

CRYOLIFE INC  
Form 10-Q  
October 31, 2017

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-Q**

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

For the quarterly period ended **September 30, 2017**

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 1-13165

**CRYOLIFE, INC.**

(Exact name of registrant as specified in its charter)

**Florida**  
(State or other jurisdiction of  
incorporation or organization)

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

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

**30144**  
(Zip Code)

**(770) 419-3355**

(Registrant's telephone number, including area code)

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

Yes

No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

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Yes

No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

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

Yes

No

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

**Class**

**Outstanding at October 23, 2017**

Common Stock

33,457,552 Shares

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

|   | <b>Three Months Ended<br/>September 30,</b> |               | <b>Nine Months Ended<br/>September 30,</b> |                |
|---|---|---------------|--|----------------|
|   | <b>2017</b>                                 | <b>2016</b>   | <b>2017</b>                                | <b>2016</b>    |
|   | <b>(Unaudited)</b>                          |               | <b>(Unaudited)</b>                         |                |
| <b>Revenues:</b>  |   |               |  |                |
| Products  | \$ 27,029                                   | \$ 28,004     | \$ 84,519                                  | \$ 85,067      |
| Preservation services                                   | 16,970                                      | 17,248        | 52,357                                     | 50,284         |
| <b>Total revenues</b>                                   | <b>43,999</b>                               | <b>45,252</b> | <b>136,876</b>                             | <b>135,351</b> |
| <b>Cost of products and preservation services:</b>      |   |               |  |                |
| Products  | 6,220                                       | 6,598         | 21,196                                     | 21,299         |
| Preservation services                                   | 7,917                                       | 8,872         | 23,401                                     | 26,348         |
| <b>Total cost of products and preservation services</b> | <b>14,137</b>                               | <b>15,470</b> | <b>44,597</b>                              | <b>47,647</b>  |
| <b>Gross margin</b>                                     | <b>29,862</b>                               | <b>29,782</b> | <b>92,279</b>                              | <b>87,704</b>  |
| <b>Operating expenses:</b>                              |   |               |  |                |
| General, administrative, and marketing                  | 24,756                                      | 20,592        | 71,016                                     | 69,302         |
| Research and development                                | 4,277                                       | 3,714         | 13,098                                     | 9,602          |
| <b>Total operating expenses</b>                         | <b>29,033</b>                               | <b>24,306</b> | <b>84,114</b>                              | <b>78,904</b>  |
| Gain from sale of business components                   | --  | --            | --   | (7,915)        |
| <b>Operating income</b>                                 | <b>829</b>                                  | <b>5,476</b>  | <b>8,165</b>                               | <b>16,715</b>  |
| Interest expense  | 851   | 742           | 2,486                                      | 2,256          |
| Interest income   | (64)  | (18)          | (159)                                      | (48)           |
| Other expense (income), net                             | 21  | 21            | (70)                                       | (146)          |

|  |                 |                 |                 |                 |
|--|-----------------|-----------------|-----------------|-----------------|
| <b>Income before income taxes</b>                  | <b>21</b>       | <b>4,731</b>    | <b>5,908</b>    | <b>14,653</b>   |
| Income tax (benefit) expense                       | (1,304)         | 1,738           | (803)           | 6,772           |
| <b>Net income</b>                                  | <b>\$ 1,325</b> | <b>\$ 2,993</b> | <b>\$ 6,711</b> | <b>\$ 7,881</b> |
| <b>Income per common share:</b>                    |                 |                 |                 |                 |
| <b>Basic</b>                                       | <b>\$ 0.04</b>  | <b>\$ 0.09</b>  | <b>\$ 0.20</b>  | <b>\$ 0.24</b>  |
| <b>Diluted</b>                                     | <b>\$ 0.04</b>  | <b>\$ 0.09</b>  | <b>\$ 0.19</b>  | <b>\$ 0.24</b>  |
| <b>Weighted-average common shares outstanding:</b> |                 |                 |                 |                 |
| Basic  | 32,887          | 32,151          | 32,665          | 31,731          |
| Diluted  | 34,057          | 33,165          | 33,851          | 32,568          |
| <b>Net income</b>                                  | <b>\$ 1,325</b> | <b>\$ 2,993</b> | <b>\$ 6,711</b> | <b>\$ 7,881</b> |
| Other comprehensive income (loss)                  | 217             | (31)            | 582             | (459)           |
| <b>Comprehensive income</b>                        | <b>\$ 1,542</b> | <b>\$ 2,962</b> | <b>\$ 7,293</b> | <b>\$ 7,422</b> |

See accompanying Notes to Summary Consolidated Financial Statements.

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

|  | <b>September 30,<br/>2017</b> | <b>December 31,<br/>2016</b> |
|--|-------------------------------|------------------------------|
|  | (Unaudited)                   |                              |
| <b>ASSETS</b>                              |                               |                              |
| <b>Current assets:</b>                     |                               |                              |
| Cash and cash equivalents                  | \$ 54,242                     | \$ 56,642                    |
| Restricted securities                      | 771                           | 699                          |
| Receivables, net                           | 33,659                        | 30,096                       |
| Inventories                                | 27,763                        | 26,293                       |
| Deferred preservation costs                | 35,008                        | 30,688                       |
| Prepaid expenses and other                 | 4,142                         | 2,815                        |
| <b>Total current assets</b>                | <b>155,585</b>                | <b>147,233</b>               |
| Property and equipment, net                | 20,607                        | 18,502                       |
| Goodwill                                   | 78,294                        | 78,294                       |
| Patents, net                               | 827                           | 1,008                        |
| Trademarks and other intangibles, net      | 62,454                        | 65,633                       |
| Deferred income taxes                      | 1,190                         | --                           |
| Investment in company owned life insurance | 4,360                         | 2,991                        |
| Other                                      | 2,823                         | 2,479                        |
| <b>Total assets</b>                        | <b>\$ 326,140</b>             | <b>\$ 316,140</b>            |
| <b>LIABILITIES AND SHAREHOLDERS EQUITY</b> |                               |                              |
| <b>Current liabilities:</b>                |                               |                              |
| Accounts payable                           | \$ 5,066                      | \$ 5,744                     |
| Accrued expenses and other                 | 17,813                        | 19,796                       |
| Current portion of long-term debt          | 3,234                         | 4,562                        |
| <b>Total current liabilities</b>           | <b>26,113</b>                 | <b>30,102</b>                |
| Long-term debt                             | 64,835                        | 67,012                       |
| Deferred compensation liability            | 3,753                         | 2,600                        |
| Deferred rent obligations                  | 2,982                         | 2,355                        |
| Other                                      | 5,101                         | 5,088                        |
| <b>Total liabilities</b>                   | <b>102,784</b>                | <b>107,157</b>               |

**Commitments and contingencies****Shareholders equity:**

|  |                   |                   |
|--|-------------------|-------------------|
| Preferred stock  | --                | --                |
| Common stock (issued shares of 34,844 in 2017 and 34,230 in 2016)  | 348               | 342               |
| Additional paid-in capital   | 194,958           | 187,061           |
| Retained earnings  | 40,616            | 34,143            |
| Accumulated other comprehensive income (loss)                      | 153               | (429)             |
| Treasury stock at cost (shares of 1,387 in 2017 and 1,356 in 2016) | (12,719)          | (12,134)          |
| <b>Total shareholders equity</b>                                   | <b>223,356</b>    | <b>208,983</b>    |
| <b>Total liabilities and shareholders equity</b>                   | <b>\$ 326,140</b> | <b>\$ 316,140</b> |

See accompanying Notes to Summary Consolidated Financial Statements.

**CRYOLIFE, INC. AND SUBSIDIARIES**

**SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(IN THOUSANDS)**

|  | <b>Nine Months Ended<br/>September 30,</b> |                 |
|--|--|-----------------|
|  | <b>2017</b>                                | <b>2016</b>     |
|  | (Unaudited)                                |                 |
| <b>Net cash flows from operating activities:</b>                           |  |                 |
| Net income   | \$ 6,711                                   | \$ 7,881        |
| Adjustments to reconcile net income to net cash from operating activities: |  |                 |
| Gain from sale of business components                                      | --   | (7,915)         |
| Depreciation and amortization  | 6,683                                      | 6,248           |
| Non-cash compensation  | 5,652                                      | 4,617           |
| Other non-cash adjustments to income                                       | 879  | 5,595           |
| Changes in operating assets and liabilities:                               |  |                 |
| Receivables  | (4,303)                                    | 3,729           |
| Inventories and deferred preservation costs                                | (6,901)                                    | (5,739)         |
| Prepaid expenses and other assets  | (3,040)                                    | (46)            |
| Accounts payable, accrued expenses, and other liabilities                  | (855)                                      | 304             |
| <b>Net cash flows provided by operating activities</b>                     | <b>4,826</b>                               | <b>14,674</b>   |
| <b>Net cash flows from investing activities:</b>                           |  |                 |
| Acquisition of On-X, net of cash acquired                                  | --   | (91,152)        |
| Acquisition of PhotoFix technology   | --   | (1,226)         |
| Proceeds from sale of business components                                  | 740  | 19,795          |
| Decrease in restricted cash  | --   | 5,000           |
| Capital expenditures   | (5,384)                                    | (3,511)         |
| Other  | 5  | (12)            |
| <b>Net cash flows used in investing activities</b>                         | <b>(4,639)</b>                             | <b>(71,106)</b> |
| <b>Net cash flows from financing activities:</b>                           |  |                 |
| Proceeds from issuance of term loan  | --   | 75,000          |
| Repayment of term loan   | (3,916)                                    | (1,406)         |
| Payment of debt issuance costs   | --   | (2,289)         |
| Proceeds from exercise of stock options and issuance of common stock       | 2,599                                      | 2,116           |
| Redemption and repurchase of stock to cover tax withholdings               | (1,600)                                    | (599)           |
| Other  | (3)  | 571             |

|  |                  |                  |
|--|------------------|------------------|
| <b>Net cash flows (used in) provided by financing activities</b> | <b>(2,920)</b>   | <b>73,393</b>    |
| Effect of exchange rate changes on cash                          | 333              | (418)            |
| <b>(Decrease) increase in cash and cash equivalents</b>          | <b>(2,400)</b>   | <b>16,543</b>    |
| Cash and cash equivalents, beginning of period                   | 56,642           | 37,588           |
| <b>Cash and cash equivalents, end of period</b>                  | <b>\$ 54,242</b> | <b>\$ 54,131</b> |

See accompanying Notes to Summary Consolidated Financial Statements.



**CRYOLIFE, INC. AND SUBSIDIARIES****NOTES TO SUMMARY CONSOLIDATED FINANCIAL STATEMENTS****(UNAUDITED)****1. Basis of Presentation***Overview*

The accompanying summary consolidated financial statements include the accounts of CryoLife, Inc. and 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, 2016 has been derived from audited financial statements. The accompanying unaudited summary consolidated financial statements as of, and for the three and nine months ended, September 30, 2017 and 2016 have been prepared in accordance with (i) accounting principles generally accepted in the U.S. for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U.S. Securities and Exchange Commission (SEC). Accordingly, such statements do not include all of the information and disclosures required by accounting principles generally accepted in the U.S. for a complete presentation of financial statements. In the opinion of management, all adjustments (including those of a normal, recurring nature) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017. These summary consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in CryoLife's Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on February 16, 2017.

*Change in Accounting for Employee Share-Based Payments*

As of January 1, 2017 we made an entity-wide accounting policy election in accordance with ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, (ASU 2016-09) to change our accounting policy to account for stock compensation forfeitures in the period awards are forfeited rather than estimating the effect of forfeitures. We elected to make this accounting policy change to simplify the accounting for share-based compensation and believe this method provides a more accurate reflection of periodic share-based compensation cost from the grant date forward. We used the modified retrospective transition method to record a net \$238,000 cumulative-effect adjustment decrease to retained earnings for the accounting policy change, which included a \$379,000 increase to additional paid-in capital and a \$141,000 increase in deferred tax assets.

Additionally, as of January 1, 2017 and in accordance with the guidance in ASU 2016-09, we made a change to account for excess tax benefits and deficiencies resulting from the settlement or vesting of share-based awards in income tax expense on our Summary Consolidated Statement of Operations and Comprehensive Income instead of accounting for these effects through additional paid in-capital on our Summary Consolidated Balance Sheets. We applied this amendment prospectively and prior periods have not been adjusted.

**2. Financial Instruments**

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

| <b>September 30, 2017</b> | <b>Level 1</b> | <b>Level 2</b> | <b>Level 3</b> | <b>Total</b> |
|---------------------------|----------------|----------------|----------------|--------------|
|---------------------------|----------------|----------------|----------------|--------------|

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|                               |           |              |           |           |           |              |
|-------------------------------|-----------|--------------|-----------|-----------|-----------|--------------|
| <b>Cash equivalents:</b>      |           |              |           |           |           |              |
| Money market funds            | \$        | 371          | \$        | --        | \$        | 371          |
| <b>Restricted securities:</b> |           |              |           |           |           |              |
| Money market funds            |           | 771          |           | --        |           | 771          |
| <b>Total assets</b>           | <b>\$</b> | <b>1,142</b> | <b>\$</b> | <b>--</b> | <b>\$</b> | <b>1,142</b> |

|                               |           |                |           |                |           |                |           |              |
|-------------------------------|-----------|----------------|-----------|----------------|-----------|----------------|-----------|--------------|
| <b>December 31, 2016</b>      |           | <b>Level 1</b> |           | <b>Level 2</b> |           | <b>Level 3</b> |           | <b>Total</b> |
| <b>Cash equivalents:</b>      |           |                |           |                |           |                |           |              |
| Money market funds            | \$        | 3,466          | \$        | --             | \$        | --             | \$        | 3,466        |
| <b>Restricted securities:</b> |           |                |           |                |           |                |           |              |
| Money market funds            |           | 699            |           | --             |           | --             |           | 699          |
| <b>Total assets</b>           | <b>\$</b> | <b>4,165</b>   | <b>\$</b> | <b>--</b>      | <b>\$</b> | <b>--</b>      | <b>\$</b> | <b>4,165</b> |

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

### 3. Cash Equivalents and Restricted Securities

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

| <b>September 30, 2017</b>     | <b>Cost Basis</b> | <b>Unrealized<br/>Holding<br/>Gains</b> | <b>Estimated<br/>Market<br/>Value</b> |
|-------------------------------|-------------------|---|---------------------------------------|
| <b>Cash equivalents:</b>      |                   |   |                                       |
| Money market funds            | \$ 371            | \$ --                                   | \$ 371                                |
| <b>Restricted securities:</b> |                   |   |                                       |
| Money market funds            | 771               | --                                      | 771                                   |

| <b>December 31, 2016</b>      | <b>Cost Basis</b> | <b>Unrealized<br/>Holding<br/>Gains</b> | <b>Estimated<br/>Market<br/>Value</b> |
|-------------------------------|-------------------|---|---------------------------------------|
| <b>Cash equivalents:</b>      |                   |   |                                       |
| Money market funds            | \$ 3,466          | \$ --                                   | \$ 3,466                              |
| <b>Restricted securities:</b> |                   |   |                                       |
| Money market funds            | 699               | --                                      | 699                                   |

As of September 30, 2017 and December 31, 2016 \$771,000 and \$699,000, respectively, of our money market funds were designated as short-term restricted securities due to a contractual commitment to hold the securities as pledged collateral relating primarily to international tax obligations.

There were no gross realized gains or losses on cash equivalents in the three and nine months ended September 30, 2017 and 2016. As of September 30, 2017 \$235,000 of our restricted securities had a maturity date within three months and \$536,000 had a maturity date between three months and one year. As of December 31, 2016 \$490,000 of our restricted securities had a maturity date within three months and \$209,000 had a maturity date between three months and one year.

### 4. Acquisition of On-X Life Technologies

#### *Overview*

On December 22, 2015 we entered into an agreement and plan of merger to acquire On-X Life Technologies Holdings, Inc. ( On-X ), an Austin, Texas-based, privately held mechanical heart valve company, for approximately \$130.0 million, subject to certain adjustments. The transaction closed on January 20, 2016, and On-X is being operated as a wholly owned subsidiary of CryoLife.

The On-X catalogue of products includes the On-X prosthetic aortic and mitral heart valves and the On-X ascending aortic prosthesis. On-X also distributes CarbonAid CO<sub>2</sub> diffusion catheters and manufactures Chord-X ePTFE sutures for mitral chordal replacement. On-X also generates revenue from pyrolytic carbon coating products produced for other medical device manufacturers. We believe that the On-X products fit well into our product portfolio of medical devices for cardiac surgery and that we are capitalizing on the significant opportunity for CryoLife's sales team to leverage their strong relationships with cardiac surgeons to introduce and to expand utilization of the On-X valves in

the U.S. and internationally.

***Accounting for the Transaction***

The purchase price of the On-X transaction totaled \$128.2 million, consisting of cash of \$93.6 million and 3,703,699 shares of CryoLife common stock, with a value of \$34.6 million as determined on the date of the closing. We recorded an allocation of the \$128.2 million purchase price to On-X's tangible and identifiable intangible assets acquired and liabilities assumed, based on their estimated fair values as of January 20, 2016. Goodwill was recorded based on the amount by which the purchase price exceeded the fair value of the net assets acquired and is not deductible for tax purposes. Goodwill from this transaction has been allocated to our Medical Devices segment.

The purchase price allocation is as follows (in thousands):

|                           |        | <b>Opening<br/>Balance Sheet</b> |
|---------------------------|--------|----------------------------------|
| Cash and cash equivalents | \$     | 2,472                            |
| Receivables               |        | 6,826                            |
| Inventories               |        | 12,889                           |
| Intangible assets         |        | 53,950                           |
| Goodwill                  |        | 68,229                           |
| Other assets              |        | 6,891                            |
| Liabilities assumed       |        | (23,040)                         |
| <br>Total purchase price  | <br>\$ | <br>128,217                      |

We incurred transaction and integration costs of \$7.4 million for the year ended December 31, 2016 related to the acquisition, which include, among other costs, expenses related to the termination of international and domestic distribution agreements. These costs were expensed as incurred and were primarily recorded as general, administrative, and marketing expenses on our Summary Consolidated Statements of Operations and Comprehensive Income.

We paid approximately \$10 million of the purchase price into an escrow account upon closing of the On-X transaction. We are currently in litigation with the representative of the former On-X shareholders concerning the resolution of these escrow funds. We believe that we are entitled to recover the escrow funds and additional damages, but the outcome of litigation is inherently uncertain, and we may not recover any of the escrow funds.

### ***Pro Forma Results***

On-X revenues were \$34.2 million from the date of acquisition through December 31, 2016. Our pro forma results of operations for the years ended December 31, 2016 and 2015, assuming the On-X acquisition had occurred as of January 1, 2015, are presented for comparative purposes below. These amounts are based on available information of the results of operations of On-X prior to the acquisition date and are not necessarily indicative of what the results of operations would have been had the acquisition been completed on January 1, 2015. This unaudited pro forma information does not project operating results post acquisition.

This pro forma information is as follows (in thousands, except per share amounts):

|  | <b>Twelve Months Ended</b> |               |
|--|----------------------------|---------------|
|  | <b>December 31,</b>        |               |
|  | <b>2016</b>                | <b>2015</b>   |
| Total revenues                                       | \$ 182,007                 | \$ 179,266    |
| Net income (loss)                                    | 17,692                     | (4,787)       |
| <br>Pro forma income (loss) per common share - basic | <br>\$ 0.54                | <br>\$ (0.15) |

|  |    |      |    |        |
|--|----|------|----|--------|
| Pro forma income (loss) per common share - diluted   | \$ | 0.53 | \$ | (0.15) |
| Pro forma net income (loss) was calculated using a normalized tax rate of approximately 38%. |    |      |    |        |

## 5. Sale of Business Components

### *Divestiture of the HeRO Graft Product Line*

On February 3, 2016 we sold our Hemodialysis Reliable Outflow Graft ( HeRO<sup>®</sup> Graft ) product line to Merit Medical Systems, Inc. ( Merit ) for \$18.5 million in cash ( HeRO Sale ), of which \$17.8 million was received on the transaction date and the remaining \$740,000 was received in the first quarter of 2017. Under terms of the agreement, Merit acquired the HeRO Graft product line, including worldwide marketing rights, customer relationships, intellectual property, inventory, and certain property and equipment. We continued to manufacture the HeRO Graft under a transition supply agreement until the manufacturing transfer to Merit was completed in the second quarter of 2016. Sales prices under the transition supply agreement were at lower average prices than our previous sales to hospitals at end-user prices. The HeRO Graft product line was included as part of our Medical Devices segment. We recorded a pre-tax gain of approximately \$8.8 million on the HeRO Sale.

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### ***ProCol Distribution Agreement and Divestiture of the ProCol Product Line***

In 2014 we acquired the exclusive worldwide distribution rights to ProCol® Vascular Bioprosthesis ( ProCol ) from Hancock Jaffe Laboratories, Inc. ( Hancock Jaffe ). In accordance with the terms of the agreement, we made payments to Hancock Jaffe totaling \$3.4 million for which we obtained the right to receive a designated amount of ProCol inventory for resale. As of March 18, 2016 we had received \$1.7 million in inventory. The remaining \$1.7 million in prepayments for inventory not yet delivered to us were settled as part of the ProCol Sale, described below.

On March 18, 2016 we sold our ProCol distribution rights and purchase option to LeMaitre Vascular, Inc. ( LeMaitre ) for \$2.0 million in cash ( ProCol Sale ), all of which was received by March 31, 2016. Under the terms of the agreement, LeMaitre acquired the ProCol related assets, including inventory, customer lists, related marketing assets, and our purchase option to acquire ProCol. LeMaitre exercised the option to acquire ProCol from Hancock Jaffe. The ProCol product was included as part of our Medical Devices segment. We recorded a pre-tax loss of approximately \$845,000 on the ProCol Sale.

### ***Disclosure of the HeRO Sale and the ProCol Sale***

Financial Accounting Standards Board ASU 2014-08, *Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity*, ( ASU 2014-08 ) defines the criteria for reporting discontinued operations and requires additional disclosures about discontinued operations. The standard requires that an entity report a disposal as a discontinued operation only if the disposal represents a strategic shift in operations that has a major effect on our operations and financial results.

In the first quarter of 2016 we completed and recorded the HeRO Sale and the ProCol Sale and received cash for these transactions. Therefore, as of March 31, 2016 both transactions met the disposed of by sale criteria under ASU 2014-08.

We evaluated the impact of the HeRO Sale and the ProCol Sale on our business to determine whether these disposals represent a strategic shift that has, or will have, a major effect on our financial position, results of operations, or cash flows. As the HeRO Graft and ProCol product lines combined represented less than 10% of our total revenues for the year ended December 31, 2015 and our total assets as of December 31, 2015, we believe that these transactions did not have a major effect on our operations and financial condition, either individually or in the aggregate, and therefore, we did not disclose these transactions as discontinued operations. The combined net gain from the HeRO Sale and ProCol Sale was therefore reported as gain from sale of business components on our Summary Consolidated Statements of Operations and Comprehensive Income.

## **6. PhotoFix Distribution Agreement and Acquisition**

### ***Overview***

In 2014 we entered into an exclusive supply and distribution agreement with Genesee Biomedical, Inc. ( GBI ) to acquire the distribution rights to PhotoFix™, a bovine pericardial patch stabilized using a dye-mediated photo-fixation process that requires no glutaraldehyde. PhotoFix has received U.S. Food and Drug Administration ( FDA ) 510(k) clearance and is indicated for use in intracardiac repair, including ventricular repair and atrial repair, great vessel repair and suture line buttressing, and pericardial closure. We believe that PhotoFix fits well into our product portfolio of medical devices for cardiac surgery. In January 2015 we received our initial shipments and launched our distribution of PhotoFix.

The agreement between CryoLife and GBI (the GBI Agreement ) had an initial five-year term and was renewable for two one-year periods at our option. Under the terms of the GBI Agreement, we purchased PhotoFix inventory for

resale at an agreed upon transfer price and had the option, which became effective in March 2015, to acquire the PhotoFix product line from GBI.

*Accounting for the Transaction*

On April 13, 2016 we exercised our right to acquire the PhotoFix technology from GBI for approximately \$2.3 million, of which \$1.2 million was paid in cash at closing, approximately \$600,000 was previously provided to GBI as an advance under the distribution agreement, and approximately \$400,000 is payable to GBI within 18 months of signing or earlier, subject to certain conditions. Our allocation of the purchase price to the tangible and identifiable intangible assets acquired, based on their estimated fair values, resulted in the allocation of the majority of the purchase price to amortizable intangible assets. GBI will continue to manufacture PhotoFix until we are able to fully establish manufacturing operations which is expected to occur in 2018.



## 7. Inventories and Deferred Preservation Costs

Inventories at September 30, 2017 and December 31, 2016 are comprised of the following (in thousands):

|                            | September 30,<br>2017 | December 31,<br>2016 |
|----------------------------|-----------------------|----------------------|
| Raw materials and supplies | \$ 11,153             | \$ 9,321             |
| Work-in-process            | 4,028                 | 3,321                |
| Finished goods             | 12,582                | 13,651               |
| Total inventories          | \$ 27,763             | \$ 26,293            |

Deferred preservation costs at September 30, 2017 and December 31, 2016 are comprised of the following (in thousands):

|                                   | September 30,<br>2017 | December 31,<br>2016 |
|-----------------------------------|-----------------------|----------------------|
| Cardiac tissues                   | \$ 17,195             | \$ 15,768            |
| Vascular tissues                  | 17,813                | 14,920               |
| Total deferred preservation costs | \$ 35,008             | \$ 30,688            |

We maintain consignment inventory, included in finished goods inventories, of our On-X heart valves at domestic and foreign hospital locations to facilitate usage. We retain title to this consignment inventory until the valve is implanted, at which time we invoice the hospital. As of September 30, 2017 we had \$5.8 million in consignment inventory, with approximately 85% in domestic locations and 15% in foreign locations. As of December 31, 2016 we had \$4.9 million in consignment inventory with approximately 80% in domestic locations and 20% in foreign locations.

## 8. Goodwill and Other Intangible Assets

### *Indefinite Lived Intangible Assets*

As of September 30, 2017 and December 31, 2016 the carrying values of our indefinite lived intangible assets are as follows (in thousands):

| September 30,<br>2017 | December 31,<br>2016 |
|-----------------------|----------------------|
|-----------------------|----------------------|

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|                                      |    |        |    |        |
|--------------------------------------|----|--------|----|--------|
| Goodwill                             | \$ | 78,294 | \$ | 78,294 |
| Procurement contracts and agreements |    | 2,013  |    | 2,013  |
| Trademarks                           |    | 841    |    | 841    |

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

As of September 30, 2017 and December 31, 2016 our entire goodwill balance is related to our Medical Devices segment and there has been no change from the balance recorded as of December 31, 2016.

**Definite Lived Intangible Assets**

As of September 30, 2017 and December 31, 2016 the gross carrying values, accumulated amortization, and approximate amortization period of our definite lived intangible assets are as follows (in thousands):

|  | <b>Gross Carrying<br/>Value</b> | <b>Accumulated<br/>Amortization</b> | <b>Amortization<br/>Period</b> |
|--|---------------------------------|-------------------------------------|--------------------------------|
| <b>September 30, 2017</b>                          |                                 |                                     |                                |
| Acquired technology                                | \$ 38,478                       | \$ 7,615                            | 11 22 Years                    |
| Patents  | 3,593                           | 2,766                               | 17 Years                       |
| Distribution and manufacturing rights and know-how | 4,059                           | 1,748                               | 11 15 Years                    |
| Customer lists and relationships                   | 29,140                          | 3,190                               | 13 22 Years                    |
| Other  | 1,418                           | 942                                 | 3 Years                        |

|  | <b>Gross<br/>Carrying<br/>Value</b> | <b>Accumulated<br/>Amortization</b> | <b>Amortization<br/>Period</b> |
|--|-------------------------------------|-------------------------------------|--------------------------------|
| <b>December 31, 2016</b>                           |                                     |                                     |                                |
| Acquired technology                                | \$ 38,478                           | \$ 5,956                            | 11 22 Years                    |
| Patents  | 3,710                               | 2,702                               | 17 Years                       |
| Distribution and manufacturing rights and know-how | 4,059                               | 1,532                               | 11 15 Years                    |
| Customer lists and relationships                   | 29,140                              | 2,141                               | 13 22 Years                    |
| Non-compete agreement                              | 381                                 | 381                                 | 10 Years                       |
| Other  | 1,262                               | 531                                 | 3 Years                        |

**Amortization Expense**

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

|                      | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|----------------------|---|-------------|--|-------------|
|                      | <b>2017</b>                                 | <b>2016</b> | <b>2017</b>                                | <b>2016</b> |
| Amortization expense | \$ 1,140                                    | \$ 1,155    | \$ 3,423                                   | \$ 3,273    |

As of September 30, 2017 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

|                      | <b>Remainder<br/>of 2017</b> | <b>2018</b> | <b>2019</b> | <b>2020</b> | <b>2021</b> | <b>2022</b> |
|----------------------|------------------------------|-------------|-------------|-------------|-------------|-------------|
| Amortization expense | \$ 1,140                     | \$ 4,444    | \$ 4,102    | \$ 3,939    | \$ 3,918    | \$ 3,390    |

**9. Income Taxes****Income Tax Expense**

Our income tax rate for the three and nine months ended September 30, 2017 was favorably affected by excess tax benefits, primarily related to the exercise of non-qualified stock options and the vesting of stock awards, as discussed in Note 1 above, which decreased income tax expense by approximately \$1.1 million and \$2.7 million, respectively.

Our effective income tax rate was 37% and 46% for the three and nine months ended September 30, 2016, respectively. Our income tax rate for the three and nine months ended September 30, 2016 was unfavorably impacted by the tax treatment of certain expenses related to the On-X acquisition, which had a larger impact on the tax rate in first quarter of 2016. Our income tax rate for the nine months ended September 30, 2016 was also unfavorably impacted by book/tax basis differences related to the HeRO Sale.

***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, in prior periods, due to operating losses. We acquired significant deferred tax assets, primarily net operating loss carryforwards, from our acquisitions of On-X in 2016,

Hemosphere in 2012, and Cardiogenesis in 2011. We recorded significant deferred tax liabilities in 2016 related to the intangible assets acquired in the On-X acquisition.

As of September 30, 2017 we maintained a total of \$1.8 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and had a net deferred tax asset of \$1.2 million. As of December 31, 2016 we had a total of \$2.2 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax liability of \$7,000.

## 10. Debt

### *Amended Debt Agreement*

In connection with the closing of the On-X acquisition, discussed above in Note 4, on January 20, 2016, CryoLife and certain of our subsidiaries entered into the Third Amended and Restated Credit Agreement ( Amended Debt Agreement ) with Capital One, National Association, who acquired GE Capital's Healthcare Financial Services lending business in late 2015. The designated credit parties are Healthcare Financial Solutions, LLC; Fifth Third Bank; and Citizens Bank, National Association. The Amended Debt Agreement amended and restated our prior credit agreement and provides us with a senior secured credit facility in an aggregate principal amount of \$95 million, which includes a \$75 million term loan and a \$20 million revolving credit facility (including a \$4 million letter of credit sub-facility and a \$3 million swing-line sub-facility). The \$75 million term loan was used to finance, in part, the acquisition of On-X and will mature on January 20, 2021.

CryoLife and our domestic subsidiaries, subject to certain exceptions and exclusions, have guaranteed the obligations of the Amended Debt Agreement. Borrowings under the Amended Debt Agreement are secured by substantially all of CryoLife's, and certain of our subsidiaries', real and personal property.

The loans under the Amended Debt Agreement (other than the swing-line loans) bear interest, at our option, at either a floating rate equal to the base rate, as defined in the Amended Debt Agreement, plus a margin of between 1.75% and 2.75%, depending on our consolidated leverage ratio, or a per annum rate equal to LIBOR plus a margin of between 2.75% and 3.75%, depending on our consolidated leverage ratio. As of September 30, 2017 the aggregate interest rate was approximately 3.99%. Swing-line loans under the Amended Debt Agreement bear interest at a floating rate equal to the base rate plus a margin of between 1.75% and 2.75%, depending on our consolidated leverage ratio. We are obligated to pay an unused commitment fee equal to 0.50% of the un-utilized 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. If and while a payment event of default exists, we are obligated to pay a per annum default rate of interest of 2.00% above the applicable interest rate on the past due principal amount of the loans outstanding. If and while a bankruptcy or insolvency event of default exists, we are obligated to pay a per annum default rate of interest of 2.00% above the applicable interest rate on all loans outstanding.

Interest is due and payable, with respect to base rate loans, on a quarterly basis. Interest is due and payable, with respect to LIBOR loans, on the last day of the applicable interest period, if the interest period is shorter than six months, or on the last day of each three month interval, if the interest period is six months or greater.

The Amended Debt Agreement prohibits us from exceeding a maximum consolidated leverage ratio during the term of the Amended Debt Agreement and requires us to maintain a minimum interest coverage ratio. In addition, the Amended Debt Agreement contains certain customary affirmative and negative covenants, including covenants that limit our ability and the ability of our subsidiaries which are parties to the loan agreement to, among other things, grant liens; incur debt; dispose of assets; make loans and investments; make acquisitions; make certain restricted payments; merge or consolidate; and change our business and accounting or reporting practices, in each case subject to customary exceptions for a credit facility of this size and type. As of October 31, 2017 CryoLife and our

subsidiaries were in compliance with the covenants of the Amended Debt Agreement.

The Amended Debt Agreement includes certain customary events of default that include, among other things, non-payment of principal, interest or fees; inaccuracy of representations and warranties; violation of covenants; cross-default on certain other 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 Amended Debt Agreement immediately due and payable, and may exercise the other rights and remedies provided for under the Amended Debt Agreement and related loan documents.

As of both September 30, 2017 and December 31, 2016 there were no outstanding balances on our revolving credit facility and the remaining availability was \$20.0 million. The short-term and long-term balances of our term loan are as follows (in thousands):

|   | <b>September 30,<br/>2017</b> | <b>December 31,<br/>2016</b> |
|---|-------------------------------|------------------------------|
| Term loan balance                       | \$ 69,678                     | \$ 73,594                    |
| Less unamortized loan origination costs | (1,609)                       | (2,020)                      |
| Net borrowings                          | 68,069                        | 71,574                       |
| Less short-term loan balance            | (3,234)                       | (4,562)                      |
| Long-term loan balance                  | \$ 64,835                     | \$ 67,012                    |

### ***Interest Expense***

Interest expense was \$851,000 and \$2.5 million for the three and nine months ended September 30, 2017, respectively, and \$742,000 and \$2.3 million for the three and nine months ended September 30, 2016, respectively. Interest expense in 2017 and 2016 included interest on debt and uncertain tax positions.

## **11. Commitments and Contingencies**

### ***Liability Claims***

Our estimated unreported loss liability was \$1.6 million as of September 30, 2017 and \$1.5 million as of December 31, 2016. As of September 30, 2017 and December 31, 2016, the related recoverable insurance amounts were \$716,000 and \$626,000, respectively. We accrue our estimate of unreported product and tissue processing liability claims as a component of other long-term liabilities and record the related recoverable insurance amount as a component of other long-term assets, as appropriate. Further analysis indicated that the estimated liability as of September 30, 2017 could have been as high as \$3.0 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. We resumed enrollment into the trial in the fourth quarter of 2016 and, assuming enrollment proceeds as anticipated, we could receive Premarket Approval from the FDA in 2019.

As of September 30, 2017 we had \$1.5 million in prepaid royalties, \$2.7 million in net intangible assets, and \$1.4 million in property and equipment, net on our Summary Consolidated Balance Sheets related to the PerClot product line. If we do not ultimately pursue or receive FDA approval to commercialize PerClot in the U.S., these assets could be materially impaired in future periods.



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## 12. Shareholders Equity

### *Change in Accounting for Employee Share-Based Payments*

As discussed in Note 1 above, as a result of the adoption of ASU 2016-09, we recorded a net \$238,000 cumulative-effect adjustment decrease to retained earnings, which included a \$379,000 increase to additional paid-in capital and a \$141,000 increase in deferred tax assets.

### *Common Shares Issued*

In January 2016 we issued 3,703,699 shares of CryoLife common stock, as part of the consideration for the acquisition of On-X. The stock had a value of \$34.6 million as determined on the date of the closing. See Note 4 for further discussion of the On-X acquisition.

## 13. Stock Compensation

### *Overview*

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

### *Equity Grants*

During the nine months ended September 30, 2017 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 384,000 shares and had an aggregate grant date market value of \$6.3 million. The PSUs granted in 2017 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 2017 is based on attaining specified levels of adjusted EBITDA, adjusted inventory levels, and trade accounts receivable days sales outstanding, each as defined in the PSU grant documents, for the 2017 calendar year. We currently believe that achievement of the performance component is probable, and we reevaluate this likelihood on a quarterly basis.

During the nine months ended September 30, 2016 the Committee authorized awards from approved stock incentive plans of RSUs to certain employees and RSAs and PSUs to certain Company officers, which, including PSUs at target levels, together totaled 478,000 shares of common stock and had an aggregate grant date market value of \$5.3 million. The PSUs granted in 2016 represented the right to receive from 60% to 150% of the target number of shares of common stock. The performance component of PSU awards granted in 2016 was based on attaining specified levels of adjusted EBITDA, adjusted inventory levels, and trade accounts receivable days sales outstanding, each as defined in the PSU grant documents, for the 2016 calendar year. The PSUs granted in 2016 earned 142% of the target number of shares.

The Committee authorized, from approved stock incentive plans, grants of stock options to purchase a total of 260,000 and 387,000 shares to certain Company officers during the nine months ended September 30, 2017 and 2016, respectively. The exercise prices of the options were equal to the closing stock prices on their respective grant dates.

Employees purchased common stock totaling 47,000 and 93,000 shares in the three and nine months ended September 30, 2017, respectively, and 52,000 and 90,000 shares in the three and nine months ended September 30, 2016, respectively, through the ESPP.

**Stock Compensation Expense**

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

|                                 | <b>Three Months Ended<br/>September 30, 2017</b> |                     | <b>Nine Months Ended<br/>September 30, 2017</b> |                     |
|---------------------------------|--|---------------------|---|---------------------|
|                                 | <b>Stock Options</b>                             | <b>ESPP Options</b> | <b>Stock Options</b>                            | <b>ESPP Options</b> |
| Expected life of options        | N/A  | 0.5 Years           | 4.8 Years                                       | 0.5 Years           |
| Expected stock price volatility | N/A  | 0.43                | 0.40  | 0.35                |
| Risk-free interest rate         | N/A  | 1.14%               | 1.87%   | 0.62%               |

|                                 | <b>Three Months Ended<br/>September 30, 2016</b> |                         | <b>Nine Months Ended<br/>September 30, 2016</b> |                         |
|---------------------------------|--|-------------------------|---|-------------------------|
|                                 | <b>Stock<br/>Options</b>                         | <b>ESPP<br/>Options</b> | <b>Stock<br/>Options</b>                        | <b>ESPP<br/>Options</b> |
| Expected life of options        | 4.8 Years  | 0.5 Years               | 4.8 Years                                       | 0.5 Years               |
| Expected stock price volatility | 0.40   | 0.30                    | 0.40  | 0.30                    |
| Risk-free interest rate         | 1.19%  | 0.49%                   | 1.20%   | 0.49%                   |

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

|   | <b>Three Months Ended<br/>September 30,<br/>2017</b> |                 | <b>Nine Months Ended<br/>September 30,<br/>2016</b> |                 |
|---|--|-----------------|---|-----------------|
|   |  |                 |   |                 |
| RSA, PSA, RSU, and PSU expense          | \$ 1,448   | \$ 1,397        | \$ 4,326  | \$ 3,616        |
| Stock option and ESPP option expense    | 519  | 421             | 1,614   | 1,203           |
| <b>Total stock compensation expense</b> | <b>\$ 1,967</b>                                      | <b>\$ 1,818</b> | <b>\$ 5,940</b>                                     | <b>\$ 4,819</b> |

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, PSAs, 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 \$111,000 and \$288,000 in the three and nine months ended September 30, 2017, respectively, and \$70,000 and \$202,000 in the three and nine months ended September 30, 2016, respectively, of the stock compensation expense into our inventory costs and deferred preservation costs.

As of September 30, 2017 we had total unrecognized compensation costs of \$6.8 million related to RSUs, RSAs, and PSUs and \$2.1 million related to unvested stock options. As of September 30, 2017 this expense is expected to be recognized over a weighted-average period of 2.1 years for RSUs, 1.7 years for stock options, 1.3 years for RSAs, and 1.0 years for PSUs.

**14. Income Per Common Share**

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

| <b><u>Basic income per common share</u></b>      | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|--|---|-------------|--|-------------|
|  | <b>2017</b>                                 | <b>2016</b> | <b>2017</b>                                | <b>2016</b> |
| Net income                                       | \$ 1,325                                    | \$ 2,993    | \$ 6,711                                   | \$ 7,881    |
| Net income allocated to participating securities | (22)  | (58)        | (126)                                      | (152)       |
| Net income allocated to common shareholders      | \$ 1,303                                    | \$ 2,935    | \$ 6,585                                   | \$ 7,729    |
| Basic weighted-average common shares outstanding | 32,887                                      | 32,151      | 32,665                                     | 31,731      |
| Basic income per common share                    | \$ 0.04                                     | \$ 0.09     | \$ 0.20                                    | \$ 0.24     |

| <b><u>Diluted income per common share</u></b>            | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|--|---|-------------|--|-------------|
|  | <b>2017</b>                                 | <b>2016</b> | <b>2017</b>                                | <b>2016</b> |
| Net income   | \$ 1,325                                    | \$ 2,993    | \$ 6,711                                   | \$ 7,881    |
| Net income allocated to participating securities         | (22)  | (56)        | (122)                                      | (148)       |
| Net income allocated to common shareholders              | \$ 1,303                                    | \$ 2,937    | \$ 6,589                                   | \$ 7,733    |
| Basic weighted-average common shares outstanding         | 32,887                                      | 32,151      | 32,665                                     | 31,731      |
| Effect of dilutive stock options and awards <sup>a</sup> | 1,170                                       | 1,014       | 1,186                                      | 837         |
| Diluted weighted-average common shares outstanding       | 34,057                                      | 33,165      | 33,851                                     | 32,568      |
| Diluted income per common share                          | \$ 0.04                                     | \$ 0.09     | \$ 0.19                                    | \$ 0.24     |

<sup>a</sup> We excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares because the inclusion of these stock options would be antidilutive to income per common share. Accordingly, stock options to purchase a weighted-average 264,000 and 215,000 shares for the three and nine months ended September 30, 2017, respectively, and 1,000 and 810,000 shares for the three and nine months ended September 30, 2016, respectively, were excluded from the calculation of diluted weighted-average common shares outstanding.

## 15. 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<sup>®</sup> Surgical Adhesive; BioFoam<sup>®</sup> Surgical Matrix; On-X products, since the acquisition of On-X; CardioGenesis cardiac laser therapy; PerClot; PhotoFix; HeRO Graft, through the second quarter of 2016; and ProCol, through the date of the sale of the ProCol product line in the first quarter of 2016. 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):

|  | <b>Three Months Ended<br/>September 30,</b> | <b>Nine Months Ended<br/>September 30,</b> |
|--|---|--|
|--|---|--|

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|   | 2017             | 2016             | 2017             | 2016             |
|---|------------------|------------------|------------------|------------------|
| <b>Revenues:</b>  |                  |                  |                  |                  |
| Medical devices   | \$ 27,029        | \$ 28,004        | \$ 84,519        | \$ 85,067        |
| Preservation services                                   | 16,970           | 17,248           | 52,357           | 50,284           |
| <b>Total revenues</b>                                   | <b>43,999</b>    | <b>45,252</b>    | <b>136,876</b>   | <b>135,351</b>   |
| <b>Cost of products and preservation services:</b>      |                  |                  |                  |                  |
| Medical devices   | 6,220            | 6,598            | 21,196           | 21,299           |
| Preservation services                                   | 7,917            | 8,872            | 23,401           | 26,348           |
| <b>Total cost of products and preservation services</b> | <b>14,137</b>    | <b>15,470</b>    | <b>44,597</b>    | <b>47,647</b>    |
| <b>Gross margin:</b>                                    |                  |                  |                  |                  |
| Medical devices   | 20,809           | 21,406           | 63,323           | 63,768           |
| Preservation services                                   | 9,053            | 8,376            | 28,956           | 23,936           |
| <b>Total gross margin</b>                               | <b>\$ 29,862</b> | <b>\$ 29,782</b> | <b>\$ 92,279</b> | <b>\$ 87,704</b> |

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

|                                     | Three Months Ended<br>September 30, |                  | Nine Months Ended<br>September 30, |                   |
|-------------------------------------|-------------------------------------|------------------|------------------------------------|-------------------|
|                                     | 2017                                | 2016             | 2017                               | 2016              |
| <b>Products:</b>                    |                                     |                  |                                    |                   |
| BioGlue and BioFoam                 | \$ 15,730                           | \$ 15,976        | \$ 48,094                          | \$ 47,479         |
| On-X                                | 8,326                               | 8,890            | 27,048                             | 25,159            |
| CardioGenesis cardiac laser therapy | 1,489                               | 1,653            | 5,130                              | 5,497             |
| PerClot                             | 886                                 | 950              | 2,641                              | 2,983             |
| PhotoFix                            | 598                                 | 535              | 1,606                              | 1,406             |
| HeRO Graft                          | --                                  | --               | --                                 | 2,325             |
| ProCol                              | --                                  | --               | --                                 | 218               |
| <b>Total products</b>               | <b>27,029</b>                       | <b>28,004</b>    | <b>84,519</b>                      | <b>85,067</b>     |
| <b>Preservation services:</b>       |                                     |                  |                                    |                   |
| Cardiac tissue                      | 7,932                               | 8,279            | 23,911                             | 22,255            |
| Vascular tissue                     | 9,038                               | 8,969            | 28,446                             | 28,029            |
| <b>Total preservation services</b>  | <b>16,970</b>                       | <b>17,248</b>    | <b>52,357</b>                      | <b>50,284</b>     |
| <b>Total revenues</b>               | <b>\$ 43,999</b>                    | <b>\$ 45,252</b> | <b>\$ 136,876</b>                  | <b>\$ 135,351</b> |

## 16. JOTEC Acquisition

On October 10, 2017 we announced that we entered into a definitive agreement to acquire JOTEC AG ( JOTEC ). The transaction is expected to close later this year, subject to customary closing conditions. JOTEC is a German-based, privately-held developer of technologically differentiated endovascular stent grafts, and cardiac and vascular surgical grafts, focused on aortic repair. The combination of CryoLife and JOTEC will create a company with a broad and highly competitive product portfolio focused on aortic surgery, and will position us to compete strongly in the important and growing endovascular surgical markets.

Under terms of the definitive agreement, we will acquire JOTEC for a purchase price of \$225 million, subject to certain adjustments, consisting of 75% in cash and 25% in CryoLife common stock issued to JOTEC s shareholders. We expect to finance the transaction and related expenses, as well as refinance our existing approximately \$69 million term loan, with a new \$255 million senior secured credit facility, consisting of a \$225 million institutional term loan B and a \$30 million undrawn revolving credit facility, \$56.25 million in CryoLife common stock as determined on the date of signing of the agreement, and available cash on hand. The senior secured credit facility is fully underwritten by Deutsche Bank, Capital One and Fifth Third Bank and is expected to be syndicated to investors prior to closing of the acquisition.

### 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 current expectations or forecasts of future events. The words could, may, might, will, would, should, pro forma, potential, pending, intend, believe, expect, anticipate, estimate, plan, future, 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. Such forward-looking statements reflect the views of management at the time such statements are made and are subject to a number of risks, uncertainties, estimates, and assumptions, including, without limitation, in addition to those identified in the text surrounding such statements, those identified under Risks and Uncertainties and elsewhere in 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 and/or expectations, are forward-looking statements, including statements about the following:

The market and growth opportunities for BioGlue in China;

The expected decrease in cardiac laser therapy revenues in 2017 relative to 2016 due to a projected decrease in handpiece sales;

The plans, costs, and expected timelines regarding clinical trials to obtain U.S. regulatory approval for PerClot;

The market and growth opportunities for PhotoFix into the U.S.;

The variability of 2017 tissue preservation services revenues 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;

The expected decrease in cost of preservation services in 2017 relative to 2016 as a result of the decrease in the per unit cost of processing tissues that we experienced in 2016;

The potential impact on our income tax rate of certain nondeductible business development costs as determined after the close of the JOTEC acquisition;

The seasonal nature of the demand for our products and preservation services and the related reasons for such seasonality, if any, and our belief that the demand for CardioGenesis is not seasonal;



Our having sufficient cash to meet our current operational liquidity needs and expected operational liquidity needs for at least the next twelve months, our expectations regarding future cash requirements, and the impact that our cash requirements for 2017 may have on our cash flows for 2017;

The potential impact of constraints imposed on us by our lenders under the existing credit facility;

The impact of certain changes in interest rates or exchange rates on our financial position, sales to distributors, profitability, or cash flows;

The potential impact of the combination of CryoLife and JOTEC; and

The impact of certain new accounting pronouncements.

These statements are 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. However, 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 risk factors set forth below under Part II, Item 1A, as well as in Part I, Item 1A of our Form 10-K for the year ended December 31, 2016, and other factors, 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 to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

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## PART I - FINANCIAL INFORMATION

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

#### Overview

CryoLife, Inc. (CryoLife, the Company, we, or us), incorporated in 1984 in Florida, is a leader in manufacturing, processing, and distribution of medical devices and implantable tissues used in cardiac surgical procedures. CryoLife's medical devices include: BioGlue® Surgical Adhesive (BioGlue); BioFoam® Surgical Matrix (BioFoam); On-X Life Technologies Holdings, Inc. (On-X) valves and surgical products; CardioGenesis cardiac laser therapy product line, which includes a laser console system and single-use, fiber-optic handpieces that are used for the treatment of coronary artery disease in patients with severe angina; PerClot®, an absorbable powdered hemostat, which we distribute internationally for Starch Medical, Inc. (SMI); and PhotoFix, a bovine pericardial patch stabilized using a dye-mediated photo-fixation process that requires no glutaraldehyde. The cardiac and vascular human tissues distributed by us include the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch (CryoPatch SG), both of which are processed using our proprietary SynerGraft® technology.

We reported quarterly revenues of \$44.0 million in the three months ended September 30, 2017, a 3% decrease from the quarter ended September 30, 2016. Third quarter revenues were adversely affected by the impact of delayed surgical procedures on our business in Florida and Texas caused by recent hurricanes, which we estimate to be approximately \$1.0 million, and due to the continued delay in obtaining the re-certification of our On-X ascending aortic prosthesis (AAP). Additionally, in connection with the anticipated JOTEC AG (JOTEC) transaction discussed below, we reversed revenues of \$1.1 million related to the estimated buyback of inventory at the end of the contracts for certain distributors in countries in which we anticipate establishing a direct market. In connection with the JOTEC transaction, we spent \$2.8 million on business development expenses in the three months ended September 30, 2017. See the Results of Operations section below for additional analysis of the three and nine months ended September 30, 2017.

#### Recent Events

##### *Acquisition of JOTEC AG*

On October 10, 2017 we announced that we entered into a definitive agreement to acquire JOTEC. JOTEC is a German-based, privately-held developer of technologically differentiated endovascular stent grafts, and cardiac and vascular surgical grafts, focused on aortic repair. Under terms of the definitive agreement, we will acquire JOTEC for a purchase price of \$225 million, subject to certain adjustments, consisting of 75 percent in cash and 25 percent in CryoLife common stock issued to JOTEC's shareholders. We expect to finance the transaction and related expenses, as well as refinance our existing approximately \$69 million term loan, with a new \$255 million senior secured credit facility, consisting of a \$225 million institutional term loan B and a \$30 million undrawn revolving credit facility, \$56.25 million in CryoLife common stock as determined on the date of signing of the agreement, and available cash on hand. The transaction is expected to close later this year, subject to customary closing conditions.

#### 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, 2016. Management believes that the consistent application of these policies enables us to provide users of the financial statements with useful and reliable information about our operating results and financial condition. The summary consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S., which require us to make estimates and assumptions. We did not experience any significant changes during the quarter ended September 30, 2017 in any

of our Critical Accounting Policies from those contained in our Form 10-K for the year ended December 31, 2016.

**New Accounting Pronouncements**

In February 2016 the Financial Accounting Standards Board ( FASB ) amended its Accounting Standards Codification and created a new Topic 842, *Leases*. The final guidance requires lessees to recognize a right-of-use asset and a lease liability for all leases (with the exception of short-term leases) at the commencement date and recognize expenses on their income statements similar to the current Topic 840, *Leases*. It is effective for fiscal years and interim periods beginning after December 15, 2018, and early adoption is permitted. We are evaluating the impact the adoption of this standard will have on our financial position, results of operations, and cash flows.

In May 2014 the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*. Since ASU 2014-09 was issued, several additional ASUs have been issued to clarify various elements of the guidance. These standards provide guidance on recognizing revenue, including a five-step model to determine when revenue recognition is appropriate. The standard requires that an entity recognize revenue to depict the transfer of control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Adoption of the new standard is effective for reporting periods beginning after December 15, 2017. We plan to use the modified retrospective method of adoption. We have completed an initial evaluation of the potential impact from adopting the new standard, including a detailed review of performance obligations for all material revenue streams. Based on this initial evaluation, we do not expect adoption will have a material impact on our financial position, results of operations, or cash flows. Related disclosures will be expanded in line with the requirements of the standard. We will continue our evaluation, including additional revenue streams associated with the proposed acquisition of JOTEC, until our adoption of the new standard.

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

|                                     | <b>Revenues for the<br/>Three Months Ended</b> |                  | <b>Revenues as a Percentage of<br/>Total Revenues for the<br/>Three Months Ended</b> |             |
|-------------------------------------|--|------------------|--|-------------|
|                                     | <b>September 30,</b>                           |                  | <b>September 30,</b>   |             |
|                                     | <b>2017</b>                                    | <b>2016</b>      | <b>2017</b>  | <b>2016</b> |
| <b>Products:</b>                    |  |                  |  |             |
| BioGlue and BioFoam                 | \$ 15,730                                      | \$ 15,976        | 36%  | 35%         |
| On-X                                | 8,326  | 8,890            | 19%  | 20%         |
| CardioGenesis cardiac laser therapy | 1,489  | 1,653            | 3%   | 4%          |
| PerClot                             | 886  | 950              | 2%   | 2%          |
| PhotoFix                            | 598  | 535              | 1%   | 1%          |
| <b>Total products</b>               | <b>27,029</b>                                  | <b>28,004</b>    | <b>61%</b>   | <b>62%</b>  |
| <b>Preservation services:</b>       |  |                  |  |             |
| Cardiac tissue                      | 7,932  | 8,279            | 18%  | 18%         |
| Vascular tissue                     | 9,038  | 8,969            | 21%  | 20%         |
| <b>Total preservation services</b>  | <b>16,970</b>                                  | <b>17,248</b>    | <b>39%</b>   | <b>38%</b>  |
| <b>Total</b>                        | <b>\$ 43,999</b>                               | <b>\$ 45,252</b> | <b>100%</b>  | <b>100%</b> |

|                                     | <b>Revenues for the<br/>Nine Months<br/>Ended</b> |               | <b>Revenues as a Percentage of<br/>Total Revenues for the<br/>Nine Months Ended</b> |             |
|-------------------------------------|---|---------------|---|-------------|
|                                     | <b>September 30,</b>                              |               | <b>September 30,</b>  |             |
|                                     | <b>2017</b>                                       | <b>2016</b>   | <b>2017</b>   | <b>2016</b> |
| <b>Products:</b>                    |   |               |   |             |
| BioGlue and BioFoam                 | \$ 48,094   | \$ 47,479     | 35%   | 35%         |
| On-X                                | 27,048  | 25,159        | 20%   | 19%         |
| CardioGenesis cardiac laser therapy | 5,130   | 5,497         | 4%  | 4%          |
| PerClot                             | 2,641   | 2,983         | 2%  | 2%          |
| PhotoFix                            | 1,606   | 1,406         | 1%  | 1%          |
| HeRO Graft                          | --  | 2,325         | --%   | 2%          |
| ProCol                              | --  | 218           | --%   | --%         |
| <b>Total products</b>               | <b>84,519</b>                                     | <b>85,067</b> | <b>62%</b>  | <b>63%</b>  |

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|                             |            |            |      |      |
|-----------------------------|------------|------------|------|------|
| Preservation services:      |            |            |      |      |
| Cardiac tissue              | 23,911     | 22,255     | 17%  | 16%  |
| Vascular tissue             | 28,446     | 28,029     | 21%  | 21%  |
| Total preservation services | 52,357     | 50,284     | 38%  | 37%  |
| Total                       | \$ 136,876 | \$ 135,351 | 100% | 100% |

Revenues decreased 3% and increased 1% for the three and nine months ended September 30, 2017, respectively, as compared to the three and nine months ended September 30, 2016, respectively. The decrease in revenues for the three months ended September 30, 2017 was primarily due to a decrease in On-X and BioGlue product revenues and preservation services revenues. The increase in revenues for the nine months ended September 30, 2017 was primarily due to an increase in preservation services revenues, and On-X and BioGlue product revenues, partially offset by a decrease in Hemodialysis Reliable Outflow Graft ( HeRO Graft ) revenues following the sale of the product line. A detailed discussion of the changes in product revenues and preservation services revenues for the three and nine months ended September 30, 2017 is presented below.

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## *Products*

Revenues from products decreased 3% and 1% for the three and nine months ended September 30, 2017, respectively, as compared to the three and nine months ended September 30, 2016, respectively. The decrease in revenues for the three months ended September 30, 2017 was primarily due to a decrease in On-X and BioGlue revenues. The decrease in revenues for the nine months ended September 30, 2017 was primary due to a decrease in HeRO Graft revenues following the sale of the product line and a decrease in CardioGenesis cardiac laser therapy revenues, partially offset by an increase in On-X and BioGlue revenues. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; On-X; CardioGenesis cardiac laser therapy; PerClot; PhotoFix; HeRO Graft; and ProCol® Vascular Bioprosthesis ( ProCol ) is presented below.

Our sales of certain products through our direct sales force to U.K. hospitals are denominated in British Pounds, and our sales to German, Austrian, French, and Irish hospitals and certain distributors are denominated in Euros and are, therefore, subject to changes in foreign exchange rates. During 2016 the U.S. Dollar strengthened materially, as compared to the British Pound and Euro and, as a result, our revenues denominated in these currencies decreased less than 1% when translated into U.S. Dollars. The U.S. Dollar remained strong during the nine months ended September 30, 2017. Any further change 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 the strong U.S. Dollar, we believe that some of our distributors may be delaying or reducing purchases of products in U.S. Dollars due to the relative price of these goods in their local currencies.

### *BioGlue and BioFoam*

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, decreased 2% for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016. This decrease was primarily due to a 3% decrease in the volume of milliliters sold, which decreased revenues by 3%, partially offset by the favorable effect of foreign currency exchange, which increased revenues by 1%.

Revenues from the sale of surgical sealants increased 1% for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016. This increase was primarily due to a 3% increase in the volume of milliliters sold, which increased revenues by 1% and an increase in average sales prices, which increased revenues by 1%, partially offset by the unfavorable effect of foreign currency exchange, which decreased revenues by 1%.

The decrease in sales volume of surgical sealants for the three months ended September 30, 2017 was primarily due to a decrease in sales of BioGlue in Japan due to changes in distributor buying patterns. The increase in sales volume of surgical sealants for the nine months ended September 30, 2017 was primarily due to an increase in sales of BioGlue in Japan and Brazil, due to increased usage, partially offset by a decrease in sales in U.S. markets.

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

Domestic revenues accounted for 52% and 54% of total BioGlue revenues for the three and nine months ended September 30, 2017, respectively, and 51% and 55% of total BioGlue revenues for the three and nine months ended September 30, 2016. BioFoam revenues accounted for less than 1% of surgical sealant revenues for the three and nine months ended September 30, 2017 and 2016. BioFoam is approved for sale in certain international markets.

### *On-X*

On January 20, 2016 we acquired On-X, an Austin, Texas-based, privately held mechanical heart valve company. The On-X catalogue of products includes the On-X prosthetic aortic and mitral heart valves and the On-X AAP. On-X product revenues also include revenues from the distribution of CarbonAid CO<sub>2</sub> diffusion catheters and from the sale of Chord-X ePTFE sutures for mitral chordal replacement. On-X products are distributed in both domestic and international markets. On-X also generates revenue from pyrolytic carbon coating products produced for other medical device manufacturers ( OEM ).

On-X product revenues decreased 6% for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016. This decrease was primarily due to a 17% decrease in volume of units sold, which decreased revenues by 1% and a decrease in average sales prices, which decreased revenues by 5%. The volume decrease of On-X products was primarily due to a revenue reversal of \$1.0 million related to the estimated buyback of inventory at the end of the contracts for certain distributors in countries in which we anticipate establishing a direct market as well as reduced On-X AAP shipments due to the delay in obtaining recertification of the On-X AAP CE Mark in Europe, partially offset by an increase in volume in the U.S. On-X product revenues, excluding the revenue reversal of \$1.0 million related to the estimated buyback of inventory, increased 6% for



the three months ended September 30, 2017, as compared to the three months ended September 30, 2016. The decrease in average selling prices was due to price reductions to certain customers in Europe as a result of pricing pressures from competitive products.

On-X product revenues increased 10% for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016. This increase in sales volume of On-X products for the September 30, 2017 was primarily due to volume increases in the U.S. and our direct markets in Europe, partially offset by revenue reversals related to the estimated buyback of inventory at the end the contract for certain distributors in countries in which the company anticipates establishing a direct market, reduced On-X AAP shipments due to the delay in obtaining re-certification of the On-X AAP CE Mark in Europe, and decreases in sales to certain distributors in Asia. On-X product revenues, excluding the revenue reversal of \$1.0 million related to the estimated buyback of inventory, increased 14% for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016.

On-X OEM revenues decreased 11% for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016. On-X OEM revenues decreased 32% for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016. On-X OEM revenues were \$358,000 and \$402,000 for the three months ended September 30, 2017 and 2016, respectively and \$1.0 million and \$1.5 million for the nine months ended September 30, 2017 and 2016, respectively. On-X OEM revenues decreased for the three and nine months ended September 30, 2017 due to an anticipated decrease in OEM activities for a major OEM customer.

#### *CardioGenesis Cardiac Laser Therapy*

Revenues from our CardioGenesis cardiac laser therapy product line consist primarily of sales of handpieces and, in certain periods, the sale of laser consoles. Revenues from cardiac laser therapy decreased 10% for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016. This decrease was primarily due to a 15% decrease in unit shipments of handpieces, partially offset by an increase in laser sales. Revenues from the sale of laser consoles were \$140,000 and zero for the three months ended September 30, 2017 and 2016, respectively.

Revenues from cardiac laser therapy decreased 7% for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016. This decrease was primarily due to a 12% decrease in unit shipments of handpieces, partially offset by an increase in laser sales. Revenues from the sale of laser consoles were \$432,000 and zero for the nine months ended September 30, 2017 and 2016, respectively.

Cardiac laser therapy is generally used adjunctively with cardiac bypass surgery by a limited number of physicians who perform these procedures. We expect that cardiac laser therapy revenues will decrease for the full year of 2017 as compared to the full year of 2016, due to a projected decrease in handpiece sales. Revenues from laser console sales are difficult to predict and can vary significantly from quarter to quarter.

#### *PerClot*

Revenues from the sale of PerClot decreased 7% for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016. This decrease was primarily due to a 9% decrease in the volume of grams sold, which decreased revenues by 7%, and a decrease in average sales prices, which decreased revenues by 1%, partially offset by the favorable effect of foreign currency exchange, which increased revenues by 1%.

Revenues from the sale of PerClot decreased 11% for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016. This decrease was primarily due to a 10% decrease in the volume of grams sold, which decreased revenues by 8%, a decrease in average sales prices, which decreased revenues by 2%, and the

unfavorable effect of foreign currency exchange, which decreased revenues by 1%.

The volume decrease for the three and nine months ended September 30, 2017 was primarily due to a decline in sales of PerClot in Europe due to competitive pressures. The decrease in average selling prices for the three and nine months ended September 30, 2017 was primarily due to price reductions to certain customers in Europe as a result of pricing pressures from competitive products.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. We resumed enrollment into the PerClot U.S. clinical trial in the fourth quarter of 2016, and assuming enrollment proceeds as anticipated, we could receive Premarket Approval ( PMA ) from the U.S. Food and Drug Administration ( FDA ) in 2019.

### *PhotoFix*

PhotoFix revenues increased 12% for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016. This increase was primarily due to an increase in units sold, which increased revenues by 12%.

PhotoFix revenues increased 14% for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016. This increase was primarily due to a 14% increase in units sold, which increased revenues by 13% and an increase in average sales prices, which increased revenues by 1%.

The increase in volume for the three and nine months ended September 30, 2017 is primarily due to an increase in the number of implanting physicians when compared to the prior year period, as this product continues to penetrate domestic markets.

PhotoFix is distributed in the U.S. for use in intracardiac repair, including ventricular repair and atrial repair, great vessel repair and suture line buttressing, and pericardial closure.

### *HeRO Graft and ProCol*

On February 3, 2016 we sold our HeRO Graft product line to Merit Medical Systems, Inc. ( Merit ), and we agreed to continue to manufacture the HeRO Graft for Merit for up to six months under a transition supply agreement. Revenues include sales to hospitals through February 3, 2016 and to Merit from that date through the second quarter of 2016. The sales transfer to Merit was completed in the second quarter of 2016, at which time we ceased sales of the HeRO Graft.

On March 18, 2016 we sold our ProCol product line to LeMaitre Vascular, Inc., at which time we ceased sales of these products.

### *Preservation Services*

Revenues from preservation services decreased 2% and increased 4% for the three and nine months ended September 30, 2017, respectively, as compared to the three and nine months ended September 30, 2016, respectively. A detailed discussion of the changes in cardiac and vascular preservation services revenues is presented below.

Preservation services revenues, particularly revenues for certain high-demand cardiac tissues, can vary from quarter to quarter and year to year due to a variety of factors including: quantity and type of incoming tissues, yields of tissue through the preservation process, timing of receipt of donor information, timing of the release of tissues to an implantable status, demand for certain tissue types due to the number and type of procedures being performed, and pressures from competing products or services. See further discussion below of specific items affecting cardiac and vascular preservation services revenues for the three and nine months ended September 30, 2017.

### *Cardiac Preservation Services*

Revenues from cardiac preservation services, consisting of revenues from the distribution of heart valves and cardiac patch tissues, decreased 4% for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016. This decrease was primarily due to a 4% decrease in unit shipments of cardiac tissues, which decreased revenues by 6%, partially offset by an increase in average service fees, which increased revenues by 2%.

Revenues from cardiac preservation services increased 7% for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016. This increase was primarily due to a 5% increase in unit

shipments of cardiac tissues, which increased revenues by 5% and an increase in average service fees, which increased revenues by 2%.

The decrease in cardiac volume for the three months ended September 30, 2017 was primarily due to the impact of recent hurricanes in Florida and Texas which delayed surgical procedures and the timing of tissue releases to an implantable status. The increase in cardiac volume for the nine months ended September 30, 2017 was primarily due to an increase in the volume of cardiac valve tissue shipments for the nine months ended September 30, 2017. The increase in average service fees for the three and nine months ended September 30, 2017 was primarily due to list fee increases in domestic markets and the routine negotiation of pricing contracts with certain customers.

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

*Vascular Preservation Services*

Revenues from vascular preservation services increased 1% for the three months ended September 30, 2017, as compared to the three months ended September 30, 2016. This increase was primarily due to a 4% increase in vascular tissue shipments, which increased revenues by 3%, and a decrease in average service fees, which decreased revenues by 2%.

Revenues from vascular preservation services increased 1% for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016. This increase was primarily due to a 3% increase in vascular tissue shipments, which increased revenues by 3%, partially offset by a decrease in average service fees, which decreased revenues by 2%.

The increase in vascular volume for the three and nine months ended September 30, 2017 was primarily due to increases in saphenous veins and femoral artery shipments. The decrease in average service fees for the three and nine months ended September 30, 2017 was primarily due to fee differences due to physical characteristics of vascular tissues and the negotiation of pricing contracts with certain customers.

The majority of our vascular preservation services revenues are related to shipments of saphenous veins, which are mainly used in peripheral vascular reconstruction surgeries to avoid limb amputations. These tissues are primarily distributed in domestic markets.

**Cost of Products and Preservation Services***Cost of Products*

|                  | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|------------------|---|-------------|--|-------------|
|                  | <b>2017</b>                                 | <b>2016</b> | <b>2017</b>                                | <b>2016</b> |
| Cost of products | \$ 6,220                                    | \$ 6,598    | \$ 21,196                                  | \$ 21,299   |

Cost of products decreased 6% and was flat for the three and nine months ended September 30, 2017, respectively, as compared to the three and nine months ended September 30, 2016, respectively. Cost of products for 2017 and 2016 includes costs related to BioGlue, BioFoam, On-X, CardioGenesis cardiac laser therapy, PerClot, and PhotoFix. Cost of products for the nine months ended September 30, 2016 also includes ProCol and HeRO Grafts.

Cost of products for the three and nine months ended September 30, 2017 includes \$32,000 and \$2.1 million in inventory basis step-up expense, primarily related to costs for On-X products re-purchased from previous international and domestic distributors in excess of the unit cost to manufacture the inventory. Cost of products for the three and nine months ended September 30, 2016 includes \$750,000 and \$2.2 million, respectively, in acquisition inventory basis step-up expense, related to the On-X inventory fair value adjustment recorded in purchase accounting.

The decrease in cost of products for the three months ended September 30, 2017 was primarily due to a significant reduction of inventory basis step-up expense differences, as compared to the prior year period as discussed above. The inventory basis step-up expense for the nine months ended September 30, 2017 was largely offset by a similar expense for the nine months ended September 30, 2016.

*Cost of Preservation Services*

|                               | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|-------------------------------|---|-------------|--|-------------|
|                               | <b>2017</b>                                 | <b>2016</b> | <b>2017</b>                                | <b>2016</b> |
| Cost of preservation services | \$ 7,917                                    | \$ 8,872    | \$ 23,401                                  | \$ 26,348   |

Cost of preservation services decreased 11% for both the three and nine months ended September 30, 2017, as compared to the three and nine months ended September 30, 2016. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services decreased in the three and nine months ended September 30, 2017 primarily due to a decrease in the per unit cost of processing tissues, partially offset by a slight increase in the number of tissue shipments. We expect that per unit cost of preservation services will decrease for the full year of 2017 when compared to 2016, primarily resulting from the impact of higher volume on the per unit cost of processing tissues during 2016 which have shipped during the current year.

**Gross Margin**

|  | Three Months Ended<br>September 30, |           | Nine Months Ended<br>September 30, |           |
|--|-------------------------------------|-----------|------------------------------------|-----------|
|  | 2017                                | 2016      | 2017                               | 2016      |
| Gross margin                                   | \$ 29,862                           | \$ 29,782 | \$ 92,279                          | \$ 87,704 |
| Gross margin as a percentage of total revenues | 68%                                 | 66%       | 67%                                | 65%       |

Gross margin was flat for the three months ended September 30, 2017 and increased 5% for the nine months ended September 30, 2017, as compared to the three and nine months ended September 30, 2016, respectively. Gross margin was flat for the three months ended September 30, 2017 as a result of a significant reduction of inventory basis step-up expenses in the three months ended September 30, 2017 as compared to the prior year period, largely offset by a decrease in revenues from the sale of BioGlue. Gross margin increased in the nine months ended September 30, 2017 primarily due to increases in tissue margins due to higher revenues and a decrease in the per unit cost of preservation services.

Gross margin as a percentage of total revenues increased in both the three and nine months ended September 30, 2017, as compared to the three and nine months ended September 30, 2016, respectively. The increases in the three and nine months ended September 30, 2017 were primarily due to increases in tissue margins as a result of a decrease in the per unit cost of processing tissues. The increase in the three months ended September 30, 2017 was additionally affected by a significant reduction of inventory basis step-up expense as compared to the prior year period.

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

|   | Three Months Ended<br>September 30, |           | Nine Months Ended<br>September 30, |           |
|---|-------------------------------------|-----------|------------------------------------|-----------|
|   | 2017                                | 2016      | 2017                               | 2016      |
| General, administrative, and marketing expenses                                   | \$ 24,756                           | \$ 20,592 | \$ 71,016                          | \$ 69,302 |
| General, administrative, and marketing expenses as a percentage of total revenues | 56%                                 | 46%       | 52%                                | 51%       |

General, administrative, and marketing expenses increased 20% and 2% for the three and nine months ended September 30, 2017, respectively, as compared to the three and nine months ended September 30, 2016, respectively.

General, administrative, and marketing expenses for the three and nine months ended September 30, 2017 included \$3.0 million and \$4.4 million, respectively, in business development costs, primarily related to the proposed acquisition of JOTEC. General, administrative, and marketing expenses for the three and nine months ended September 30, 2016 included \$413,000 and \$7.0 million, respectively, in transaction and integration costs primarily related to the acquisition of On-X in January 2016, which include, among other costs, expenses related to the termination of international and domestic distribution agreements.

The increase in general, administrative, and marketing expenses for the three months ended September 30, 2017 was primarily due to the increase in business development expenses, as well as higher expenses to support the Company's

increasing revenue base, international expansion, and increasing employee headcount. The increase in general, administrative, and marketing expenses for the nine months ended September 30, 2017 was primarily due to higher expenses to support the Company's increasing revenue base, international expansion, and increasing employee headcount.

***Research and Development Expenses***

|   | <b>Three Months Ended<br/>September 30,<br/>2017</b> |          | <b>Nine Months Ended<br/>September 30,<br/>2016</b> |          |
|---|--|----------|---|----------|
| Research and development expenses                                   | \$ 4,277   | \$ 3,714 | \$ 13,098   | \$ 9,602 |
| Research and development expenses as a percentage of total revenues | 10%  | 8%       | 10%   | 7%       |

Research and development expenses increased 15% and 36% for the three and nine months ended September 30, 2017, respectively, as compared to the three and nine months ended September 30, 2016, respectively. Research and development



spending in these periods was primarily focused on clinical work with respect to our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S, and to a lesser extent, NeoPatch™, On-X products, and BioGlue projects.

### Gain from Sale of Business Components

Gain from sale of business components for the three months ended September 30, 2016 consisted of the net of an \$8.8 million gain on the HeRO Sale and an \$845,000 loss on the ProCol Sale. We sold our HeRO Graft and ProCol product lines during the first quarter of 2016.

### Interest Expense

Interest expense was \$851,000 and \$2.5 million for the three and nine months ended September 30, 2017, respectively, and \$742,000 and \$2.3 million for the three and nine months ended September 30, 2016, respectively. Interest expense in 2017 and 2016 included interest on debt and uncertain tax positions.

### Earnings

|  | Three Months Ended<br>September 30, |          | Nine Months Ended<br>September 30, |           |
|--|-------------------------------------|----------|------------------------------------|-----------|
|  | 2017                                | 2016     | 2017                               | 2016      |
| Income before income taxes                         | \$ 21                               | \$ 4,731 | \$ 5,908                           | \$ 14,653 |
| Income tax (benefit) expense                       | (1,304)                             | 1,738    | (803)                              | 6,772     |
| Net income   | \$ 1,325                            | \$ 2,993 | \$ 6,711                           | \$ 7,881  |
| Diluted income per common share                    | \$ 0.04                             | \$ 0.09  | \$ 0.19                            | \$ 0.24   |
| Diluted weighted-average common shares outstanding | 34,057                              | 33,165   | 33,851                             | 32,568    |

Income before income taxes decreased for the three and nine months ended September 30, 2017, as compared to the three and nine months ended September 30, 2016, respectively. The decrease in income before income taxes for the three months ended September 30, 2017 was due to an increase in operating expenses largely as a result of increased business development costs, primarily related to the proposed acquisition of JOTEC. The decrease in income before income taxes for the nine months ended September 30, 2017 was primarily due to the gain from sale of business components in 2016, which did not recur in 2017, and an increase in research and development expenses, partially offset by an increase in gross margins.

Our income tax rate for the three and nine months ended September 30, 2017 was favorably affected by excess tax benefits related to the exercise of non-qualified stock options and the vesting of stock awards, which decreased income tax expense by approximately \$1.1 million and \$2.7 million, respectively. Our effective income tax rate was 37% and 46% for the three and nine months ended September 30, 2016, respectively. Business development costs included in general, administrative and marketing expenses for the three and nine months ended September 30, 2017 may impact our income tax rate in future reporting periods. Upon the close of the acquisition of JOTEC, the income tax deductibility of these costs must be evaluated and certain of these costs will be permanently capitalized for income

tax purposes. The capitalization of these costs will substantially increase our income tax rate, primarily in the quarter and year of the acquisition. Our income tax rate for the three and nine months ended September 30, 2016 was unfavorably impacted by the tax treatment of certain expenses related to the On-X acquisition, which had a larger impact on the tax rate in first quarter of 2016. Our income tax rate for the nine months ended September 30, 2016 was also unfavorably impacted by book/tax basis differences related to the HeRO Sale.

Net income and diluted income per common share decreased for the three and nine months ended September 30, 2017, as compared to the three and nine months ended September 30, 2016, respectively. The decrease for the three and nine months ended September 30, 2017 was primarily due to a decrease in income before income taxes, partially offset by an income tax benefit, as discussed above.

### **Seasonality**

We believe the demand for BioGlue 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 for BioGlue may be due to the summer holiday season in Europe and the U.S. We further believe that demand for BioGlue in Japan may continue to be lowest in the second quarter of each year due to distributor ordering patterns driven by the slower summer holiday season in Japan, although this trend could vary somewhat from year to year.

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

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

Demand for our cardiac preservation services has traditionally been seasonal, with peak demand generally occurring in the third quarter. We believe that 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.

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

## **Liquidity and Capital Resources**

### ***Net Working Capital***

As of September 30, 2017 net working capital (current assets of \$155.6 million less current liabilities of \$26.1 million) was \$129.5 million, with a current ratio (current assets divided by current liabilities) of 6 to 1, compared to net working capital of \$117.1 million and a current ratio of 5 to 1 at December 31, 2016.

### ***Overall Liquidity and Capital Resources***

Our primary cash requirements for the nine months ended September 30, 2017 were general working capital needs, interest and principal payments under our debt agreement, capital expenditures for facilities and equipment, business development expenses, and to a lesser extent repurchases of stock to cover tax withholdings. We funded our cash requirements through our existing cash reserves and our operating activities, which generated cash during the period.

We believe that our cash from operations and existing cash and cash equivalents will enable us to meet our current operational liquidity needs for at least the next twelve months. Our future cash requirements are expected to include funding for the acquisition of JOTEC and the related interest and principal payments under a new senior secured credit facility, as discussed in Recent Events, as well as expenditures for clinical trials, additional research and development expenditures, general working capital needs, capital expenditures, and other corporate purposes, and may include cash to fund other business development activities. These items may have a significant effect on our cash flows during the next twelve months.

### ***Significant Sources and Uses of Liquidity***

In connection with the closing of the On-X acquisition on January 20, 2016, CryoLife and certain of our subsidiaries entered into the Third Amended and Restated Credit Agreement ( Amended Debt Agreement ) with Capital One, National Association. Capital One Financial Corporation acquired GE Capital's Healthcare Financial Services lending business in late 2015. The designated credit parties are Healthcare Financial Solutions, LLC; Fifth Third Bank; and Citizens Bank, National Association. The Amended Debt Agreement amended and restated our prior credit agreement and provides us with a senior secured credit facility in an aggregate principal amount of \$95 million, which includes a \$75 million term loan and a \$20 million revolving credit facility (including a \$4 million letter of credit sub-facility and a \$3 million swing-line sub-facility). The \$75 million term loan was used to finance, in part, the acquisition of On-X and will mature on January 20, 2021. CryoLife and our domestic subsidiaries, subject to certain exceptions and exclusions, have guaranteed the obligations of the Amended Debt Agreement. Borrowings under the Amended Debt

Agreement are secured by substantially all of CryoLife's, and certain of our subsidiaries', real and personal property. As of September 30, 2017 the remaining availability on our revolving credit facility was \$20.0 million.

As of September 30, 2017 approximately 6% of our cash and cash equivalents were held in foreign jurisdictions.

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

Net cash provided by operating activities was \$4.8 million for the nine months ended September 30, 2017, as compared to \$14.7 million for the nine months ended September 30, 2016. The decrease in current year cash provided was primarily due to an increase in working capital needs, as discussed below.

We use the indirect method to prepare our cash flow statement and, accordingly, the operating cash flows are based on our net income, which is then adjusted to remove non-cash items, items classified as investing and financing cash flows, and for changes

in operating assets and liabilities from the prior year end. For the nine months ended September 30, 2017 these non-cash items included \$6.7 million in depreciation and amortization expenses and \$5.7 million in non-cash compensation. The prior year non-cash items included a one-time \$7.9 million gain from sale of business components.

Our working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the nine months ended September 30, 2017 these changes included an unfavorable adjustment of \$6.9 million due to increases in inventory balances and deferred preservation costs; \$4.3 million due to the timing difference between recording receivables and the receipt of cash; \$3.0 million due to increases in prepaid expenses and other assets; and \$855,000 due to timing differences between recording accounts payable, accrued expenses, and other liabilities and the payment of cash.

### *Net Cash Flows from Investing Activities*

Net cash used in investing activities was \$4.6 million for the nine months ended September 30, 2017, as compared to \$71.1 million for the nine months ended September 30, 2016. The prior year cash used was primarily due to \$91.2 million for the acquisition of On-X, net of cash acquired, partially offset by the proceeds from the sale of business components of \$19.8 million. The current year cash used was primarily due to \$5.4 million in capital expenditures, partially offset by \$740,000 in proceeds related to the HeRO Sale.

### *Net Cash Flows from Financing Activities*

Net cash used in financing activities was \$2.9 million for the nine months ended September 30, 2017, as compared to cash provided of \$73.4 million for the nine months ended September 30, 2016. The prior year cash provided was primarily due to \$75.0 million in proceeds from the issuance of a term loan, which was used to finance, in part, the acquisition of On-X, partially offset by \$2.3 million in debt issuance costs. The current year cash used was primarily due to \$3.9 million in principal payments on debt and \$1.6 million for repurchases of common stock to cover tax withholdings, partially offset by \$2.6 million in proceeds from the exercise of stock options and issuance of common stock.

### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements.

### **Scheduled Contractual Obligations and Future Payments**

Scheduled contractual obligations and the related future payments as of September 30, 2017 were as follows (in thousands):

|                            | Total     | Remainder of |          |          |          |           |            |
|----------------------------|-----------|--------------|----------|----------|----------|-----------|------------|
|                            |           | 2017         | 2018     | 2019     | 2020     | 2021      | Thereafter |
| Long-term debt obligations | \$ 68,741 | \$ --        | \$ 3,750 | \$ 3,750 | \$ 5,157 | \$ 56,084 | \$ --      |
| Operating leases           | 23,002    | 909          | 5,093    | 5,024    | 4,381    | 3,807     | 3,788      |
| Interest payments          | 8,336     | 686          | 2,649    | 2,499    | 2,321    | 181       | --         |
| Research obligations       | 6,037     | 1,522        | 3,817    | 328      | 235      | 135       | --         |
| Purchase commitments       | 3,582     | 1,709        | 1,696    | 177      | --       | --        | --         |
| Contingent payments        | 1,000     | --           | --       | 1,000    | --       | --        | --         |

|                               |            |          |           |           |           |           |          |
|-------------------------------|------------|----------|-----------|-----------|-----------|-----------|----------|
| Other long-term liabilities   | 475        | 465      | 10        | --        | --        | --        | --       |
| Total contractual obligations | \$ 111,173 | \$ 5,291 | \$ 17,015 | \$ 12,778 | \$ 12,094 | \$ 60,207 | \$ 3,788 |

Our long-term debt obligations and interest payments obligations result from scheduled principal payments and anticipated interest payments related to our Amended Debt Agreement.

Our operating lease obligations result from the lease of land and buildings that comprise our corporate headquarters and manufacturing facilities, leases related to additional office and warehouse space, leases on our vehicles, and leases on a variety of office equipment.

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

Our purchase commitments include obligations from agreements with suppliers, one of which is the minimum purchase requirements for PerClot under a worldwide distribution agreement (the Distribution Agreement) with Starch Medical, Inc. ( SMI ). Pursuant to the terms of the Distribution Agreement, we may terminate that agreement, including the minimum purchase

requirements set forth in the agreement for various reasons, one of which is if we obtain FDA approval for PerClot. These minimum purchases are included in the table above through 2018, based on the assumption that we will not terminate the Distribution Agreement before our target date for receiving FDA approval for PerClot in 2019. However, if we do not obtain FDA approval for PerClot, and if we choose not to terminate the Distribution Agreement, CryoLife may have minimum purchase obligations of up to \$1.75 million per year through the end of the contract term in 2025.

The contingent payments obligation includes payments that we may make if certain U.S. regulatory approvals and certain commercial milestones are achieved related to our transaction with SMI for PerClot.

The schedule of contractual obligations above excludes (i) obligations for estimated liability claims unless they are due as a result of a settlement agreement or other contractual obligation, as no assessments have been made for specific litigation, and (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be \$3.4 million, as no specific assessments have been made by any taxing authorities.

### **Capital Expenditures**

Capital expenditures were \$5.4 million and \$3.5 million for the nine months ended September 30, 2017 and 2016, respectively. Capital expenditures in the nine months ended September 30, 2017 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 \$54.2 million as of September 30, 2017 and interest paid on the outstanding balances, if any, of our revolving credit facility and \$69.7 million term loan balance. A 10% adverse change in interest rates, as compared to the rates experienced by us in the nine months ended September 30, 2017, affecting our cash and cash equivalents, restricted cash and securities, \$69.7 million term loan balance, 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, and PerClot revenues are denominated in British Pounds, Euros, and Canadian Dollars and a portion of our general, administrative, and marketing expenses are denominated in British Pounds, Euros, Swiss Francs, Canadian Dollars, and Singapore Dollars. These foreign currency transactions are sensitive to changes in exchange

rates. In this regard, changes in exchange rates could cause a change in the U.S. Dollar equivalent of net income from transactions conducted in other currencies. As a result, we could recognize a reduction in revenues or an increase in expenses related to a change in exchange rates.

An additional 10% adverse change in exchange rates from the exchange rates in effect on September 30, 2017, affecting our balances denominated in foreign currencies, would not have had a material effect on our financial position, results of operations, or cash flows. An additional 10% adverse change in exchange rates from the weighted-average exchange rates experienced by us for the nine months ended September 30, 2017, affecting our revenue and expense transactions denominated in foreign currencies, would not have had a material effect on our financial position, results of operations, or cash flows.



#### **Item 4. Controls and Procedures.**

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

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

Our management utilizes the criteria set forth in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our Disclosure Controls over financial reporting. Based upon the most recent Disclosure Controls evaluation conducted by management with the participation of the CEO and CFO, as of September 30, 2017, the CEO and CFO have concluded that our Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by us in our periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms. During the quarter ended September 30, 2017 there were no changes in our internal control over financial reporting that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

## **Part II - OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

We are currently involved in litigation with the representative of the former shareholders of On-X Life Technologies Holdings, Inc. ( On-X ) over our indemnification claims under the On-X purchase agreement and the approximately \$10 million of the purchase price paid into escrow. The On-X shareholder representative filed a complaint in Delaware Chancery Court on June 1, 2017, seeking declaratory relief that our indemnification claims were invalid. We timely filed an answer and counterclaim on June 22, 2017, and initial discovery is underway.

### **Item 1A. Risk Factors.**

#### **Risks Relating To Our Business**

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

BioGlue® Surgical Adhesive ( BioGlue ) is a significant source of our revenues, representing approximately 36% and 35% of revenues in the three months ended September 30, 2017 and 2016, respectively. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

BioGlue is a mature product, our U.S. Patent for BioGlue expired in mid-2012, and our patents in most of the rest of the world for BioGlue expired in mid-2013. Other companies may use the inventions disclosed in the expired patents to develop and make competing products;

Another company launched competitive products in 2016 and another is in the process of doing so. These companies have greater financial, technical, manufacturing, and marketing resources than we do and are well established in their markets. Companies other than these may also pursue regulatory approval for competitive products;

We may be unable to obtain regulatory approvals to commercialize BioGlue in certain countries other than the U.S. at the same rate as our competitors or at all. We also may not be able to capitalize on new regulatory approvals we obtain for BioGlue in countries other than the U.S., including approvals for new indications;

BioGlue contains a bovine blood protein. Animal-based products are increasingly subject to scrutiny from the public and regulators, who may have concerns about the use of animal-based products or concerns about the transmission of disease from animals to humans. These concerns could lead to additional regulations or product bans in certain countries; and

BioGlue is subject to potential adverse developments with regard to its safety, efficacy, or reimbursement practices.

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

Tissue preservation services are a significant source of our revenues, representing 39% and 38% of revenues in the three months ended September 30, 2017 and 2016, respectively. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows, if we are unable to:

Source sufficient quantities of some tissue types from human donors or address potential excess supply of other tissue types. We rely primarily upon the efforts of third-party procurement organizations, tissue banks (most of which are not-for-profit), and others to educate the public and foster a willingness to donate tissue. Factors beyond our control such as supply, regulatory changes, negative publicity concerning methods of tissue recovery or disease transmission from donated tissue, or public opinion of the donor process as well as our own reputation in the industry can negatively impact the supply of tissue;

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

Compete effectively in tissue preservation services, as 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:

The National Organ Transplant Act of 1984 or NOTA, which prohibits the acquisition or transfer of human organs for valuable consideration for use in human transplantation, but allows for the payment of reasonable expenses associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of human organs;

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; and

European Union directives, called the EUCTD, which require that countries in the European Economic Area take responsibility for regulating tissues and cells through a Competent Authority.

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 may not realize all of the anticipated benefits of the On-X acquisition.***

On January 20, 2016 we acquired On-X at a price of \$128.2 million, subject to certain adjustments, which is the largest acquisition we have ever made. Pursuant to the acquisition, we borrowed \$75.0 million through a senior secured credit facility, subject to certain restrictions on our business, and we issued shares of common stock worth, at the time, approximately \$34.6 million.

Our ability to realize the anticipated business opportunities, growth prospects, cost savings, synergies, and other benefits of the On-X acquisition continues to depend on a number of factors including:

The success of our integration of the direct sales forces of On-X and CryoLife into a single sales force to sell, with limited exception, the entire suite of products of the combined businesses;

Our ability to successfully manage independent sales representatives and distributor relationships, particularly internationally;

The success of moving to a direct sales model with the On-X products in certain international markets;

Our ability to resolve unanticipated or undisclosed pre-existing On-X liabilities including any regulatory or quality issues;

Our ability to execute on existing On-X clinical trials in a compliant, timely, and cost effective manner;

Our ability to retain existing customers and obtain new customers for On-X products; and

Unforeseen negative economic or market conditions impacting the On-X business.

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. As a result of these or other factors, we may not realize the full benefits of the acquisition, including achieving anticipated sales, capitalizing on the FDA's approved reduced international normalized ratio ( INR ) indication and other growth opportunities, capturing market share from major competitors, all of whom are substantially larger and better resourced than CryoLife, or realizing expected synergies and costs savings. 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.

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

On-X is a significant source of our revenues, representing 19% and 20% of revenues in the three months ended September 30, 2017 and 2016, respectively. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

Our ability to achieve anticipated On-X revenues;

Our ability to capitalize on the FDA's approved reduced INR indication;

Our ability to overcome high levels of inventory in certain markets;

Our ability to compete effectively with our major competitors, as they may have advantages over us in terms of cost structure, pricing, sales force footprint, and brand recognition;

Our ability to manage the risks associated with less favorable contract terms for On-X products on consignment at hospitals with more bargaining power;

Changes in technology that may impact the market for mechanical heart valves, such as transcatheter aortic valve replacement, or TAVR devices; and

Enhanced regulatory enforcement activities that could cause interruption in our ability to sell On-X products in certain markets.

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

On November 22, 2016, we received a letter from LNE/G-Med ( G-Med ), which acts as our Notified Body for the On-X product line, indicating that it was temporarily suspending the CE Mark for the On-X AAP in the European Economic Area ( EEA ), due to an allegedly untimely and allegedly deficient plan by us to address certain technical documentation issues found by G-Med during a review and renewal of the design examination certificate for the On-X AAP. On July 26, 2017, we received a letter from G-Med indicating that it was continuing the suspension of the CE Mark for the AAP product for a period of up to 18 months pending further assessment. We have since withdrawn our application with G-Med for certification of the AAP product and are currently pursuing another pathway to CE Mark for the AAP product with a goal of returning the product to the European market in the first quarter of 2018. Failure to obtain CE Mark for the On-X AAP in the EEA could have a material adverse effect on EEA revenues in 2018 and beyond.

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

On October 10, 2017 we entered a definitive agreement to acquire JOTEC at a price of \$225 million, subject to certain adjustments, which would be the largest acquisition we have ever made. We anticipate financing the transaction and related expenses, as well as refinancing our existing approximately \$69 million loan, with a new \$255 million senior secured credit facility, consisting of a \$225 million institutional term loan B and a \$30 million undrawn revolving credit facility, \$56.25 million in CryoLife common stock as determined on the date of signing of the agreement, and available cash on hand.

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

Our ability to consummate the acquisition;

The continued growth of the global market for stent grafts used in endovascular and open repair of aortic disease;

Our ability to leverage our global infrastructure, including in the markets in which JOTEC is already direct; minimize difficulties and costs associated with transitioning away from distributors in key markets; and accelerate our ability to go direct in Europe in developed markets with the CryoLife and JOTEC product portfolios;

Our ability to foster cross-selling opportunities between the CryoLife and JOTEC product portfolios;

Our ability to bring JOTEC products to the U.S. market;

Our ability to harness the JOTEC new product pipeline and R&D capabilities to drive long-term growth, including our ability to obtain CE Mark for pipeline products;

Our ability to drive gross margin expansion;

Our ability to successfully integrate the JOTEC business with ours, including integrating the combined European sales force;

Our ability to compete effectively;

Our ability to carry significantly more debt and repayment obligations after the acquisition closes; and

Our ability to manage the unforeseen risks and uncertainties related to JOTEC's business. 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 investment in PerClot is subject to significant risks, and our ability to fully realize our investment is dependent on our ability to obtain FDA approval and to successfully commercialize PerClot in the U.S. either directly or indirectly.***

In 2010 and 2011, we entered into various agreements with Starch Medical, Inc. ( SMI ) pursuant to which, among other things, we (a) may distribute PerClot in certain international markets and are licensed to manufacture PerClot in the U.S.; (b) acquired some technology to assist in the production of a potentially key component in the manufacture of PerClot; and (c) obtained the exclusive right to pursue, obtain, and maintain FDA Premarket Approval ( PMA ) for PerClot. The initial consideration under those SMI agreements was approximately \$8.0 million paid in cash and stock. We made additional payments of \$1.75 million through 2016 and may pay contingent amounts of up to an additional \$1.0 million if certain U.S. regulatory and other commercial milestones are achieved. We may also pay SMI, subject to certain offsets, royalties on our future sales of PerClot that we manufacture.

In March 2014, we received approval of our investigational device exemption ( IDE ) for PerClot from the FDA, pursuant to which we began, in the first half of 2015, our pivotal clinical trial for surgical indications in the U.S. We began enrollment in the trial in the second quarter of 2015 but later suspended enrollment pending consultation with the FDA regarding the trial protocol. These discussions resulted in two amendments to the trial protocol, the last of which was approved by the FDA in July 2016.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. We resumed enrollment into the PerClot U.S. clinical trial in the fourth quarter of 2016, and assuming enrollment proceeds as anticipated, we could receive PMA from the FDA in 2019. On October 3, 2017 SMI provided notice to terminate our exclusive license to pursue, obtain, and maintain PMA approval (but not our exclusive licenses to manufacture and sell PerClot or to SMI's technology), and the parties have begun contractually required, good faith negotiations to resolve this issue. Even though the FDA



has approved the revised protocol, we may not be able to continue, or may elect to discontinue, the pivotal clinical trial. Finally, we are subject to the terms of our resolution with Medafor, which resulted from an April 28, 2014 declaratory judgment lawsuit regarding our manufacture, use, offer for sale, and sale of PerClot in the U.S. and Medafor's U.S. Patent No. 6,060,461. Under the terms of the resolution with Medafor, we are precluded from marketing, selling, or distributing PerClot in the U.S. until February 8, 2019, even if we obtain FDA PMA for PerClot before that date.

We cannot sell PerClot for surgical indications in the U.S. in future years unless, and until, we obtain FDA approval and only after the Medafor injunction has expired on February 8, 2019. Failure to obtain FDA approval could materially, adversely affect our financial condition, anticipated future revenues, and profitability. There is no guarantee that we will obtain FDA approval when anticipated, or at all. The estimated timing of regulatory approval for PerClot is based on factors beyond our control, including but not limited to, the pace of enrollment in the pivotal clinical trial and the approval process may be delayed because of unforeseen scheduling difficulties and unfavorable results at various stages in the pivotal clinical trial or the process. Management 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.

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

***Reclassification by the FDA of CryoValve® SGPV may make it commercially infeasible to continue processing the CryoValve SGPV.***

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

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

***Our investment in PhotoFix is subject to a variety of risks.***

In April 2016 we exercised our option and acquired the PhotoFix product line from Genesee Biomedical, Inc. ( GBI ). We began distribution of PhotoFix in the first quarter of 2015 and have continued to sell PhotoFix after the

acquisition.

Simultaneously with our acquisition of the PhotoFix product line, we entered into a Transition Supply Agreement with GBI, pursuant to which GBI will continue to manufacture product for us until we have completed the transfer of manufacturing operations to us. During this transition period, we are reliant on GBI to produce quality products in the quantities we and our customers require. If GBI experiences quality, supply, or production challenges, its products could be subject to recall or other quality action; its business operations and/or its facilities that make the products could be shut down temporarily or permanently, whether by government order, natural disaster, or otherwise; and there may not be sufficient product to enable us to meet demand. Even though we have acquired PhotoFix, we may be unable to continue the manufacturing, marketing, or distribution of the product consistent with our current projections or within the time frame anticipated. Further, we may be unable to secure anticipated approvals from the FDA or international regulatory bodies to remove certain labelling restrictions or to be able to commercialize PhotoFix in key international markets, such as Europe. Any of these occurrences or actions could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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

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

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

Certain of the materials, supplies, and services that are key components of our product manufacturing or our tissue processing are sourced from single vendors. As a result, our ability to negotiate favorable terms with those vendors may be limited, and if those vendors experience operational, financial, quality, or regulatory difficulties, or those vendors and/or their facilities cease operations temporarily or permanently, we could be forced to cease product manufacturing or tissue processing until the vendors resume operations or alternative vendors could be identified and qualified. We could also be forced to purchase alternative materials, supplies, or services with unfavorable terms due to diminished bargaining power. We also conduct substantially all of our operations at two facilities: Austin, Texas, for our On-X product line, and Kennesaw, Georgia, for all our other products. If one of these facilities ceases operations temporarily or permanently, due to natural disaster or other reason, our business could be substantially disrupted.

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

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

Our products and tissues may be recalled or placed on hold by us, the FDA, or other regulatory bodies;

Our products and tissues allegedly have caused, and may in the future cause, injury to patients, which has exposed, and could in the future expose, us to product and tissue processing liability claims, and such claims could lead to additional regulatory scrutiny and inspections;

Our manufacturing and tissue processing operations are subject to regulatory scrutiny and inspections, including by the FDA and foreign regulatory agencies, and these agencies could require us to change or modify our manufacturing operations, processes, and procedures;

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

European Notified Bodies have recently engaged in more rigorous regulatory enforcement activities and may continue to do so, and the European Union has adopted a new Medical Device Regulation (MDR 2017/745), which could result in product reclassifications that adversely impact our clearances and approvals; and

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

As an example of these risks, in January 2013 we received a warning letter from the FDA related to the manufacture of our products and our processing, preservation, and distribution of human tissue, as well as a subsequent 2014 Form 483, after a re-inspection by the FDA related to the warning letter that included observations concerning design and process validations, environmental monitoring, product controls and handling, corrective and preventive actions, and employee training. Despite an FDA re-inspection in the first quarter of 2015, after which the FDA closed out the warning letter issued in 2013, we remain subject to further inspections and oversight by the FDA and, if the FDA is not satisfied with our quality and regulatory compliance, it could institute a wide variety of enforcement actions, ranging from issuing additional Form 483s or warning letters, to more severe sanctions such as fines; injunctions; civil penalties; recalls of our products and/or tissues; operating restrictions; suspension of production; non-approval or withdrawal of approvals or clearances for new products or existing products; and criminal prosecution. Any further Form 483s, warning letters, recalls, holds, or other adverse action from the FDA may decrease demand for our products or tissues or cause us to write down our inventories or deferred preservation costs and could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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

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

- The sale of mechanical, synthetic, and animal-based tissue valves for implantation;
- The sale of 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 Life Sciences Corp., C.R. Bard, Inc., Integra Life Sciences Holdings, or LifeNet. 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 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 and managing foreign operations, including foreign distributor relationships and developing direct sales operations in key foreign countries;

Expanded compliance obligations, including obligations associated with the Foreign Corrupt Practices Act, the U.K. Bribery Law, local anti-corruption laws, and Office of Foreign Asset Control administered sanction programs;

Broader exposure to corruption;

Overlapping and potentially conflicting international legal and regulatory requirements, as well as unexpected changes in international legal and regulatory requirements or reimbursement policies and programs;

Longer accounts receivable collection cycles in certain foreign countries and additional cost of collection of those receivables;

Diminished protection for intellectual property and the presence of a growing number of generic or smaller competitors in some countries;

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

Differing local product preferences and product requirements;

Adverse economic or political changes or political instability;

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

Potential adverse tax consequences of overlapping tax structures.

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

***The outcome of the 2016 U.S. Presidential and Congressional elections might result in material changes to governmental regulation of various aspects of our business and operations or cause disruptions to our business.***

The outcome of the 2016 U.S. Presidential and Congressional election might result in material changes to governmental regulation of various aspects of our business and operations. We devote significant operational and managerial resources to comply with existing laws and regulations. Different interpretations and enforcement policies of existing laws and regulations, the possible repeal of existing laws and regulations, as well as the enactment of new laws and regulations, could require additional operational and managerial resources and could subject our current practices to allegations of impropriety or illegality or could require us to make significant changes to our products and operations.

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

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

We could be exposed to product and tissue processing liability claims and security claims greater than the amount that we have insured;

We may be unable to obtain future insurance policies in an amount sufficient to cover our anticipated claims at a reasonable cost or at all; or

Because we are not insured against all potential losses, uninsured losses due to natural disasters or other catastrophes could adversely impact our business.

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

If we are unsuccessful in arranging acceptable settlements of future product or tissue processing liability claims or future securities class action or derivative claims, we may not have sufficient insurance coverage and liquid assets to meet these obligations. If we are unable to obtain satisfactory insurance coverage in the future, we may be subject to additional future exposure from product or tissue processing liability or securities claims. Additionally, if one or more claims with respect to which we may become, in the future, a defendant should result in a substantial verdict rendered in favor of the plaintiff(s), such verdict(s) could exceed our available insurance coverage and liquid assets. If we are unable to meet required future cash payments to resolve any outstanding or any future claims, this will materially, adversely affect our financial condition, profitability, and cash flows.



Further, although we have an estimated reserve for our unreported product and tissue processing liability claims for which we do expect that we will obtain recovery under our insurance policies, these costs could exceed our current estimates. Finally, our facilities could be materially damaged by tornadoes, flooding, other natural disasters, or catastrophic circumstances, for which we are not fully covered by business interruption and disaster insurance, and, even with such coverage, we could suffer substantial losses in our inventory and operational capacity, along with a potential adverse impact on our customers and opportunity costs for which our insurance would not compensate us.

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

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

We may experience decreasing prices for our goods and services due to pricing pressure experienced by our customers from managed care organizations and other third-party payors, increased market power of our customers as the medical device industry consolidates, and increased competition among medical engineering and manufacturing services providers. If the prices for our goods and services decrease and we are unable to reduce our expenses, our results of operations will be adversely affected.

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

We own patents, patent applications, and licenses relating to our technologies, which we believe provide us with important competitive advantages. In addition, we have certain proprietary technologies and methods that we believe provide us with important competitive advantages. We cannot be certain that our pending patent applications will issue as patents or that no one will challenge the validity or enforceability of any patent that we own or license.

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

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

***We may be subject to damages resulting from claims that we, our employees, or our independent contractors have wrongfully used or disclosed alleged trade secrets of others.***

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

***Our key growth vectors may not generate anticipated benefits.***

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

*New Products* Drive growth through new products including the On-X heart valve and, as anticipated, the JOTEC family of products;

*New Indications* Broaden the reach of certain of our products, including the On-X heart valve and BioGlue, with new or expanded approvals and indications in the U.S. or in international markets;

*Global Expansion* Expand our current products and services into new markets, including emerging markets, and accelerate growth by developing new direct sales territories overseas; and

*Business Development* Selectively pursue potential acquisition, licensing, or distribution rights of companies or technologies that complement CryoLife's existing products, services, and infrastructure, and expand our footprint in the cardiac and vascular surgery space, such as the 2016 acquisition of On-X and the anticipated acquisition of JOTEC, as well as divestitures of certain of our non-core product lines, such as the HeRO Graft in 2016, and strategic licensing of certain products developed internally. To the extent we identify new non-core products or additional applications for our core products, we may attempt to license these products to corporate partners for further development or seek funding from outside sources to continue commercial development.

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

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

One of our growth strategies is to selectively pursue potential acquisition, licensing, or distribution rights of companies or technologies that complement CryoLife's 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, we recently entered a definitive agreement to acquire JOTEC, which we anticipate financing by incurring further debt, using cash on hand, and issuing additional equity securities. This anticipated acquisition poses many of the same risks as set forth above.

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

***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 certain of the intangible assets acquired in connection with acquisitions during such estimated useful lives;

We will incur additional depreciation expense as a result of recording purchased tangible assets;

To the extent the value of goodwill or intangible assets becomes impaired, we may be required to incur material charges relating to the impairment of those assets;

Cost of sales may increase temporarily following an acquisition as a result of acquired inventory being recorded at its fair market value;

Earnings may be affected by changes in estimates of future contingent consideration to be paid when an earn-out is part of the consideration; or

Earnings may be affected by transaction and implementation costs, which are expensed immediately.

***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, including restrictions or prohibitions on our ability to, among other things:

Incur or guarantee additional debt;

Pay dividends on or make distributions in respect of our share capital or make other restricted payments;

Repurchase or redeem capital stock or subordinated indebtedness;

Transfer or sell certain assets;

Create liens on certain assets;

Consolidate or merge with, or sell or otherwise dispose of all, or substantially all, of our assets to other companies;

Enter into certain transactions with our affiliates;

Pledge the capital stock of any of our subsidiaries;

Enter into agreements which restrict our ability to pay dividends or incur liens;

Make material changes in our equity capital structure;

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

Make certain investments, including strategic acquisitions.

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 assets as collateral under our existing debt agreement. If we default on the terms of such debt 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.***

Under our existing credit agreement, we are required to satisfy and maintain specified financial ratios including a maximum consolidated leverage ratio and a minimum interest coverage ratio. Our ability to meet those financial ratios can be affected by events beyond our control, and there can be no assurance that we will meet those ratios. A failure to

comply with the covenants contained in our existing debt 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 thereunder:

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.

***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 and Austin, Texas, 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.

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

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

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

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

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

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

The Patient Protection and Affordable Care Act ( ACA ) and the Health Care and Education Affordability Reconciliation Act of 2010 imposed significant new taxes on medical device makers in the form of a 2.3 percent excise tax on all U.S. medical device sales that commenced in January 2013. While this tax has been suspended for 2016 and 2017, there is no guarantee that the excise tax will not be reinstated and the underlying legislation might not be repealed or replaced despite the outcome of the 2016 U.S.



Presidential and Congressional election. On January 20, 2017, President Trump issued an executive order titled "Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal." Congressional efforts to repeal and replace the ACA have been ongoing since the election, but it is unclear whether Congress will be successful in its repeal-and-replace efforts. The impact of the executive order and the future of the ACA remain unclear. There are many programs and requirements for which the details have not yet been fully established or the consequences are not fully understood. These proposals may affect aspects of our business. We cannot predict what further reform proposals, if any, will be adopted, when they will be adopted, or what impact they may have on us. However, any changes that lower reimbursement for our products or reduce medical procedure volumes could adversely affect our business and profitability.

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

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

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

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

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

As noted above, we are currently engaged in a PMA clinical trial for PerClot, as well as clinical trials in China for BioGlue and in the U.S. for the On-X valve. Each of these trials is subject to the risks outlined herein.

We cannot give assurance that the relevant regulatory agencies will clear or approve these or any new products and services, or new indications, on a timely basis, if ever, or that the new products and services, or new indications, will adequately meet the requirements of the applicable market or achieve market acceptance. We may encounter delays or rejections during any stage of the regulatory approval process if clinical or other data fails to demonstrate satisfactory 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, and quality may become more stringent due to changes in

applicable laws, regulatory agency policies, or the adoption of new regulations. Clinical trials may also be delayed or halted due to the following, among other factors:

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

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

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

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

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

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

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

sufficient reimbursement from third-party payors for our products or preservation services or the screenings conducted with our products, we may not achieve significant market acceptance. Acceptance of our products in international markets will depend upon the availability of adequate reimbursement or funding within prevailing healthcare payment systems. Reimbursement, funding, and healthcare payment systems vary significantly by country. We may not obtain approvals for reimbursement in a timely manner or at all.

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

Our relationships with physicians, hospitals, and other healthcare providers are subject to scrutiny under various federal anti-kickback, self-referral, false claims, privacy, and transparency laws, and similar laws, often referred to collectively as healthcare compliance laws. Healthcare compliance laws are broad, can be ambiguous, and are complex, and even minor inadvertent violations can give rise to claims that the relevant law has been violated. Possible sanctions for violation of these healthcare compliance laws include monetary fines, civil and criminal penalties, exclusion from federal and state healthcare programs, including Medicare, Medicaid, Veterans Administration health programs, workers compensation programs, and TRICARE (the healthcare system administered by or on behalf of the U.S. Department of Defense for uniformed services beneficiaries, including active duty and their dependents and retirees and their dependents), and forfeiture of amounts collected in violation of such prohibitions. Any government investigation or a finding of a violation of these laws could result in a material, adverse effect on our business, financial condition, and profitability.

Anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation, or receipt of any form of remuneration in return for the referral of an individual or the ordering or recommending of the use of a product or service for which payment may be made by Medicare, Medicaid, or other government-sponsored healthcare programs. We have entered into consulting agreements, speaker agreements, research agreements, and product development agreements with healthcare professionals, including some who may order our products or make decisions to use them. While these transactions were structured with the intention of complying with all applicable laws, including state anti-referral laws and other applicable anti-kickback laws, it is possible that regulatory or enforcement agencies or courts may in the future view these transactions as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties. We have also adopted the AdvaMed Code of Conduct into our Code of Business Conduct, which governs our relationships with healthcare professionals, including our payment of travel and lodging expenses, research and educational grant procedures, and sponsorship of third-party conferences. In addition, we have conducted training sessions on these principles. However, 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. Because our strategy relies on the involvement of healthcare professionals who consult with us on the design of our products, perform clinical research on our behalf, or educate the market about the efficacy and uses of our products, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with healthcare professionals, who refer or order our products, to be in violation of applicable laws and determine that we would be unable to achieve compliance with such applicable laws. This could harm our reputation and the reputations of the healthcare professionals we engage to provide services on our behalf. In addition, the cost of noncompliance with these laws could be substantial since we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from federally funded healthcare programs, including Medicare and Medicaid, for noncompliance.

The Federal False Claims Act ( FCA ) imposes civil liability on any person or entity that submits, or causes the submission of, a false or fraudulent claim to the U.S. Government. Damages under the FCA can be significant and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity with knowledge of past or present fraud against the federal government to sue on behalf of the government to recover the civil penalties and treble damages. The U.S. Department of Justice ( DOJ ) on behalf of the government has previously alleged that the marketing and promotional practices of pharmaceutical and medical device manufacturers, including the off-label promotion of products or the payment of prohibited kickbacks to doctors, violated the FCA, resulting in the submission of improper claims to federal and state healthcare entitlement programs such as Medicaid. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts, and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions going forward.

The Physician Payments Sunshine Act and similar state laws require us to annually report in detail certain payments and transfer of value from us to healthcare professionals, such as reimbursement for travel and meal expenses or compensation for services provided such as training, consulting, and research and development. This information is then posted on the website of the Center of Medicare and Medicaid Services ( CMS ). Certain states also prohibit some forms of these payments, require adoption of marketing codes of conduct, and regulate our relationships with physicians and other referral sources.

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

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

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

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

In recent years, shareholder activists have become involved in numerous public companies. Shareholder activists frequently propose to involve themselves in the governance, strategic direction, and operations of the company. We may in the future

become subject to such shareholder activity 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.

***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, Inc. ( Hemosphere ) and Cardiogenesis Corporation, as mandated by Section 382 of the Internal Revenue Code of 1986, as amended. We believe that our acquisitions of these companies each constituted a change in control, and that prior to our acquisition, Hemosphere had experienced other equity ownership changes that should be considered a change in control. We also acquired net operating loss carryforwards in the acquisition of On-X Life Technologies that are limited under Section 382. However, we believe that such net operating loss carryforwards from On-X will be fully realizable prior to expiration. The deferred tax assets recorded on our Consolidated Balance Sheets exclude amounts that it expects 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 management believes 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.

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

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

Changes in demand for the products we sell;

Increased product and price competition, due to the announcement or introduction of new products by our competitors, market conditions, the regulatory landscape, or other factors;

Changes in the mix of products we sell;

Availability of materials and supplies, including donated tissue used in preservation services;

Our pricing strategy with respect to different product lines;

Strategic actions by us, such as acquisitions of businesses, products, or technologies;

Effects of domestic and foreign economic conditions and exchange rates on our industry and/or customers;

The divestiture or discontinuation of a product line or other revenue generating activity;

The relocation and integration of manufacturing operations and other strategic restructuring;

Regulatory actions that may necessitate recalls of our products or warning letters that negatively affect the markets for our products;

Failure of government and private health plans to adequately and timely reimburse the users of our products;

Costs incurred by us in connection with the termination of contractual and other relationships, including distributorships;

Our ability to collect outstanding accounts receivable in selected countries outside of the U.S.;

The expiration or utilization of deferred tax assets such as net operating loss carryforwards;

Market reception of our new or improved product offerings; and

The loss of any significant customer, especially in regard to any product that has a limited customer base. We have based our current and future expense levels largely on our investment plans and estimates of future events, although certain 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 and 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.

### Risks Related to Ownership of our Common Stock

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

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

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

We are subject to the Florida affiliated transactions statute, which generally requires approval by the disinterested directors or supermajority approval by shareholders for affiliated transactions between a corporation and an interested stockholder. Additionally our organizational documents contain provisions restricting persons who may call shareholder meetings and allowing the Board of Directors to fill vacancies and fix the number of directors. These provisions of Florida law and our articles of incorporation and bylaws could prevent attempts by shareholders to remove current management, prohibit or delay mergers or other changes of control transactions, and discourage attempts by other companies to acquire us, even if such a transaction would be beneficial to our shareholders.

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

- (c) The following table provides information about purchases by us during the quarter ended September 30, 2017 of equity securities that are registered by us pursuant to Section 12 of the Securities Exchange Act of 1934:

| Period              | Total Number of<br>Common<br>Shares<br>and Common Stock<br>Units<br>Purchased | Average Price<br>Paid per<br>Common Share | Total Number<br>of Common Shares<br>Purchased<br>as Part of<br>Publicly<br>Announced<br>Plans or<br>Programs |       | Dollar Value<br>of Common Shares<br>That May<br>Yet Be<br>Purchased Under the<br>Plans or<br>Programs |
|---------------------|---|---|--|-------|---|
|                     |   |   |  |       |   |
| 07/01/17 - 07/31/17 | 654   | \$ 18.90                                  | --   | \$ -- | --  |
| 08/01/17 - 08/31/17 | 762   | 18.79                                     | --   | --    | --  |
| 09/01/17 - 09/30/17 | 954   | 21.75                                     | --   | --    | --  |

|       |       |       |    |
|-------|-------|-------|----|
| Total | 2,370 | 20.01 | -- |
|-------|-------|-------|----|

The common shares purchased during the quarter ended September 30, 2017 were tendered to us in payment of taxes on stock compensation and were not part of a publicly announced plan or program.

Under our Amended Debt 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.

| <b>Exhibit Number</b> | <b>Description</b>  |
|-----------------------|---|
| 2.4**                 | <u>Securities Purchase Agreement, dated as of October 10, 2017, by and among CryoLife, Inc., CryoLife Germany HoldCo GmbH, Jolly Buyer Acquisition GmbH, JOTEC AG, each of the security holders identified therein, and Lars Sunnanväder as the representative of such security holders. (Incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed October 11, 2017.)</u> |
| 3.1                   | <u>Amended and Restated Articles of Incorporation of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed November 23, 2015.)</u>   |
| 3.2                   | <u>Amended and Restated By-Laws of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed March 1, 2016.)</u>   |
| 4.1                   | <u>Form of Certificate for our Common Stock. (Incorporated herein by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.)</u>  |
| 31.1*                 | <u>Certification by J. Patrick Mackin pursuant to section 302 of the Sarbanes-Oxley Act of 2002.</u>  |
| 31.2*                 | <u>Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.</u>  |
| 32**                  | <u>Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.</u>  |
| 101.INS*              | XBRL Instance Document  |
| 101.SCH*              | XBRL Taxonomy Extension Schema Document   |
| 101.CAL*              | XBRL Taxonomy Extension Calculation Linkbase Document   |
| 101.DEF*              | XBRL Taxonomy Extension Definition Linkbase   |
| 101.LAB*              | XBRL Taxonomy Extension Label Linkbase Document   |
| 101.PRE*              | XBRL Taxonomy Extension Presentation Linkbase Document  |

\* Filed herewith.

\*\* Furnished herewith.



**SIGNATURES**

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

CRYOLIFE, INC.  
(Registrant)

/s/ J. PATRICK MACKIN

/s/ D. ASHLEY LEE

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

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

October 31, 2017

DATE