitals | $ 36,336 | $ 35,611 |
| International hospitals | 19,737 | 20,570 |
| International distributors | 10,245 | 9,610 |
| CardioGenesis cardiac laser therapy | 111 | 1,714 |
| **Total sources of revenue** | **$ 66,429** | **$ 67,505** |

Also see segment disaggregation information in Note 14 below.

***Contract Balances***

We may generate contract assets during the pre-delivery design and manufacturing stage of E-xtra DESIGN ENGINEERING product order fulfillment. We assess the balance related to any arrangements in process and determine if the enforceable right to payment creates a material contract asset requiring disclosure. No material arrangements in process existed as of March 31, 2020 and 2019.

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, 2020 and 2019 was not material.

**12. Stock Compensation**

***Overview***

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

***Equity Grants***

During the three months ended March 31, 2020 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 255,000 shares and had an aggregate grant date market value of $6.6 million. The PSUs granted in 2020 represent the right to receive from 60% to 150% of the target number of shares of common stock. The performance component of PSU awards granted in 2020 is based on attaining specified levels of adjusted EBITDA, as defined in the PSU grant documents, for the 2020 calendar year.

During the three months ended March 31, 2019 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, an annual grant with a one year performance period ("Annual PSU") and a special Long-Term Incentive Program PSU grant ("LTIP"), which has multiple performance periods over a five year period. If the highest performance threshold is met, the Annual PSU granted in 2019 represented the right to receive up to 150% of the target number of shares of common stock. The performance component of the Annual PSU awards granted in 2019 was based on attaining specified levels of adjusted earnings before interest, taxes, depreciation, and amortization, ("EBITDA"), as defined in the Annual PSU grant documents, for the 2019 calendar year. The Annual PSU granted in 2019 earned approximately 83% of the target number of shares. If the highest performance thresholds are met, the PSUs granted in 2019 under the LTIP represent the right to receive up to 288%, and up to 192% for a certain key executive, of the target number of shares of common stock. The performance component of the LTIP awards granted in 2019 is based on attaining specified levels of adjusted revenue growth and gross margin, as defined in the LTIP grant document, for the years 2019 through 2023. The first performance period under the LTIP will not conclude until December 31, 2021.

The Committee authorized, from approved stock incentive plans, grants of stock options to purchase a total of 212,000 and 169,000 shares to certain Company officers during the three months ended March 31, 2020 and 2019, respectively. The exercise prices of the options were equal to the closing stock prices on their respective grant dates.

Employees purchased common stock totaling 30,000 shares and 24,000 shares in the three months ended March 31, 2020 and 2019, respectively, through the ESPP.

***Stock Compensation Expense***

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

| | Three Months Ended March 31, 2020 | | Three Months Ended March 31, 2019 | |
|---|---|---|---|---|
| | **Stock Options** | **ESPP** | **Stock Options** | **ESPP** |
| Expected life | 5.0 Years | 0.5 Years | 5.0 Years | 0.5 Years |
| Expected stock price volatility | 0.35 | 0.31 | 0.40 | 0.39 |
| Risk-free interest rate | 1.41% | 1.57% | 2.54% | 2.56% |

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| RSA, RSU, and PSU expense | $ 2,156 | $ 1,510 |
| Stock option and ESPP expense | 533 | 471 |
| **Total stock compensation expense** | **$ 2,689** | **$ 1,981** |

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 $125,000 in the three months ended March 31, 2020, and $132,000 in the three months ended March 31, 2019, of the stock compensation expense into our inventory costs and deferred preservation costs.

As of March 31, 2020 we had total unrecognized compensation costs of $16.2 million related to RSAs, RSUs, and PSUs and $3.4 million related to unvested stock options. As of March 31, 2020 this expense is expected to be recognized over a weighted-average period of 2.4 years for PSUs, 2.3 years for stock options, 2.1 years for RSUs, and 1.6 years for RSAs.

## 13. 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** | **2020** | **2019** |
| Net loss | $ (6,665) | $ (297) |
| Net loss allocated to participating securities | 43 | 2 |
| **Net loss allocated to common shareholders** | **$ (6,622)** | **$ (295)** |
| **Basic weighted-average common shares outstanding** | **37,390** | **36,778** |
| **Basic loss per common share** | **$ (0.18)** | **$ (0.01)** |

| | Three Months Ended March 31, | |
|---|---|---|
| **Diluted loss per common share** | **2020** | **2019** |
| Net loss | $ (6,665) | $ (297) |
| Net loss allocated to participating securities | 43 | 2 |
| **Net loss allocated to common shareholders** | **$ (6,622)** | **$ (295)** |
| Basic weighted-average common shares outstanding | 37,390 | 36,778 |
| Effect of dilutive stock options and awards | -- | -- |
| **Diluted weighted-average common shares outstanding** | **37,390** | **36,778** |
| **Diluted loss per common share** | **$ (0.18)** | **$ (0.01)** |

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, 2020 and 2019 all stock options and awards were excluded from the calculation of diluted weighted-average common shares outstanding as these would be antidilutive due to the net loss.

## 14. Segment Information

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

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

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| Revenues: | | |
| Medical devices | $ 46,420 | $ 48,401 |
| Preservation services | 20,009 | 19,104 |
| **Total revenues** | **66,429** | **67,505** |
| | | |
| Cost of products and preservation services: | | |
| Medical devices | 13,040 | 13,826 |
| Preservation services | 9,218 | 9,406 |
| **Total cost of products and preservation services** | **22,258** | **23,232** |
| | | |
| Gross margin: | | |
| Medical devices | 33,380 | 34,575 |
| Preservation services | 10,791 | 9,698 |
| **Total gross margin** | **$ 44,171** | **$ 44,273** |

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| Products: | | |
| BioGlue | $ 16,737 | $ 17,222 |
| JOTEC | 15,268 | 15,954 |
| On-X | 12,202 | 11,731 |
| PhotoFix | 1,042 | 730 |
| PerClot | 860 | 1,050 |
| NEXUS | 200 | -- |
| CardioGenesis cardiac laser therapy | 111 | 1,714 |
| **Total products** | **46,420** | **48,401** |
| | | |
| Preservation services: | | |
| Cardiac tissue | 10,033 | 8,930 |
| Vascular tissue | 9,976 | 10,174 |
| **Total preservation services** | **20,009** | **19,104** |
| | | |
| **Total revenues** | **$ 66,429** | **$ 67,505** |

**15. Subsequent Events**

***Credit Agreement Amendment***

On April 29, 2020 we entered into an amendment to our Credit Agreement. As part of the amendment we obtained a waiver of our maximum first lien net leverage ratio covenant through the end of 2020. In addition, the amendment to our Credit Agreement provides that EBITDA, for covenant testing purposes, in each quarter of 2020 will be deemed equal to a fixed value, equal to our bank covenant EBITDA in the fourth quarter of 2019, when our first lien net leverage was 3.4x. As a result of these changes, we are subject to a new minimum liquidity covenant and restrictions on certain payments, including cash dividends. We are required to maintain a minimum liquidity of at least $12.0 million as of the last day of any month in

2020, and as of the last day of any quarter through the third quarter of 2021 when our Revolving Credit Facility is drawn in excess of 25% (or $7.5 million) of the amount available as of the last day of any fiscal quarter during that period. Beginning in 2021, if we repay borrowings under our Revolving Credit Facility to 25% or less, no financial maintenance covenants, including the minimum liquidity covenant and the maximum first lien net leverage ratio covenant, are applicable.

**Forward-Looking Statements**

This Form 10-Q includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934 (the “Exchange Act”). Forward-looking statements give our expectations or forecasts of future events as of the date of this Form 10-Q. The words “could,” “may,” “might,” “will,” “would,” “shall,” “should,” “pro forma,” “potential,” “pending,” “intend,” “believe,” “expect,” “anticipate,” “estimate,” “plan,” “future,” “assume,” and other similar expressions generally identify forward-looking statements. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements, which are made as of the date of this Form 10-Q.

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

- Our expectations regarding the potential impacts of the COVID-19 pandemic on our business operations, cash flow, business development, and employees;
- Our belief that our distributors may delay or reduce purchases of products in U.S. Dollars depending on the relative price of goods in their local currencies;
- Our belief regarding the international growth opportunity that would be provided by obtaining regulatory approval for BioGlue in China;
- Our beliefs about the unavailability of handpieces for cardiac laser therapy, the temporary nature of this unavailability, and a possible resolution of this unavailability during the second half of 2020;
- Our belief that revenue from cardiac laser therapy can vary from quarter to quarter and year to year due to the use of cardiac laser therapy adjunctively with cardiac bypass surgery by a limited number of physicians;
- Our ability to realize the anticipated business opportunities, growth prospects, synergies, and other benefits of the agreements with Endospan, and our beliefs about the costs and expected timeline regarding certain clinical trial milestones for the regulatory approval of the NEXUS stent graft system in the U.S.;
- Our plans, costs, and expected timeline regarding regulatory approval for PerClot in the U.S. and additional international markets and the distribution of PerClot in those markets after the requisite regulatory approvals are obtained;
- Our belief that revenues for preservation services, particularly revenues for certain high-demand cardiac tissues, can vary from quarter to quarter and year to year due to a variety of factors including: quantity and type of incoming tissues, yields of tissue through the preservation process, timing of receipt of donor information, timing of the release of tissues to an implantable status, demand for certain tissue types due to the number and type of procedures being performed, and pressures from competing products or services;
- Our beliefs regarding the seasonal nature of the demand for some of our products and services and the reasons for such seasonality, if any;
- Our belief that our cash from operations and existing cash and cash equivalents, including the entire amount borrowed under our Revolving Credit Facility, 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 expectations regarding the possible benefits to us of the Coronavirus Aid, Relief, and Economic Security Act or “CARES Act”;
- Our belief that we will incur expenses for clinical research work to gain regulatory approvals for products or indications, including JOTEC, On-X, PerClot, and BioGlue products, and expenses for research and development for new products;
- Our expectations regarding the timing of clinical research work and regulatory approvals for and expected distribution of products or indications, including JOTEC, On-X, PerClot, and BioGlue products;
- Our expectations regarding the utilization of net operating loss carryforwards from our acquisitions of JOTEC, On-X, Hemosphere, Inc., and Cardiogenesis Corporation; and
- Other statements regarding projections of future financial and business performance; anticipated growth and trends in our business and the markets relevant to our business, including as our growth relates to our competitors; future production capacity and product supply; the availability and benefits of our products in the future; and the expected timing and impact of our strategic initiatives.

These and other forward-looking statements reflect the views of management at the time such statements are 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, 2019 and elsewhere throughout that report, and other risks which we may not be able to identify in advance, many of which are beyond our control. Consequently, all of the forward-looking statements made in this Form 10-Q are qualified by these cautionary statements, and there can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us or our business or operations. We assume no obligation, and expressly disclaim, any duty to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

## PART I - FINANCIAL INFORMATION

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

### Overview

CryoLife, Inc. ("CryoLife," the "Company," "we," or "us") is a leader in the manufacturing, processing, and distribution of medical devices and implantable human tissues used in cardiac and vascular surgical procedures for patients with aortic disease. We have four major product families: BioGlue® Surgical Adhesive ("BioGlue") products, JOTEC stent grafts and surgical products, On-X mechanical heart valves and surgical products, and implantable cardiac and vascular human tissues. In addition to these four major product families, we sell or distribute PhotoFix™ bovine surgical patch, PerClot® hemostatic powder, NEXUS™ endovascular stent graft system, and CardioGenesis cardiac laser therapy.

We reported quarterly revenues of $66.4 million for the three months ended March 31, 2020, a 2% decrease from the three months ended March 31, 2019 primarily due to decreases in revenues from CardioGenesis cardiac laser therapy, JOTEC, and BioGlue products, partially offset by increases in revenues from preservation services and On-X products.

See the "Results of Operations" section below for additional analysis of the three months ended March 31, 2020.

### Initial Effects of COVID-19

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

Because of the uncertainty created by the COVID-19 pandemic, as well as the potential social and economic impacts of COVID-19 upon the markets in which we operate and the resulting impact on our results of operations and cash flow, we have reevaluated the need for, and timing of, certain expenses and have taken pre-emptive steps to reduce spending. These steps have included implementing hiring restrictions; imposing senior management cash salary reductions, in exchange for cash payments in the second quarter of 2021; obtaining the agreement of our Board of Directors to accept CryoLife stock instead of their cash compensation; deferring management merit increases; reducing most discretionary spending; reducing capital expenditures; and reducing spending on certain R&D and clinical research projects.

We have implemented specific protocols to minimize workplace exposures to COVID-19 by our employees and we have been able to, and expect to, continue to operate all manufacturing sites at near full production to supply our customers.

We have implemented remote work arrangements for employees we deem able to do so and have restricted business travel, each since mid-March, and to date, these arrangements have not materially affected our ability to maintain our business operations, including the operation of financial reporting systems, internal control over financial reporting, or disclosure controls and procedures.

As a precautionary measure to increase cash and maintain maximum financial flexibility during the current uncertainty in global markets resulting from the COVID-19 pandemic, we borrowed the entire amount available under our $30 million revolving credit facility.

We are actively monitoring the impact of the COVID-19 pandemic, and we expect that it will negatively impact our business and results of operations for at least the second and perhaps the third quarters of 2020. We currently anticipate the most severe impact to our revenues to be in the second quarter 2020 followed by recovery in the third quarter of 2020. The extent to which our operations will be impacted by the pandemic will depend largely on future developments, which are highly uncertain and difficult to predict. New information is continually emerging regarding the severity of the pandemic and the various government, regulatory, expert, and recommended actions to contain it or address its impact.

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

**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, 2019. 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 three months ended March 31, 2020 in any of our Critical Accounting Policies from those contained in our Form 10-K for the year ended December 31, 2019.

**New Accounting Pronouncements**

See Note 1 of “Notes to Summary Consolidated Financial Statements” identified in Part I, Item I of this form 10-Q for further discussion of new accounting standards that have been adopted.

**Results of Operations**
***(Tables in thousands)***

**Revenues**

| | Revenues for the Three Months Ended March 31, | | Percent Change From Prior Year | Revenues as a Percentage of Total Revenues for the Three Months Ended March 31, | |
|---|---|---|---|---|---|
| | **2020** | **2019** | | **2020** | **2019** |
| Products: | | | | | |
| BioGlue | $ 16,737 | $ 17,222 | -3% | 26% | 26% |
| JOTEC | 15,268 | 15,954 | -4% | 23% | 24% |
| On-X | 12,202 | 11,731 | 4% | 18% | 17% |
| PhotoFix | 1,042 | 730 | 43% | 2% | 1% |
| PerClot | 860 | 1,050 | -18% | 1% | 1% |
| NEXUS | 200 | -- | 100% | 0% | 0% |
| CardioGenesis cardiac laser therapy | 111 | 1,714 | -94% | 0% | 3% |
| **Total products** | **46,420** | **48,401** | **-4%** | **70%** | **72%** |
| Preservation services: | | | | | |
| Cardiac tissue | 10,033 | 8,930 | 12% | 15% | 13% |
| Vascular tissue | 9,976 | 10,174 | -2% | 15% | 15% |
| **Total preservation services** | **20,009** | **19,104** | **5%** | **30%** | **28%** |
| **Total** | **$ 66,429** | **$ 67,505** | **-2%** | **100%** | **100%** |

Revenues decreased 2% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. The decrease in revenues was primarily due to decreases in revenues from CardioGenesis cardiac laser therapy, JOTEC, and BioGlue products, partially offset by increases in revenues from preservation services and On-X products. Excluding the effects for foreign exchange, revenues decreased 1% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. A detailed discussion of the changes in product revenues and preservation services revenues for the three months ended March 31, 2020 is presented below.

***Products***

Revenues from products decreased 4% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. The decrease was primarily due to decreases in revenues from CardioGenesis cardiac laser therapy, JOTEC, and BioGlue products, partially offset by an increase in revenues from On-X products. A detailed discussion of the changes in product revenues for BioGlue, JOTEC, On-X, PhotoFix, PerClot, NEXUS, and CardioGenesis cardiac laser therapy is presented below.

Sales of certain products through our direct sales force and distributors across Europe and various other countries are denominated in a variety of currencies including Euros, British Pounds, Polish Zlotys, Swiss Francs, Brazilian Reals, and Canadian Dollars, with a concentration denominated in Euros. Each of which is subject to exchange rate fluctuations. For the three months ended March 31, 2020 as compared to the three months ended March 31, 2019, the U.S. Dollar strengthened in comparison to major currencies, resulting in revenue decreases when these foreign currency denominated transactions were translated into U.S. Dollars. Future changes in these exchange rates could have a material, adverse effect on our revenues denominated in these currencies. Additionally, our sales to many distributors around the world are denominated in U.S. Dollars, and although these sales are not directly impacted by currency exchange rates, we believe that some of our distributors may delay or reduce purchases of products in U.S. Dollars depending on the relative price of these goods in their local currencies.

*BioGlue*

BioGlue is used as an adjunct to standard methods of achieving hemostasis (such as sutures and staples) in adult patients in open surgical repair of large vessels (such as aorta, femoral, and carotid arteries).

Revenues from the sales of BioGlue decreased 3% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. This decrease was primary due to a 2% decrease in volume of millimeters sold, which decreased revenues by 2%, and the effect of foreign exchange rates, which decreased revenues by 1%. Excluding the effects for foreign exchange, revenues decreased 2% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019.

On a constant currency basis, revenues from sales of BioGlue decreased in the three months ended March 31, 2020 compared to the three months ended March 31, 2019 in North America markets and the European Economic Area, the Middle East, and Africa (collectively, "EMEA"). This decrease was partially offset by growth in the Latin America market and, to a lesser extent, growth in the Asia Pacific market. The North American and EMEA markets were impacted by a decrease in volume of units sold in the three months ended March 31, 2020 as compared to the three months ended March 31, 2019 primarily due to the delay in surgical procedures due to the COVID-19 pandemic. The increase in Latin America market was primarily due to further penetration into the Brazilian market since we began direct sales in the second quarter of 2019 as well as a change in distributor buying patterns during the first quarter of 2020.

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 49% and 53% of total BioGlue revenues for the three months ended March 31, 2020 and 2019 respectively.

*JOTEC*

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

JOTEC revenues decreased 4% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019.

JOTEC revenues, excluding original equipment manufacturing ("OEM"), decreased 4% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. This decrease was primarily due to a decrease in average sales prices, which decreased revenues by 3%, and by the effect of foreign exchange rates, which decreased revenues by 3%, partially offset by a 15% increase in volume of units sold, which increased revenues by 2%. Excluding the effects for foreign exchange, revenues were flat for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. JOTEC OEM sales accounted for less than 1% of product revenues for both the three months ended March 31, 2020 and 2019.

On a constant currency basis, revenues for JOTEC, excluding OEM, were flat in the three months ended March 31, 2020 compared to the three months ended March 31, 2019. Revenues decreased in EMEA primarily in direct markets due to the delay in surgical procedures due to the COVID-19 pandemic, offset by an increase in Asia Pacific due to growth in distributor markets.

*On-X*

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

On-X product revenues increased 4% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019.

On-X product revenues, excluding OEM, increased 4% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. This increase was primarily due to an increase in average sales prices, which increased revenues by 2%, and a 1% increase in volume of units sold, which increased revenues by 2%. Excluding the effects for foreign exchange, On-X revenues, excluding OEM, increased 4% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019.

On a constant currency basis, On-X revenues, excluding OEM, increased in the three months ended March 31, 2020 compared to the three months ended March 31, 2019 primarily in North America, Latin America, and, to a lesser extent, in EMEA as a result of increases in market share, partially offset by a decrease in Asia Pacific due to the delay in surgical procedures due to the COVID-19 pandemic. On-X OEM sales accounted for less than 1% of product revenues for both the three months ended March 31, 2020 and 2019.

*PhotoFix*

PhotoFix revenues increased 43% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. This increase was primarily due to a 26% increase in units sold, which increased revenues by 42%, and an increase in average sales prices, which increased revenues 1%.

The increase in units sold for the three months ended March 31, 2020 was primarily due to an increase in the number of implanting physicians compared to the three months ended March 31, 2019, as this product continues to penetrate domestic and European markets. Additional increases in unit shipments for the three months ended March 31, 2020 were from the introduction of a larger size PhotoFix patch in the second quarter of 2019.

*PerClot*

Revenues from the sale of PerClot decreased 18% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. The decrease in the three months ended March 31, 2020 was primarily due to a change in average sales prices, which decreased revenues by 9%, a 26% decrease in the volume of grams sold, which decreased revenues by 8%, and the effect of foreign exchange rates, which decreased revenues by 1%.

The change in average selling prices for the three months ended March 31, 2020 occurred in direct markets due to price reductions to certain customers in EMEA as a result of pricing pressures from competitive products. The decrease in volume for the three months ended March 31, 2020 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, and we anticipate PMA submission to the FDA in the second half of 2020.

*NEXUS*

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

NEXUS revenues for the three months ended March 31, 2020 were $200,000 resulting from sales in EMEA with no corresponding sales in the three months ended March 31, 2019.

*CardioGenesis Cardiac Laser Therapy*

Revenues from our CardioGenesis cardiac laser therapy product line historically consist primarily of sales of handpieces and, in certain periods, the sale of laser consoles. During the three months ended March 31, 2020, we did not have a supply of handpieces as our manufacturer of handpieces is unable to supply them until the FDA approves our supplier’s change in manufacturing location, pending our supplier’s resolution of several observations the FDA raised during a manufacturing site change inspection. We do not believe these observations relate to quality or safety. We will not have any handpieces available to ship until our supplier resolves these issues with the FDA. We currently anticipate resumption of supply during the second half of 2020.

Revenues from cardiac laser therapy decreased 94% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019 as a result of this handpiece supply issue.

Cardiac laser therapy is generally used adjunctively with cardiac bypass surgery by a limited number of physicians who perform these procedures, which usage patterns can cause period over period revenue fluctuations.

***Preservation Services***

Preservation services include revenues from the preservation of cardiac and vascular tissues. Revenues from preservation services increased 5% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019.

We continue to evaluate modifications to our tissue processing procedures in an effort to improve tissue processing throughput, reduce costs, and maintain quality across our tissue processing business. Preservation services revenues, particularly revenues for certain high-demand cardiac tissues, can vary from quarter to quarter and year to year due to a variety of factors including: quantity and type of incoming tissues, yields of tissue through the preservation process, timing of receipt of donor information, timing of the release of tissues for implant, demand for certain tissue types due to the number and type of procedures being performed, and pressures from competing products or services. See further discussion below of specific items affecting cardiac and vascular preservation services revenues for the three months ended March 31, 2020.

*Cardiac Preservation Services*

Our cardiac valves are primarily used in cardiac replacement and reconstruction surgeries, including the Ross procedure, for patients with endocarditis or congenital heart defects. Our cardiac tissues are primarily distributed in domestic markets.

Revenues from cardiac preservation services, consisting of revenues from the distribution of heart valves and cardiac patch tissues, increased 12% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. This increase during the three months ended March 31, 2020 was primarily due to a 14% increase in unit shipments of cardiac tissues, which increased revenues by 13%, partially offset by a decrease in average service fees, which decreased revenues by 1%.

The increase in cardiac volume for the three months ended March 31, 2020 was primarily due to an increase in the volume of cardiac valve shipments and, to a lesser extent, cardiac patch shipments.

*Vascular Preservation Services*

The majority of our vascular preservation services revenues are related to shipments of saphenous veins, which are mainly used in peripheral vascular reconstruction surgeries to avoid limb amputations. Competition with synthetic product alternatives and the availability of tissues for processing are key factors affecting revenue volume that can fluctuate from quarter to quarter. Our vascular tissues are primarily distributed in domestic markets.

Revenues from vascular preservation services decreased 2% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. This decrease was due to a change in average service fees, which decreased revenues by 1%, and a 4% decrease in vascular tissue shipments, which decreased revenues by 1%.

The change in average service fees for the three months ended March 31, 2020 was primarily driven by fee differences due to physical characteristics of vascular tissues, the routine negotiation of pricing contracts with certain customers, and competitive pricing pressures. The decrease in shipments of vascular tissues for the three months ended March 31, 2020 was primarily due to decreases in femoral vein and artery shipments, partially offset by increases in saphenous vein and aortoiliac shipments.

**Cost of Products and Preservation Services**

***Cost of Products***

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| Cost of products | $ 13,040 | $ 13,826 |

Cost of products decreased 6% for three months ended March 31, 2020, as compared to the three months ended March 31, 2019. Cost of products for the three months ended March 31, 2020 and 2019 included costs related to JOTEC, On-X, BioGlue, PhotoFix, PerClot and CardioGenesis cardiac laser therapy products. Cost of products for the three months ended March 31, 2020 also included costs related to NEXUS which we began distributing in the fourth quarter of 2019.

The decrease in cost of products for the three months ended March 31, 2020 was primarily due to a decrease in shipments.

***Cost of Preservation Services***

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| Cost of preservation services | $ 9,218 | $ 9,406 |

Cost of preservation services decreased 2% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services decreased in the three months ended March 31, 2020 primarily due to an increase in the unit shipments of lower cost tissue as a percentage of overall tissue as well as a decrease in overall unit costs.

***Gross Margin***

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| Gross margin | $ 44,171 | $ 44,273 |
| Gross margin as a percentage of total revenues | 66% | 66% |

Gross margin remained flat for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019, due to increases in revenues in preservation services and a reduction of costs in products and preservation services, offset by reduction of revenue from products. Gross margin as a percentage of total revenues remained flat for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019.

**Operating Expenses**

***General, Administrative, and Marketing Expenses***

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| General, administrative, and marketing expenses | $ 39,002 | $ 36,520 |
| General, administrative, and marketing expenses as a percentage of total revenues | 59% | 54% |

General, administrative, and marketing expenses increased 7% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. The increases in general, administrative, and marketing expenses for the three months ended March 31, 2020 were primarily due to higher expenses to support our employee headcount, offset by decreased business development and integration expenses, as well as decreased travel expenses from reduced and cancelled travel due to the COVID-19 pandemic.

***Research and Development Expenses***

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| Research and development expenses | $ 6,356 | $ 5,548 |
| Research and development expenses as a percentage of total revenues | 10% | 8% |

Research and development expenses increased 15% for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. Research and development spending in the three months ended March 31, 2020 was primarily focused on clinical work to gain regulatory approval for On-X products, and to a lesser extent, to gain regulatory approval for JOTEC products. Research and development spending in the three months ended March 31, 2019 was primarily focused on clinical work regarding JOTEC and On-X products and our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S.

**Interest Expense**

Interest expense was $3.4 million for the three months ended March 31, 2020, as compared to $3.9 million for the three months ended March 31, 2019. Interest expense in the three months ended March 31, 2020 and 2019 included interest on debt and uncertain tax positions.

**Other Expense, Net**

Other expense, net was $3.7 million for the three months ended March 31, 2020, as compared to $77,000 for the three months ended March 31, 2019. Other expense primarily includes the realized and unrealized effects of foreign currency gains and losses.

**Earnings**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| Loss before income taxes | $ (8,135) | $ (1,650) |
| Income tax benefit | (1,470) | (1,353) |
| **Net loss** | **$ (6,665)** | **$ (297)** |
| Diluted loss per common share | **$ (0.18)** | **$ (0.01)** |
| Diluted weighted-average common shares outstanding | **37,390** | **36,778** |

We experienced a loss before income taxes for the three months ended March 31, 2020 and 2019. The loss before income taxes for the three months ended March 31, 2020 was primarily due to the effect of foreign currency gains and losses and a decrease in operating income.

Our effective income tax rate was a benefit of 18% and 82% for the three months ended March 31, 2020 and 2019, respectively. The change in the tax rate for the three months ended March 31, 2020 is primarily due to a change in pre-tax book income for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019, as well as a reduction in the excess tax benefit related to stock compensation.

The income tax rate for the three months ended March 31, 2020 was impacted by excess tax benefit deductions related to stock compensation, which increased income tax benefits by approximately $250,000. These factors were partially offset by unfavorable impacts of non-deductible operating expenses and executive compensation expenses.

The income tax rate for the three months ended March 31, 2019 was impacted by excess tax benefit deductions related to stock compensation, research and development tax credit, and losses in high rate jurisdictions. These factors were partially offset by impacts of non-deductible operating expenses and executive compensation expenses.

In response to the COVID-19 pandemic, the US government enacted the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”) on March 27, 2020. The CARES Act provides various forms of relief and assistance to US businesses. The Company recorded a reduction to income taxes payable and deferred tax assets of approximately $1.3 million for the anticipated change to the 2019 Section 163(j) interest expense deduction limitation. The Company will continue to analyze the impacts of the CARES Act as interpretations are published.

Net loss and diluted loss per common share increased for the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. The increase for the three months ended March 31, 2020 was primarily due to an increase in loss before income taxes and by an income tax benefit, as discussed above.

**Seasonality**

We believe the demand for BioGlue and On-X products is seasonal, with a decline in demand generally occurring in the third quarter followed by stronger demand in the fourth quarter. We believe that this trend may be due to the summer holiday season in Europe and the U.S. We believe the seasonality for On-X products may be obscured as the On-X products have not fully penetrated many markets.

We believe the demand for JOTEC products is seasonal, with a decline in demand generally occurring in the third quarter due to the summer holiday season in Europe. However, the nature of any seasonal trends may be obscured due to integration activities in 2018 and 2019 subsequent to the JOTEC Acquisition including the implementation of our distributor-to-direct strategy and our European sales force realignment.

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

We are uncertain whether the demand for PhotoFix is seasonal, as this product has not fully penetrated many markets and, therefore, the nature of any seasonal trends may not yet be obvious.

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

Demand for our vascular preservation services is seasonal, with lowest demand generally occurring in the fourth quarter. We believe this trend for vascular preservation services is primarily due to fewer vascular surgeries being scheduled during the winter holiday months.

As a result of the uncertain impact of the COVID-19 pandemic and the resulting shifts of timing in revenue, our historically observable seasonality of revenues may be obscured in 2020.

**Liquidity and Capital Resources**

***Net Working Capital***

As of March 31, 2020 net working capital (current assets of $214.1 million less current liabilities of $43.7 million) was $170.4 million, with a current ratio (current assets divided by current liabilities) of 5 to 1, compared to net working capital of $142.2 million and a ratio of 4 to 1 at December 31, 2019.

***Overall Liquidity and Capital Resources***

Our primary cash requirements for the three months ended March 31, 2020 were for general working capital needs, interest and principal payments under our debt agreement, capital expenditures for facilities and equipment, and repurchases of stock to cover tax withholdings. 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 Credit Agreement (described in "Significant Sources and Uses of Liquidity" section below), expenditures for clinical trials, research and development expenditures, general working capital needs, capital expenditures, and other corporate purposes and may include cash to fund business development activities including obligations in the Endospan agreements. These items may have a significant effect on our future cash flows during the next twelve months. Subject to the terms of our Credit Agreement, we may seek additional borrowing capacity or financing, pursuant to our current or any future shelf registration statement, for general corporate purposes or to fund other future cash requirements. If we undertake any further significant business development activity, we may need to finance such activities by obtaining additional debt financing or using a registration statement to sell 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 $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.

In March 2020 as a precautionary measure to increase cash and maintain maximum financial flexibility during the current uncertainty in global markets resulting from the COVID-19 pandemic, we borrowed the entire amount available under our $30.0 million Revolving Credit Facility at an aggregate interest rate of 5.20%. Under the terms of the Credit Agreement at the time of borrowing and as of March 31, 2020, because the principal amount of loans outstanding under the Revolving Credit Facility was in excess of 25% of the entire amount of the Revolving Credit Facility on the last day of the

fiscal quarter ending March 31, 2020, the Credit Agreement required us to comply with a maximum first lien net leverage ratio of 5.25x bank EBITDA as of the end of such fiscal quarter and any subsequent fiscal quarter if the principal amount of the loans remains in excess of such threshold as of the last day of such fiscal quarter. A breach of the 5.25x leverage ratio would become an event of default only to the extent that this leverage level occurs when the Revolving Credit Facility balance exceeds 25%, or $7.5 million, at the end of a test period. The outstanding principal of the Revolving Credit Facility must be repaid on or before December 2022, unless extended further.

On April 29, 2020 we entered into an amendment to our Credit Agreement. As part of the amendment we obtained a waiver of our maximum first lien net leverage ratio covenant through the end of 2020. In addition, the amendment to our Credit Agreement provides that EBITDA, for covenant testing purposes, in each quarter of 2020 will be deemed equal to a fixed value, equal to our bank covenant EBITDA in the fourth quarter of 2019, when our first lien net leverage was 3.4x. As a result of these changes, we are subject to a new minimum liquidity covenant and restrictions on certain payments, including cash dividends. We are required to maintain a minimum liquidity of at least $12.0 million as of the last day of any month in 2020, and as of the last day of any quarter through the third quarter of 2021 when our Revolving Credit Facility is drawn in excess of 25% (or $7.5 million) of the amount available as of the last day of any fiscal quarter during that period. Beginning in 2021, if we repay borrowings under our Revolving Credit Facility to 25% or less, no financial maintenance covenants, including the minimum liquidity covenant and the maximum first lien net leverage ratio covenant, are applicable.

While we have reduced spending on R&D and clinical research projects for the remainder of 2020, we nonetheless expect to incur expenses for clinical research work to gain regulatory approvals for new products or indications, including JOTEC, On-X, PerClot, and BioGlue products, and to incur expenses for research and development for new products.

We also expect to fund two additional $5.0 million tranches when they become due after completion of certain clinical trial milestones in connection with the Endospan Loan.

We believe utilization of net operating loss carryforwards from our acquisitions of JOTEC, On-X, Hemosphere, Inc., and Cardiogenesis Corporation will not have a material impact on income taxes for the 2020 tax year.

We expect to benefit from various aspects of the CARES Act including the deferment of a portion of the 2020 employer’s portion of social security tax into 2021 and 2022, and a decrease in the amount of interest expense limitation in 2019 and 2020.

As of March 31, 2020 approximately 21% of our cash and cash equivalents were held in foreign jurisdictions.

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

Net cash provided by operating activities was $2.6 million for the three months ended March 31, 2020, as compared to net cash provided by operating activities of $1.2 million for the three months ended March 31, 2019.

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 changes in operating assets and liabilities from the prior year end. For the three months ended March 31, 2020 these non-cash items included $4.9 million in depreciation and amortization expenses and $2.6 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, 2020 these changes included unfavorable adjustments of $2.9 million increase in inventory balances and deferred preservation costs, and $2.5 million due to timing differences between recording accounts payable, accrued expenses, and other liabilities and the payment of cash, partially offset by $3.6 million due to the timing differences between recording receivables and the receipt of cash.

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

Net cash used in investing activities was $2.9 million for the three months ended March 31, 2020, as compared to $1.4 million for the three months ended March 31, 2019 primarily due to capital expenditures in both years.

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

Net cash provided by financing activities was $28.5 million for the three months ended March 31, 2020, as compared to net cash used in financing activities of $1.2 million for the three months ended March 31, 2019. The current year cash

provided by financing activities was primarily due to $30.0 million cash proceeds resulting from the borrowing on the Revolving Credit Facility described in the "Significant Sources and Uses of Liquidity" section above.

**Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements.

**Scheduled Contractual Obligations and Future Payments**

Scheduled contractual obligations and the related future payments as of March 31, 2020 were as follows (in thousands):

| | Total | Remainder of 2020 | 2021 | 2022 | 2023 | 2024 | Thereafter |
|---|---|---|---|---|---|---|---|
| Long-Term Debt Obligations | $ 252,418 | $ 2,076 | 2,767 | 32,767 | 2,767 | 211,835 | $ 206 |
| Interest Payments | 51,525 | 8,961 | 11,794 | 11,678 | 10,012 | 9,078 | 2 |
| Research Obligations | 27,082 | 6,404 | 8,536 | 7,495 | 4,195 | 452 | -- |
| Operating Leases | 24,961 | 4,833 | 6,289 | 3,834 | 2,547 | 2,539 | 4,919 |
| Contingent Payments | 14,000 | 5,500 | 6,500 | 2,000 | -- | -- | -- |
| Purchase Commitments | 13,833 | 10,922 | 2,673 | 163 | 29 | 24 | 22 |
| Finance leases | 6,331 | 519 | 642 | 598 | 597 | 595 | 3,380 |
| **Total contractual obligations** | **$ 390,150** | **$ 39,215** | **$ 39,201** | **$ 58,535** | **$ 20,147** | **$ 224,523** | **$ 8,529** |

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

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

Our operating and finance lease obligations result from the lease of land and buildings that comprise our corporate headquarters and our various manufacturing facilities, leases related to additional manufacturing, office, and warehouse space, leases on Company vehicles, and leases on a variety of office equipment and other equipment. The operating and finance lease obligations in this schedule are based on actual payments which includes both interest and lease liability. The contingent payments obligation includes two additional $5.0 million tranches under the Endospan Loan that we are required, subject to certain conditions, to advance to Endospan upon receipt of certification that certain approvals and clinical trial milestones have been achieved. The contingent payments obligation also includes payments that we may make if certain U.S. regulatory approvals and certain commercial milestones are achieved related to our transaction with Starch Medical, Inc. ("SMI") for PerClot and other licensed technologies.

Our purchase commitments include obligations from agreements with suppliers, one of which is the minimum purchase requirements for PerClot under a distribution agreement with SMI. Pursuant to the terms of the distribution agreement, we may terminate that agreement, including the minimum purchase requirements set forth in the agreement for various reasons, one of which is if we obtain FDA approval for PerClot. These minimum purchases are included in the table above through 2021, based on the assumption that we will not terminate the distribution agreement before receiving FDA approval for PerClot. However, if we do not obtain FDA approval for PerClot and/or we choose not to terminate the distribution agreement, we may have minimum purchase obligations of up to $1.75 million per year through the end of the contract term in 2025.

The schedule of contractual obligations above excludes (i) obligations for estimated liability claims unless they are due as a result of a settlement agreement or other contractual obligation, as no assessments have been made for specific litigation, and (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be $4.0 million, as no specific assessments have been made by any taxing authorities.

**Capital Expenditures**

Capital expenditures were $2.5 million and $1.2 million for the three months ended March 31, 2020 and 2019, respectively. Capital expenditures in the three months ended March 31, 2020 were primarily related to the routine purchases

of manufacturing and tissue processing equipment, leasehold improvements needed to support our business, computer software, and computer and office equipment.

**Risks and Uncertainties**

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

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

**Interest Rate Risk**

Our interest income and interest expense are sensitive to changes in the general level of U.S. interest rates. In this regard, changes in U.S. interest rates affect the interest earned on our cash and cash equivalents of $63.4 million as of March 31, 2020 and interest paid on the outstanding balances, if any, of our variable rate Revolving Credit Facility and 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, 2020, affecting our cash and cash equivalents, restricted cash and securities, 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, JOTEC, and NEXUS revenues are denominated in Euros, British Pounds, Swiss Francs, Polish Zlotys, Canadian Dollars, and Brazilian Reals, and a portion of our general, administrative, and marketing expenses are denominated in Euros, British Pounds, Swiss Francs, Polish Zlotys, Canadian Dollars, Brazilian Reals, and Singapore Dollars. These foreign currency transactions are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the U.S. Dollar equivalent of net income from transactions conducted in other currencies. As a result, revenues and expenses could fluctuate related to a change in exchange rates.

**Item 4. Controls and Procedures.**

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

Our management, including our President and CEO and our Executive Vice President of Finance, Chief Operating Officer, and CFO, does not expect that our Disclosure Controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within CryoLife have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Our Disclosure Controls have been designed to provide reasonable assurance of achieving their objectives.

Our management utilizes the criteria set forth in “Internal Control-Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our Disclosure Controls over financial reporting. Based upon the most recent Disclosure Controls evaluation conducted by management with the participation of the CEO and CFO, as of March 31, 2020, the CEO and CFO have concluded that our Disclosure

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

**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**

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

An outbreak of respiratory illness caused by a novel coronavirus named "2019-nCoV" (the "COVID -19") has resulted in millions of infections and continues to spread worldwide. On March 11, 2020, the World Health Organization ("WHO") declared the COVID-19 outbreak a "pandemic." In response, governments worldwide have undertaken significant efforts to contain COVID-19 and slow its spread, including various "shelter-in-place" and "stay-at-home" orders. In addition, hospitals and other healthcare providers have had to refocus their care on the surge of the COVID-19 cases and have postponed elective and non-emergent procedures, restricted access to these facilities, and in some cases re-allocated scarce resources to their critically ill patients. These efforts have impacted and could continue to impact our business activities, including the following activities:

- Our product sales. We have experienced an impact on revenues in the three months ending March 31, 2020 due to the COVID-19 pandemic, and we anticipate our second quarter 2020 revenues will be more severely impacted for our products and tissue preservation services, including BioGlue, JOTEC, and On-X. We expect negative impacts on the second and third quarters of 2020, and negative impacts on future quarters might also occur.
- Our business operations. We have implemented specific protocols to minimize exposure to COVID-19 among all of our employees, including those working at our three primary manufacturing facilities. In addition, we have implemented remote work arrangements for employees we deem able to do so and have significantly restricted business travel to non-essential travel only. There can be no guarantee, however, that these arrangements will prevent COVID-19 from spreading among our employees, including members of our key personnel, adversely impacting our business operations, or that these arrangements will not create additional risks, such a cyber security, productivity, internal controls, or employee attrition risks. Although we have not experienced a significant supply

chain interruption to date, such an interruption could occur. In addition, the availability of tissue for processing could decrease as the pandemic persists.

- Our management of our indebtedness. As a precautionary measure to increase cash and maintain maximum financial flexibility during the COVID-19 pandemic, we borrowed the entire amount available under our $30.0 million Revolving Credit Facility, increasing the level of our indebtedness and our repayment obligations. We have also reevaluated the need for and timing of certain expenses and have taken pre-emptive steps to reduce spending. However, there can be no guarantee that these precautionary measures will provide us with all the liquidity we need going forward, particularly if the COVID-19 pandemic continues for an extended period of time, grows in severity or has impacts on our supply chain or operations that we do not anticipate.
- Our R&D and clinical research projects. We have reduced spending on R&D and clinical research projects. These reductions could adversely impact future revenue, and additional reductions in spending might be required, further impacting future revenue. In addition, our ability to conduct our ongoing R&D and clinical research projects in markets that are affected by COVID-19 has been and could continue to be adversely impacted.

If COVID-19 continues to spread, if efforts to contain COVID-19 continue or are unsuccessful as intended, or if COVID-19 spreads among our employees or impacts our supply chain, it could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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

On December 1, 2017 we acquired JOTEC AG, a Swiss entity that we converted to JOTEC GmbH and subsequently merged with our Swiss acquisition entity, Jolly Buyer Acquisition GmbH ("JOTEC"), and its subsidiaries (the "JOTEC Acquisition") for $169.1 million in cash and 2,682,754 shares of CryoLife common stock with a value of $53.1 million on the date of closing, for a total purchase price of approximately $222.2 million, including debt and cash acquired on the date of closing. We paid part of the cash portion of the purchase price using available cash on hand and financed the remainder of the cash portion of the purchase price and related expenses and refinanced our then existing approximately $69.0 million term loan, with a new $255.0 million senior secured credit facility, consisting of a $225.0 million secured term loan facility and a $30.0 million 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 to sell JOTEC products, including in the markets in which JOTEC is already direct;
- Our ability to foster cross-selling opportunities between the CryoLife and JOTEC product portfolios;
- Our ability to bring JOTEC products to the U.S. market;
- Our ability to harness the JOTEC new product pipeline and R&D capabilities to drive long-term growth, including our ability to obtain Conformité Européene Mark product certification ("CE Mark") for pipeline products;
- Our ability to drive gross margin expansion;
- Our ability to compete effectively;
- Our ability to carry, service, and manage significantly more debt and repayment obligations; and
- Our ability to manage the unforeseen risks and uncertainties related to JOTEC's business, including any related to intellectual property rights.

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

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

Our current and future levels of indebtedness could:

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

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

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

- Incur or guarantee additional debt;
- Deviate from a minimum liquidity of at least $12.0 million as of the last day of any month in 2020, and as of the last day of any quarter through the third quarter of 2021 when our Revolving Credit Facility is drawn in excess of 25% (or $7.5 million) of the amount available as of the last day of any fiscal quarter during that period;
- Pay dividends on or make distributions in respect of our share capital, including repurchasing or redeeming capital stock or make other restricted payments, including restricted junior payments;
- Enter into agreements that restrict our subsidiaries' ability to pay dividends to us, repay debt owed to us or our subsidiaries, or make loans or advances to us or our other subsidiaries;
- Comply with certain financial ratios set forth in the agreement;
- Enter into any transaction or merger or consolidation, liquidation, winding-up, or dissolution; convey, sell, lease, exchange, transfer or otherwise dispose of all or any part of our business, assets or property; or sell, assign, or otherwise dispose of any capital stock of any subsidiary;
- Create liens on certain assets;
  Enter into certain transactions with our affiliates;
- Enter into certain rate swap transactions, basis swaps, credit derivative transactions, and other similar transactions, whether relating to interest rates, commodities, investments, securities, currencies, or any other relevant measure, or transactions of any kind subject to any form of master purchase agreement governed by the International Swaps and Derivatives Association, Inc., any International Foreign Exchange Master Agreement, or any other master agreement;
- Amend, supplement, waive, or otherwise modify our organizational documents or the organizational documents of a subsidiary in a manner that would be materially adverse to the interests of the lenders, or change or amend the terms of documentation regarding junior financing in a manner that would be materially adverse to the interests of the lenders;
- Change our, or permit a subsidiary to change its, fiscal year without notice to the administrative agent under the agreement;
- Enter into agreements which restrict our ability to incur liens;
- Engage in any line of business substantially different from that in which we are currently engaged; and
- Make certain investments, including strategic acquisitions or joint ventures.

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

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

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

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

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

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

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

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

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

Tissue preservation services are a significant source of our revenues, accounting for 30% and 28% of revenues in the three months ended March 31, 2020 and 2019, 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.

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

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

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

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

BioGlue® Surgical Adhesive ("BioGlue") is a significant source of our revenues, accounting for 26% of revenues in the three months ended March 31, 2020 and 2019. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

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

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

JOTEC is a significant source of our revenues, accounting for 23% and 24% of revenues in the three months ended March 31, 2020 and 2019, 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 meet demand for JOTEC products as we seek to expand our business globally;
- Our ability to compete effectively with our major competitors, as they may have advantages over us in terms of cost structure, supply chain, pricing, sales force footprint, and brand recognition;

- Our ability to develop innovative and in-demand products in the aortic surgery space;
- Our ability to contend with enhanced regulatory requirements and enforcement activities; and
- Our ability to maintain a productive working relationship with our Works Council in Germany.

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

On-X is a significant source of our revenues, accounting for 18% and 17% of revenues in the three months ended March 31, 2020 and 2019, respectively. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

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

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

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

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

Further, on May 25, 2017, the European Union adopted a new Medical Device Regulation (MDR 2017/745) ("MDR"). Although MDR was originally scheduled to become effective on May 26, 2020, due to the COVID-19 pandemic, on April 23, 2020, the European Union enacted legislation postponing the full MDR implementation by one year until May 26, 2021. Upon implementation, among other changes, MDR will place 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, on November 22, 2016, our Notified Body for the On-X product line temporarily suspended the CE Mark for the On-X ascending aortic prosthesis ("AAP"), which has now returned to the market in the EEA. Further, in anticipation of MDR, Notified Bodies have declined to review routine submissions unless they are submitted in accordance with MDR, and they may continue to do so despite the potential postponement of MDR implementation. Our inability to timely adapt to these new requirements of our Notified Bodies could adversely impact our clearances and approvals, which could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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

On September 11, 2019, we entered into various agreements with Endospan, Ltd. ("Endospan"), an Israeli medical device manufacturer (the "Endospan Transaction"). The Endospan Transaction included an exclusive distribution agreement for NEXUS stent graft system ("NEXUS") in certain countries in Europe for a fixed distribution fee of $9.0 million; a loan agreement ("Endospan Loan") for a secured loan from CryoLife to Endospan in an amount up to $15.0 million, funded over three tranches of $5.0 million each upon the completion of certain milestones (the first tranche of which was paid in September 2019); and a security purchase option agreement providing CryoLife the option to purchase all the then outstanding securities of Endospan from Endospan's existing securityholders for a price between $350.0 million and $450.0 million before or upon FDA approval of NEXUS, for which option CryoLife paid to Endospan $1.0 million.

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

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

Many of these factors are outside of our control and any one of them could result in increased costs, decreased revenues, and diversion of management's time and energy, which could materially, adversely impact our business, financial condition, profitability, and cash flows. These benefits may not be achieved within the anticipated time frame or at all. Any of these factors could negatively impact our earnings per share and negatively impact the price of our common stock.

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

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

Our technologies, products, or services could infringe patents or other rights owned by others, or others could infringe our patents. If we become involved in a patent dispute, the costs of the dispute could be expensive, and if we were to lose or decide to settle the dispute, the amounts or effects of the settlement or award by a tribunal could be costly.

We also have obtained licenses from third parties for certain patents and patent application rights. 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 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 during the second half of 2020. There is no guarantee, however, that we will obtain FDA approval when anticipated or at all. The estimated timing of regulatory approval for PerClot is based on factors beyond our control, including but not limited to, unforeseen scheduling difficulties and unfavorable results at various stages in the PMA application process. We may also decide to delay or terminate our pursuit of U.S. regulatory approval for PerClot at any time due to changing conditions at CryoLife, in the marketplace, or in the economy in general.

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

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

In October 2014 the FDA convened an advisory committee meeting to consider the FDA's recommendation to re-classify more than minimally manipulated ("MMM") allograft heart valves from an unclassified medical device to a Class III medical device. The class of allograft heart valves potentially covered by this recommendation 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. In December 2019, we learned that the FDA is preparing to issue a proposed rule for reclassification of MMM allograft heart valves as Class III medical devices, which would be subject to a comment period before publication of a final rule. Upon publication of a final rule, should the CryoValve SGPV be determined to be MMM, we expect to have approximately thirty months to submit a PMA application, after which the FDA will determine if, and for how long, we may continue to provide these tissues to customers during review of the PMA application. To date, the FDA has not issued a final rule for reclassification of 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, and if there are delays in obtaining the PMA, if we are unsuccessful in obtaining the PMA, or if the costs associated with these activities are significant, 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 product development and commercialization of new and next-generation products and services focused on aortic repair;
- *New Indications* – Drive growth through new regulatory approvals and expanded indications for our existing products and services to increase the size of our addressable U.S. or international markets;

- *Global Expansion* – Drive growth by entering new international markets, establishing new international direct sales territories, and developing our commercial infrastructure in new markets, including emerging markets, China and Brazil; and
- *Business Development* – Drive growth by selectively pursuing acquisitions, licensing, and distribution opportunities that are aligned to our objectives and complement our existing products, services, and infrastructure. Examples include our acquisitions of JOTEC and On-X and our distribution agreement and purchase option for NEXUS. To the extent that we identify, develop, or acquire non-core products or applications, we may dispose of these assets or pursue licensing or distribution agreements with third-party partners for development or commercialization.

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

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

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

We are currently engaged in several clinical trials and post-market clinical studies for our products, including our PROACT Xa clinical trial to determine if patients with an On-X mechanical aortic valve can be maintained safely and effectively on apixaban (Eliquis®) rather than on warfarin, and we also have begun efforts to initiate future U.S. clinical trials for certain JOTEC products. Each of these trials or studies is subject to the risks outlined herein.

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

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

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

If we are unable to successfully complete the development of a product, service, or application, or if we determine for financial, technical, competitive, or other reasons not to complete development or obtain regulatory approval or clearance of any product, service, or application, particularly in instances when we have expended significant capital, this could materially, adversely affect our revenues, financial condition, profitability, and cash flows. Research and development efforts are time consuming and expensive, and we cannot be certain that these efforts will lead to commercially successful products or services. Even the successful commercialization of a new product or service in the medical industry can be characterized by slow growth and high costs associated with marketing, under-utilized production capacity, and continuing research and development and education costs. The introduction of new products or services may require significant physician training and years of clinical evidence derived from follow-up studies on human patients in order to gain acceptance in the medical community.

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

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

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

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

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

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

The materials and supplies used in our product manufacturing and our tissue processing are subject to stringent quality standards and requirements, and many of these materials and supplies are subject to significant regulatory oversight and action. If materials or supplies used in our processes fail to meet these standards and requirements or are subject to recall or other quality action, an outcome could be the rejection or recall of our products or tissues and/or the immediate expense of the costs of the manufacturing or preservation. In addition, if these materials and supplies or changes to them do not receive regulatory approval or are recalled, if the related suppliers and/or their facilities are shut down temporarily or permanently, whether by government order, natural disaster, or other reason, or if the related suppliers are otherwise unable or unwilling to supply us, there may not be sufficient materials or supplies available for purchase to allow us to manufacture our products or process tissues. In addition, we rely on contract manufacturers to manufacture some of our products or to provide additional manufacturing capacity for other products. If these contract manufacturers fail to meet our quality standards and requirements or if they are unable or unwilling to supply the products, we may not be able to meet demand for these products. Any of these occurrences or actions could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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

Some of the materials, supplies, and services that are key components of our product manufacturing or our tissue processing, as well as some of our products, are sourced from single- or sole-source suppliers. As a result, our ability to negotiate favorable terms with those suppliers may be limited, and if those suppliers experience operational, financial, quality, or regulatory difficulties, or if those suppliers and/or their facilities refuse to supply us or cease operations temporarily or permanently, we could be forced to cease product manufacturing or tissue processing until the suppliers resume operations, until alternative suppliers could be identified and qualified, or permanently if the suppliers do not resume operations and no alternative suppliers could be identified and qualified. We could also be forced to purchase alternative materials, supplies, or services with unfavorable terms due to diminished bargaining power.

As an example of these risks, we will not have a supply of handpieces for cardiac laser therapy until the FDA approves our supplier’s change in manufacturing location, pending our supplier’s resolution of several observations the FDA raised during a manufacturing site change inspection. We do not believe these observations relate to quality or safety. We currently anticipate resumption of supply during the second half of 2020.

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

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

Some of our products, including our On-X products in the U.S., are sterilized using ethylene oxide (“EtO”). Although we have a small-scale EtO facility in Austin, Texas, we rely primarily on large-scale EtO facilities to sterilize our products. In addition, some of our suppliers use, or rely upon third parties to use, EtO to sterilize some of our product components. Concerns about the release of EtO into the environment at unsafe levels have led to various regulatory enforcement activities

against EtO facilities, including closures and temporary closures. For example, in February 2019, the Illinois Environmental Protection Agency issued an order to stop Sterigenics from using EtO at its Willowbrook, Illinois facility; Sterigenics subsequently announced that the facility would not reopen. The number of EtO facilities in the U.S. is limited, and any permanent or temporary closures or disruption to their operations could delay, impede, or prevent our ability to commercialize our products, which could materially, adversely affect our revenues, financial condition, profitability, and cash flows. In addition, any regulatory enforcement activities against us for our use of EtO could result in financial, legal, business, and reputational harm to us.

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

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

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

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

Several of our competitors enjoy competitive advantages over us, including:

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

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

***We are dependent on our key personnel.***

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

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

The December 2017 tax reform legislation known as H.R. 1, commonly referred to as the "Tax Cuts and Jobs Act" ("the Tax Act"), made significant changes to U.S. federal income tax law. In response, the U.S. Treasury Department issued multiple significant proposed regulation packages to further interpret certain provisions of the Tax Act. As of March 31, 2020, certain significant proposed regulation packages have not yet been finalized. It is possible that when released in final form, these regulation 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 products, materials, and supplies, including donated tissue used in preservation services;
- Our pricing strategy with respect to different product lines;
- Strategic actions by us, such as acquisitions of businesses, products, or technologies;
- Unanticipated costs and expenses;
- Effects of domestic and foreign economic conditions and exchange rates on our industry and/or customers;
- The divestiture or discontinuation of a product line or other revenue generating activity;
- The relocation and integration of manufacturing operations and other strategic restructuring;
- Regulatory actions that may necessitate recalls of our products or warning letters that negatively affect the markets for our products;
- Failure of government and private health plans to adequately and timely reimburse the users of our products or changes in reimbursement policies;
- Costs incurred by us in connection with the termination of contractual and other relationships, including distributorships;
- Our ability to collect outstanding accounts receivable in selected countries outside of the U.S.;
- The expiration or utilization of deferred tax assets such as net operating loss carryforwards;
- Market reception of our new or improved product offerings; and
- The loss of any significant customer, especially in regard to any product that has a limited customer base.

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

***Significant disruptions of information technology systems or breaches of information security systems 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 systems 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 security breaches, service interruptions, or data loss from inadvertent or intentional actions by our employees or vendors. Our information technology and information security systems and records 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 expertise and motives (including, but not limited to, financial crime, industrial espionage, and market manipulation).

As an example of these risks, on November 1, 2019, we were notified that we had become a victim of a business e-mail compromise. During the fourth quarter of 2019, a company email account was compromised by a third-party impersonator and a payment intended for one of our U.S. vendors in the amount of $2.6 million was fraudulently re-directed into an individual bank account controlled by this third-party impersonator. The impersonator had taken a number of steps to deceive our employees and reduce the likelihood of detection. Our cyber-insurance covered all but a de minimis amount of the unrecovered losses from this compromise.

While we have invested, and continue to invest, significantly in our information technology and information security systems, there can be no assurance that our efforts will prevent further security breaches, service interruptions, or data losses. We have only limited cyber-insurance coverage that does not cover all possible events, and this insurance is subject to deductibles and coverage limitations. In addition, we may not be able to maintain this insurance. We thus do not have insurance coverage for all possible claims that could be raised and, for those where we do have coverage, those claims could exceed the limits of our coverage. Any security breaches, service interruptions, or data losses could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business, and reputational harm to us or allow third parties to gain material, inside information that they may use to trade in our securities.

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

The European Union’s General Data Protection Regulation (“GDPR”) took effect in May 2018. GDPR includes significant new requirements for companies that receive or process the personal data of residents of the European Union (including company employees), which increase our operating costs and require significant management time and energy. GDPR also includes significant penalties for noncompliance. Although our personal data practices, policies, and procedures are intended to comply with GDPR, there can be no assurance that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws, or that one or more of our employees or agents will not disregard the rules we have established. Any GDPR related government enforcement activities may be costly to comply with, result in negative publicity, and subject us to significant penalties, any of which could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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

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

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

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

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

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

Our business and future growth depend on the continued use of our products for specific approved uses. Generally, unless the products are approved or cleared by the FDA for the alternative uses, the FDA contends that we may not make claims about the safety or effectiveness of our products, or promote them, for such uses. Such limitations present a risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales, marketing, and/or support activities, though designed to comply with all FDA requirements, constitute the promotion of our products for an unapproved use in violation of the Federal Food, Drug, and Cosmetic Act. We also face the risk that the FDA or other governmental authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs, and other activities. Investigations concerning the promotion of unapproved uses and related issues are typically expensive, disruptive, and burdensome and generate negative publicity. If our promotional activities are found to be in violation of the law, we may face significant fines and penalties and may be required to substantially change our sales, promotion, grant, and educational activities. There is also a possibility that we could be enjoined from selling some or all of our products for any unapproved use. In addition, as a result of an enforcement action against us or our executive officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid.

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

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

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

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

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

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

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

***Healthcare policy changes 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, third-party payors, and elected office holders and candidates 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. We cannot predict what further reform proposals, if any, will be adopted, when they will be adopted, or what impact they may have on us. Any changes that lower reimbursement for our products or reduce medical procedure volumes, however, could adversely affect our business and profitability.

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

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

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

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

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

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

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

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

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

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

## Risks Related to Ownership of our Common Stock

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

In December 2015 our Board of Directors discontinued dividend payments on our common stock for the foreseeable future. If we do not pay cash dividends, our shareholders may receive a return on their investment in our common stock only if the market price of our common stock has increased when they sell shares of our common stock that they own. Future dividends, if any, will be authorized by our Board of Directors and declared by us based upon a variety of factors deemed relevant by our directors, including, among other things, our financial condition, liquidity, earnings projections, and business prospects. In addition, restrictions in our credit facility limit our ability to pay future dividends. We can provide no assurance of our ability to pay cash dividends in the future.

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

We are subject to the Florida affiliated transactions statute, which generally requires approval by the disinterested directors or supermajority approval by shareholders for “affiliated transactions” between a corporation and an “interested stockholder.” Additionally, our organizational documents contain provisions that restrict persons who may call shareholder meetings, allow the issuance of blank-check preferred stock without the vote of shareholders, and allow the Board of Directors to fill vacancies and fix the number of directors. These provisions of Florida law and our articles of incorporation and bylaws could prevent attempts by shareholders to remove current management, prohibit or delay mergers or other changes of control transactions, and discourage attempts by other companies to acquire us, even if such a transaction would be beneficial to our shareholders.

**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, 2020 of equity securities that are registered by us pursuant to Section 12 of the Securities Exchange Act of 1934:

| Period | Total Number of Common Shares and Common Stock Units Purchased | Average Price Paid per Common Share | Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs | Dollar Value of Common Shares That May Yet Be Purchased Under the Plans or Programs |
|---|---|---|---|---|
| 01/01/20 - 01/31/20 | -- | $ -- | -- | $ -- |
| 02/01/20 - 02/29/20 | 25,209 | 26.20 | -- | -- |
| 03/01/20 - 03/31/20 | 44,670 | 23.54 | -- | -- |
| **Total** | **69,879** | 24.50 | -- | |

The common shares purchased during the quarter ended March 31, 2020 were tendered to us in payment of taxes on stock compensation and were not part of a publicly announced plan or program.

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

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

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

The exhibit index can be found below.

| Exhibit Number | Description |
|---|---|
| 3.1 | Amended and Restated Articles of Incorporation of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed July 31, 2019.) |
| 3.2 | Amended and Restated By-Laws of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed February 22, 2018.) |
| 4.1 | Form of Certificate for our Common Stock. (Incorporated herein by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.) |
| 31.1* | Certification by J. Patrick Mackin pursuant to section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002. |
| 32** | Certification Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant To Section 906 Of The Sarbanes-Oxley Act Of 2002. |
| 101.INS* | XBRL Instance Document |
| 101.SCH* | XBRL Taxonomy Extension Schema Document |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document |

* Filed herewith.

** Furnished herewith.

† Portions of the exhibit have been omitted.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CRYOLIFE, INC.
(Registrant)

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

May 1, 2020
---
DATE

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

**Exhibit 31.1**

CERTIFICATIONS

I, James Patrick Mackin, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 1, 2020

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

**Exhibit 31.2**

I, David Ashley Lee, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 1, 2020

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

**Exhibit 32**

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

In connection with the Quarterly Report of CryoLife, Inc. (the "Company") on Form 10-Q for the quarter ending March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of James Patrick Mackin, the Chairman, President, and Chief Executive Officer of the Company, and David Ashley Lee, the Executive Vice President, Chief Operating Officer, and Chief Financial Officer of the Company, hereby certifies, pursuant to and for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

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

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

/s/ J. PATRICK MACKIN
J. PATRICK MACKIN
Chairman, President, and
Chief Executive Officer
May 1, 2020

/s/ D. ASHLEY LEE
D. ASHLEY LEE
Executive Vice President,
Chief Operating Officer, and Chief Financial Officer
May1, 2020