**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, 2020**

OR

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

For the transition period from _____ to _____

Commission file number: 1-13165

# CRYOLIFE INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

| Class | Outstanding at October 30, 2020 |
|---|---|
| Common Stock, $0.01 par value | 38,857,435 |

**TABLE OF CONTENTS**

**Part I – FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| | (Unaudited) | | (Unaudited) | |
| **Revenues:** | | | | |
| Products | $ 45,109 | $ 47,484 | $ 128,797 | $ 147,053 |
| Preservation services | 20,022 | 20,397 | 56,534 | 59,472 |
| **Total revenues** | **65,131** | **67,881** | **185,331** | **206,525** |
| **Cost of products and preservation services:** | | | | |
| Products | 12,998 | 12,706 | 36,078 | 41,021 |
| Preservation services | 9,001 | 9,953 | 26,060 | 29,043 |
| **Total cost of products and preservation services** | **21,999** | **22,659** | **62,138** | **70,064** |
| **Gross margin** | **43,132** | **45,222** | **123,193** | **136,461** |
| **Operating expenses:** | | | | |
| General, administrative, and marketing | 33,743 | 34,259 | 105,033 | 105,402 |
| Research and development | 5,755 | 6,259 | 17,633 | 17,648 |
| **Total operating expenses** | **39,498** | **40,518** | **122,666** | **123,050** |
| **Operating income** | **3,634** | **4,704** | **527** | **13,411** |
| Interest expense | 4,940 | 3,555 | 11,980 | 11,260 |
| Interest income | (13) | (259) | (181) | (608) |
| Other expense, net | 2,888 | 2,400 | 5,810 | 2,662 |
| **(Loss) income before income taxes** | **(4,181)** | **(992)** | **(17,082)** | **97** |
| Income tax benefit | (1,311) | (858) | (3,858) | (2,304) |
| **Net (loss) income** | $ **(2,870)** | $ **(134)** | $ **(13,224)** | $ **2,401** |
| **(Loss) income per common share:** | | | | |
| **Basic** | $ **(0.08)** | $ **(0.00)** | $ **(0.35)** | $ **0.06** |
| **Diluted** | $ **(0.08)** | $ **(0.00)** | $ **(0.35)** | $ **0.06** |
| **Weighted-average common shares outstanding:** | | | | |
| Basic | 37,912 | 37,255 | 37,608 | 37,065 |
| Diluted | 37,912 | 37,255 | 37,608 | 37,850 |
| **Net (loss) income** | $ **(2,870)** | $ **(134)** | $ **(13,224)** | $ **2,401** |
| **Other comprehensive income (loss):** | | | | |
| Foreign currency translation adjustments | 8,698 | (8,017) | 8,669 | (8,803) |
| **Comprehensive income (loss)** | $ **5,828** | $ **(8,151)** | $ **(4,555)** | $ **(6,402)** |

See accompanying Notes to Summary Consolidated Financial Statements

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

| | September 30, 2020 | December 31, 2019 |
|---|---|---|
| | (Unaudited) | |
| **ASSETS** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 64,122 | $ 33,766 |
| Restricted securities | 513 | 528 |
| Trade receivables, net | 46,911 | 52,940 |
| Other receivables | 2,520 | 2,921 |
| Inventories | 69,402 | 53,071 |
| Deferred preservation costs | 35,952 | 32,551 |
| Prepaid expenses and other | 14,279 | 11,613 |
| **Total current assets** | **233,699** | **187,390** |
| Property and equipment, net | 31,799 | 32,150 |
| Operating lease right-of-use assets, net | 19,438 | 21,994 |
| Goodwill | 253,995 | 186,697 |
| Acquired technology, net | 185,010 | 115,415 |
| Other intangibles, net | 40,697 | 42,319 |
| Deferred income taxes | 3,274 | 5,481 |
| Other assets | 14,288 | 14,208 |
| **Total assets** | **$ 782,200** | **$ 605,654** |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| **Current liabilities:** | | |
| Accounts payable | $ 10,399 | $ 9,796 |
| Accrued compensation | 11,644 | 12,260 |
| Accrued procurement fees | 4,057 | 4,362 |
| Current maturities of operating leases | 5,678 | 5,487 |
| Current portion of long-term debt | 1,165 | 1,164 |
| Taxes payable | 6,140 | 2,984 |
| Accrued expenses | 10,344 | 6,733 |
| Other liabilities | 4,240 | 2,409 |
| **Total current liabilities** | **53,667** | **45,195** |
| Long-term debt | 289,697 | 214,571 |
| Deferred income taxes | 24,813 | 25,844 |
| Non-current maturities of operating leases | 15,026 | 17,918 |
| Deferred compensation liability | 4,982 | 4,434 |
| Contingent consideration | 55,407 | -- |
| Other liabilities | 12,842 | 11,996 |
| **Total liabilities** | **$ 456,434** | **$ 319,958** |
| **Commitments and contingencies** | | |
| **Shareholders' equity:** | | |
| Preferred stock | -- | -- |
| Common stock (issued shares of 40,341 in 2020 and 39,018 in 2019) | 403 | 390 |
| Additional paid-in capital | 316,394 | 271,782 |
| Retained earnings | 23,480 | 36,704 |
| Accumulated other comprehensive income (loss) | 80 | (8,589) |
| Treasury stock at cost (shares of 1,484 in each of 2020 and 2019) | (14,591) | (14,591) |
| **Total shareholders' equity** | **325,766** | **285,696** |
| **Total liabilities and shareholders' equity** | **$ 782,200** | **$ 605,654** |

See accompanying Notes to Summary Consolidated Financial Statements.

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2020** | **2019** |
| **Net cash flows from operating activities:** | | |
| Net (loss) income | $ (13,224) | $ 2,401 |
| | | |
| Adjustments to reconcile net (loss) income to net cash from operating activities: | | |
| Depreciation and amortization | 14,818 | 13,257 |
| Non-cash compensation | 7,432 | 6,581 |
| Non-cash lease expense | 5,324 | 3,491 |
| Change in fair value of long-term loan | 4,949 | -- |
| Deferred income taxes | (4,916) | (1,064) |
| Non-cash interest expense | 2,261 | 1,266 |
| Other non-cash adjustments to net (loss) income | 1,631 | 1,328 |
| | | |
| Changes in operating assets and liabilities: | | |
| Receivables | 7,718 | (4,496) |
| Inventories and deferred preservation costs | (19,744) | (3,864) |
| Prepaid expenses and other assets | (2,560) | (3,020) |
| Accounts payable, accrued expenses, and other liabilities | 3,230 | (1,113) |
| **Net cash flows provided by operating activities** | **6,919** | **14,767** |
| | | |
| **Net cash flows from investing activities:** | | |
| Acquisition of Ascyrus, net of cash acquired | (59,643) | -- |
| Payments for Endospan agreements | (5,000) | (15,000) |
| Capital expenditures | (5,171) | (5,222) |
| Other | (968) | (531) |
| **Net cash flows used in investing activities** | **(70,782)** | **(20,753)** |
| | | |
| **Net cash flows from financing activities:** | | |
| | | |
| Proceeds from issuance of convertible debt | 100,000 | -- |
| Proceeds from revolving line of credit | 30,000 | -- |
| Proceeds from financing insurance premiums | 2,816 | -- |
| Proceeds from exercise of stock options and issuance of common stock | 2,079 | 4,519 |
| Repayment of revolving line of credit | (30,000) | -- |
| Payment of debt issuance costs | (3,647) | -- |
| Repayment of debt | (3,727) | (2,072) |
| Redemption and repurchase of stock to cover tax withholdings | (1,768) | (2,723) |
| Other | (463) | (560) |
| **Net cash flows provided by (used in) financing activities** | **95,290** | **(836)** |
| | | |
| Effect of exchange rate changes on cash, cash equivalents, and restricted securities | (1,086) | 1,763 |
| **Increase (decrease) in cash, cash equivalents, and restricted securities** | **30,341** | **(5,059)** |
| | | |
| Cash, cash equivalents, and restricted securities beginning of period | 34,294 | 42,236 |
| **Cash, cash equivalents, and restricted securities end of period** | **$ 64,635** | **$ 37,177** |

See accompanying Notes to Summary Consolidated Financial Statements

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

| | Common Stock | | Additional Paid-In Capital | Retained Earnings | Accumulated Other Comprehensive (Loss) Income | Treasury Stock | | Total Shareholders' Equity |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | | | | Shares | Amount | |
| **Balance at June 30, 2020** | **39,288** | **393** | **293,022** | **26,350** | **(8,618)** | **(1,484)** | **(14,591)** | **296,556** |
| Net loss | -- | -- | -- | (2,870) | -- | -- | -- | (2,870) |
| Other comprehensive income: | | | | | | | | |
| Foreign currency translation adjustment | -- | -- | -- | -- | 8,698 | -- | -- | 8,698 |
| Comprehensive income | | | | | | | | 5,828 |
| Stock Issued for Ascyrus Transaction | 992 | 10 | 19,990 | -- | -- | -- | -- | 20,000 |
| Equity compensation | 6 | -- | 2,518 | -- | -- | -- | -- | 2,518 |
| Exercise of options | 3 | -- | 31 | -- | -- | -- | -- | 31 |
| Employee stock purchase plan | 54 | -- | 873 | -- | -- | -- | -- | 873 |
| Redemption and repurchase of stock to cover tax withholdings | (2) | -- | (40) | -- | -- | -- | -- | (40) |
| **Balance at September 30, 2020** | **40,341** | **$ 403** | **$ 316,394** | **$ 23,480** | **$ 80** | **(1,484)** | **$ (14,591)** | **$ 325,766** |

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| | Common Stock | | Additional Paid-In Capital | Retained Earnings | Accumulated Other Comprehensive (Loss) Income | Treasury Stock | | Total Shareholders' Equity |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | | | | Shares | Amount | |
| **Balance at December 31, 2019** | **39,018** | **390** | **271,782** | **36,704** | **(8,589)** | **(1,484)** | **(14,591)** | **$ 285,696** |
| Net loss | -- | -- | -- | (13,224) | -- | -- | -- | (13,224) |
| Other comprehensive loss: | | | | | | | | |
| Foreign currency translation adjustment | -- | -- | -- | -- | 8,669 | -- | -- | 8,669 |
| Comprehensive loss | | | | | | | | (4,555) |
| Stock Issued for Ascyrus Transaction | 992 | 10 | 19,990 | -- | -- | -- | -- | 20,000 |
| Equity component of the convertible note issuance | -- | -- | 16,426 | -- | -- | -- | -- | 16,426 |
| Equity compensation | 273 | 3 | 7,885 | -- | -- | -- | -- | 7,888 |
| Exercise of options | 47 | 1 | 517 | -- | -- | -- | -- | 518 |
| Employee stock purchase plan | 84 | -- | 1,561 | -- | -- | -- | -- | 1,561 |
| Redemption and repurchase of stock to cover tax withholdings | (73) | (1) | (1,767) | -- | -- | -- | -- | (1,768) |
| **Balance at September 30, 2020** | **40,341** | **$ 403** | **$ 316,394** | **$ 23,480** | **$ 80** | **(1,484)** | **$ (14,591)** | **$ 325,766** |

See accompanying Notes to Consolidated Financial Statements

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

| | Common Stock | | Additional Paid-In Capital | Retained Earnings | Accumulated Other Comprehensive Loss | Treasury Stock | | Total Shareholders' Equity |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | | | | Shares | Amount | |
| **Balance at June 30, 2019** | **38,943** | **$ 389** | **$ 265,694** | **$ 37,519** | **$ (6,858)** | **(1,484)** | **$ (14,591)** | **$ 282,153** |
| Net loss | -- | -- | -- | (134) | -- | -- | -- | (134) |
| Other comprehensive loss: | | | | | | | | |
| Foreign currency translation adjustment | -- | -- | -- | -- | (8,017) | -- | -- | (8,017) |
| Comprehensive loss | | | | | | | | (8,151) |
| Equity compensation | 6 | -- | 2,620 | -- | -- | -- | -- | 2,620 |
| Exercise of options | 5 | -- | 53 | -- | -- | -- | -- | 53 |
| Employee stock purchase plan | 36 | 1 | 884 | -- | -- | -- | -- | 885 |
| Redemption and repurchase of stock to cover tax withholdings | (2) | -- | (59) | -- | -- | -- | -- | (59) |
| **Balance at September 30, 2019** | **38,988** | **$ 390** | **$ 269,192** | **$ 37,385** | **$ (14,875)** | **(1,484)** | **$ (14,591)** | **$ 277,501** |

| | Common Stock | | Additional Paid-In Capital | Retained Earnings | Accumulated Other Comprehensive Loss | Treasury Stock | | Total Shareholders' Equity |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | | | | Shares | Amount | |
| **Balance at December 31, 2018** | **38,463** | **385** | **260,361** | **34,984** | **(6,072)** | **(1,484)** | **(14,591)** | **$ 275,067** |
| Net income | -- | -- | -- | 2,401 | -- | -- | -- | 2,401 |
| Other comprehensive loss: | | | | | | | | |
| Foreign currency translation adjustment | -- | -- | -- | -- | (8,803) | -- | -- | (8,803) |
| Comprehensive loss | | | | | | | | (6,402) |
| Equity compensation | 251 | 2 | 7,037 | -- | -- | -- | -- | 7,039 |
| Exercise of options | 306 | 3 | 3,054 | -- | -- | -- | -- | 3,057 |
| Employee stock purchase plan | 61 | 1 | 1,462 | -- | -- | -- | -- | 1,463 |
| Redemption and repurchase of stock to cover tax withholdings | (93) | (1) | (2,722) | -- | -- | -- | -- | (2,723) |
| **Balance at September 30, 2019** | **38,988** | **$ 390** | **$ 269,192** | **$ 37,385** | **$ (14,875)** | **(1,484)** | **$ (14,591)** | **$ 277,501** |

See accompanying Notes to Consolidated Financial Statements

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

## 1. Basis of Presentation

***Overview***

The accompanying summary consolidated financial statements include the accounts of CryoLife, Inc. and its subsidiaries ("CryoLife," the "Company," "we," or "us"). All significant intercompany accounts and transactions have been eliminated in consolidation. The accompanying Summary Consolidated Balance Sheet as of December 31, 2019 has been derived from audited financial statements. The accompanying unaudited summary consolidated financial statements as of, and for the three and nine months ended, September 30, 2020 and 2019 have been prepared in accordance with (i) accounting principles generally accepted in the U.S. for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U.S. Securities and Exchange Commission ("SEC"). Accordingly, such statements do not include all the information and disclosures that are required by accounting principles generally accepted in the U.S. for a complete presentation of financial statements. In the opinion of management, all adjustments (including those of a normal, recurring nature) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020. These summary consolidated financial statements should be read in conjunction with the consolidated financial statements and notes included in CryoLife's Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on February 19, 2020.

***New Accounting Standards***

*Recently Adopted*

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASC Update No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). The purpose of Update No. 2016-13 is to replace the current incurred loss impairment methodology for financial assets measured at amortized cost with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information, including forecasted information, to develop credit loss estimates. Update No. 2016-13 is effective for annual periods beginning after December 15, 2019. The Company adopted this new guidance on January 1, 2020. The adoption of ASU 2016-13 did not result in a material effect on the Company's financial condition, results of operations, or cash flows.

*Not Yet Effective*

In August 2020, the FASB issued ASC Update No. 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity* ("ASU 2020-06") The update simplifies the accounting for convertible debt instruments and convertible preferred stock by reducing the number of accounting models and the number of embedded conversion features that could be recognized separately from the primary contract. ASU 2020-06 also enhances transparency and improves disclosures for convertible instruments and earnings per share guidance. ASU 2020-06 is effective for annual reporting periods beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. This update permits the use of either the modified retrospective or fully retrospective method of transition. We are in the process of evaluating the effect that the adoption of this standard will have on our financial position and results of operations.

## 2. Acquisition of Ascyrus

***Overview***

On September 2, 2020, we entered into a Securities Purchase Agreement (the "Ascyrus Agreement") to acquire 100% of the outstanding equity interests of Ascyrus Medical LLC, ("Ascyrus"). Ascyrus is the developer of the Ascyrus Medical Dissection Stent ("AMDS"), the world's first aortic arch remodeling device for use in the treatment of acute Type A aortic dissections.

Under the terms of the Ascyrus Agreement, we will pay an aggregate of up to $200.0 million in consideration, consisting of: (i) a cash payment of approximately $60.0 million and the issuance of $20.0 million in shares of CryoLife common stock, in each case, delivered at the closing of the acquisition, (ii) if the U.S. Food and Drug Administration (the "FDA") approves an Investigational Device Exemption ("IDE") application for the AMDS, a cash payment of $10.0 million and the issuance of $10.0 million in shares of CryoLife common stock, (iii) if the FDA approves a Premarket Approval ("PMA") application submitted for the AMDS, a cash payment of $25.0 million, (iv) if regulatory approval of the AMDS is obtained in Japan on or before June 30, 2027, a cash payment of $10.0 million, (v) if regulatory approval of the AMDS is obtained in China on or before June 30, 2027, a cash payment of $10.0 million and (vi) a potential cash payment of up to $55.0 million (or up to $65.0 million to $75.0 million if the Japanese or Chinese approvals are not secured on or before June 30, 2027) calculated as two times the incremental worldwide sales of the AMDS (or any other acquired technology or derivatives of such acquired technology) outside of the European Union during the three-year period following the date the FDA approves a Premarket Approval application submitted for the AMDS.

***Accounting for the Transaction***

Upon closing of the acquisition on September 2, 2020, we paid $83.7 million consisting of $63.7 million in cash consideration, and $20.0 million in shares of CryoLife common stock. The number of shares issued was based on a 10-day moving volume weighted average closing price of a share of CryoLife common stock as of the date immediately prior to closing, resulting in an issuance of 991,800 shares of CryoLife common stock.

As part of the acquisition, we may be required to pay additional consideration in cash and equity up to $120.0 million to the former shareholders of Ascyrus upon the achievement of certain milestones and the sales-based additional earnout described above. The fair value of the total potential purchase consideration of $200.0 million was calculated to be $139.1 million, which includes total purchase consideration, as well as the contingent consideration liability discussed below. Our preliminary allocation of the purchase consideration was allocated to Ascyrus's tangible and identifiable intangible assets acquired and liabilities assumed, based on their estimated fair values as of September 2, 2020.

We recorded the contingent consideration liability of $55.4 million in Other long-term liabilities in the Summary Consolidated Balance Sheets, representing the estimated fair value of future potential payments. The fair value of the contingent consideration liability was estimated by discounting to present value the contingent payments expected to be made based on a probability-weighted scenario approach. We applied a discount rate based on our unsecured credit spread and the term commensurate risk-free rate to the additional consideration to be paid, and then applied a risk-based estimate of the probability of achieving each scenario to calculate the fair value of the contingent consideration. This fair value measurement was based on unobservable inputs, including management estimates and assumptions about the future achievement of milestones and future estimate of revenues, and is, therefore, classified as Level 3 within the fair value hierarchy presented in Note 4. We will remeasure this liability at each reporting date and will record changes in the fair value of the contingent consideration in operating expenses on the Summary Consolidated Statements of Operations and Comprehensive Income (Loss). Increases or decreases in the fair value of the contingent consideration liability can result from changes in discount periods and rates, changes in the timing and amount of our revenue estimates, and changes in the timing and expectation of regulatory approvals.

We performed an assessment of the fair value of the contingent consideration as of September 30, 2020 and concluded that an adjustment to the fair value as a result of this assessment was not material.

We recorded $62.7 million of preliminary goodwill, that we expect to deduct for tax purposes, based on the amount by which the total purchase consideration price exceeded the fair value of the net assets acquired and liabilities assumed. Goodwill from this transaction has been allocated to our Medical Devices segment. The estimated allocation of assets acquired and liabilities assumed is based on the information available to us as of September 30, 2020. We are completing our procedures related to the purchase price allocation and if new information regarding these values is received that would result in a material adjustment to the values recorded, we will recognize the adjustment, which may include the recognition of additional expenses, impairments, or other allocation adjustments, in the period this determination is made.

The preliminary purchase consideration allocated as of September 2, 2020 consisted of the following (in thousands):

| | | |
|---|---|---|
| **Consideration** | | |
| Cash paid for acquisition | $ | 63,660 |
| Common stock issued | | 20,000 |
| Contingent consideration | | 55,407 |
| **Fair value of total consideration** | **$** | **139,067** |
| | | |
| **Purchase Price Allocation** | | |
| Cash and cash equivalents | $ | 4,017 |
| Intangible assets | | 72,600 |
| Net other assets/liabilities acquired | | (274) |
| Goodwill | | 62,724 |
| **Net assets acquired** | **$** | **139,067** |

We incurred transaction costs of $618,000 and $677,000 for the three and nine months ended September 30, 2020, respectively, primarily related to the acquisition, which included, among other costs, expenses related to legal and professional fees. These costs were expensed as incurred and were primarily recorded as general, administrative, and marketing expenses on our Summary Consolidated Statements of Operations and Comprehensive Income (Loss).

Pro forma financial information related to the Ascyrus Agreement has not been provided as it is not material to our consolidated results of operations.

**3. Agreements with Endospan**

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

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

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

***Loan Agreement***

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

The first tranche of the Endospan Loan was funded upon execution of the agreement in September 2019. During September 2020, we funded the second tranche payment of $5.0 million upon the certification of Investigational Device Exemption ("IDE") approval from the FDA of NEXUS. The third tranche is required to be funded upon certification of enrollment of at least 50% of the required number of patients in the primary arm of the FDA approved clinical trial for NEXUS, in each case subject to Endospan's continued compliance with the Endospan Loan and certain other conditions. If a termination fee becomes payable by Endospan under the Endospan Distribution Agreement, it will be added to the amount payable to CryoLife under the Endospan Loan.

***Variable Interest Entity***

We consolidate the results of a variable interest entity ("VIE") when it is determined that we are the primary beneficiary. Based on our evaluation of Endospan and the related agreements with Endospan, we determined that Endospan is a VIE. Although the arrangement with Endospan resulted in our holding a variable interest, it did not empower us to direct those activities of Endospan that most significantly impact the VIE economic performance. Therefore, we are not the primary beneficiary, and we have not consolidated Endospan into our financial results. Our payments to Endospan in September 2019 totaled $15.0 million which included a $9.0 million distribution fee, a $1.0 million securities purchase option, and $5.0 million for the first tranche of the Endospan Loan. An additional $5.0 million was funded as part of the second tranche payment described above. Our payments to date, including any loans, guarantees, and other subordinated financial support related to this VIE, totaled $20.0 million as of September 30, 2020, representing our maximum exposure to loss, and were not individually significant to our consolidated financial statements.

***Valuation***

The agreements with Endospan were entered into concurrently and had certain terms that are interrelated. In our evaluation of the initial relative fair value of each of the Endospan agreements to determine the amount to record, we utilized discounted cash flows to estimate the fair market value for the Endospan Loan and for the Endospan Distribution Agreement. We estimated the fair value of the Endospan Option Agreement utilizing the Monte Carlo simulation. Inputs in our valuation of the Endospan agreements included cash payments and anticipated payments based on the executed agreements with Endospan, projected discounted cash flows in connection with the Endospan transaction, our expected internal rate of return and discount rates, and our assessed probability and timing of receipt of certification of certain approvals and milestones in obtaining FDA approval. Based on the initial fair value of the Endospan Loan and the relative fair values of the Endospan Distribution Agreement and Endospan Option Agreement, we recorded the Endospan Loan value of $358,000 in Other long-term assets in the Summary Consolidated Balance Sheets as of December 31, 2019. The Endospan Option Agreement was valued at $4.8 million in Other long-term assets in the Summary Consolidated Balance Sheets as of September 30, 2020 and December 31, 2019. The Endospan Distribution Agreement was recorded at $8.1 million and $9.8 million in Other Intangibles, net in the Summary Consolidated Balance Sheets as of September 30, 2020 and December 31, 2019, respectively.

We elected the fair value option for recording the Endospan Loan. We assess the fair value of the Endospan Loan based on quantitative and qualitative characteristics, and adjust the amount recorded to its current fair market value at each reporting period. We performed an assessment of the fair value of the Endospan Loan after funding the second tranche payment and adjusted the fair value of the Endospan Loan to $409,000 as of September 30, 2020. As a result of the fair value adjustment, we recorded an expense of $4.9 million in Other Expense on the Consolidated Statements of Operations and Comprehensive Income (Loss) during the three months ended September 30, 2020.

**4. Financial Instruments**

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

| **September 30, 2020** | **Level 1** | **Level 2** | **Level 3** | **Total** |
|---|---|---|---|---|
| Cash equivalents: | | | | |
| Money market funds | $ 11,483 | $ -- | $ -- | $ 11,483 |
| Restricted securities: | | | | |
| Money market funds | 513 | -- | -- | 513 |
| Endospan loan | -- | -- | 409 | 409 |
| **Total assets** | **$ 11,996** | **$ --** | **$ 409** | **$ 12,405** |
| | | | | |
| Long-term liabilities: | | | | |
| Contingent consideration | -- | -- | (55,407) | (55,407) |
| **Total liabilities** | **$ --** | **$ --** | **$ (55,407)** | **$ (55,407)** |

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

We used prices quoted from our investment advisors to determine the Level 1 valuation of our investments in money market funds. We recorded the Endospan Loan, classified as Level 3, as a result of an agreement with Endospan in September 2019. The contingent consideration component of the Ascyrus acquisition was classified as a Level 3 financial instrument. See Note 2 and Note 3 for further discussion of the Ascyrus acquisition, and the Endospan Loan, respectively. Changes in fair value of Level 3 assets and liabilities are listed in the tables below (in thousands):

| | Endospan Loan | | Contingent Consideration |
|---|---|---|---|
| Balance as of December 31, 2019 | $ 358 | Balance as of December 31, 2019 | $ -- |
| Additional investment in Endospan | 5,000 | Discounted value at acquisition | (55,407) |
| Change in valuation | (4,949) | Change in valuation | -- |
| Balance as of September 30, 2020 | $ **409** | Balance as of September 30, 2020 | $ **(55,407)** |

## 5. Cash Equivalents and Restricted Securities

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

| September 30, 2020 | Cost Basis | Unrealized Holding Gains | Estimated Market Value |
|---|---|---|---|
| Cash equivalents: | | | |
| Money market funds | $ 11,483 | $ -- | $ 11,483 |
| Restricted securities: | | | |
| Money market funds | 513 | -- | 513 |
| **Total assets** | $ 11,996 | $ -- | $ 11,996 |

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

As of September 30, 2020 and December 31, 2019 $513,000 and $528,000, 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 to international tax obligations.

There were no gross realized gains or losses on cash equivalents and restricted securities in the three and nine months ended September 30, 2020 and 2019. As of September 30, 2020 $513,000 of our restricted securities had a maturity date within three months. As of December 31, 2019 $528,000 of our restricted securities had a maturity date within three months.

**6. Inventories and Deferred Preservation Costs**

Inventories at September 30, 2020 and December 31, 2019 were comprised of the following (in thousands):

| | September 30, 2020 | December 31, 2019 |
|---|---|---|
| Raw materials and supplies | $ 30,875 | $ 21,180 |
| Work-in-process | 7,461 | 5,127 |
| Finished goods | 31,066 | 26,764 |
| **Total inventories** | **$ 69,402** | **$ 53,071** |

Deferred preservation costs at September 30, 2020 and December 31, 2019 were comprised of the following (in thousands):

| | September 30, 2020 | December 31, 2019 |
|---|---|---|
| Cardiac tissues | $ 16,300 | $ 15,365 |
| Vascular tissues | 19,254 | 17,186 |
| NeoPatch | 398 | - |
| **Total deferred preservation costs** | **$ 35,952** | **$ 32,551** |

To facilitate product usage, we maintain consignment inventory of our On-X heart valves at domestic hospital locations and both On-X heart valves and JOTEC products at international hospital locations. We retain title and control over this consignment inventory until the device is implanted, at which time we invoice the hospital and recognize revenue. As of September 30, 2020 we had $12.8 million in consignment inventory, with approximately 47% in domestic locations and 53% in international locations. As of December 31, 2019 we had $12.0 million in consignment inventory, with approximately 51% in domestic locations and 49% in international locations.

**7. Goodwill and Other Intangible Assets**

***Indefinite Lived Intangible Assets***

As of September 30, 2020 and December 31, 2019 the carrying values of our indefinite lived intangible assets were as follows (in thousands):

| | September 30, 2020 | December 31, 2019 |
|---|---|---|
| Goodwill | $ 253,995 | $ 186,697 |
| In-process R&D | 2,283 | 2,190 |
| Procurement contracts and agreements | 2,013 | 2,013 |
| Trademarks | 765 | 844 |

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

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

We evaluate our goodwill and non-amortizing intangible assets for impairment on an annual basis during the fourth quarter of the year, and, if necessary, during interim periods if factors indicate that an impairment review is warranted. As of

September 30, 2020 we concluded that our assessment of current factors did not indicate that goodwill or non-amortizing intangible assets are more likely than not to be impaired. We will continue to evaluate the recoverability of these non-amortizing intangible assets in future periods as necessary.

The goodwill balance increased during the nine months ended September 30, 2020 as a result of the goodwill recorded in connection with the Ascyrus acquisition as further described in Note 2 above. As of September 30, 2020 and December 31, 2019 our entire goodwill balance was related to our Medical Devices segment.

| | Medical Devices Segment |
|---|---|
| Balance as of December 31, 2019 | $ 186,697 |
| Ascyrus acquisition | 62,724 |
| Revaluation of goodwill denominated in foreign currency | 4,574 |
| **Balance as of September 30, 2020** | **$ 253,995** |

***Definite Lived Intangible Assets***

The definite lived intangible balance includes balances related to acquired technology, customer relationships, distribution and manufacturing rights and know-how, patents and other definite lived intangible assets. The acquired technology balance increased $72.6 million during the nine months ended September 30, 2020 related to developed technology acquired as a result of the Ascyrus acquisition as further described in Note 2 above. As of September 30, 2020 and December 31, 2019 the gross carrying values, accumulated amortization, and approximate amortization period of our definite lived intangible assets were as follows (in thousands):

| **September 30, 2020** | **Gross Carrying Value** | **Accumulated Amortization** | **Amortization Period** |
|---|---|---|---|
| Acquired technology | $ 217,085 | $ 32,075 | 11 – 22 Years |
| Customer lists and relationships | 31,215 | 7,733 | 13 – 22 Years |
| Distribution and manufacturing rights and know-how | 14,239 | 4,678 | 5 – 15 Years |
| Patents | 3,888 | 3,104 | 17 Years |
| Other | 2,712 | 903 | 4 – 5 Years |

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

***Amortization Expense***

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| Amortization expense | $ 3,397 | $ 2,660 | $ 9,430 | $ 7,796 |

As of September 30, 2020 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

| | Remainder of 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | Total |
|---|---|---|---|---|---|---|---|
| Amortization expense | $ 4,127 | 16,506 | 15,959 | 15,486 | 15,160 | 13,079 | $ 80,317 |

**8. Income Taxes**

***Income Tax Expense***

Our effective income tax rate was a benefit of 31% and 23% for the three and nine months ended September 30, 2020, respectively, as compared to a benefit of 87% and 2,375% for the three and nine months ended September 30, 2019, respectively. The change in the tax rate for the three and nine months ended September 30, 2020 is primarily due to a change in pre-tax book loss, as well as a reduction in the excess tax benefit related to stock compensation for the three and nine months ended September 30, 2020, as compared to the three and nine months ended September 30, 2019.

The income tax rate for the three and nine months ended September 30, 2020 and 2019 was favorably impacted by excess tax benefit deductions related to stock compensation, the research and development tax credit, and losses in high rate jurisdictions. These factors were partially offset by the unfavorable impacts of non-deductible operating expenses and executive compensation expenses.

***Deferred Income Taxes***

We generate deferred tax assets primarily as a result of the difference in fixed asset depreciation lives for book and tax purposes, accruals for which the timing of deductibility is different for book and tax purposes, the timing of tax deductions related to stock compensation, and operating losses. We acquired significant deferred tax assets, primarily net operating loss carryforwards, from our acquisitions of JOTEC and its subsidiaries in 2017, On-X in 2016, Hemosphere, Inc. in 2012, and Cardiogenesis Corporation in 2011. We believe utilization of these net operating losses will not have a material impact on income taxes for the 2020 tax year.

As of September 30, 2020 we maintained a total of $2.7 million in valuation allowances against deferred tax assets, primarily related to state and foreign net operating loss carryforwards, and a net deferred tax liability of $21.5 million. As of December 31, 2019 we maintained a total of $3.2 million in valuation allowances against deferred tax assets, primarily related to state and foreign net operating loss carryforwards, and a net deferred tax liability of $20.4 million.

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

In response to the novel coronavirus disease ("COVID-19") pandemic, the U.S. government enacted the CARES Act on March 27, 2020. The CARES Act provides various forms of relief and assistance to U.S. businesses. We recorded a reduction to income taxes payable and deferred tax assets of approximately $1.3 million for the anticipated change to the 2019 Section 163(j) interest expense deduction limitation. We will continue to monitor and assess the impact the CARES Act and similar legislation in other countries may have on our business and financial results.

**9. Leases**

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

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

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

| **Operating leases:** | **September 30, 2020** | **December 31, 2019** |
|---|---|---|
| Operating lease right-of-use assets | $ 28,365 | $ 27,007 |
| Accumulated amortization | (8,927) | (5,013) |
| **Operating lease right-of-use assets, net** | **$ 19,438** | **$ 21,994** |
| | | |
| Current maturities of operating leases | $ 5,678 | $ 5,487 |
| Non-current maturities of operating lease | 15,026 | 17,918 |
| **Total operating lease liabilities** | **$ 20,704** | **$ 23,405** |
| | | |
| **Finance leases:** | | |
| Property and equipment, at cost | $ 7,369 | $ 7,161 |
| Accumulated amortization | (1,743) | (1,279) |
| **Property and equipment, net** | **$ 5,626** | **$ 5,882** |
| | | |
| Current maturities of finance leases | $ 595 | $ 597 |
| Non-current maturities of finance leases | 5,206 | 5,415 |
| **Total finance lease liabilities** | **$ 5,801** | **$ 6,012** |
| | | |
| **Weighted average remaining lease term (in years):** | | |
| Operating leases | 5.2 | 5.5 |
| Finance leases | 10.0 | 10.6 |
| | | |
| **Weighted average discount rate:** | | |
| Operating leases | 5.2% | 5.4% |
| Finance leases | 2.0% | 2.0% |

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

| | **Three Months Ended September 30,** | | **Nine Months Ended September 30,** | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| Amortization of property and equipment | $ 164 | $ 188 | $ 487 | $ 608 |
| Interest expense on finance leases | 30 | 30 | 89 | 93 |
| **Total finance lease expense** | **194** | **218** | **576** | **701** |
| Operating lease expense | 1,806 | 1,717 | 5,324 | 4,870 |
| Sublease income | (226) | (227) | (679) | (679) |
| **Total lease expense** | **$ 1,774** | **$ 1,708** | **$ 5,221** | **$ 4,892** |

A summary of our cash flow information related to leases is as follows (in thousands):

| Cash paid for amounts included in the measurement of lease liabilities: | **Nine Months Ended September 30, 2020** | **Nine Months Ended September 30, 2019** |
|---|---|---|
| Operating cash flows for operating leases | $ 5,438 | $ 5,004 |
| Financing cash flows for finance leases | 465 | 561 |
| Operating cash flows for finance leases | 92 | 91 |

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

| | Finance Leases | Operating Leases | Sublease Income |
|---|---|---|---|
| Remainder of 2020 | $ 178 | $ 1,435 | $ 226 |
| 2021 | 695 | 6,823 | 905 |
| 2022 | 639 | 4,340 | 306 |
| 2023 | 638 | 2,877 | -- |
| 2024 | 636 | 2,706 | -- |
| Thereafter | 3,612 | 5,283 | -- |
| Total minimum lease payments | $ 6,398 | $ 23,464 | $ 1,437 |
| Less amount representing interest | (597) | (2,760) | |
| Present value of net minimum lease payments | 5,801 | 20,704 | |
| Less current maturities | (595) | (5,678) | |
| **Lease liabilities, less current maturities** | **$ 5,206** | **$ 15,026** | |

**10. Debt**

***Credit Agreement***

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

On December 1, 2017 we borrowed the entire $225.0 million Term Loan Facility. The proceeds of the Term Loan Facility were used along with cash on hand and shares of CryoLife common stock to (i) fund the acquisition of JOTEC and its subsidiaries (the "JOTEC Acquisition"), (ii) pay certain fees and expenses related to the JOTEC Acquisition and the Credit Agreement, and (iii) pay the outstanding balance of our prior credit facility. The Revolving Credit Facility may be used for working capital, capital expenditures, acquisitions permitted under the Credit Agreement, and other general corporate purposes pursuant to the terms of the Credit Agreement.

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

In October 2018 we finalized an amendment to the Credit Agreement to reprice interest rates, resulting in a reduction in the interest rate margins over base rates on the Term Loan Facility. The loan under the Term Loan Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of 2.25%, or LIBOR, plus a margin of 3.25%. Prior to the repricing, the optional floating annual rate was equal to either the base rate plus a margin of 3.00%, or LIBOR, plus a margin of 4.00%. The loan under the Revolving Credit Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of between 3.00% and 3.25%, depending on our consolidated leverage ratio, or LIBOR, plus a margin of between 4.00% and 4.25%, depending on our consolidated leverage ratio. While a payment event of default or bankruptcy event of default exists, we are obligated to pay a per annum default rate of interest of 2.00% in excess of the interest rate otherwise payable with respect to the overdue principal amount of any loans outstanding and overdue interest payments and other overdue fees and amounts. As of September 30, 2020 the aggregate interest rate was 4.25% per annum. We are obligated to pay an unused commitment fee equal to 0.50% of the unutilized portion of the revolving loans. In addition, we are also obligated to pay other customary fees for a credit facility of this size and type.

The Credit Agreement contains certain customary affirmative and negative covenants, including covenants that limit our ability and the ability of our subsidiaries to, among other things, grant liens, incur debt, dispose of assets, make loans and investments, make acquisitions, make certain restricted payments (including cash dividends), merge or consolidate, change business or accounting or reporting practices, in each case subject to customary exceptions for a credit facility of this size and type. In addition, with respect to the Revolving Credit Facility, when the principal amount of loans outstanding thereunder is in excess of 25% of the Revolving Credit Facility, the Credit Agreement requires us to comply with a specified maximum first lien net leverage ratio.

The Credit Agreement includes certain customary events of default that include, among other things, non-payment of principal, interest, or fees; inaccuracy of representations and warranties; breach of covenants; cross-default to certain material indebtedness; bankruptcy and insolvency; and change of control. Upon the occurrence and during the continuance of an event of default, the lenders may declare all outstanding principal and accrued but unpaid interest under the Credit Agreement immediately due and payable and may exercise the other rights and remedies provided under the Credit Agreement and related loan documents.

In March 2020 as a precautionary measure to increase cash and maintain maximum financial flexibility during the current uncertainty in global markets resulting from the COVID-19 pandemic, we borrowed the entire amount available under our $30.0 million Revolving Credit Facility at an aggregate interest rate of 5.20%. On June 29, 2020 we used the net proceeds from the issuance of Convertible Senior Notes, as discussed below, to repay the $30.0 million outstanding under our Revolving Credit Facility.

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

***Convertible Senior Notes***

On June 18, 2020 we issued $100.0 million aggregate principal amount of 4.25% convertible senior notes with a maturity date of July 1, 2025 (the "Convertible Senior Notes"). The net proceeds from this offering, after deducting initial purchasers' discounts and costs directly related to this offering, were approximately $96.5 million. The Convertible Senior Notes may be settled in cash, stock, or a combination thereof, solely at our discretion. Our current intent is to settle in cash the principal amount outstanding and any note conversion value over the principal amount with shares of our common stock. The initial conversion rate of the Convertible Senior Notes is 42.6203 shares per $1,000 principal amount, which is equivalent to a conversion price of approximately $23.46 per share, subject to adjustments. We use the treasury stock method for assumed conversion of the Convertible Senior Notes to compute the weighted average shares of common stock outstanding for diluted earnings per share.

The conversion feature of the Convertible Senior Notes required bifurcation from the notes and was initially accounted for as an equity instrument classified to stockholders' equity, which resulted in recognizing $16.4 million in additional paid-in-capital during the nine months ended September 30, 2020. The interest expense recognized on the Convertible Senior Notes includes approximately $2.0 million and $2.2 million for the aggregate of the contractual coupon interest, the accretion of the debt discount, and the amortization of the debt issuance costs as of three and nine months ended September 30, 2020, respectively. The interest on the Convertible Senior Notes includes the contractual coupon interest, accretion of the debt discount, and amortization of the debt issuance costs. Interest on the Convertible Senior Notes began accruing upon issuance and is payable semi-annually.

Holders of the Convertible Senior Notes may convert their notes at their option at any time prior to January 1, 2025 but only under the following circumstances: (i) during any calendar quarter commencing after the calendar quarter ending on September 30, 2020 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (ii) during the five business day period after any five consecutive trading day period in which the trading price per $1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; (iii) we give a notice of redemption with respect to any or all of the notes, at any time prior to the close of business on the second scheduled trading day immediately preceding the redemption date; or (iv) upon the occurrence of specified corporate events. On or after January 1, 2025 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their notes at any time, regardless of the foregoing circumstances.

We cannot redeem the Convertible Senior Notes before July 5, 2023. We can redeem them on or after July 5, 2023, in whole or in part, at our option, if the last reported sale price per share of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption. We may redeem for cash all or part of the Convertible Senior Notes at a redemption price equal to 100% of the principal amount of the redeemable Convertible Senior Notes, plus accrued and unpaid interest to, but excluding, the redemption date. No principal payments are due on the Convertible Senior Notes prior to maturity. Other than restrictions relating to certain fundamental changes and consolidations, mergers or asset sales and customary anti-dilution adjustments, the Convertible Senior Notes do not contain any financial covenants and do not restrict us from conducting significant restructuring transactions or issuing or repurchasing any of its other securities. As of September 30, 2020, we are not aware of any current events or market conditions that would allow holders to convert the Convertible Senior Notes. We have used a portion of the proceeds to pay off the $30.0 million outstanding under our Revolving Credit Facility and finance the Ascyrus transaction and anticipate using the remaining funds for general corporate purposes.

***Government Supported Bank Debt***

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

***Loan Balances***

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

| | September 30, 2020 | December 31, 2019 |
|---|---|---|
| Term loan balance | $ 218,812 | $ 220,500 |
| Convertible senior notes | 78,662 | -- |
| 2.45% Sparkasse Zollernalb (KFW Loan 1) | 911 | 1,061 |
| 1.40% Sparkasse Zollernalb (KFW Loan 2) | 1,463 | 1,615 |
| Total loan balance | 299,848 | 223,176 |
| Less unamortized loan origination costs | (8,986) | (7,441) |
| Net borrowings | 290,862 | 215,735 |
| Less short-term loan balance | (1,165) | (1,164) |
| Long-term loan balance | $ 289,697 | $ 214,571 |

***Interest Expense***

Interest expense was $4.9 million and $12.0 million for the three and nine months ended September 30, 2020, as compared to $3.6 million and $11.3 million for the three and nine months ended September 30, 2019. Interest expense includes interest on debt and uncertain tax positions in both periods.

**11. Commitments and Contingencies**

***Liability Claims***

Our estimated unreported loss liability was $2.0 million and $1.9 million as of September 30, 2020 and December 31, 2019, respectively. As of September 30, 2020 and December 31, 2019, the related recoverable insurance amounts were $1.0 million and $935,000, respectively. We accrue our estimate of unreported product and tissue processing liability claims as a component of other long-term liabilities and record the related recoverable insurance amount as a component of Other long-term assets, as appropriate. Further analysis indicated that the estimated liability as of September 30, 2020 could have been as high as $3.9 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

***Employment Agreements***

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

***PerClot Technology***

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

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

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Enrollment was completed in January 2019. We anticipate being in a position to submit Premarket Approval ("PMA") to the FDA in the fourth quarter of 2020.

As of September 30, 2020 we had $1.5 million in prepaid royalties, $1.8 million in intangible assets, net, and $1.2 million in property and equipment, net, on our Summary Consolidated Balance Sheets related to the PerClot product line. If we do not ultimately pursue or receive FDA approval to commercialize PerClot in the U.S., these assets could be materially impaired in future periods.

**12. Revenue Recognition**

***Sources of Revenue***

We have identified the following revenues disaggregated by revenue source:

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

For the three and nine months ended September 30, 2020 and 2019 the sources of revenue were as follows (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| | (Unaudited) | | (Unaudited) | |
| Domestic hospitals | $ 36,249 | $ 36,627 | $ 102,813 | $ 108,582 |
| International hospitals | 20,764 | 20,246 | 56,638 | 63,204 |
| International distributors | 8,035 | 9,654 | 25,522 | 29,773 |
| CardioGenesis cardiac laser therapy | 83 | 1,354 | 358 | 4,966 |
| **Total sources of revenue** | **$ 65,131** | **$ 67,881** | **$ 185,331** | **$ 206,525** |

Also see segment disaggregation information in Note 14 below.

***Contract Balances***

We may generate contract assets during the pre-delivery design and manufacturing stage of E-xtra DESIGN ENGINEERING product order fulfillment. We assess the balance related to any arrangements in process and determine if the enforceable right to payment creates a material contract asset requiring disclosure. No material arrangements in process existed as of September 30, 2020 and 2019.

We also incur contract obligations on general customer purchase orders that have been accepted but unfulfilled. Due to the short duration of time between order acceptance and delivery of the related product or service, we have determined that the balance related to these contract obligations is generally immaterial at any point in time. We monitor the value of orders accepted but unfulfilled at the close of each reporting period to determine if disclosure is appropriate. The value of orders accepted but unfulfilled as of September 30, 2020 and 2019 was not material.

## 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"), 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, 2020 the Compensation Committee of our Board of Directors (the "Committee") authorized awards from approved stock incentive plans of RSUs to certain employees, RSAs to non-employee Directors, and RSAs and PSUs to certain Company officers, which, assuming that performance under the PSUs were to be achieved at target levels, together totaled 330,000 shares and had an aggregate grant date market value of $8.2 million. The PSUs granted in 2020 represent the right to receive from 60% to 150% of the target number of shares of common stock. The performance component of PSU awards granted in 2020 is based on attaining specified levels of adjusted EBITDA, as defined in the PSU grant documents, for the 2020 calendar year.

During the nine months ended September 30, 2019 the Committee authorized awards from approved stock incentive plans of RSUs to certain employees, RSAs to non-employee Directors, and RSAs and PSUs to certain Company officers, which, assuming that performance under the PSUs were to be achieved at target levels, together totaled 503,000 shares and had an aggregate grant date market value of $14.9 million. Two types of PSUs were granted in 2019, an annual grant with a one year performance period ("Annual PSU") and a special Long-Term Incentive Program PSU grant ("LTIP"), which has multiple performance periods over a five year period. If the highest performance thresholds were met, the Annual PSU granted in 2019 represented the right to receive up to 150% of the target number of shares of common stock. The performance component of the Annual PSU awards granted in 2019 was based on attaining specified levels of adjusted earnings before interest, taxes, depreciation, and amortization, ("EBITDA"), as defined in the Annual PSU grant documents, for the 2019 calendar year. The annual PSU granted in 2019 earned approximately 83% of the target number of shares. If the highest performance thresholds were met, the PSUs granted in 2019 under the LTIP represent the right to receive up to 288%, and up to 192% for Mr. Mackin, of the target number of shares of common stock. The performance component of the LTIP awards granted in 2019 is based on attaining specified levels of adjusted revenue growth and gross margin, as defined in the LTIP grant document, for the years 2019 through 2023. The first performance period under the LTIP will not conclude until December 31, 2021.

The Committee authorized, from approved stock incentive plans, grants of stock options to purchase a total of 212,000 and 169,000 shares to certain Company officers during the nine months ended September 30, 2020 and 2019, respectively. The exercise prices of the options were equal to the closing stock prices on their respective grant dates.

Employees purchased common stock totaling 84,000 shares and 61,000 shares in the nine months ended September 30, 2020 and 2019, respectively, through the ESPP. There were no purchases of shares through the ESPP during the three months ended September 30, 2020 and 2019.

***Stock Compensation Expense***

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

| | Three Months Ended September 30, 2020 | | Nine Months Ended September 30, 2020 | |
|---|---|---|---|---|
| | **Stock Options** | **ESPP** | **Stock Options** | **ESPP** |
| Expected life | N/A | 0.5 Years | 5 Years | 0.5 Years |
| Expected stock price volatility | N/A | 0.83 | 0.35 | 0.31 |
| Risk-free interest rate | N/A | 0.17% | 1.41% | 1.57% |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| RSA, RSU, and PSU expense | $ 1,984 | $ 2,133 | $ 6,189 | $ 5,579 |
| Stock option and ESPP expense | 534 | 487 | 1,699 | 1,460 |
| **Total stock compensation expense** | **$ 2,518** | **$ 2,620** | **$ 7,888** | **$ 7,039** |

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, RSUs, PSUs, and stock options issued in each respective year, as well as those issued in prior periods that continue to vest during the period, and compensation related to the ESPP. These amounts were recorded as stock compensation expense and were subject to our normal allocation of expenses to inventory costs and deferred preservation costs. We capitalized $160,000 and $456,000 in the three and nine months ended September 30, 2020, and $158,000 and $458,000 in the three and nine months ended September 30, 2019, of the stock compensation expense into our inventory costs and deferred preservation costs.

As of September 30, 2020 we had total unrecognized compensation costs of $12.5 million related to RSAs, RSUs, and PSUs and $2.5 million related to unvested stock options. As of September 30, 2020 this expense is expected to be recognized over a weighted-average period of 1.9 years for PSUs, 1.8 years for stock options, 1.8 years for RSUs, and 1.2 years for RSAs.

**14. (Loss) Earnings per Share**

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| **Basic (loss) income per common share** | 2020 | 2019 | 2020 | 2019 |
| Net (loss) income | $ (2,870) | $ (134) | $ (13,224) | $ 2,401 |
| Net income (loss) allocated to participating securities | 20 | 1 | 93 | (17) |
| **Net (loss) income allocated to common shareholders** | **$ (2,850)** | **$ (133)** | **$ (13,131)** | **$ 2,384** |
| **Basic weighted-average common shares outstanding** | **37,912** | **37,255** | **37,608** | **37,065** |
| **Basic (loss) income per common share** | **$ (0.08)** | **$ (0.00)** | **$ (0.35)** | **$ 0.06** |

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| **Diluted (loss) income per common share** | 2020 | 2019 | 2020 | 2019 |
| Net (loss) income | $ (2,870) | $ (134) | $ (13,224) | $ 2,401 |
| Net income (loss) allocated to participating securities | 20 | 1 | 93 | (16) |
| **Net (loss) income allocated to common shareholders** | **$ (2,850)** | **$ (133)** | **$ (13,131)** | **$ 2,385** |
| Basic weighted-average common shares outstanding | 37,912 | 37,255 | 37,608 | 37,065 |
| Effect of dilutive stock options and awards | -- | -- | -- | 785 |
| **Diluted weighted-average common shares outstanding** | **37,912** | **37,255** | **37,608** | **37,850** |
| **Diluted (loss) income per common share** | **$ (0.08)** | **$ (0.00)** | **$ (0.35)** | **$ 0.06** |

We excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares because the inclusion of these stock options would be antidilutive to loss per common share. Accordingly, for the three and nine months ended September 30, 2020 all stock options and awards were excluded from the calculation of diluted weighted-average common shares outstanding as these would be antidilutive due to the net loss. For the three months ended September 30, 2019 all stock

options and awards were excluded from the calculation of diluted weighted-average common shares outstanding as these would be antidilutive due to the net loss. For the nine months ended September 30, 2019 stock options to purchase a weighted-average of 123,000 shares were antidilutive and 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, JOTEC (which includes AMDS and NEXUS revenues), On-X, CardioGenesis cardiac laser therapy, PerClot, and PhotoFix. The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues and NeoPatch. There are no intersegment revenues.

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

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| Revenues: | | | | |
| Medical devices | $ 45,109 | $ 47,484 | $ 128,797 | $ 147,053 |
| Preservation services | 20,022 | 20,397 | 56,534 | 59,472 |
| **Total revenues** | **65,131** | **67,881** | **185,331** | **206,525** |
| | | | | |
| Cost of products and preservation services: | | | | |
| Medical devices | 12,998 | 12,706 | 36,078 | 41,021 |
| Preservation services | 9,001 | 9,953 | 26,060 | 29,043 |
| **Total cost of products and preservation services** | **21,999** | **22,659** | **62,138** | **70,064** |
| | | | | |
| Gross margin: | | | | |
| Medical devices | 32,111 | 34,778 | 92,719 | 106,032 |
| Preservation services | 11,021 | 10,444 | 30,474 | 30,429 |
| **Total gross margin** | **$ 43,132** | **$ 45,222** | **$ 123,193** | **$ 136,461** |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Products: | | | | |
| BioGlue | $ 15,811 | $ 15,679 | $ 44,985 | $ 50,834 |
| JOTEC | 15,290 | 15,774 | 43,932 | 48,936 |
| On-X | 12,067 | 12,610 | 34,385 | 36,751 |
| PhotoFix | 1,134 | 1,087 | 3,056 | 2,752 |
| PerClot | 724 | 980 | 2,081 | 2,814 |
| CardioGenesis cardiac laser therapy | 83 | 1,354 | 358 | 4,966 |
| **Total products** | **45,109** | **47,484** | **128,797** | **147,053** |
| | | | | |
| Preservation services: | | | | |
| Cardiac tissue | 10,679 | 11,304 | 28,758 | 30,734 |
| Vascular tissue | 9,285 | 9,093 | 27,657 | 28,738 |
| NeoPatch | 58 | -- | 119 | -- |
| **Total preservation services** | **20,022** | **20,397** | **56,534** | **59,472** |
| | | | | |
| **Total revenues** | **$ 65,131** | **$ 67,881** | **$ 185,331** | **$ 206,525** |

**Forward-Looking Statements**

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

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

- Our expectations regarding the potential impacts of the COVID-19 pandemic on our business operations, cash flow, business development, employees, and research and development projects, including clinical research projects;
- Our belief that our distributors may delay or reduce purchases of products in U.S. Dollars depending on the relative price of goods in their local currencies;
- Our belief regarding the international growth opportunity that would be provided by obtaining regulatory approval for BioGlue in China;
- Our beliefs about the unavailability of handpieces for cardiac laser therapy, the temporary nature of this unavailability, and a possible resolution of this unavailability during the first half of 2021;
- Our ability to realize the anticipated business opportunities, growth prospects, synergies, and other benefits of the agreements with Endospan and Ascyrus, and our beliefs about the costs and expected timeline regarding certain clinical trial milestones for the regulatory approvals of the AMDS globally and the NEXUS stent graft system in the U.S.;
- Our plans, costs, and expected timeline regarding regulatory approval for PerClot in the U.S. and additional international markets and the distribution of PerClot in those markets after the requisite regulatory approvals are obtained;
- Our belief that revenues for preservation services, particularly revenues for certain high-demand cardiac tissues, can vary from quarter to quarter and year to year due to a variety of factors including: quantity and type of incoming tissues, yields of tissue through the preservation process, timing of receipt of donor information, timing of the release of tissues to an implantable status, demand for certain tissue types due to the number and type of procedures being performed, and pressures from competing products or services;
- Our beliefs regarding the seasonal nature of the demand for some of our products and services and the reasons for such seasonality, if any;
- Our belief that our cash from operations and existing cash and cash equivalents, will enable us to meet our current operational liquidity needs for at least the next twelve months, our expectations regarding future cash requirements, and the impact that our cash requirements might have on our cash flows for the next twelve months;
- Our expectation regarding the impact on cash flows of undertaking significant business development activities and the potential need to obtain additional borrowing capacity or financing;
- Our expectations regarding the possible benefits to us of the Coronavirus Aid, Relief, and Economic Security Act or “CARES Act” or similar legislation;
- Our belief that we will incur expenses for research and development projects, including for clinical research projects to gain regulatory approvals for products or indications, including JOTEC, On-X, PerClot, and BioGlue products, and for research and development for new products despite reduced planned spending due to COVID-19;
- Our expectations regarding the timing of clinical research work and regulatory approvals for and expected distribution of products or indications, including JOTEC, On-X, PerClot, and BioGlue products;
- Our expectations regarding the utilization of net operating loss carryforwards from our acquisitions of JOTEC, On-X, Hemosphere, Inc., and Cardiogenesis Corporation; and
- Other statements regarding projections of future financial and business performance; anticipated growth and trends in our business and the markets relevant to our business, including as our growth relates to our competitors; future production capacity and product supply; the availability and benefits of our products in the future; and the expected timing and impact of our strategic initiatives.

These and other forward-looking statements reflect the views of management at the time such statements are originally made based on certain assumptions and analyses made by us in light of our experience and our perception of historical trends,

current conditions, and expected future developments as well as other factors we believe are appropriate in the circumstances and are subject to a number of risks, uncertainties, estimates, and assumptions. Whether actual results and developments will conform with our expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially and adversely from our expectations, including, without limitation, in addition to those specified in the text surrounding such statements, the risks described in Part II, Item 1A, "Risks Factors" in this Form 10-Q and elsewhere throughout this report, the risks described in our other filings with the Securities and Exchange Commission including the risks described under in Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2019 and elsewhere throughout that report, and other risks which we may not be able to identify in advance, many of which are beyond our control. Consequently, all of the forward-looking statements made in this Form 10-Q are qualified by these cautionary statements, and there can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us or our business or operations. We assume no obligation, and expressly disclaim, any duty to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

## PART I - FINANCIAL INFORMATION

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

#### Overview

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

We reported quarterly revenues of $65.1 million for the three months ended September 30, 2020, a 4% decrease from the three months ended September 30, 2019. This was primarily due to decreases in revenues from CardioGenesis cardiac laser therapy, cardiac preservation service revenues, and On-X, JOTEC and PerClot product revenues, partially offset by increases in vascular preservation services revenues, BioGlue and PhotoFix product revenues.

See the "Results of Operations" section below for additional analysis of the three and nine months ended September 30, 2020.

#### Effects of COVID-19

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

Because of the uncertainty created by the COVID-19 pandemic, as well as the potential social and economic impacts of COVID-19 upon the markets in which we operate and the resulting impact on our results of operations and cash flows, we have reevaluated the need for, and timing of, certain expenses and have taken pre-emptive steps to reduce spending. These steps have included implementing hiring restrictions; imposing senior management cash salary reductions, in exchange for cash payments in the second quarter of 2021; requiring our Board of Directors to accept CryoLife stock instead of cash compensation for a six month period through October 2020; deferring management merit increases; reducing most discretionary spending; reducing capital expenditures; and reducing planned spending on certain research and development projects, including clinical research projects.

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

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

As a precautionary measure to increase cash and maintain maximum financial flexibility during the current uncertainty in global markets resulting from the COVID-19 pandemic, we borrowed the entire amount available under our $30.0 million revolving credit facility during the first quarter of 2020, which we subsequently repaid in the second quarter of 2020 from part of the proceeds of our $100.0 million aggregate principal amount convertible senior notes ("Convertible Senior Notes"). See the "Liquidity and Capital Resources" identified in Part I, Item 2 of this form 10-Q for further detail of this transaction.

We are monitoring the impact of the COVID-19 pandemic on our business, and recognize that it could continue to negatively impact our business and results of operations through at least the fourth quarter of 2020 and potentially beyond. To date, we have experienced the most severe impact of COVID-19 on our revenues in April of the second quarter of 2020 followed by some sequential recovery each month during the second quarter of 2020 and further recovery during the third quarter of 2020. The extent to which our operations and employees will be impacted by the pandemic in the fourth quarter of 2020 and beyond will depend largely on future developments, including further increases in COVID-19 cases in key markets and the impact of COVID-19 on procedure volumes involving our products, including patients' willingness to undergo procedures even when the number of COVID-19 cases flattens out or decreases. These future developments remain uncertain and difficult to predict. New information is continually emerging regarding the severity of the pandemic and the various government, regulatory, expert, and recommended actions to contain it or address its impact.

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

**Critical Accounting Policies**

A summary of our significant accounting policies is included in Note 1 of the "Notes to Consolidated Financial Statements" contained in our Form 10-K for the year ended December 31, 2019. Management believes that the consistent application of these policies enables us to provide users of the financial statements with useful and reliable information about our operating results and financial condition. The summary consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S., which require us to make estimates and assumptions. We did not experience any significant changes during the three and nine months ended September 30, 2020 in any of our Critical Accounting Policies from those contained in our Form 10-K for the year ended December 31, 2019.

**New Accounting Pronouncements**

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

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

**Revenues**

| | Revenues for the Three Months Ended September 30, | | Percent Change From Prior Year | Revenues as a Percentage of Total Revenues for the Three Months Ended September 30, | |
|---|---|---|---|---|---|
| | **2020** | **2019** | | **2020** | **2019** |
| Products: | | | | | |
| BioGlue | $ 15,811 | $ 15,679 | 1% | 24% | 23% |
| JOTEC | 15,290 | 15,774 | -3% | 24% | 23% |
| On-X | 12,067 | 12,610 | -4% | 19% | 19% |
| PhotoFix | 1,134 | 1,087 | 4% | 2% | 2% |
| PerClot | 724 | 980 | -26% | 1% | 1% |
| CardioGenesis cardiac laser therapy | 83 | 1,354 | -94% | 0% | 2% |
| **Total products** | **45,109** | **47,484** | **-5%** | **70%** | **70%** |
| Preservation services: | | | | | |
| Cardiac tissue | 10,679 | 11,304 | -6% | 16% | 17% |
| Vascular tissue | 9,285 | 9,093 | 2% | 14% | 13% |
| NeoPatch | 58 | -- | 100% | 0% | 0% |
| **Total preservation services** | **20,022** | **20,397** | **-2%** | **30%** | **30%** |
| **Total** | **$ 65,131** | **$ 67,881** | **-4%** | **100%** | **100%** |

| | Revenues for the Nine Months Ended September 30, | | Percent Change From Prior Year | Revenues as a Percentage of Total Revenues for the Nine Months Ended September 30, | |
|---|---|---|---|---|---|
| | **2020** | **2019** | | **2020** | **2019** |
| Products: | | | | | |
| BioGlue | $ 44,985 | $ 50,834 | -12% | 24% | 25% |
| JOTEC | 43,932 | 48,936 | -10% | 23% | 24% |
| On-X | 34,385 | 36,751 | -6% | 19% | 18% |
| PhotoFix | 3,056 | 2,752 | 11% | 2% | 1% |
| PerClot | 2,081 | 2,814 | -26% | 1% | 1% |
| CardioGenesis cardiac laser therapy | 358 | 4,966 | -93% | 0% | 2% |
| **Total products** | **128,797** | **147,053** | **-12%** | **69%** | **71%** |
| Preservation services: | | | | | |
| Cardiac tissue | 28,758 | 30,734 | -6% | 16% | 15% |
| Vascular tissue | 27,657 | 28,738 | -4% | 15% | 14% |
| NeoPatch | 119 | -- | 100% | 0% | 0% |
| **Total preservation services** | **56,534** | **59,472** | **-5%** | **31%** | **29%** |
| **Total** | **$ 185,331** | **$ 206,525** | **-10%** | **100%** | **100%** |

Revenues decreased 4% and 10% for the three and nine months ended September 30, 2020, respectively, as compared to the three and nine months ended September 30, 2019. The decrease in revenues for the three months ended September 30, 2020 was primarily due to decreases in revenues from CardioGenesis cardiac laser therapy, cardiac preservation service revenues, and On-X, JOTEC and PerClot product revenues, partially offset by increases in vascular preservation services revenues, BioGlue and PhotoFix product revenues. The decrease in revenues for the nine months ended September 30, 2020 was primarily due to decreases in revenues from all products, except PhotoFix, and from preservation services. Excluding the effects for foreign exchange, revenues decreased 4% and 10% for the three and nine months ended September 30, 2020, respectively, as compared to the three and nine months ended September 30, 2019. Revenues for the three and nine months ended September 30, 2020 were negatively impacted by delays or cancellations of some surgical procedures as a result of reduced hospital capacity and hospital restrictions due to the COVID-19 pandemic, as well as patient reluctance to undergo procedures once the adverse impacts to capacity and restrictions decreased. Revenue decreases during 2020 as compared to 2019 were larger during the second quarter with smaller sequential decreases during the third quarter as procedure volumes increased throughout the third quarter. A detailed discussion of the changes in product revenues and preservation services revenues for the three and nine months ended September 30, 2020 is presented below.

***Products***

Revenues from products decreased 5% and 12% for the three and nine months ended September 30, 2020, respectively, as compared to the three and nine months ended September 30, 2019. The decrease for the three months ended September 30, 2020 was due to decreases in revenues from CardioGenesis cardiac laser therapy product, On-X, JOTEC and PerClot products, partially offset by increases in revenues from BioGlue and PhotoFix products. The decrease for the nine months ended September 30, 2020 was due to decreases in revenues from all products except for PhotoFix. A detailed discussion of the changes in product revenues for BioGlue, JOTEC, On-X, PhotoFix, PerClot, and CardioGenesis cardiac laser therapy is presented below.

Sales of certain products through our direct sales force and distributors across Europe and various other countries are denominated in a variety of currencies including Euros, British Pounds, Polish Zlotys, Swiss Francs, Brazilian Reals, and Canadian Dollars, with a concentration denominated in Euros. Each currency is subject to exchange rate fluctuations. For the three months ended September 30, 2020 as compared to the three months ended September 30, 2019, the U.S. Dollar weakened in comparison to major currencies, resulting in revenue increases when these foreign currency denominated transactions were translated into U.S. Dollars. For the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019, the U.S. Dollar strengthened in comparison to major currencies, excluding Euros, resulting in revenue decreases when these foreign currency denominated transactions were translated into U.S. Dollars. Future changes in these exchange rates could have a material, adverse effect on our revenues denominated in these currencies. Additionally, our sales to many distributors around the world are denominated in U.S. Dollars, and although these sales are not directly impacted by currency exchange rates, we believe that some of our distributors may delay or reduce purchases of products in U.S. Dollars depending on the relative price of these goods in their local currencies.

*BioGlue*

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

Revenues from the sales of BioGlue increased 1% for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019. This increase was primarily due to a 5% increase in volume of milliliters sold, which increased revenues by 1%. Excluding the effects for foreign exchange, revenues increased 1% for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019.

Revenues from the sales of BioGlue decreased 12% for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019. This decrease was primarily due to an 11% decrease in volume of milliliters sold, which decreased revenues by 11%, and the effect of foreign exchange rates, which decreased revenues by 1%. Excluding the effects for foreign exchange, revenues decreased 11% for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019.

On a constant currency basis, revenues from sales of BioGlue increased in the three months ended September 30, 2020 compared to the three months ended September 30, 2019 primarily in Asia Pacific, partially offset by decreases in North America and Latin America. The increase in the Asia Pacific market was primarily due to distributor buying patterns. The decreases in North America and Latin America were primarily due to delays and cancellations of surgical procedures due to the COVID-19 pandemic.

On a constant currency basis, revenues from sales of BioGlue decreased in the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 in North America and the European Economic Area, the Middle East, and Africa (collectively, "EMEA") and to a lesser extent in Latin America, partially offset by an increase in the Asia Pacific market. These markets were impacted by a decrease in volume of milliliters sold in the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019 primarily due to delays and cancellations of surgical procedures due to the COVID-19 pandemic.

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

Domestic revenues from BioGlue accounted for 50% of total BioGlue revenues for the three and nine months ended September 30, 2020, and 53% and 51% of total BioGlue revenues for the three and nine months ended September 30, 2019, respectively.

*JOTEC*

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

On September 11, 2019, CryoLife and its wholly-owned subsidiary JOTEC entered into exclusive distribution and loan agreements with Endospan Ltd. ("Endospan"), an Israeli corporation, under which JOTEC obtained exclusive distribution rights for Endospan's NEXUS stent graft system ("NEXUS") and accessories in certain countries in Europe. NEXUS revenues are included as a component of JOTEC product revenues.

On September 2, 2020 CryoLife entered into an agreement to acquire all of equity interests of Ascyrus Medical LLC ("Ascyrus"). Ascyrus has developed the Ascyrus Medical Dissection Stent, an aortic arch remodeling device used for the treatment of acute Type A aortic dissections ("AMDS"). AMDS is currently distributed in EMEA and Canada and is included as a component of JOTEC product revenues.

JOTEC revenues decreased 3% and 10% for the three and nine months ended September 30, 2020, respectively as compared to the three and nine months ended September 30, 2019.

JOTEC revenues, excluding original equipment manufacturing ("OEM"), decreased 3% for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019. This decrease was primarily due to a decrease in the average sales prices, which decreased revenues by 3%.

JOTEC revenues, excluding OEM, decreased 10% for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019. This decrease was primarily due to a change in the mix of volume sold, which decreased revenues by 5%, a decrease in average sales prices, which decreased revenues by 3%, and the effect of foreign exchange rates, which decreased revenues by 2%.

On a constant currency basis, revenues for JOTEC, excluding OEM, decreased 4% and 7% in the three and nine months ended September 30, 2020, respectively, as compared to the three and nine months ended September 30, 2019. Revenues for the three months ended September 30, 2020 decreased primarily in Latin America and Asia Pacific markets. The decrease in Latin America was primarily in direct markets due to the delay in surgical procedures due to the COVID-19 pandemic. The decrease in Asia Pacific was primarily due to a decrease in certain distributor markets. Revenues for the nine months ended September 30, 2020 decreased in EMEA and Latin America primarily in direct markets due to the delay in surgical procedures due to the COVID-19 pandemic, offset by an increase in Asia Pacific due to growth in distributor markets. JOTEC OEM sales accounted for less than 1% of product revenues for both the three and nine months ended September 30, 2020 and 2019.

*On-X*

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

On-X product revenues decreased 4% and 6% for the three and nine months ended September 30, 2020, respectively, as compared to the three and nine months ended September 30, 2019.

On-X product revenues, excluding OEM, decreased 1% for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019. This decrease was primarily due to a decrease in volume of units sold, and the effect of foreign exchange rates, which collectively decreased revenues by 1%.

On-X product revenues, excluding OEM, decreased 6% for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019. This decrease was primarily due to an 18% decrease in volume of units sold, which decreased revenues by 5%, and the effect of foreign exchange rates, which decreased revenues by 1%.

On a constant currency basis, On-X revenues, excluding OEM, decreased 1% and 5% in the three and nine months ended September 30, 2020, respectively, as compared to the three and nine months ended September 30, 2019. This decrease in the three months ended September 30, 2020 as compared to three months ended September 30, 2019 was primarily in EMEA and in Asia Pacific due to delays and cancellations of surgical procedures due to the COVID-19 pandemic, partially offset by an increase in North America due to increases in market share. The decrease in the nine months ended September 30, 2020 as compared to nine months ended September 30, 2019 was primarily in EMEA and, to a lesser extent, in Asia Pacific due to delays and cancellations of surgical procedures due to the COVID-19 pandemic, partially offset by an increase in North America due to increases in market share. On-X OEM sales accounted for less than 1% of product revenues for both the three and nine months ended September 30, 2020 and 2019.

*PhotoFix*

PhotoFix revenues increased 4% for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019. This increase was primarily due to a 6% increase in units sold, which increased revenues by 2%, a change in average sales prices, which increased revenues 1%, and the effect of foreign exchange rates, which increased revenues by 1%.

PhotoFix revenues increased 11% for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019. This increase was primarily due to a 4% increase in units sold, which increased revenues by 6%, an increase in average sales prices, which increased revenues 4%, and the effect of foreign exchange rates, which increased revenues by 1%.

The increase in units sold for the three and nine months ended September 30, 2020 was primarily due to an increase in the number of physicians who implant the product compared to the three and nine months ended September 30, 2019 as this product continues to increase penetration in domestic and European markets.

*PerClot*

Revenues from the sale of PerClot decreased 26% for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019. The decrease in the three months ended September 30, 2020 was primarily due to a 22% decrease in the volume of grams sold, which decreased revenues 18%, combined with a decrease in average sales prices, which decreased revenues by 9%, partially offset by the effect of foreign exchange rates, which increased revenues by 1%.

Revenues from the sale of PerClot decreased 26% for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019. The decrease in the nine months ended September 30, 2020 was primarily due to a 26% decrease in the volume of grams sold, which decreased revenues 20%, combined with a change in average sales prices, which decreased revenues by 6%.

The decrease in volume for both the three and nine months ended September 30, 2020 was primarily due to a decrease in sales of PerClot in Asia Pacific and EMEA due to delays and cancellations of surgical procedures due to the COVID-19 pandemic and competitive pressures in certain regions.

We are conducting our pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Enrollment was completed in January 2019, and we anticipate being in a position to submit the PMA to the FDA in the fourth quarter of 2020.

*CardioGenesis Cardiac Laser Therapy*

Revenues from our CardioGenesis cardiac laser therapy product line historically consisted primarily of sales of handpieces and, in certain periods, the sale of laser consoles. During the three and nine months ended September 30, 2020, we did not have a supply of handpieces as our manufacturer of handpieces is unable to supply them until the FDA approves our supplier's change in manufacturing location, pending our supplier's resolution of several observations the FDA raised during a manufacturing site change inspection. We do not believe these observations relate to quality or safety. We will not have any handpieces available to ship until our supplier resolves these issues with the FDA. We currently anticipate resumption of supply during the first half of 2021.

Revenues from cardiac laser therapy decreased 94% and 93% for the three and nine months ended September 30, 2020, respectively, as compared to the three and nine months ended September 30, 2019 as a result of this handpiece supply issue.

***Preservation Services***

Preservation services primarily include revenues from the preservation of cardiac and vascular tissues. Revenues from preservation services decreased 2% and 5% for the three and nine months ended September 30, 2020, respectively, as compared to the three and nine months ended September 30, 2019. Revenues decreased for the three months ended September 30, 2020 from a decrease of cardiac preservation service revenues, partially offset by an increase in revenues from vascular preservation services. Revenues decreased for the nine months ended September 30, 2020 from a decrease of cardiac and vascular preservation service revenues as compared to the nine months ended September 30, 2019. The detailed discussion of cardiac and vascular preservation services is presented below:

We continue to evaluate modifications to our tissue processing procedures in an effort to improve tissue processing throughput, reduce costs, and maintain quality across our tissue processing business. Preservation services revenues, particularly revenues for certain high-demand cardiac tissues, can vary from quarter to quarter and year to year due to a variety of factors including: quantity and type of incoming tissues, yields of tissue through the preservation process, timing of receipt of donor information, timing of the release of tissues for implant, demand for certain tissue types due to the number and type of procedures being performed, and pressures from competing products or services. See further discussion below of specific items affecting cardiac and vascular preservation services revenues for the three and nine months ended September 30, 2020.

*Cardiac Preservation Services*

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

Revenues from cardiac preservation services, consisting of revenues from the distribution of heart valves and cardiac patch tissues, decreased 6% for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019. This decrease during the three months ended September 30, 2020 was primarily due to a 7% decrease in unit shipments of cardiac tissues, which decreased revenues by 6%.

Revenues from cardiac preservation services, decreased 6% for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019. This decrease during the nine months ended September 30, 2020 was primarily due to a 6% decrease of unit shipments of cardiac tissues, which decreased revenues by 6%.

The decrease in unit shipments for the three months ended September 30, 2020, was primarily due to a decrease in aortic and pulmonary valve shipments due to delays and cancellations of surgical procedures due to the COVID-19 pandemic. The decrease in unit shipments for nine months ended September 30, 2020, was primarily due to a decrease in pulmonary and aortic valve shipments due to delays and cancellations of surgical procedures due to the COVID-19 pandemic, partially offset by an increase in cardiac patch shipments.

*Vascular Preservation Services*

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

Revenues from vascular preservation services increased 2% for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019. This increase was due to a 3% increase in vascular tissue shipments, which increased revenues by 4%, partially offset by a decrease in average service fees, which decreased revenues by 2%.

Revenues from vascular preservation services decreased 4% for the nine months ended September 30, 2020, as compared to the nine months ended September 30, 2019. This decrease was due to a 4% decrease in vascular tissue shipments, which decreased revenues by 2% and a decrease in average service fees, which decreased revenues by 2%.

The increase in shipments of vascular tissues for the three months ended September 30, 2020 was due to increases in saphenous vein shipments, partially offset by a decrease in femoral artery shipments. The decrease in shipments of vascular tissues for the nine months ended September 30, 2020 was due to a decrease in femoral artery and femoral vein shipments, partially offset by an increase in saphenous vein shipments. The decrease in shipments for the three and nine months ended September 30, 2020 are due to delays and cancellations of surgical procedures due to the COVID-19 pandemic.

**Cost of Products and Preservation Services**

***Cost of Products***

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| Cost of products | $ 12,998 | $ 12,706 | $ 36,078 | $ 41,021 |

Cost of products increased 2% for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019. Cost of products decreased 12% for the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019. Cost of products for the three and nine months ended September 30, 2020 and 2019 included costs related to JOTEC (including AMDS and NEXUS), On-X, BioGlue, PhotoFix, PerClot, and CardioGenesis cardiac laser therapy products.

The increase in cost of products for the three months ended September 30, 2020 was primarily due to an increase in costs related to a change in the mix of products sold, partially offset by a decrease in unit shipments during the three months ended September 30, 2020. The decrease in cost of products for the nine months ended September 30, 2020 was primarily due to a decrease in unit shipments.

***Cost of Preservation Services***

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| Cost of preservation services | $ 9,001 | $ 9,953 | $ 26,060 | $ 29,043 |

Cost of preservation services decreased 10% for both the three and nine months ended September 30, 2020, as compared to the three and nine months ended September 30, 2019. 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, 2020 primarily due to a reduction of unit costs and to a lesser degree, the cost of unit shipments of cardiac and vascular tissue.

***Gross Margin***

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| Gross margin | $ 43,132 | $ 45,222 | $ 123,193 | $ 136,461 |
| Gross margin as a percentage of total revenues | 66% | 67% | 66% | 66% |

Gross margin decreased 5% and 10% for the three and nine months ended September 30, 2020, respectively, as compared to the three and nine months ended September 30, 2019 due to an overall decrease in revenues from products and preservation services and a corresponding overall decrease in costs of products and preservation services. Gross margin as a percentage of total revenues decreased in the three months ended September 30, 2020 as compared to the three months ended September 30, 2019, primarily due to a change in the mix of products sold during the three months ended September 30, 2020.

**Operating Expenses**

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| General, administrative, and marketing expenses | $ 33,743 | $ 34,259 | $ 105,033 | $ 105,402 |
| General, administrative, and marketing expenses as a percentage of total revenues | 52% | 50% | 57% | 51% |

General, administrative, and marketing expenses decreased 2% for the three months ended September 30, 2020, as compared to the three months ended September 30, 2019, and were flat for the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019. The decreases in general, administrative, and marketing expenses for the three months ended September 30, 2020 were primarily due to decreased travel and marketing expenses from reduced and cancelled travel and events as well as reduced commissions due to the COVID-19 pandemic. General, administrative, and marketing expenses included $981,000 and $1.2 million of business development expenses as of the three and nine months ended September 30, 2020 as compared to $1.2 million and $2.6 million as of the three and nine months ended September 30, 2019. Business development expenses during three and nine months ended September 30, 2020 were primarily comprised of expenses related to the Ascyrus acquisition. Business development expenses during the three and nine months ended September 30, 2019 primarily consisted of expenses related to the Endospan agreements.

***Research and Development Expenses***

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| Research and development expenses | $ 5,755 | $ 6,259 | $ 17,633 | $ 17,648 |
| Research and development expenses as a percentage of total revenues | 9% | 9% | 10% | 9% |

Research and development expenses decreased 8% for the three months ended September 30, 2020, as compared to September 30, 2019 and were flat for the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019. Research and development spending in the three and nine months ended September 30, 2020 was primarily focused on clinical work to gain regulatory approvals for On-X and JOTEC products. Research and development spending in the three and nine months ended September 30, 2019 was primarily focused on clinical work with respect to our pivotal clinical trial to gain regulatory approval for JOTEC products, and to a lesser extent, to gain regulatory approval for On-X products as well as approval to commercialize PerClot for surgical indications in the U.S.

During the second and third quarters of 2020 we reduced spending on research and development projects due to the COVID-19 pandemic. While we have reduced planned spending on research and development projects during 2020 due to the COVID-19 pandemic, we nonetheless expect to incur expenses during the remainder of the year for clinical research

projects to gain regulatory approvals for new products or indications, including JOTEC, On-X, PerClot, and BioGlue products, and to incur expenses for research and development for new products.

**Interest Expense**

Interest expense was $4.9 million and $12.0 million for the three and nine months ended September 30, 2020, respectively, as compared to $3.6 million and $11.3 million for the three and nine months ended September 30, 2019, respectively. Interest expense for the three and nine months ended September 30, 2020 and 2019 relates to interest on debt and uncertain tax positions. Interest on debt includes $1.4 million and $2.3 million of non-cash interest related to the convertible and term loan debt for the three and nine months ended September 30, 2020, respectively. Interest on debt includes $407,000 and $1.2 million of non-cash interest related to the term loan debt for the three and nine months ended September 30, 2019, respectively.

**Other Expense, Net**

Other expense, net was $2.9 million and $5.8 million for the three and nine months ended September 30, 2020, respectively, as compared to other expense of $2.4 million and $2.7 million for the three and nine months ended September 30, 2019, respectively. Other expense, net includes $4.9 million in fair value adjustments of financial instruments for the three and nine months ended September 30, 2020, respectively. Other expense, net includes $2.1 million in realized and unrealized gains and $846,000 in realized and unrealized losses due of foreign currency fluctuations for the three and nine months ended September 30, 2020, respectively. Other expense, net included $2.4 million and $2.7 million in realized and unrealized losses due to foreign currency fluctuations during the three and nine months ended September 30, 2019, respectively.

**Earnings**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| (Loss) income before income taxes | $ (4,181) | $ (992) | $ (17,082) | $ 97 |
| Income tax benefit | (1,311) | (858) | (3,858) | (2,304) |
| **Net (loss) income** | **$ (2,870)** | **$ (134)** | **$ (13,224)** | **$ 2,401** |
| **Diluted (loss) income per common share** | **$ (0.08)** | **$ (0.00)** | **$ (0.35)** | **$ 0.06** |
| **Diluted weighted-average common shares outstanding** | **37,912** | **37,255** | **37,608** | **37,850** |

We experienced a loss before income taxes for the three months ended September 30, 2020 and three months ended September 30, 2019. We experienced a loss before income taxes for the nine months ended September 30, 2020 as compared to income before income taxes for the nine months ended September 30, 2019. The loss before income taxes for the three and nine months ended September 30, 2020 was primarily due to decreases in revenues impacted by delays and cancellations of some surgical procedures as a result of reduced hospital capacity and hospital restrictions due to the COVID-19 pandemic as well as the fixed nature of certain operating expenses.

Our effective income tax rate was a benefit of 31% and 23% for the three and nine months ended September 30, 2020, respectively, as compared to a benefit of 87% and 2,375% for the three and nine months ended September 30, 2019, respectively. The change in the tax rate for the three and nine months ended September 30, 2020 is primarily due to a change in pre-tax book loss, as well as a reduction in the excess tax benefit related to stock compensation for the three and nine months ended September 30, 2020, as compared to the three and nine months ended September 30, 2019.

The income tax rate for the three and nine months ended September 30, 2020 and 2019 was favorably impacted by excess tax benefit deductions related to stock compensation, the research and development tax credit, and losses in high rate jurisdictions. These factors were partially offset by the unfavorable impacts of non-deductible operating expenses and executive compensation expenses.

In response to the COVID-19 pandemic, the U.S. government enacted the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") on March 27, 2020. The CARES Act provides various forms of relief and assistance to U.S. businesses. We recorded a reduction to income taxes payable and deferred tax assets of approximately $1.3 million for the anticipated change to the 2019 Section 163(j) interest expense deduction limitation. We will continue to monitor and assess the impact the CARES Act and similar legislation in other countries may have on our business and financial results.

We experienced a net loss and diluted loss per common share for three months ended September 30, 2020 as compared to a net loss for the three months ended September 30, 2019. We experienced net loss and diluted loss per common share for the nine months ended September 30, 2020 as compared to a net income and diluted income per common share for nine months ended September 30, 2019. Net loss and diluted loss per common share for the three and nine months ended September 30, 2020 was primarily due to an increase in loss before income taxes, as discussed above.

**Seasonality**

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

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

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

We are uncertain whether the demand for PhotoFix, Endospan, and Ascyrus products is seasonal, as these products have not fully penetrated many markets and, therefore, the nature of any seasonal trends may not yet be obvious.

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

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

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

**Liquidity and Capital Resources**

***Net Working Capital***

As of September 30, 2020 net working capital (current assets of $233.7 million less current liabilities of $53.7 million) was $180.0 million, with a current ratio (current assets divided by current liabilities) of 4 to 1, compared to net working capital of $142.2 million and a ratio of 4 to 1 at December 31, 2019.

***Overall Liquidity and Capital Resources***

Our primary cash requirements for the nine months ended September 30, 2020 were for the acquisition of Ascyrus as further described below, funding of the second tranche payment related to the Endospan Loan, general working capital needs, interest and principal payments under our Credit Agreement, defined below, and debt issuance costs under our Convertible Senior Notes, capital expenditures for facilities and equipment, and repurchases of stock to cover tax withholdings. We funded our cash requirements through our existing cash reserves and proceeds from stock option exercises.

We believe our cash from operations and existing cash and cash equivalents will enable us to meet our current operational liquidity needs for at least the next twelve months. Our future cash requirements are expected to include interest and principal payments under our Credit Agreement and Convertible Senior Notes (described in "Significant Sources and Uses of Liquidity" section below), expenditures for clinical trials, research and development expenditures, general working capital needs, capital expenditures, and other corporate purposes and may include cash to fund business development activities including obligations in the Endospan and Ascyrus agreements. These items may have a significant effect on our future cash flows during the next twelve months. Subject to the terms of our Credit Agreement, we may seek additional borrowing capacity or financing, pursuant to our current or any future shelf registration statement, for general corporate purposes or to fund other future cash requirements. If we undertake any further significant business development activity, we may need to finance such activities by obtaining additional debt financing or using a registration statement to sell equities. There can be no assurance that we will be able to obtain any additional debt or equity financing at the time needed or that such financing will be available on terms that are favorable or acceptable to us.

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

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

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

In October 2018 we finalized an amendment to the Credit Agreement to reprice interest rates, resulting in a reduction in the interest rate margins over base rates on the Term Loan Facility. The loan under the Term Loan Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of 2.25%, or LIBOR, plus a margin of 3.25%. Prior to the repricing, the optional floating annual rate was equal to either the base rate, plus a margin of 3.00%, or LIBOR, plus a margin of 4.00%. The loan under the Revolving Credit Facility bears interest, at our option, at a floating annual rate equal to either the base rate, plus a margin of between 3.00% and 3.25%, depending on our consolidated leverage ratio, or LIBOR, plus a margin of between 4.00% and 4.25%, depending on our consolidated leverage ratio. While a payment or bankruptcy event of default exists, we are obligated to pay a per annum default rate of interest of 2.00% in excess of the interest rate otherwise payable with respect to the overdue principal amount of any loans outstanding and overdue interest payments and other overdue fees and amounts.

In March 2020 as a precautionary measure to increase cash and maintain maximum financial flexibility during the current uncertainty in global markets resulting from the COVID-19 pandemic, we borrowed the entire amount available under our $30.0 million Revolving Credit Facility at an aggregate interest rate of 5.20%. On June 29, 2020 we used some of the net proceeds from the issuance of Convertible Senior Notes to repay the $30.0 million outstanding under our Revolving Credit Facility.

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

On June 18, 2020 we issued $100.0 million aggregate principal amount of 4.25% convertible senior notes with a maturity date of July 1, 2025 ("Convertible Senior Notes"). The net proceeds from this offering, after deducting initial

purchasers' discounts and costs directly related to this offering, were approximately $96.5 million. The Convertible Senior Notes may be settled in cash, stock, or a combination thereof, solely at our discretion. Our current intent is to settle in cash the principal amount outstanding and any note conversion value over the principal amount with shares of our Common Stock. The initial conversion rate of the Convertible Senior Notes is 42.6203 shares per $1,000 principal amount, which is equivalent to a conversion price of approximately $23.46 per share, subject to adjustments. We use the treasury stock method for assumed conversion of the Convertible Senior Notes to compute the weighted average shares of common stock outstanding for diluted earnings per share.

The conversion feature of the Convertible Senior Notes required bifurcation from the notes and was initially accounted for as an equity instrument classified to stockholders' equity, which resulted in recognizing $16.4 million in additional paid-in-capital during the nine months ended September 30, 2020. The interest expense recognized on the Convertible Senior Notes includes approximately $2.0 million and $2.2 million for the aggregate of contractual coupon interest, the accretion of the debt discount, and the amortization of the debt issuance costs as of three and nine months ended September 30, 2020, respectively. The interest on the Convertible Senior Notes includes the contractual coupon interest, accretion of the debt discount, and amortization of the debt issuance costs. Interest on the Convertible Senior Notes began accruing upon issuance and is payable semi-annually.

Holders of the Convertible Senior Notes may convert their notes at their option at any time prior to January 1, 2025 but only under the following circumstances: (i) during any calendar quarter commencing after the calendar quarter ending on September 30, 2020 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (ii) during the five business day period after any five consecutive trading day period in which the trading price per $1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; (iii) we give a notice of redemption with respect to any or all of the notes, at any time prior to the close of business on the second scheduled trading day immediately preceding the redemption date; or (iv) upon the occurrence of specified corporate events. On or after January 1, 2025 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their notes at any time, regardless of the foregoing circumstances.

We cannot redeem the Convertible Senior Notes before July 5, 2023. We can redeem them on or after July 5, 2023, in whole or in part, at our option, if the last reported sale price per share of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption. We may redeem for cash all or part of the Convertible Senior Notes at a redemption price equal to 100% of the principal amount of the redeemable Convertible Senior Notes, plus accrued and unpaid interest to, but excluding, the redemption date. No principal payments are due on the Convertible Senior Notes prior to maturity. Other than restrictions relating to certain fundamental changes and consolidations, mergers or asset sales and customary anti-dilution adjustments, the Convertible Senior Notes do not contain any financial covenants and do not restrict us from conducting significant restructuring transactions or issuing or repurchasing any of its other securities. As of September 30, 2020, we are not aware of any current events or market conditions that would allow holders to convert the Convertible Senior Notes. I We have used a portion of the proceeds to pay off the $30.0 million outstanding under our Revolving Credit Facility and finance the Ascyrus transaction and anticipate using the remaining funds for general corporate purposes.

On September 2, 2020, we entered into a Securities Purchase Agreement (the "Ascyrus Agreement") to acquire 100% of the outstanding equity interests of Ascyrus. Ascyrus is the developer of AMDS, the world's first aortic arch remodeling device for the use in the treatment of acute Type A aortic dissections.

Under the terms of the Ascyrus Agreement, we will pay an aggregate of up to $200.0 million in consideration, consisting of: (i) a cash payment of approximately $60.0 million and the issuance of $20.0 million in shares of CryoLife common stock, in each case, delivered at the closing of the acquisition, (ii) if the U.S. Food and Drug Administration (the "FDA") approves an Investigational Device Exemption ("IDE") application for the AMDS, a cash payment of $10.0 million and the issuance of $10.0 million in shares of CryoLife common stock, (iii) if the FDA approves a Premarket Approval ("PMA") application submitted for the AMDS, a cash payment of $25.0 million, (iv) if regulatory approval of the AMDS is obtained in Japan on or before June 30, 2027, a cash payment of $10.0 million, (v) if regulatory approval of the AMDS is obtained in China on or before June 30, 2027, a cash payment of $10.0 million and (vi) a potential cash payment of up to $55.0 million (or up to $65.0 million to $75.0 million if the Japanese or Chinese approvals are not secured on or before June 30, 2027) calculated as

two times the incremental worldwide sales of the AMDS (or any other acquired technology or derivatives of such acquired technology) outside of the European Union during the three-year period following the date the FDA approves a Premarket Approval application submitted for the AMDS. Upon closing of the acquisition on September 2, 2020, we paid $83.7 million consisting of $63.7 million in cash consideration, and $20.0 million in shares of CryoLife common stock. The number of shares issued was based on a 10-day moving volume weighted average closing price of a share of CryoLife common stock as of the date immediately prior to closing, resulting in an issuance of 991,800 shares of CryoLife common stock.

While we have reduced spending on some research and development projects during 2020 due to the COVID-19 pandemic, we nonetheless expect to incur expenses during the remainder of 2020 for clinical research projects to gain regulatory approvals for new products or indications, including for JOTEC, On-X, PerClot, and BioGlue products, and to incur expenses for research and development for new products.

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

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

As of September 30, 2020 approximately 24% of our cash and cash equivalents were held in foreign jurisdictions.

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

Net cash provided by operating activities was $6.9 million for the nine months ended September 30, 2020, as compared to $14.8 million for the nine months ended September 30, 2019.

We use the indirect method to prepare our cash flow statement and, accordingly, the operating cash flows are based on our net (loss) income, which is then adjusted to remove non-cash items, items classified as investing and financing cash flows, and changes in operating assets and liabilities from the prior year end. For the nine months ended September 30, 2020 these non-cash items included $14.8 million in depreciation and amortization expenses, $7.4 million in non-cash compensation, $5.3 million in non-cash lease expense, and $4.9 million related to fair value adjustment of long-term loan.

Our working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the nine months ended September 30, 2020 these changes included unfavorable adjustments of $19.7 million due to an increase in inventory balances and deferred preservation costs and $2.6 million due to an increase in prepaid expenses and other assets, partially offset by $7.7 million due to the timing differences between recording receivables and the receipt of cash and favorable effect of $3.2 million due to timing differences between the recording of accounts payable and other current liabilities.

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

Net cash used in investing activities was $70.8 million for the nine months ended September 30, 2020, as compared to $20.8 million for the nine months ended September 30, 2019. During the nine months ended September 30, 2020 cash flows used in investing activities included $59.6 million of payments related to the Ascyrus acquisition, net of cash acquired, $5.0 million in cash payments related to the Endospan agreements as described in the "Significant Sources of and Uses of Liquidity" section above, and of $5.2 million related to capital expenditures.

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

Net cash provided by financing activities was $95.3 million for the nine months ended September 30, 2020, as compared to net cash used in financing activities of $836,000 for the nine months ended September 30, 2019. The current year cash provided by financing activities was primarily due to the $100.0 million cash proceeds from the issuance of the Convertible Senior Notes partially offset by $3.6 million of debt issuance costs associated with these Convertible Senior Notes as described in the "Significant Sources and Uses of Liquidity" section above. During the nine months ended September 30, 2020, we borrowed and subsequently repaid $30.0 million from the Revolving Credit Facility, as described in the "Significant Sources and Uses of Liquidity" section above.

**Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements.

**Scheduled Contractual Obligations and Future Payments**

Scheduled contractual obligations and the related future payments as of September 30, 2020 were as follows (in thousands):

| | Total | Remainder of 2020 | 2021 | 2022 | 2023 | 2024 | Thereafter |
|---|---|---|---|---|---|---|---|
| Long-term debt obligations | $ 321,187 | $ 701 | 2,803 | 2,803 | 2,803 | 211,858 | 100,219 |
| Contingent payments | 129,194 | -- | 25,048 | 2,097 | 2,048 | -- | 100,001 |
| Interest payments on long-term debt | 59,411 | 2,370 | 13,601 | 13,412 | 13,306 | 12,460 | 4,262 |
| Research obligations | 24,158 | 3,282 | 8,733 | 7,495 | 4,196 | 452 | -- |
| Operating leases | 23,464 | 1,435 | 6,823 | 4,340 | 2,877 | 2,706 | 5,283 |
| Purchase commitments | 7,026 | 4,145 | 2,651 | 163 | 18 | 25 | 24 |
| Finance leases | 6,398 | 178 | 695 | 639 | 638 | 636 | 3,612 |
| **Total contractual obligations** | **$ 570,838** | **$ 12,111** | **$ 60,354** | **$ 30,949** | **$ 25,886** | **$ 228,137** | **$ 213,401** |

Our long-term debt obligations and interest payments above result from scheduled principal payments and anticipated interest payments related to our Credit Agreement, Convertible Senior Notes, and JOTEC governmental loans. Long-term debt obligations include $100.0 million aggregate principal of Convertible Senior Notes with a maturity date of July 1, 2025, of which $78.7 million has been recorded as long-term debt as of September 30, 2020 on the "Summary Consolidated Balance Sheets" included in Part I, Item 1 of this form 10-Q.

The contingent payments obligation includes $120.0 million to be paid to the former shareholders of Ascyrus, of which $10.0 million is expected to be paid in CryoLife common stock, upon the achievement of certain milestones described in the "Significant Sources of and Uses of Liquidity" section above. We anticipate making a $5.0 million third tranche payment under the Endospan Loan upon receipt of certification that certain approvals and clinical trial milestones have been achieved. The contingent payments obligation also includes payments that we may make if certain U.S. regulatory approvals and certain commercial milestones are achieved related to our transaction with Starch Medical, Inc. ("SMI") for PerClot and other licensed technologies.

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

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

Our purchase commitments include obligations from agreements with suppliers, one of which is the minimum purchase requirements for PerClot under a distribution agreement with SMI. Pursuant to the terms of the distribution agreement, we may terminate that agreement, including the minimum purchase requirements set forth in the agreement for various reasons, one of which is if we obtain FDA approval for PerClot. These minimum purchases are included in the table above through 2021, based on the assumption that we will not terminate the distribution agreement before receiving FDA approval for PerClot. However, if we do not obtain FDA approval for PerClot and/or we choose not to terminate the distribution agreement, we may have minimum purchase obligations of up to $1.8 million per year through the end of the contract term in 2025.

The schedule of contractual obligations above excludes (i) obligations for estimated liability claims unless they are due as a result of a settlement agreement or other contractual obligation, as no assessments have been made for specific litigation, and (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be $4.5 million, as no specific assessments have been made by any taxing authorities.

**Capital Expenditures**

Capital expenditures were $5.2 million for both the nine months ended September 30, 2020 and 2019, respectively. Capital expenditures in the nine months ended September 30, 2020 were primarily related to leasehold improvements needed to support our business, routine purchases of manufacturing and tissues processing equipment and computer software.

**Risks and Uncertainties**

See the “Risk Factors” 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 $64.1 million as of September 30, 2020 and interest paid on the outstanding balances, if any, of our variable rate Revolving Credit Facility, Term Loan Facility, and Convertible Senior Notes. A 10% adverse change in interest rates, as compared to the rates experienced by us in the nine months ended September 30, 2020, affecting our cash and cash equivalents, restricted cash and securities, Term Loan Facility, Revolving Credit Facility, and Convertible Senior Notes would not have a material effect on our financial position, results of operations, or cash flows.

**Foreign Currency Exchange Rate Risk**

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

We have revenues and expenses that are denominated in foreign currencies. Specifically, a portion of our international BioGlue, On-X, PerClot, and JOTEC revenues are denominated in Euros, British Pounds, Swiss Francs, Polish Zlotys, Canadian Dollars, and Brazilian Reals, and a portion of our general, administrative, and marketing expenses are denominated in Euros, British Pounds, Swiss Francs, Polish Zlotys, Canadian Dollars, Brazilian Reals and Singapore Dollars. These foreign currency transactions are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the U.S. Dollar equivalent of net income from transactions conducted in other currencies. As a result, revenues and expenses could fluctuate related to a change in exchange rates.

**Item 4. Controls and Procedures.**

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

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

Our management utilizes the criteria set forth in “Internal Control-Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our Disclosure Controls over financial reporting. Based upon the most recent Disclosure Controls evaluation conducted by management with the participation of the CEO and CFO, as of September 30, 2020, the CEO and CFO have concluded that our Disclosure Controls were effective at a reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by us in our periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission’s rules and forms.

As disclosed above, on September 2, 2020 we entered into the Ascyrus Agreement to acquire 100% of the outstanding equity interests of Ascyrus. We are currently in the process of implementing CryoLife’s internal control structure over these operations.

**Part II - OTHER INFORMATION**

**Item 1. Legal Proceedings.**

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

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

**Item 1A. Risk Factors.**

## Risks Relating To Our Business

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

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

- Our product sales. We have experienced an impact on revenues in the three months ending September 30, 2020, due to the COVID-19 pandemic. Although to date we experienced the most severe impact to our revenues in April of the second quarter 2020 followed by some sequential recovery in May and June and further recovery during the third quarter of 2020, the extent to which our revenue will be impacted by the pandemic in the fourth quarter of 2020 and beyond will depend largely on future developments.
- Our business operations. We have taken several steps to address the impact of COVID-19 on our business operations. We have reevaluated the need for, and timing of, certain expenses and have taken pre-emptive steps to reduce spending. These spending reductions, however, might not be adequate and could potentially adversely impact our business operations or delay our recovery after the effects of the pandemic subside. We also have implemented specific protocols to minimize exposure to COVID-19 among all of our employees, including those working at our three primary manufacturing facilities. In addition, we have implemented remote work arrangements for employees we deem able to do so and have significantly restricted business travel to essential travel only. There can be no guarantee, however, that these arrangements will reduce the spread of COVID-19 among our employees and key personnel, potentially adversely impacting our business operations, or that these arrangements will not create additional risks, such a cyber security, productivity, internal controls, or employee attrition risks. Although we have not experienced a significant supply chain interruption to date, such an interruption could occur. In addition, the availability of tissue for processing could decrease as the pandemic persists.
- Our management of our indebtedness. As a precautionary measure to increase cash and maintain maximum financial flexibility during the COVID-19 pandemic, we borrowed the entire amount available under our $30.0 million secured revolving credit facility ("the Revolving Credit Facility"), increasing the level of our indebtedness and our repayment obligations. Subsequently, we issued $100.0 million aggregate principal amount of 4.25% convertible senior notes with a maturity date of July 1, 2025 ("Convertible Senior Notes"). We used portions of those proceeds to repay the Revolving Credit Facility and finance the Ascyrus transaction and the remainder we anticipate continuing to use for general corporate purposes. We have also reevaluated the need for and timing of certain expenses and have taken pre-emptive steps to reduce spending. However, there can be no guarantee that these precautionary measures will provide us with all the liquidity we need going forward, particularly if the COVID-19 pandemic continues for an extended period of time, grows in severity or has impacts on our supply chain or operations that we do not anticipate.
- Our research and development projects. We have reduced spending on research and development projects, including clinical research projects. These reductions could adversely impact future revenue, and additional reductions in spending might be required, further impacting future revenue. In addition, our ability to conduct our ongoing research and development projects in markets that are affected by COVID-19 has been, and could continue to be, adversely impacted. Enrollment and timelines for our clinical trials have been and might continue to be impacted as healthcare providers reprioritize resources and limit access to healthcare facilities or as patients decline to participate or are hesitant to voluntarily visit healthcare facilities. In addition, COVID-19-related closures of government and regulatory agencies have slowed and might continue to slow the timelines for regulatory approvals.

If COVID-19 continues to spread, if efforts to contain COVID-19 continue or are unsuccessful, if we experience new infections of COVID-19 in areas previously successful in containing its spread, or if COVID-19 spreads among our employees or impacts our supply chain, it could materially, adversely affect our revenues, financial condition, profitability, and cash flows. These future developments remain uncertain and difficult to predict but may intensify the impacts that we have already experienced. New information is continually emerging regarding the severity of the pandemic and the various government, regulatory, expert, and recommended actions to contain it or address its impact.

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

On December 1, 2017 we acquired JOTEC AG, a Swiss entity that we converted to JOTEC GmbH and subsequently merged with our Swiss acquisition entity, Jolly Buyer Acquisition GmbH ("JOTEC"), and its subsidiaries (the "JOTEC Acquisition") for $169.1 million in cash and 2,682,754 shares of CryoLife common stock with a value of $53.1 million on the date of closing, for a total purchase price of approximately $222.2 million, including debt and cash acquired on the date of closing. We paid part of the cash portion of the purchase price using available cash on hand and financed the remainder of the cash portion of the purchase price and related expenses and refinanced our then existing approximately $69.0 million term loan, with a new $255.0 million senior secured credit facility, consisting of a $225.0 million secured term loan facility and a $30.0 million secured revolving credit facility.

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

- The continued growth of the global market for stent grafts used in endovascular and open repair of aortic disease;
- Our ability to leverage our global infrastructure to sell JOTEC products, including in the markets in which JOTEC is already direct;
- Our ability to foster cross-selling opportunities between the CryoLife and JOTEC product portfolios;
- Our ability to bring JOTEC products to the U.S. market;
- Our ability to harness the JOTEC new product pipeline and research and development capabilities to drive long-term growth, including our ability to obtain Conformité Européene Mark product certification ("CE Mark") for pipeline products and obtain or maintain certification for pipeline and current products as the European Union adopted a new Medical Device Regulation (MDR 2017/745) ("MDR") or as existing certifications may be deemed or may become out of date;
- Our ability to drive gross margin expansion;
- Our ability to compete effectively;
- Our ability to carry, service, and manage significantly more debt and repayment obligations;
- Our ability to manufacture and supply sufficient JOTEC products to meet market demand; and
- Our ability to manage the unforeseen risks and uncertainties related to JOTEC's business, including any related to intellectual property rights.

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

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

Our current and future levels of indebtedness could:

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

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

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

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

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

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

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

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

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

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

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

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

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

Tissue preservation services are a significant source of our revenues, accounting for 30% of revenues in the three months ended September 30, 2020 and 2019. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows, if we are unable to:

- Source sufficient quantities of some tissue types from human donors or address potential excess supply of other tissue types. We rely primarily upon the efforts of third-party procurement organizations, tissue banks (most of which are not-for-profit), and others to educate the public and foster a willingness to donate tissue. Factors beyond our control such as supply, regulatory changes, negative publicity concerning methods of tissue recovery or disease transmission from donated tissue, or public opinion of the donor process as well as our own reputation in the industry can negatively impact the supply of tissue;
- Compete effectively in tissue preservation services, as we may be unable to capitalize on our clinical advantage or our competitors may have advantages over us in terms of cost structure, pricing, back office automation, marketing, and sourcing tissue; or
- Mitigate sufficiently the risk that processed tissue cannot be sterilized and hence carries an inherent risk of infection or disease transmission; there is no assurance that our quality controls will be adequate to mitigate such risk.

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

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

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

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

BioGlue® Surgical Adhesive ("BioGlue") is a significant source of our revenues, accounting for 24% and 23% of revenues in the three months ended September 30, 2020 and 2019, respectively. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

- Our ability to achieve anticipated BioGlue revenue in the U.S. and in international markets outside the U.S.;
- BioGlue is a mature product, our U.S. Patent for BioGlue expired in mid-2012, and our patents in most of the rest of the world for BioGlue expired in mid-2013. Other companies may use the inventions disclosed in the expired patents to develop and make competing products;
- Some companies have launched competitive products and others may pursue regulatory approval for competitive products in the future. These companies may have greater financial, technical, manufacturing, and marketing resources than we do and may be better established in their markets;
- We may be unable to obtain regulatory approvals to commercialize BioGlue in certain countries other than the U.S. at the same rate as our competitors or at all. We also may not be able to capitalize on new regulatory approvals we obtain for BioGlue in countries other than the U.S., including approvals for new indications;
- BioGlue contains a bovine blood protein. Animal-based products are subject to increased scrutiny from the public and regulators, who may have concerns about the use of animal-based products or concerns about the transmission of disease from animals to humans. These concerns could lead to additional regulations or product bans in certain countries;
- Changes to components in the BioGlue product, including in the delivery system, require regulatory approval, which, if delayed, could cause prolonged disruptions to our ability to supply BioGlue; and
- On June 13, 2019 our European Notified Body for BioGlue, Lloyd's Register Quality Assurance Limited, which is headquartered in the U.K., informed us that it would no longer provide Notified Body services to companies in European Economic Area ("EEA") effective September 2019. On July 5, 2019 the U.K. Medicines and Healthcare Products Regulatory Agency ("MHRA") granted us a one-year grace period to transfer BioGlue (and PhotoFix) to a new Notified Body. Due to the Brexit transition period that currently is scheduled to end on December 31, 2020, and after which the MHRA will no longer be recognized as a competent authority in the European Union, we approached the governing German competent authority, the Regierungspraesidium-Tubingen (RP-T), to request an extension of the MHRA-granted grace period. On June 4, 2020, the RP-T provided a letter granting an additional one-year extension of the grace period, until September 30, 2021, provided that we meet certain conditions similar to those required by MHRA, including the demonstration of adequate progress in the CE Mark certification process with our new Notified Body. If we are delayed or unsuccessful in transferring to a new Notified Body for BioGlue (and PhotoFix) in the EEA, or if we are otherwise unable to timely meet applicable regulatory requirements, we may be unable to place BioGlue (or PhotoFix) on the market in the EEA until the situation is resolved.

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

JOTEC, inclusive of revenue from NEXUS and AMDS, is a significant source of our revenues, accounting for 24% and 23% of revenues in the three months ended September 30, 2020 and 2019, respectively. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

- Our ability to achieve anticipated JOTEC revenue in international markets outside the U.S.;
- Our ability to meet demand for JOTEC products as we seek to expand our business globally;
- Our ability to compete effectively with our major competitors, as they may have advantages over us in terms of cost structure, supply chain, pricing, sales force footprint, and brand recognition;
- Our ability to develop innovative and in-demand products in the aortic surgery space;
- Our ability to contend with enhanced regulatory requirements and enforcement activities; and
- Our ability to maintain a productive working relationship with our Works Council in Germany.

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

On-X is a significant source of our revenues, accounting for 19% of revenues in both the three months ended September 30, 2020 and 2019. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

- Our ability to achieve anticipated On-X revenue in the U.S. and in international markets outside the U.S.;
- Our ability to capitalize on the FDA's approved reduced International Normalized Ratio ("INR") indication;

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

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

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

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

Further, on May 25, 2017, the European Union adopted a new Medical Device Regulation (MDR 2017/745) ("MDR"). Although the MDR was originally scheduled to become effective on May 26, 2020, due to the COVID-19 pandemic, on April 23, 2020, the European Union enacted legislation postponing the full MDR implementation by one year until May 26, 2021. Upon implementation, among other changes, MDR will place more stringent requirements on manufacturers and European Notified Bodies regarding product classifications, pre- and post-market clinical studies, and other regulatory requirements for product clearances and approvals. These changes could result in product reclassifications and the imposition of other regulatory requirements that could delay, impede, or prevent our ability to commercialize existing, improved, or new products in the EEA. In addition, we or our Notified Bodies (or both) might be unable to timely meet the requirements of MDR. If either of the foregoing were to occur, it could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

At the same time, European Notified Bodies have begun engaging in more rigorous regulatory enforcement activities and may continue to do so. For example, on November 22, 2016, our Notified Body for the On-X product line temporarily suspended the CE Mark for the On-X ascending aortic prosthesis ("AAP"), which has now returned to the market in the EEA. Further, in anticipation of MDR, Notified Bodies have declined to review routine submissions unless they are submitted in accordance with MDR, and they may continue to do so despite the postponement of MDR implementation. Our inability to timely adapt to these new requirements of our Notified Bodies could adversely impact our clearances and approvals, which could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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

On September 11, 2019, we entered into various agreements with Endospan, Ltd. ("Endospan"), an Israeli medical device manufacturer (the "Endospan Transaction"). The Endospan Transaction included an exclusive distribution agreement for NEXUS stent graft system ("NEXUS") in certain countries in Europe for a fixed distribution fee of $9.0 million; a loan agreement ("Endospan Loan") for a secured loan from CryoLife to Endospan in an amount up to $15.0 million, funded over three tranches of $5.0 million each upon the completion of certain milestones (the first and second tranche of which was paid in September 2019 and September 2020, respectively); and a security purchase option agreement providing CryoLife the option to purchase all the then outstanding securities of Endospan from Endospan's existing securityholders for a price between $350.0 million and $450.0 million before or upon FDA approval of NEXUS, for which option CryoLife paid to Endospan $1.0 million.

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

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

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

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

On September 2, 2020, we entered into a Securities Purchase Agreement (the "Ascyrus Agreement") to acquire 100% of the outstanding equity interests of Ascyrus Medical LLC ("Ascyrus"). Ascyrus is the developer of the Ascyrus Medical Dissection Stent ("AMDS"), the world's first aortic arch remodeling device for use in the treatment of acute Type A aortic dissections.

Under the terms of the Ascyrus Agreement, we will pay an aggregate of up to $200.0 million in consideration, consisting of: (i) a cash payment of approximately $60.0 million and the issuance of $20.0 million in shares of CryoLife common stock, in each case, delivered at the closing of the acquisition, (ii) if the FDA approves an Investigational Device Exemption ("IDE") application for the AMDS, a cash payment of $10.0 million and the issuance of $10.0 million in shares of CryoLife common stock, (iii) if the FDA approves a Premarket Approval ("PMA") application submitted for the AMDS, a cash payment of $25.0 million, (iv) if regulatory approval of the AMDS is obtained in Japan on or before June 30, 2027, a cash payment of $10.0 million, (v) if regulatory approval of the AMDS is obtained in China on or before June 30, 2027, a cash payment of $10.0 million, and (vi) a potential cash payment of up to $55.0 million (or up to $65.0 million to $75.0 million if the Japanese or Chinese approvals are not secured on or before June 30, 2027) calculated as two times the incremental worldwide sales of the AMDS (or any other acquired technology or derivatives of such acquired technology) outside of the European Union during the three-year period following the date the FDA approves a Premarket Approval application submitted for the AMDS.

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

- Our ability to leverage our global infrastructure to sell the AMDS, including in its existing markets and expansion into new markets accessible with the AMDS's existing CE Mark but not yet served;
- Our ability to foster cross-selling opportunities between the AMDS and the JOTEC product portfolio;
- Our ability to obtain regulatory approval for the AMDS in the U.S. and other markets;
- Our ability to execute on the existing development and clinical trial timelines for the AMDS;
- Our ability to meet demand for the AMDS; and
- Our ability to manage the unforeseen risks and uncertainties related to Ascyrus's business, including any related to intellectual property rights.

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

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

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

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

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

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

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

Further, even if we receive FDA PMA for PerClot, we may be unsuccessful in selling PerClot in the U.S. By the time we secure approvals, competitors may have substantial market share or significant market protections due to contracts, among other things. We may also be unsuccessful in selling in countries other than the U.S. due, in part, to a proliferation in other countries of multiple generic competitors, any breach by SMI of its contractual obligations, or the lack of adequate

intellectual property protection or enforcement. Any of these occurrences could materially, adversely affect our future revenues, financial condition, profitability, and cash flows.

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

In October 2014 the FDA convened an advisory committee meeting to consider the FDA's recommendation to re-classify more than minimally manipulated ("MMM") allograft heart valves from an unclassified medical device to a Class III medical device. The class of allograft heart valves potentially covered by this recommendation includes our CryoValve SGPV. At the meeting, a majority of the advisory committee panel recommended to the FDA that MMM allograft heart valves be re-classified as a Class III product. In December 2019, we learned that the FDA is preparing to issue a proposed rule for reclassification of MMM allograft heart valves as Class III medical devices, which would be subject to a comment period before publication of a final rule. Upon publication of a final rule, should the CryoValve SGPV be determined to be MMM, we expect to have approximately thirty months to submit a PMA application, after which the FDA will determine if, and for how long, we may continue to provide these tissues to customers during review of the PMA application. To date, the FDA has not issued a final rule for reclassification of MMM allograft heart valves.

We have continued to process and ship our CryoValve SGPV tissues. If the FDA ultimately classifies our CryoValve SGPV as a Class III medical device, and if there are delays in obtaining the PMA, if we are unsuccessful in obtaining the PMA, or if the costs associated with these activities are significant, this could materially, adversely affect our revenues, financial condition, profitability, and/or cash flows in future periods. In addition, we could decide that the requirements for obtaining a PMA make continued processing of the CryoValve SGPV too onerous, leading us to discontinue distribution of these tissues.

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

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

- *New Products* – Drive growth through product development and commercialization of new and next-generation products and services focused on aortic repair;
- *New Indications* – Drive growth through new regulatory approvals and expanded indications for our existing products and services to increase the size of our addressable U.S. or international markets;
- *Global Expansion* – Drive growth by entering new international markets, establishing new international direct sales territories, and developing our commercial infrastructure in new markets, including emerging markets, China and Brazil; and
- *Business Development* – Drive growth by selectively pursuing acquisitions, licensing, and distribution opportunities that are aligned to our objectives and complement our existing products, services, and infrastructure. Examples include our acquisitions of JOTEC, On-X, and Ascyrus, and our distribution agreement and purchase option for NEXUS. To the extent that we identify, develop, or acquire non-core products or applications, we may dispose of these assets or pursue licensing or distribution agreements with third-party partners for development or commercialization.

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

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

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

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

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

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

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

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

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

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

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

- Difficulties and costs associated with staffing, establishing and maintaining internal controls, managing foreign operations, including foreign distributor relationships, and developing direct sales operations in key foreign countries;
- Expanded compliance obligations, including obligations associated with the Foreign Corrupt Practices Act, the U.K. Bribery Law, local anti-corruption laws, Office of Foreign Asset Control administered sanction programs, and the European Union's General Data Protection Regulation;
- Broader exposure to corruption;

- Overlapping and potentially conflicting international legal and regulatory requirements, as well as unexpected changes in international legal and regulatory requirements or reimbursement policies and programs;
- Longer accounts receivable collection cycles in certain foreign countries and additional cost of collection of those receivables;
- Diminished protection for intellectual property and the presence of a growing number of generic or smaller competitors in some countries;
- Changes in currency exchange rates, particularly fluctuations in the Euro as compared to the U.S. Dollar;
- Differing local product preferences and product requirements;
- Differing local labor and employment laws, including those related to terminations, unionization, and the formation of works councils or other similar employee organizations;
- Adverse economic or political changes or political instability;
- Potential trade restrictions, exchange controls, and import and export licensing requirements including tariffs;
- Potential adverse tax consequences of overlapping tax structures; and
- Potential adverse financial consequences resulting from the exit of the U.K. from the European Union, or "Brexit," including a potential disruption of sales into the U.K.

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

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

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

- Issue additional equity securities that would dilute our stockholders' ownership interest in us;
- Use cash that we may need in the future to operate our business;
- Incur debt, including on terms that could be unfavorable to us or debt that we might be unable to repay;
- Structure the transaction in a manner that has unfavorable tax consequences, such as a stock purchase that does not permit a step-up in the tax basis for the assets acquired;
- Be unable to realize the anticipated benefits, such as increased revenues, cost savings, or synergies from additional sales;
- Be unable to integrate, upgrade, or replace the purchasing, accounting, financial, sales, billing, employee benefits, payroll, and regulatory compliance functions of an acquisition target;
- Be unable to secure or retain the services of key employees related to the acquisition;
- Be unable to succeed in the marketplace with the acquisition; or
- Assume material unknown liabilities associated with the acquired business.

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

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

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

The materials and supplies used in our product manufacturing and our tissue processing are subject to stringent quality standards and requirements, and many of these materials and supplies are subject to significant regulatory oversight and action. If materials or supplies used in our processes fail to meet these standards and requirements or are subject to recall or other quality action, an outcome could be the rejection or recall of our products or tissues and/or the immediate expense of the costs of the manufacturing or preservation. In addition, if these materials and supplies or changes to them do not receive regulatory approval or are recalled, if the related suppliers and/or their facilities are shut down temporarily or permanently, whether by government order, natural disaster, or other reason, or if the related suppliers are otherwise unable or unwilling to supply us, there may not be sufficient materials or supplies available for purchase to allow us to manufacture our products or

process tissues. In addition, we rely on contract manufacturers to manufacture some of our products or to provide additional manufacturing capacity for other products. If these contract manufacturers fail to meet our quality standards and requirements or if they are unable or unwilling to supply the products, we may not be able to meet demand for these products. Any of these occurrences or actions could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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

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

As an example of these risks, we will not have a supply of handpieces for cardiac laser therapy until the FDA approves our supplier's change in manufacturing location, pending our supplier's resolution of several observations the FDA raised during a manufacturing site change inspection. We do not believe these observations relate to quality or safety. We currently anticipate resumption of supply during the first half of 2021.

We also conduct nearly all our internal manufacturing operations at three facilities: Austin, Texas for our On-X product line, Hechingen, Germany for our JOTEC product line, and Kennesaw, Georgia for all our other products. The NEXUS product is solely produced by Endospan in Herzelia, Israel, and the AMDS product is solely supplied by our supplier in Charlotte, North Carolina. If one of these facilities ceases operations temporarily or permanently, due to natural disaster or other reason, our business could be substantially disrupted.

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

Some of our products, including our On-X products are sterilized using ethylene oxide ("EtO"). Although we have a small-scale EtO facility in Austin, Texas, we rely primarily on large-scale EtO facilities to sterilize our products. In addition, some of our suppliers use, or rely upon third parties to use, EtO to sterilize some of our product components. Concerns about the release of EtO into the environment at unsafe levels have led to various regulatory enforcement activities against EtO facilities, including closures and temporary closures. For example, in February 2019, the Illinois Environmental Protection Agency issued an order to stop Sterigenics from using EtO at its Willowbrook, Illinois facility; Sterigenics subsequently announced that the facility would not reopen. The number of EtO facilities in the U.S. is limited, and any permanent or temporary closures or disruption to their operations could delay, impede, or prevent our ability to commercialize our products, which could materially, adversely affect our revenues, financial condition, profitability, and cash flows. In addition, any regulatory enforcement activities against us for our use of EtO could result in financial, legal, business, and reputational harm to us.

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

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

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

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

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

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

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

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

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

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

The December 2017 tax reform legislation known as H.R. 1, commonly referred to as the "Tax Cuts and Jobs Act" ("the Tax Act"), made significant changes to U.S. federal income tax law. In response, the U.S. Treasury Department issued multiple significant proposed and final regulation packages to further interpret certain provisions of the Tax Act. As of September 30, 2020, a number of significant regulations have been finalized, including those for Section 163(j) business interest expense limitations and Section 250 FDII and GILTI deductions. In general, these finalized regulation packages are not effective for our tax year beginning January 1, 2020 and we are not electing to early-adopt most of these finalized regulations. However, we have analyzed these final regulations to determine their potential impact for the current year, and we have found such impact to be immaterial. In addition, we continue to await responses from various state taxing jurisdictions on the impact of the Tax Act on their local taxing regimes. Additional uncertainty is anticipated particularly in light of the current presidential election in the United States and the impact the presidential and congressional elections may have on federal regulation and taxation relating to the healthcare industry. We will continue to monitor and account for the future impacts of federal regulatory and state guidance in the interim period in which such additional guidance is issued.

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

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

- Changes in demand for the products we sell;
- Increased product and price competition, due to the announcement or introduction of new products by our competitors, market conditions, the regulatory landscape, or other factors;
- Changes in the mix of products we sell;
- Availability of products, materials, and supplies, including donated tissue used in preservation services;
- Our pricing strategy with respect to different product lines;
- Strategic actions by us, such as acquisitions of businesses, products, or technologies;
- Unanticipated costs and expenses;
- Effects of domestic and foreign economic conditions and exchange rates on our industry and/or customers;
- The divestiture or discontinuation of a product line or other revenue generating activity;
- The relocation and integration of manufacturing operations and other strategic restructuring;
- Regulatory actions that may necessitate recalls of our products or warning letters that negatively affect the markets for our products;
- Failure of government and private health plans to adequately and timely reimburse the users of our products or changes in reimbursement policies;
- Costs incurred by us in connection with the termination of contractual and other relationships, including distributorships;
- Our ability to collect outstanding accounts receivable in selected countries outside of the U.S.;
- The expiration or utilization of deferred tax assets such as net operating loss carryforwards;
- Market reception of our new or improved product offerings; and
- The loss of any significant customer, especially in regard to any product that has a limited customer base.

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

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

We rely upon a combination of sophisticated information technology systems and traditional recordkeeping to operate our business. In the ordinary course of business, we collect, store, and transmit large amounts of confidential information (including, but not limited to, information about our business, personal information, intellectual property, and, in some instances, patient data). We have also outsourced elements of our operations to third parties, including elements of our information technology systems and, as a result, we manage a number of independent vendor relationships with third parties who may or could have access to our confidential information. Our information technology and information security systems and records are potentially vulnerable to security breaches, service interruptions, or data loss from inadvertent or intentional actions by our employees or vendors. Our information technology and information security systems and records are also potentially vulnerable to malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of expertise and motives (including, but not limited to, financial crime, industrial espionage, and market manipulation). In addition, due to the COVID-19 pandemic, we have implemented remote work arrangements for employees we deem able to do so, and those employees may use outside technology and systems that are vulnerable to security breaches, service interruptions, data loss or malicious attacks by third parties.

As an example of these risks, on November 1, 2019, we were notified that we had become a victim of a business e-mail compromise. During the fourth quarter of 2019, a company email account was compromised by a third-party impersonator

and a payment intended for one of our U.S. vendors in the amount of $2.6 million was fraudulently re-directed into an individual bank account controlled by this third-party impersonator. The impersonator had taken a number of steps to deceive our employees and reduce the likelihood of detection. Our cyber-insurance covered all but a de minimis amount of the unrecovered losses from this compromise.

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

***The implementation of new data privacy laws, including the General Data Protection Regulation in the European Union in May 2018, could adversely affect our business.***

An increasing number of federal, state, and foreign laws and regulations, which can be enforced by private parties or governmental entities, are being promulgated and are constantly evolving. These privacy laws and regulations may include significant new requirements for companies that receive or process individual's personal data (including company employees), which increases our operating costs and requires significant management time and energy. Many of these laws and regulations, including the European Union's General Data Protection Regulation ("GDPR") also include significant penalties for noncompliance. Although our personal data practices, policies, and procedures are intended to comply with GDPR and other data privacy laws and regulations, there can be no assurance that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws, or that one or more of our employees or agents will not disregard the rules we have established. Any privacy related government enforcement activities may be costly to comply with, result in negative publicity, and subject us to significant penalties, any of which could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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

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

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

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

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

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

Our business and future growth depend on the continued use of our products for specific approved uses. Generally, unless the products are approved or cleared by the FDA for the alternative uses, the FDA contends that we may not make claims about the safety or effectiveness of our products, or promote them, for such uses. Such limitations present a risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales,

marketing, and/or support activities, though designed to comply with all FDA requirements, constitute the promotion of our products for an unapproved use in violation of the Federal Food, Drug, and Cosmetic Act. We also face the risk that the FDA or other governmental authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs, and other activities. Investigations concerning the promotion of unapproved uses and related issues are typically expensive, disruptive, and burdensome and generate negative publicity. If our promotional activities are found to be in violation of the law, we may face significant fines and penalties and may be required to substantially change our sales, promotion, grant, and educational activities. There is also a possibility that we could be enjoined from selling some or all of our products for any unapproved use. In addition, as a result of an enforcement action against us or our executive officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid.

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

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

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

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

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

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

with these laws could be substantial since we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from government funded healthcare programs, including Medicare and Medicaid, for noncompliance.

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

***Healthcare policy changes may have a material, adverse effect on us.***

In response to perceived increases in healthcare costs in recent years, there have been, and continue to be, proposals by the federal government, state governments, regulators, third-party payors, and elected office holders and candidates to control these costs and, more generally, to reform the U.S. healthcare system. Additional uncertainty is anticipated particularly in light of the current presidential election in the United States and the impact the presidential and congressional elections may have on federal regulation law relating to the healthcare industry. Many healthcare laws, such as the Affordable Care Act, are complex, subject to change, and dependent on interpretation and enforcement decisions from government agencies with broad discretion. The application of these laws to us, our customers or the specific services and relationships we have with our customers is not always clear. Our failure to anticipate accurately any changes to or the repeal of the Affordable Care Act and similar or future laws and regulations, or our failure to comply with them, could create liability for us, result in adverse publicity and negatively affect our business, results of operations and financial condition. Further, the growth of our business, results of operations and financial condition rely, in part, on customers in the healthcare industry that receive substantial revenues from governmental and other third-party payer programs. A reduction or less than expected increase in government funding for these programs or a change in reimbursement or allocation methodologies could negatively affect our customers' businesses and, in turn, negatively impact our business, results of operations and financial condition. Some of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of some or all of these proposals could have a material, adverse effect on our financial condition and profitability. We cannot predict what further reform proposals, if any, will be adopted, when they will be adopted, or what impact they may have on us. Any changes that lower reimbursement for our products or reduce medical procedure volumes, however, could adversely affect our business and profitability.

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

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

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

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

- We could be exposed to product and tissue processing liability claims and security claims greater than the amount that we have insured;
- We may be unable to obtain future insurance policies in an amount sufficient to cover our anticipated claims at a reasonable cost or at all; or

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

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

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

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

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

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

**Risks Related to Ownership of our Common Stock**

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

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

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

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

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

(c) The following table provides information about purchases by us during the quarter ended September 30, 2020 of equity securities that are registered by us pursuant to Section 12 of the Securities Exchange Act of 1934:

| Period | Total Number of Common Shares and Common Stock Units Purchased | Average Price Paid per Common Share | Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs | Dollar Value of Common Shares That May Yet Be Purchased Under the Plans or Programs |
|---|---|---|---|---|
| 07/01/20 - 07/31/20 | -- | $ -- | -- | $ -- |
| 08/01/20 - 08/31/20 | 1,199 | 21.06 | -- | -- |
| 09/01/20 - 09/30/20 | 846 | 17.63 | -- | -- |
| **Total** | **2,045** | 19.64 | -- | |

The common shares purchased during the quarter ended September 30, 2020 were tendered to us in payment of taxes on stock compensation and were not part of a publicly announced plan or program.

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

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

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

On July 29, 2020, we filed Articles of Correction with the Florida Department of State (the "Department") to correct a scrivener's error contained in our Amended and Restated Articles of Incorporation (the "Articles"). As most recently filed with the Department in 2019, the Articles inadvertently omitted the $0.01 par value of our common stock, which omission has been corrected under the Articles of Correction. A complete copy of the Articles, as corrected, is filed as Exhibit 3.1 to this Quarterly Report on Form 10-Q and incorporated by reference in this Item 5.

**Item 6. Exhibits.**

The exhibit index can be found below.

| Exhibit Number | Description |
|---|---|
| 2.1 | Securities Purchase Agreement, dated September 2, 2020, by and among CryoLife, Inc., Ascyrus Medical LLC, the securityholders of Ascyrus Medical LLC and the Securityholder Representative (as defined therein) (Incorporated herein by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed September 2, 2020.) |
| 3.1 | Amended and Restated Articles of Incorporation of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed July 31, 2020.) |
| 3.2 | Amended and Restated By-Laws of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed February 22, 2018.) |
| 4.1 | Form of Certificate for our Common Stock. (Incorporated herein by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.) |
| 4.2 | Indenture, dated as of June 23, 2020, by and between CryoLife, Inc. and U.S. Bank National Association, as trustee. (Incorporated herein by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed June 23, 2020.) |
| 4.3 | Form of Note (included in Exhibit 4.2 above). (Incorporated herein by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed June 23, 2020.) |
| 10.1 | Form of Salary Reduction Letter for the Company's Senior Management Operating Team, dated April 24, 2020. (Incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed July 31, 2020.) |
| 10.2 | Form of 2020 Non-Executive Director Restricted Stock Award Agreement. (Incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed July 31, 2020.) |
| 10.3 | Second Amendment to Credit and Guaranty Agreement by and among CryoLife, Inc., CryoLife International, Inc., On-X Life Technologies Holdings, Inc., On-X Life Technologies, Inc., AuraZyme Pharmaceuticals, Inc., the financial institutions party thereto from time to time as lenders, and Deutsche Bank AG New York Branch, as administrative agent and collateral agent, dated as of April 29, 2020. (Incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed July 31, 2020.) |
| 10.4 | Purchase Agreement, dated as of June 18, 2020, by and between CryoLife, Inc. and Morgan Stanley & Co. LLC, as the initial purchaser. (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 23, 2020. |
| 31.1* | Certification by J. Patrick Mackin pursuant to section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002. |
| 32** | Certification Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant To Section 906 Of The Sarbanes-Oxley Act Of 2002. |
| 101.INS* | XBRL Instance Document |
| 101.SCH* | XBRL Taxonomy Extension Schema Document |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document |
| 104 | Cover Page Interactive Data File – formatted as Inline XBRL and contained in Exhibit 101 |

* Filed herewith.

** Furnished herewith.

† Portions of the exhibit have been omitted.

**SIGNATURES**

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

CRYOLIFE, INC.
(Registrant)

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

November 5, 2020
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DATE

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

**Exhibit 31.1**

CERTIFICATIONS

I, James Patrick Mackin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2020

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

**Exhibit 31.2**

I, David Ashley Lee, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2020

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

**Exhibit 32**

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

In connection with the Quarterly Report of CryoLife, Inc. (the "Company") on Form 10-Q for the quarter ending September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of James Patrick Mackin, the Chairman, President, and Chief Executive Officer of the Company, and David Ashley Lee, the Executive Vice President, Chief Operating Officer, and Chief Financial Officer of the Company, hereby certifies, pursuant to and for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, in his capacity as an officer of the Company and to his knowledge:

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

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

/s/ J. PATRICK MACKIN
J. PATRICK MACKIN
Chairman, President, and
Chief Executive Officer
November 5, 2020

/s/ D. ASHLEY LEE
D. ASHLEY LEE
Executive Vice President,
Chief Operating Officer, and Chief Financial Officer
November 5, 2020