

CRYOLIFE INC
Form 10-Q
October 27, 2011

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, 2011**

OR

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

For the transition period from _____ to _____

Commission file number: 1-13165

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

Florida
(State or other jurisdiction of
incorporation or organization)

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

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

30144
(Zip Code)

(770) 419-3355

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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

Yes

No

Edgar Filing: CRYOLIFE INC - Form 10-Q

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

Yes No

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

Yes No

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

| Class |
|--|
| Common Stock, \$0.01 par value per share |

| Outstanding at October 21, 2011 |
|---------------------------------|
| 28,138,775 shares |

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

| | Three Months Ended | | Nine Months Ended | |
|---|---------------------------|----------------|--------------------------|---------------|
| | September 30, | | September 30, | |
| | 2011 | 2010 | 2011 | 2010 |
| | (Unaudited) | | (Unaudited) | |
| Revenues: | | | | |
| Preservation services | \$ 14,656 | \$ 15,111 | \$ 45,018 | \$ 45,699 |
| Products | 14,923 | 13,175 | 43,932 | 41,276 |
| Other | 75 | 157 | 279 | 448 |
| Total revenues | 29,654 | 28,443 | 89,229 | 87,423 |
| Cost of preservation services and products: | | | | |
| Preservation services | 8,349 | 8,911 | 25,709 | 27,322 |
| Products | 2,393 | 4,310 | 7,051 | 9,318 |
| Total cost of preservation services and products | 10,742 | 13,221 | 32,760 | 36,640 |
| Gross margin | 18,912 | 15,222 | 56,469 | 50,783 |
| Operating expenses: | | | | |
| General, administrative, and marketing | 14,726 | 11,376 | 42,676 | 36,863 |
| Research and development | 1,690 | 1,590 | 5,099 | 4,122 |
| Acquired in-process research and development | -- | 3,513 | -- | 3,513 |
| Total operating expenses | 16,416 | 16,479 | 47,775 | 44,498 |
| Operating income (loss) | 2,496 | (1,257) | 8,694 | 6,285 |
| Interest expense | 49 | 29 | 116 | 145 |
| Interest income | (1) | (6) | (13) | (16) |
| Gain on valuation of derivative | -- | (143) | -- | (1,345) |
| Other than temporary investment impairment | -- | 3,638 | -- | 3,638 |
| Other expense (income), net | 159 | (187) | (12) | 44 |
| Income (loss) before income taxes | 2,289 | (4,588) | 8,603 | 3,819 |
| Income tax expense (benefit) | 270 | (1,557) | 3,098 | 1,990 |

Edgar Filing: CRYOLIFE INC - Form 10-Q

| | | | | |
|-------------------|----------|------------|----------|----------|
| Net income (loss) | \$ 2,019 | \$ (3,031) | \$ 5,505 | \$ 1,829 |
|-------------------|----------|------------|----------|----------|

Income (loss) per common share:

| | | | | |
|-------|---------|-----------|---------|---------|
| Basic | \$ 0.07 | \$ (0.11) | \$ 0.20 | \$ 0.07 |
|-------|---------|-----------|---------|---------|

| | | | | |
|---------|---------|-----------|---------|---------|
| Diluted | \$ 0.07 | \$ (0.11) | \$ 0.20 | \$ 0.06 |
|---------|---------|-----------|---------|---------|

Weighted-average common shares outstanding:

| | | | | |
|-------|--------|--------|--------|--------|
| Basic | 27,523 | 27,783 | 27,431 | 28,086 |
|-------|--------|--------|--------|--------|

| | | | | |
|---------|--------|--------|--------|--------|
| Diluted | 27,850 | 27,783 | 27,765 | 28,356 |
|---------|--------|--------|--------|--------|

See accompanying Notes to Summary Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS)

| | September 30, 2011 | December 31, 2010 |
|---|-----------------------|----------------------|
| (Unaudited) | | |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 21,050 | \$ 35,497 |
| Restricted securities | 5,313 | 5,309 |
| Receivables, net | 15,308 | 14,313 |
| Deferred preservation costs | 29,454 | 31,570 |
| Inventories | 6,995 | 6,429 |
| Deferred income taxes | 7,436 | 6,096 |
| Prepaid expenses and other current assets | 3,298 | 2,276 |
| Total current assets | 88,854 | 101,490 |
| Property and equipment, net | 12,634 | 13,086 |
| Investment in equity securities | 6,248 | 2,594 |
| Goodwill | 4,597 | -- |
| Patents, net | 2,973 | 3,282 |
| Trademarks and other intangibles, net | 17,951 | 5,601 |
| Deferred income taxes | 12,390 | 9,182 |
| Other long-term assets | 2,352 | 2,203 |
| Total assets | \$ 147,999 | \$ 137,438 |
| LIABILITIES AND SHAREHOLDERS EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 5,021 | \$ 4,243 |
| Accrued compensation | 3,254 | 3,357 |
| Accrued procurement fees | 3,906 | 3,081 |
| Accrued expenses and other current liabilities | 8,041 | 6,552 |
| Deferred income | 2,056 | 2,095 |
| Total current liabilities | 22,278 | 19,328 |
| Other long-term liabilities | 4,943 | 4,168 |
| Total liabilities | 27,221 | 23,496 |
| Commitments and contingencies | | |
| Shareholders equity: | | |
| Preferred stock | -- | -- |
| Common stock (issued shares of 30,088 in 2011 and 29,950 in 2010) | 301 | 300 |
| Additional paid-in capital | 134,692 | 133,845 |

Edgar Filing: CRYOLIFE INC - Form 10-Q

| | | |
|--|-------------------|-------------------|
| Retained deficit | (2,903) | (8,408) |
| Accumulated other comprehensive loss | (27) | (32) |
| Treasury stock at cost (shares of 1,949 in 2011 and 2,049 in 2010) | (11,285) | (11,763) |
| Total shareholders equity | 120,778 | 113,942 |
| Total liabilities and shareholders equity | \$ 147,999 | \$ 137,438 |

See accompanying Notes to Summary Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

| | Nine Months Ended September 30, | |
|--|------------------------------------|----------------|
| | 2011 | 2010 |
| | (Unaudited) | |
| Net cash from operating activities: | | |
| Net income | \$ 5,505 | \$ 1,829 |
| Adjustments to reconcile net income to net cash from operating activities: | | |
| Depreciation and amortization | 3,557 | 2,908 |
| Deferred income taxes | 41 | (801) |
| Other than temporary investment impairment | -- | 3,638 |
| Non-cash compensation | 2,140 | 1,938 |
| Acquired in-process research and development expense | -- | 3,513 |
| Write-down of deferred preservation costs and inventories | 270 | 1,965 |
| Gain on valuation of derivative | -- | (1,345) |
| Other non-cash adjustments to income | 217 | 170 |
| Changes in operating assets and liabilities: | | |
| Receivables | 1 | (738) |
| Deferred preservation costs and inventories | 2,300 | 2,495 |
| Prepaid expenses and other assets | (968) | (2,108) |
| Accounts payable, accrued expenses, and other liabilities | 644 | 358 |
| Net cash flows provided by operating activities | 13,707 | 13,822 |
| Net cash from investing activities: | | |
| Acquisition of Cardiogenesis, net of cash acquired | (21,062) | -- |
| Acquisition of PerClot intangible assets | -- | (5,392) |
| Capital expenditures | (1,993) | (1,475) |
| Purchases of restricted securities and investments | (3,569) | (2,705) |
| Other | (506) | (369) |
| Net cash flows used in investing activities | (27,130) | (9,941) |
| Net cash from financing activities: | | |
| Principal payments on debt | -- | (315) |
| Proceeds from financing of insurance policies | -- | 1,475 |
| Principal payments on short-term notes payable | -- | (1,086) |
| Proceeds from exercise of stock options and issuance of common stock | 703 | 236 |
| Repurchase of common stock | (1,607) | (4,295) |
| Other | (109) | 979 |
| Net cash flows used in financing activities | (1,013) | (3,006) |

Edgar Filing: CRYOLIFE INC - Form 10-Q

| | | |
|---|------------------|------------------|
| (Decrease) Increase in cash and cash equivalents | (14,436) | 875 |
| Effect of exchange rate changes on cash | (11) | 6 |
| Cash and cash equivalents, beginning of period | 35,497 | 30,121 |
| Cash and cash equivalents, end of period | \$ 21,050 | \$ 31,002 |
| Supplemental disclosures of cash flow information - non-cash investing activities: | | |
| Issuance of common stock for acquisition of PerClot intangible assets | \$ -- | \$ 989 |

See accompanying Notes to Summary Consolidated Financial Statements.

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

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, 2010 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, 2011 and 2010 have been prepared in accordance with (i) accounting principles generally accepted in the U.S. for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U.S. Securities and Exchange Commission (SEC). Accordingly, such statements do not include all of the information and disclosures required by accounting principles generally accepted in the U.S. for a complete presentation of financial statements. In the opinion of management, all adjustments (including those of a normal, recurring nature) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011. These summary consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in CryoLife's Annual Report on Form 10-K for the year ended December 31, 2010.

2. Financial Instruments

The Company's financial instruments include cash equivalents, marketable securities, restricted securities, accounts receivable, and accounts payable. The Company typically values financial assets and liabilities such as receivables, accounts payable, and debt obligations at their carrying values, which approximate fair value due to their generally short-term duration.

The Company records certain financial instruments at fair value, including: cash equivalents, certain marketable securities, and certain restricted securities. These financial instruments are discussed in further detail in the notes below. The Company may make an irrevocable election to measure other financial instruments at fair value on an instrument-by-instrument basis, although as of September 30, 2011 the Company has not chosen to make any such elections. Fair value financial instruments are recorded in accordance with the fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair values in their broad levels. These levels from highest to lowest priority are as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities;

Level 2: Quoted prices in active markets for similar assets or liabilities or observable prices that are based on inputs not quoted on active markets, but corroborated by market data; and

Level 3: Unobservable inputs or valuation techniques that are used when little or no market data is available.

The determination of fair value and the assessment of a measurement's placement within the hierarchy require judgment. Although the Company believes that the recorded fair values of its financial instruments are appropriate, these fair values may not be indicative of net realizable value or reflective of future fair values.

The following is a summary of the Company's financial instruments measured at fair value (in thousands):

| September 30, 2011 | Level 1 | Level 2 | Level 3 | Total |
|---------------------------|----------------|----------------|----------------|--------------|
| Cash equivalents: | | | | |
| Money market funds | \$ -- | \$ 5,239 | \$ -- | \$ 5,239 |

Edgar Filing: CRYOLIFE INC - Form 10-Q

| | | | | |
|------------------------|-------|-----------|-------|-----------|
| Restricted securities: | | | | |
| Money market funds | -- | 5,313 | -- | 5,313 |
| Total assets | \$ -- | \$ 10,552 | \$ -- | \$ 10,552 |

| December 31, 2010 | Level 1 | Level 2 | Level 3 | Total |
|-------------------------------|------------------|-----------------|----------------|------------------|
| Cash equivalents: | | | | |
| Money market funds | \$ -- | \$ 2,056 | \$ -- | \$ 2,056 |
| U.S. Treasury debt securities | 14,099 | -- | -- | 14,099 |
| Restricted securities: | | | | |
| Money market funds | -- | 309 | -- | 309 |
| U.S. Treasury debt securities | 5,000 | -- | -- | 5,000 |
| Total assets | \$ 19,099 | \$ 2,365 | \$ -- | \$ 21,464 |

The Company uses prices quoted from its investment management companies to determine the level 2 valuation of its investments in money market funds and securities.

3. Cash Equivalents and Restricted Securities

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

| | Cost Basis | Unrealized Holding Gains | Estimated Market Value |
|-------------------------------|-------------------|---------------------------------|-------------------------------|
| September 30, 2011 | | | |
| Cash equivalents: | | | |
| Money market funds | \$ 5,239 | \$ -- | \$ 5,239 |
| Restricted securities: | | | |
| Money market funds | 5,313 | -- | 5,313 |
| December 31, 2010 | | | |
| Cash equivalents: | | | |
| Money market funds | \$ 2,056 | \$ -- | \$ 2,056 |
| U.S. Treasury debt securities | 14,099 | -- | 14,099 |
| Restricted securities: | | | |
| Money market funds | 309 | -- | 309 |
| U.S. Treasury debt securities | 5,000 | -- | 5,000 |

As of September 30, 2011 and December 31, 2010 \$313,000 and \$309,000, respectively, of the Company's 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. As of September 30, 2011 \$5.0 million of the Company's money market funds and as of December 31, 2010 \$5.0 million of the Company's U.S. Treasury debt securities were designated as restricted securities due to a financial covenant requirement under the Company's credit agreement with General Electric Capital Corporation (GE Capital) as discussed in Note 11.

There were no material realized gains or losses on cash equivalents in the nine months ended September 30, 2011 and 2010. At September 30, 2011 \$5.0 million of restricted securities had a maturity date within three months and \$313,000 of restricted securities had a maturity date of between three months and one year. As of December 31, 2010 \$5.3 million of the Company's restricted securities had a maturity date within three months.

4. Investment in ValveXchange

In July 2011 the Company purchased approximately 2.4 million shares of series A preferred stock of ValveXchange, Inc. (ValveXchange) for approximately \$3.5 million. ValveXchange is a private medical device company that was spun off from Cleveland Clinic to develop a lifetime heart valve replacement technology platform featuring exchangeable bioprosthetic leaflets. The Company's carrying value of this investment includes the purchase price and certain transaction costs. CryoLife's investment represents an approximate 19% equity ownership in ValveXchange. As ValveXchange's stock is not actively traded on any public stock exchange and as the Company's investment is in preferred stock, the Company accounted for this investment using the cost method. The Company recorded its investment as a long-term asset, investment in equity securities, on the Company's Summary Consolidated Balance Sheet.

In July 2011 the Company entered into an agreement with ValveXchange to make available up to \$2.0 million to ValveXchange in debt financing through a revolving credit facility (ValveXchange Loan). The ValveXchange Loan includes various affirmative

and negative covenants, including financial covenant requirements, and expires on July 30, 2018, unless terminated earlier. Amounts loaned under the ValveXchange Loan earn interest at an 8% annual rate and are secured by substantially all of the tangible and intangible assets of ValveXchange. The Company incurred loan origination costs, net of fees charged to ValveXchange, of approximately \$117,000, which will be expensed on a straight-line basis over the life of the loan facility. The Company will record advances to ValveXchange as long-term notes receivable. As of September 30, 2011 there were no outstanding receivable balances under the ValveXchange Loan and the remaining availability was \$2.0 million.

Concurrently with the ValveXchange Loan described above, CryoLife entered into an option agreement with ValveXchange through which CryoLife obtained the right of first refusal to acquire ValveXchange during a period that extends through the completion of initial commercialization milestones and the right to negotiate with ValveXchange for European distribution rights.

5. Cardiogenesis Acquisition

Overview

On May 17, 2011 CryoLife completed its acquisition of all of the outstanding shares of Cardiogenesis Corporation (Cardiogenesis) for \$0.457 per share or approximately \$21.7 million. CryoLife used cash on hand to fund the transaction and operates Cardiogenesis as a wholly owned subsidiary.

Cardiogenesis is a leading developer of surgical products used in the treatment of patients with refractory angina resulting from diffuse coronary artery disease. Cardiogenesis markets the Cardiogenesis Transmyocardial Revascularization (TMR) Holmium Laser System, which includes the holmium: YAG laser console and single use, fiber-optic handpieces, which are U.S. Food and Drug Administration (FDA) approved for performing a surgical procedure known as TMR, used for treating patients with angina that is not responsive to standard medications. Patients undergoing TMR treatment with Cardiogenesis products have been shown to have angina reduction, longer event-free survival, reduction in cardiac related hospitalizations, and increased exercise tolerance.

Accounting for the Transaction

The Company has recorded a preliminary allocation of the \$21.7 million purchase price to Cardiogenesis tangible and identifiable intangible assets acquired and liabilities assumed based on their fair values as of May 17, 2011. Goodwill has been recorded based on the amount by which the purchase price exceeds the fair value of the net assets acquired. The preliminary purchase price allocation is as follows (in thousands):

| | Balance Sheet May 17, 2011 |
|---------------------------|---------------------------------------|
| Cash and cash equivalents | \$ 650 |
| Receivables | 1,055 |
| Inventory | 852 |
| Property and equipment | 248 |
| Intangible assets | 11,900 |
| Goodwill | 4,597 |
| Net deferred tax assets | 4,589 |
| Other assets | 230 |
| Liabilities assumed | (2,409) |
| | |
| Total purchase price | \$ 21,712 |

The preliminary allocation of the purchase price to intangible assets is based on valuations performed to determine the fair value of such assets as of the acquisition date. The Company may adjust the amounts recorded as of September 30, 2011 to reflect any revised evaluations of the assets acquired or liabilities assumed.

CryoLife incurred approximately \$3.0 million in transaction and integration costs related to the acquisition in the nine months ended September 30, 2011.

Pro Forma

Edgar Filing: CRYOLIFE INC - Form 10-Q

Cardiogenesis revenues of \$3.3 million from the date of acquisition for the second and third quarters of 2011 are included in the Summary Consolidated Statement of Operations. Selected unaudited pro forma results of operations for the nine months ended

September 30, 2011 and 2010, assuming the Cardiogenesis acquisition had occurred as of January 1 of each respective period, are presented for comparative purposes below (in thousands, except per share amounts):

| | Nine Months Ended September 30, | |
|---|--|-------------|
| | 2011 | 2010 |
| Total revenues | \$ 93,554 | \$ 95,849 |
| Net income | 3,999 | 1,487 |
| Pro forma income per common share - basic | \$ 0.15 | \$ 0.05 |
| Pro forma income per common share - diluted | \$ 0.14 | \$ 0.05 |

Pro forma results for the nine months ended September 30, 2011 include Cardiogenesis acquisition and integration related costs of approximately \$3.0 million, on a pre-tax basis. Pro forma disclosures were calculated using a tax rate of approximately 36%.

6. PerClot Technology Acquisition

Overview

On September 28, 2010 CryoLife entered into a worldwide distribution agreement (the *Distribution Agreement*) and a license and manufacturing agreement (the *License Agreement*) with Starch Medical, Inc. (*SMI*) of San Jose, California for PerClot, a polysaccharide hemostatic agent used in surgery. PerClot is an absorbable powder hemostat that has CE Mark designation allowing commercial distribution into the European Community and other markets. It is indicated for use in surgical procedures, including cardiac, vascular, orthopaedic, spinal, neurological, gynecological, ENT, and trauma surgery, as an adjunct hemostat when control of bleeding from capillary, venous, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical. Under the terms of the agreements, CryoLife received the worldwide rights to commercialize PerClot for all approved surgical indications and a license to manufacture the PerClot product, subject to certain exclusions. CryoLife also received an assignment of the PerClot trademark from SMI as part of the terms of the agreements.

The *Distribution Agreement* contains certain minimum purchase requirements and has a term of 15 years. CryoLife may begin manufacturing PerClot under the terms of the *License Agreement*, which extends for an indefinite period. Following the start of manufacturing and U.S. regulatory approval, CryoLife may terminate the *Distribution Agreement* and sell PerClot pursuant to the *License Agreement*. CryoLife will pay royalties to SMI at stated rates on net revenues of products manufactured under the *License Agreement*. In addition to allowing CryoLife to manufacture PerClot, the *License Agreement* granted CryoLife a three-year option to purchase certain remaining related technology from SMI, which the Company exercised in September 2011. The Company's *Distribution Agreement* with SMI contains minimum purchase requirements for PerClot through the end of the contract term. Upon FDA approval, the Company may terminate such minimum purchase requirements.

As part of the initial transaction, CryoLife paid SMI \$6.75 million in cash, which included \$1.5 million in cash for prepaid royalties, and approximately 209,000 shares of restricted CryoLife common stock. CryoLife made an additional contingent payment of \$250,000 in 2011 and will pay additional contingent amounts of up to \$2.5 million to SMI if certain FDA regulatory and other commercial milestones are achieved.

Accounting for the Transaction

CryoLife accounted for the agreements discussed above as an asset acquisition. The initial consideration aggregated approximately \$8.0 million, including: \$6.75 million in cash, restricted common stock valued at approximately \$1.0 million, and direct transaction costs. CryoLife recorded a non-current asset for the \$1.5 million in prepaid royalties, a deferred tax asset of \$145,000, and allocated the remaining consideration to the individual intangible assets acquired based on their relative fair values as determined by a valuation study. As a result, CryoLife recorded intangible assets of \$327,000 for the PerClot trademark, \$2.6 million for the PerClot distribution and manufacturing rights in certain international countries, and \$3.5 million for the PerClot distribution and manufacturing rights in the U.S. and certain other countries which do not have current regulatory approvals. This \$3.5 million was considered in-process research and development as it is dependent upon regulatory approvals which have not yet been obtained. Therefore, CryoLife expensed the \$3.5 million as in-process research and development upon acquisition in the third quarter of 2010. The PerClot trademark acquired by the Company has an indefinite useful life; therefore, that asset will not be amortized, but will instead be subject to annual impairment testing. The \$2.6 million intangible asset will be amortized over its useful life of 15 years. See additional disclosures in Note 9 below.

CryoLife expects to record future contingent payment amounts of up to \$2.5 million initially as research and development expense or, after FDA approval or issuance of a patent, as acquired intangible assets. As of September 30, 2011 CryoLife recorded research and development expenses of \$250,000 for the contractual milestone payment due to SMI upon filing of the Investigational Device Exemption.

The common stock issued to SMI will be held by CryoLife until March 31, 2012, when the restricted provisions of the stock lapse.

Starch Technology Purchase

On September 2, 2011 CryoLife entered into an additional license agreement with SMI to purchase the technology to produce and use modified starch, the key component for manufacturing PerClot, for \$1.0 million plus transaction related expenses. The Company recorded the technology purchased as an intangible asset which will be amortized over its useful life of 14 years.

7. Medafor Matters

Overview

CryoLife began distributing HemoStase in 2008 for Medafor, Inc. (Medafor) under an Exclusive Distribution Agreement (EDA). In November 2009 and in 2010 the Company executed stock purchase agreements to purchase a total of approximately 2.4 million shares of common stock in Medafor for \$4.9 million. The Company's carrying value of this investment included the purchase price and adjustments to record certain of the stock purchase agreements' embedded derivative liabilities at the fair market value on the purchase date, as discussed further below. As Medafor's common stock is not actively traded on any public stock exchange, as Medafor is a non-reporting company for which financial information is not readily available, and as the Company does not exert significant influence over the operations of Medafor, the Company accounted for this investment using the cost method and recorded it as the long-term asset, investment in equity securities, on the Company's Summary Consolidated Balance Sheets.

HemoStase Inventory

Based on Medafor's final termination of the EDA in late September 2010, the Company performed a review of its HemoStase inventory to determine if the carrying value of the inventory had been impaired. At the time of the termination, CryoLife expected to continue to sell HemoStase for a six-month period following the final termination of the EDA. As a result, the Company determined that the carrying value of the HemoStase inventory was impaired and increased its cost of products by \$1.6 million to write down related finished goods inventory in the third quarter of 2010. After the write-down as of September 30, 2010, the Company believed that the remaining \$1.7 million of HemoStase inventory was recoverable over the six-month selling period following the termination of the EDA. The amount of this write-down reflected management's estimate based on information available at that time. As of September 30, 2011 and December 31, 2010 the Company had zero and \$559,000, respectively, in remaining value of HemoStase inventory on its Summary Consolidated Balance Sheets.

The Company was able to sell more HemoStase than it originally estimated and that had previously been written down; therefore, cost of products in the first nine months of 2011 was favorably impacted by approximately \$330,000.

Investment in Medafor Common Stock

During the quarter ended September 30, 2010, the Company reviewed available information to determine if factors indicated that a decrease in value of the investment in Medafor common stock had occurred. CryoLife determined that the available information, particularly Medafor's termination of its largest distributor, indicated that the Company should evaluate its investment in Medafor common stock for impairment.

CryoLife used a market based approach for the valuation, including comparing Medafor to a variety of comparable publicly traded companies, recent merger targets, and company groups. CryoLife considered both qualitative and quantitative factors that could affect the valuation of Medafor's common stock. Based on its analysis, the Company believed that its investment in Medafor was impaired and that this impairment was other than temporary. Therefore, in the third quarter of 2010 CryoLife recorded a non-operating expense, other than temporary investment impairment, of \$3.6 million to write down its investment in Medafor common stock to \$2.6 million. During the nine months ended September 30, 2011, the Company reviewed available information and determined that no factors were present indicating that the Company should evaluate its investment in Medafor

common stock for further impairment. The carrying value of the Company's 2.4 million shares of Medafor common stock was approximately \$2.6 million as of both September 30, 2011 and December 31, 2010.

The Company will continue to evaluate the carrying value of this investment if changes to the factors discussed above or additional factors become known that indicate the Company should evaluate its investment in Medafor common stock for further impairment. If the Company subsequently determines that the value of its Medafor common stock has been impaired further, or if the Company decides to sell its Medafor common stock for less than the carrying value, the resulting impairment charge or realized loss on sale of the investment in Medafor could be material.

Medafor Derivative

Per the terms of certain of the stock purchase agreements for the Medafor shares discussed above, in the event that CryoLife acquires more than 50% of the diluted outstanding stock of Medafor or merges with Medafor within a three-year period from each respective agreement date (a Triggering Event), CryoLife is required to make a future per share payment (the Purchase Price Make-Whole Payment) to such sellers. The payment would be equal to the difference between an amount calculated using the average cost of any subsequent shares purchased, as defined in each respective agreement, and the price of the shares purchased pursuant to each applicable stock purchase agreement. The Company was required to account for these Purchase Price Make-Whole Payment provisions as embedded derivatives (collectively the Medafor Derivative).

CryoLife performed a valuation of the Medafor Derivative using a Black-Scholes model to estimate the future value of the shares on the purchase date. Management's assumptions as to the likelihood of a Triggering Event occurring coupled with the valuation of the Purchase Price Make-Whole Payment were then used to calculate the derivative liability. The fair value of the Medafor Derivative was initially recorded as an increase to the investment in equity securities and a corresponding derivative liability on the Company's Summary Consolidated Balance Sheets. The Medafor Derivative was revalued quarterly, and any change in the value of the derivative subsequent to the purchase date was recorded in the Company's Summary Consolidated Statements of Operations.

During the quarter ended March 31, 2010, the Company's estimate of the likelihood of a Triggering Event decreased significantly, largely due to the Company withdrawing its offer to purchase Medafor. As of September 30, 2011 and December 31, 2010 the Company believed that the likelihood of a Triggering Event was remote.

The value of the Medafor Derivative was zero as of both September 30, 2011 and December 31, 2010. The change in the value of the derivative recorded on the Summary Consolidated Statements of Operations was zero and a gain of \$143,000 for the three months ended September 30, 2011 and 2010, respectively, and zero and a gain of \$1.3 million for the nine months ended September 30, 2011 and 2010, respectively.

Legal Action

As previously reported, CryoLife filed a lawsuit against Medafor in 2009 in the U.S. District Court for the Northern District of Georgia (Georgia Court). In 2010 Medafor filed counterclaims against CryoLife. On August 2, 2011 Medafor withdrew, without prejudice, its Motion for Partial Summary Judgment with respect to its contention that CryoLife owes Medafor approximately \$1.3 million plus prejudgment interest for product Medafor shipped to CryoLife, stating that it would renew its motion at a later date. On September 30, 2011 the Georgia Court denied CryoLife's motion for partial summary judgment regarding Medafor's alleged wrongful termination of the EDA. The Georgia Court found that, at this early stage of discovery, CryoLife had not established as a matter of law that the parties drafted a certain section of the EDA clearly so as to supplant a specific aspect of the Georgia Uniform Commercial Code. The Georgia Court also found that the evidence submitted did not establish as a matter of law that the letter on which Medafor based its termination of the EDA failed to comport with the Georgia Uniform Commercial Code.

As previously reported, on July 5, 2011 the Georgia Court appointed a Discovery Special Master to manage and supervise discovery pursuant to a Joint Motion for Appointment of Special Master filed by the parties. Pursuant to the appointment, the parties have met repeatedly with the Special Master since July regarding discovery issues. Both parties filed motions to compel certain discovery, and on October 14, 2011, the Special Master granted in part and denied in part both parties' motions. The Georgia Court has scheduled a status conference for November 29, 2011, at which the parties will discuss various discovery-related issues and deadlines. CryoLife expects discovery to continue for a significant period of time. CryoLife believes that the trial will not occur until 2013.

As previously reported, on July 14, 2011 Medafor filed a lawsuit against CryoLife in the U.S. District Court for the District of Minnesota (Minnesota Court). Medafor's lawsuit requests that the Minnesota Court grant a declaratory judgment that Medafor's

reverse stock split on December 31, 2010 reduced the number of Medafor shareholders to below 500 and that, therefore, Medafor is not required to comply with the registration requirements of Section 12(g) of the Securities Exchange Act of 1934 (i.e., not required to register as a public company with the SEC). Medafor's lawsuit also requests that the Minnesota Court award Medafor its costs and expenses in the lawsuit. On August 5, 2011 CryoLife filed a Motion to Dismiss Medafor's claims arguing that there was no private right cause of action under Section 12(g) of the Securities Exchange Act of 1934. The parties argued the Motion to Dismiss in front of the Minnesota Court on October 11, 2011. As of October 25, 2011 the Minnesota Court had not ruled on the Motion to Dismiss. At this time CryoLife is unable to predict the outcome of this matter.

8. Inventories

Inventories are comprised of the following (in thousands):

| | September 30, 2011 | December 31, 2010 |
|-------------------|-----------------------|----------------------|
| Raw materials | \$ 4,466 | \$ 4,301 |
| Work-in-process | 309 | 349 |
| Finished goods | 2,220 | 1,779 |
| Total inventories | \$ 6,995 | \$ 6,429 |

9. Goodwill and Other Intangible Assets

The Company's intangible assets consist of goodwill, patents, trademarks, and other intangible assets, as discussed further below. These assets include goodwill, acquired technology, customer lists, and other intangible assets from the acquisition of Cardiogenesis, as discussed in Note 5 above, and PerClot distribution and manufacturing rights acquired from SMI as discussed in Note 6 above.

Indefinite Lived Intangible Assets

The carrying values of the Company's indefinite lived intangible assets are as follows (in thousands):

| | September 30, 2011 | December 31, 2010 |
|--------------------------------------|-----------------------|----------------------|
| Goodwill | \$ 4,597 | \$ -- |
| Procurement contracts and agreements | 2,013 | 2,013 |
| Trademarks | 805 | 790 |
| Other | 250 | -- |

Based on its experience with similar agreements, the Company believes that its acquired contracts and procurement agreements have an indefinite useful life, as the Company expects to continue to renew these contracts for the foreseeable future. Accordingly, the Company's indefinite lived intangible assets do not amortize, but are instead subject to periodic impairment testing.

Definite Lived Intangible Assets

The Company generally amortizes its definite lived intangible assets over their expected useful lives using the straight-line method. The gross carrying values, accumulated amortization, and approximate amortization periods of the Company's definite lived intangible assets are as follows (in thousands):

Edgar Filing: CRYOLIFE INC - Form 10-Q

| September 30, 2011 | Gross Carrying Value | Accumulated Amortization | Amortization Period |
|--|---------------------------------|-------------------------------------|--------------------------------|
| Acquired technology | \$ 9,230 | \$ 315 | 11 Years |
| Patents | 5,749 | 2,776 | 17 Years |
| Distribution and manufacturing rights and know-how | 3,559 | 171 | 15 Years |
| Customer lists | 2,370 | 68 | 13 Years |
| Non-compete agreement | 381 | 181 | 10 Years |
| Other | 114 | 36 | 2-3 Years |

| December 31, 2010 | Gross Carrying Value | Accumulated Amortization | Amortization Period |
|--------------------------------------|---------------------------------|-------------------------------------|--------------------------------|
| Patents | \$ 5,885 | \$ 2,603 | 17 Years |
| Distribution and manufacturing right | 2,559 | 43 | 15 Years |
| Non-compete agreements | 381 | 152 | 10 Years |
| Customer list | 64 | 11 | 3 Years |

Amortization Expense

The following is a summary of amortization expense (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|----------------------|---|-------------|--|-------------|
| | 2011 | 2010 | 2011 | 2010 |
| Amortization expense | \$ 436 | \$ 132 | \$ 917 | \$ 395 |

As of September 30, 2011 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

| | Remainder of | | | | | |
|----------------------|---------------------|-------------|-------------|-------------|-------------|-------------|
| | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 |
| Amortization expense | \$ 453 | \$ 1,801 | \$ 1,696 | \$ 1,598 | \$ 1,570 | \$ 1,558 |

10. Deferred Income Taxes

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company generates deferred tax assets primarily as a result of write-downs of deferred preservation costs, inventory, and in-process research and development; accruals for tissue processing and product liability claims; asset impairments; and operating losses. The Company acquired significant deferred tax assets from its acquisition of Cardiogenesis in the second quarter of 2011 as discussed below.

As of September 30, 2011 the Company maintained a total of \$2.3 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax asset of \$19.8 million. As of December 31, 2010 the Company had a total of \$1.8 million in valuation allowances against deferred tax assets and a net deferred tax asset of \$15.3 million.

The increase in the Company's net deferred tax assets is due to the acquisition of Cardiogenesis in the second quarter of 2011, as Cardiogenesis had significant deferred tax assets, primarily due to its net operating loss carryforwards. The Company believes that the realizability of its acquired net operating loss carryforwards will be limited in future periods due to a change in control of its subsidiary Cardiogenesis, as mandated by Section 382 of the Internal Revenue Code of 1986, as amended. The Company believes that its acquisition of Cardiogenesis constitutes a change in control. The deferred tax assets recorded on the Company's Summary Consolidated Balance Sheets do not include amounts that it expects will not be realizable due to this change in control. A portion of the acquired net operating loss carryforwards is related to state income taxes and can only be used by the Company's subsidiary Cardiogenesis. Due to Cardiogenesis' history of losses when operated as a stand-alone company, management believes it is more likely than not that these deferred tax assets will not be realized. Therefore, the Company recorded a valuation allowance against these state net operating loss carryforwards. See also Note 5 above for a further discussion of the Company's acquisition of Cardiogenesis.

The Company's effective income tax rate was approximately 12% and 36% for the three and nine months ended September 30, 2011, respectively, as compared to a benefit of 34% for the three months ended September 30, 2010 and expense of 52% for the nine months ended September 30, 2010. The significant change in the Company's effective income tax rate for the three months ended September 30, 2011 as compared to the prior year period was due to the discrete and favorable effect of deductions taken on the Company's 2010 federal tax returns, which were filed in the third quarter of 2011. For the nine months ended September 30, 2011, this favorable effect was largely offset by the unfavorable tax treatment recognized in the second quarter of 2011 of certain acquisition related expenses, which the Company incurred related to its acquisition of Cardiogenesis.

Edgar Filing: CRYOLIFE INC - Form 10-Q

The Company's tax years 2008 through 2010 generally remain open to examination by the major taxing jurisdictions to which the Company is subject. However, certain returns from years prior to 2008, in which net operating losses and tax credits have arisen, are still open for examination by the tax authorities.

11. Debt***GE Credit Agreement***

On March 26, 2008 CryoLife entered into a credit agreement with GE Capital as lender (the "GE Credit Agreement"). The GE Credit Agreement provides for a revolving credit facility in an aggregate amount not to exceed the initial commitment of \$15.0 million (including a letter of credit subfacility). The initial commitment may be reduced or increased from time to time pursuant to the terms of the GE Credit Agreement. The Company amended the GE Credit Agreement three times during 2011 to extend the term of the credit facility, which now expires on October 31, 2011.

The GE Credit Agreement places limitations on the amount that the Company may borrow and includes various affirmative and negative covenants, including financial covenants such as a requirement that CryoLife (i) not exceed a defined leverage ratio, (ii) maintain a minimum adjusted earnings subject to defined adjustments as of specified dates, and (iii) not make or commit capital expenditures in excess of a defined limitation. Further, since April 15, 2008, as required under the terms of the GE Credit Agreement, the Company has been maintaining cash and cash equivalents of at least \$5.0 million in accounts in which GE Capital has a first priority perfected lien. These amounts are recorded as restricted securities as of September 30, 2011 and December 31, 2010 on the Company's Summary Consolidated Balance Sheets, as they are restricted for the term of the GE Credit Agreement. Also, the GE Credit Agreement requires that after giving effect to a stock repurchase the Company maintain liquidity, as defined within the agreement, of at least \$20.0 million. The GE Credit Agreement includes customary conditions on incurring new indebtedness and prohibits payments of cash dividends on the Company's common stock. There is no restriction on the payment of stock dividends. Commitment fees are paid based on the unused portion of the facility. As of September 30, 2011 the Company was in compliance with the covenants of the GE Credit Agreement.

Amounts borrowed under the GE Credit Agreement are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries and bear interest at LIBOR, with a minimum rate of 3%, or GE Capital's base rate, with a minimum rate of 4% each, plus the applicable margin. As of September 30, 2011 and December 31, 2010 the outstanding balance of the GE Credit Agreement was zero, the aggregate interest rate was 6.25%, and the remaining availability was \$14.8 million.

Other

Total interest expense was \$49,000 and \$29,000 for the three months ended September 30, 2011 and 2010, respectively, and \$116,000 and \$145,000 for the nine months ended September 30, 2011 and 2010, respectively, which included interest on debt, capital leases, and uncertain tax positions.

12. Commitments and Contingencies***Liability Claims***

The estimated unreported loss liability and any related recoverable insurance amounts are as follows (in thousands):

| | September 30, 2011 | December 31, 2010 |
|--|-----------------------|----------------------|
| Short-term liability | \$ 1,183 | \$ 1,310 |
| Long-term liability | 1,094 | 1,310 |
| Total liability | 2,277 | 2,620 |
| Short-term recoverable | 379 | 500 |
| Long-term recoverable | 390 | 550 |
| Total recoverable | 769 | 1,050 |
| Total net unreported loss liability | \$ 1,508 | \$ 1,570 |

Edgar Filing: CRYOLIFE INC - Form 10-Q

Further analysis indicated that the liability as of September 30, 2011 could be estimated to be as high as \$4.3 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

Employment Agreement

The Company has an employment agreement with its Chief Executive Officer (CEO) that confers benefits which become payable upon a change in control or upon certain termination events. As of both September 30, 2011 and December 31, 2010 the

Company has recorded \$2.1 million in accrued expenses and other current liabilities on the Summary Consolidated Balance Sheets representing benefits payable upon the CEO's voluntary retirement.

13. Common Stock Repurchase

On June 1, 2010 the Company announced that its Board of Directors authorized the purchase of up to \$15.0 million of its common stock over the course of the following two years. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions, on such terms as management deems appropriate, and will be dependent upon various factors, including: price, regulatory requirements, and other market conditions. For the nine months ended September 30, 2011 the Company purchased approximately 280,000 shares of its common stock for an aggregate purchase price of \$1.5 million. For the twelve months ended December 31, 2010 the Company purchased approximately 1.0 million shares of its common stock for an aggregate purchase price of \$5.8 million. These shares were accounted for as part of treasury stock, carried at cost, and reflected as a reduction of shareholders' equity on the Company's Summary Consolidated Balance Sheets.

14. Stock Compensation

Overview

The Company has 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), and options to purchase shares of Company common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. The Company also maintains a shareholder approved Employee Stock Purchase Plan (the ESPP) for the benefit of its employees. The ESPP allows eligible employees the right 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

The Compensation Committee of the Company's Board of Directors authorized awards of RSAs from approved stock incentive plans to non-employee Directors and certain Company officers totaling 360,000 and 215,000 shares during the nine months ended September 30, 2011 and 2010, respectively, which had an aggregate market value of \$1.9 million and \$1.3 million, respectively.

The Compensation Committee of the Company's Board of Directors authorized grants of stock options from approved stock incentive plans to certain Company officers and employees totaling 599,000 and 427,000 shares during the nine months ended September 30, 2011 and 2010, respectively, with exercise prices equal to the stock prices on the respective grant dates.

Employees purchased common stock totaling 64,000 and 43,000 shares in the nine months ended September 30, 2011 and 2010, respectively, through the Company's ESPP.

Stock Compensation Expense

The Company values its RSAs and RSUs based on the stock price on the date of grant and expenses the related compensation cost using the straight-line method over the vesting period. The Company uses a Black-Scholes model to value its stock option grants and expenses the related compensation cost using the straight-line method over the vesting period. The fair value of the Company's ESPP options is also determined using a Black-Scholes model and is expensed over the vesting period. The fair value of stock options and ESPP options is determined on the grant date using assumptions for the expected term, expected volatility, dividend yield, and the risk-free interest rate. The period expense is then determined based on this valuation and, at that time, an estimated forfeiture rate is used to reduce the expense recorded. The Company's estimate of pre-vesting forfeitures is primarily based on the recent historical experience of the Company and is adjusted to reflect actual forfeitures at each vesting date.

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

Three Months Ended

September 30, 2011

Nine Months Ended

September 30, 2011

Stock Options ESPP Options Stock Options ESPP Options

| | | | | |
|---------------------------------|-----|-----------|------------|-----------|
| Expected life of options | N/A | .50 Years | 4.00 Years | .50 Years |
| Expected stock price volatility | N/A | .355 | .650 | .406 |
| Risk-free interest rate | N/A | 0.10% | 1.25% | 0.16% |

| | Three Months Ended | | Nine Months Ended | |
|---------------------------------|--------------------|--------------|--------------------|--------------|
| | September 30, 2010 | | September 30, 2010 | |
| | Stock Options | ESPP Options | Stock Options | ESPP Options |
| Expected life of options | N/A | .50 Years | 3.75 Years | .34 Years |
| Expected stock price volatility | N/A | .467 | .650 | .472 |
| Risk-free interest rate | N/A | 0.22% | 1.29% | 0.16% |

The following table summarizes stock compensation expenses (in thousands):

| | Three Months Ended | | Nine Months Ended | |
|---|--------------------|---------------|-------------------|-----------------|
| | September 30, | | September 30, | |
| | 2011 | 2010 | 2011 | 2010 |
| RSA and RSU expense | \$ 369 | \$ 139 | \$ 1,038 | \$ 691 |
| Stock option and ESPP option expense | 388 | 424 | 1,270 | 1,464 |
| Total stock compensation expense | \$ 757 | \$ 563 | \$ 2,308 | \$ 2,155 |

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, RSUs, 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 Company's ESPP. These amounts were recorded as stock compensation expense and were subject to the Company's normal allocation of expenses to deferred preservation costs and inventory costs. The Company capitalized \$61,000 and \$80,000 in the three months ended September 30, 2011 and 2010, respectively, and \$168,000 and \$217,000 in the nine months ended September 30, 2011 and 2010, respectively, of the stock compensation expense into its deferred preservation costs and inventory costs.

As of September 30, 2011 the Company had a total of \$2.1 million, \$2.0 million, and \$259,000 in unrecognized compensation costs related to unvested stock options, RSAs, and RSUs, respectively, before considering the effect of expected forfeitures. As of September 30, 2011 this expense is expected to be recognized over a weighted-average period of 1.8 years for stock options, 1.7 years for RSAs, and 2.1 years for RSUs.

15. Comprehensive Income (Loss)

The following is a summary of comprehensive income (loss) (in thousands):

| | Three Months Ended | | Nine Months Ended | |
|---|--------------------|-------------------|-------------------|-----------------|
| | September 30, | | September 30, | |
| | 2011 | 2010 | 2011 | 2010 |
| Net income (loss) | \$ 2,019 | \$ (3,031) | \$ 5,505 | \$ 1,829 |
| Change in cumulative translation adjustment | (5) | 22 | 5 | 29 |
| Comprehensive income (loss) | \$ 2,014 | \$ (3,009) | \$ 5,510 | \$ 1,858 |

The tax effect on the cumulative translation adjustment is zero for each period presented. The accumulated other comprehensive loss of \$27,000 as of September 30, 2011 and loss of \$32,000 as of December 31, 2010, consisted solely of currency translation adjustments.

16. Income (Loss) Per Common Share

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

| <u>Basic income (loss) per common share</u> | Three Months Ended | | Nine Months Ended | |
|--|---------------------------|-------------|--------------------------|-------------|
| | September 30, | | September 30, | |
| | 2011 | 2010 | 2011 | 2010 |
| Net income (loss) | \$ 2,019 | \$ (3,031) | \$ 5,505 | \$ 1,829 |
| Basic weighted-average common shares outstanding | 27,523 | 27,783 | 27,431 | 28,086 |
| Basic income (loss) per common share | \$ 0.07 | \$ (0.11) | \$ 0.20 | \$ 0.07 |

| <u>Diluted income (loss) per common share</u> | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|---|-------------|--|-------------|
| | 2011 | 2010 | 2011 | 2010 |
| Net income (loss) | \$ 2,019 | \$ (3,031) | \$ 5,505 | \$ 1,829 |
| Basic weighted-average common shares outstanding | 27,523 | 27,783 | 27,431 | 28,086 |
| Effect of dilutive stock options ^a | 95 | -- | 118 | 126 |
| Effect of dilutive RSAs and RSUs ^b | 232 | -- | 216 | 144 |
| Diluted weighted-average common shares outstanding | 27,850 | 27,783 | 27,765 | 28,356 |
| Diluted income (loss) per common share | \$ 0.07 | \$ (0.11) | \$ 0.20 | \$ 0.06 |

^a The Company excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares, because the inclusion of these stock options would be antidilutive to income (loss) per common share. Accordingly, stock options to purchase a weighted average 2.1 million and 1.6 million shares for the three months ended September 30, 2011 and 2010, respectively, and 2.0 million and 1.5 million shares for the nine months ended September 30, 2011 and 2010, respectively, were excluded from the calculation of diluted weighted-average common shares outstanding.

^b The Company excluded 145,000 in invested restricted stock awards from the calculation of diluted weighted-average common shares outstanding for the three months ended September 30, 2010 because the inclusion of these stock awards would be antidilutive to income (loss) per common share.

17. Segment Information

The Company has two reportable segments organized according to its services and products: Preservation Services and Medical Devices. The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues. The Medical Devices segment includes external revenues from product sales of BioGlue[®] Surgical Adhesive (BioGlue), BioFoam[®] Surgical Matrix (BioFoam), PerClot, HemoStase, and revascularization technology, as well as sales of other medical devices. There are no intersegment revenues.

The primary measure of segment performance, as viewed by the Company's management, is segment gross margin, or net external revenues less cost of preservation services and products. The Company does not segregate assets by segment; therefore, asset information is excluded from the segment disclosures below. The following table summarizes revenues, cost of services and products, and gross margins for the Company's operating segments (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|-----------------------|---|-------------|--|-------------|
| | 2011 | 2010 | 2011 | 2010 |
| Revenues: | | | | |
| Preservation services | \$ 14,656 | \$ 15,111 | \$ 45,018 | \$ 45,699 |
| Medical devices | 14,923 | 13,175 | 43,932 | 41,276 |
| Other ^a | 75 | 157 | 279 | 448 |
| Total revenues | 29,654 | 28,443 | 89,229 | 87,423 |

Edgar Filing: CRYOLIFE INC - Form 10-Q

Cost of preservation services and products:

| | | | | |
|---|---------------|---------------|---------------|---------------|
| Preservation services | 8,349 | 8,911 | 25,709 | 27,322 |
| Medical devices | 2,393 | 4,310 | 7,051 | 9,318 |
| Total cost of preservation services and products | 10,742 | 13,221 | 32,760 | 36,640 |

Gross margin:

| | | | | |
|---------------------------|------------------|------------------|------------------|------------------|
| Preservation services | 6,307 | 6,200 | 19,309 | 18,377 |
| Medical devices | 12,530 | 8,865 | 36,881 | 31,958 |
| Other ^a | 75 | 157 | 279 | 448 |
| Total gross margin | \$ 18,912 | \$ 15,222 | \$ 56,469 | \$ 50,783 |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|-------------------------------|-------------------------------------|-----------|------------------------------------|-----------|
| | 2011 | 2010 | 2011 | 2010 |
| Preservation services: | | | | |
| Cardiac tissue | \$ 6,764 | \$ 7,189 | \$ 19,989 | \$ 20,953 |
| Vascular tissue | 7,892 | 7,922 | 25,029 | 24,746 |
| Total preservation services | 14,656 | 15,111 | 45,018 | 45,699 |
| Products: | | | | |
| BioGlue and BioFoam | 12,190 | 11,046 | 36,936 | 35,219 |
| PerClot | 620 | -- | 1,911 | -- |
| HemoStase | -- | 2,129 | 1,795 | 6,127 |
| Revascularization technology | 2,113 | -- | 3,290 | -- |
| Other medical devices | -- | -- | -- | (70) |
| Total products | 14,923 | 13,175 | 43,932 | 41,276 |
| Other ^a | 75 | 157 | 279 | 448 |
| Total revenues | \$ 29,654 | \$ 28,443 | \$ 89,229 | \$ 87,423 |

^a For the three and nine months ended September 30, 2011 and 2010, the Other designation includes grant revenue.

PART I - FINANCIAL INFORMATION
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**Overview**

CryoLife, Inc. (CryoLife, the Company, we, or us), incorporated January 19, 1984 in Florida, preserves and distributes human tissues and develops, manufactures, and commercializes medical devices for cardiac and vascular transplant applications. The human tissues distributed by CryoLife include the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch tissue (CryoPatch SG), both processed using CryoLife's proprietary SynerCryo technology. CryoLife's surgical sealants and hemostats include BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), and PerClot® an absorbable powder hemostat, which the Company distributes for Starch Medical, Inc. (SMI) in the European Community and other select international markets. CryoLife, through its subsidiary Cardiogenesis Corporation (Cardiogenesis), specializes in the treatment of cardiovascular disease using a laser console system and single-use, fiber-optic handpieces that are used to treat severe angina.

During the third quarter of 2011, CryoLife made a \$3.5 million equity investment in ValveXchange, Inc. (ValveXchange). ValveXchange is a private medical device company currently developing a lifetime heart valve replacement technology platform featuring exchangeable bioprosthetic leaflets. Also during the third quarter, CryoLife purchased an additional technology related to the manufacture of PerClot. See further discussion under Recent Events below. In addition, CryoLife continued its integration efforts for the operations of its newly acquired subsidiary, Cardiogenesis.

For the third quarter ended September 30, 2011, CryoLife reported its highest revenues ever in a third quarter and in the first nine months of a year, with revenues of \$29.7 million and \$89.2 million, respectively, largely due to revenues from revascularization technology, as a result of the Company's acquisition of Cardiogenesis in the second quarter of 2011, and due to BioGlue revenues. CryoLife also reported its highest BioGlue revenues ever in a third quarter and first nine months of a year. Revenues from BioGlue in the first nine months of 2011 included \$1.2 million in sales of BioGlue to Japan. However, the Company's operating expenses and earnings were negatively impacted by higher general, administrative, and marketing expenses due to the acquisition of Cardiogenesis and other business development expenses. See the Results of Operations section below for additional analysis of the results of operations for the three and nine months ended September 30, 2011.

Recent Events*ValveXchange*

In July 2011 CryoLife announced it had purchased a \$3.5 million equity investment in ValveXchange. Under the agreement, CryoLife received an approximate 19% equity ownership in ValveXchange and the right of first refusal to acquire ValveXchange during a period that extends through the completion of initial commercialization milestones, and the right to negotiate with ValveXchange for European distribution rights. Further, CryoLife has agreed to provide funding of up to \$2.0 million to ValveXchange in additional debt financing through a revolving credit facility.

PerClot Technology Purchase

In September 2011 CryoLife entered into an additional license agreement with SMI to purchase the technology to produce and use modified starch, the key component for manufacturing PerClot, for \$1.0 million plus transaction related expenses.

Critical Accounting Policies

A summary of the Company's significant accounting policies is included in Note 1 of the Notes to Consolidated Financial Statements, contained in the Company's Form 10-K for the year ended December 31, 2010. Management believes that the consistent application of these policies enables the Company to provide users of the financial statements with useful and reliable information about the Company's 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 the Company to make estimates and assumptions. The Company did not experience any significant changes during the quarter ended September 30, 2011 in any of its other Critical Accounting Policies from those contained in the Company's Form 10-K for the year ended December 31, 2010 and Form 10-Q for the quarter ended June 30, 2011.

New Accounting Pronouncements

There were no new accounting pronouncements relevant to the Company that management anticipates implementing during the year ending December 31, 2011.

Results of Operations

(Tables in thousands)

Revenues

| | Revenues as a Percentage of Total Revenues for the | | | |
|-------------------------------|---|-----------|-------------------------------------|------|
| | Revenues for the Three Months Ended September 30, | | Three Months Ended September 30, | |
| | 2011 | 2010 | 2011 | 2010 |
| Preservation services: | | | | |
| Cardiac tissue | \$ 6,764 | \$ 7,189 | 23% | 25% |
| Vascular tissue | 7,892 | 7,922 | 27% | 28% |
| Total preservation services | 14,656 | 15,111 | 50% | 53% |
| Products: | | | | |
| BioGlue and BioFoam | 12,190 | 11,046 | 41% | 39% |
| PerClot | 620 | -- | 2% | --% |
| HemoStase | -- | 2,129 | --% | 7% |
| Revascularization technology | 2,113 | -- | 7% | --% |
| Total products | 14,923 | 13,175 | 50% | 46% |
| Other | 75 | 157 | --% | 1% |
| Total | \$ 29,654 | \$ 28,443 | 100% | 100% |

| | Revenues as a Percentage of Total Revenues for the | | | |
|-------------------------------|--|-----------|------------------------------------|------|
| | Revenues for the Nine Months Ended September 30, | | Nine Months Ended September 30, | |
| | 2011 | 2010 | 2011 | 2010 |
| Preservation services: | | | | |
| Cardiac tissue | \$ 19,989 | \$ 20,953 | 23% | 24% |
| Vascular tissue | 25,029 | 24,746 | 28% | 28% |
| Total preservation services | 45,018 | 45,699 | 51% | 52% |
| Products: | | | | |
| BioGlue and BioFoam | 36,936 | 35,219 | 41% | 40% |
| PerClot | 1,911 | -- | 2% | --% |
| HemoStase | 1,795 | 6,127 | 2% | 7% |
| Revascularization technology | 3,290 | -- | 4% | --% |
| Other medical devices | -- | (70) | --% | --% |

Edgar Filing: CRYOLIFE INC - Form 10-Q

| | | | | |
|----------------|-----------|-----------|------|------|
| Total products | 43,932 | 41,276 | 49% | 47% |
| Other | 279 | 448 | --% | 1% |
| Total | \$ 89,229 | \$ 87,423 | 100% | 100% |

Preservation Services

Preservation service revenues decreased 3% for the three months and 1% for the nine months ended September 30, 2011 as compared to the three and nine months ended September 30, 2010, respectively. A detailed discussion of the changes in tissue preservation service revenues for both cardiac and vascular tissues is presented below.

Cardiac Preservation Services

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, 2011 as compared to the three months ended September 30, 2010. This decrease was primarily due to the aggregate impact of a decrease in volume and unfavorable tissue mix, which decreased revenues by 7%, partially offset by an increase in average service fees, which increased revenues by 1%.

Revenues from cardiac preservation services decreased 5% for the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010. This decrease was primarily due to the aggregate impact of a decrease in volume and unfavorable tissue mix, which decreased revenues by 6%, partially offset by an increase in average service fees, which increased revenues by 1%.

The reduction in revenues from the decrease in volume and cardiac tissue mix was primarily due to a decrease in volume of cardiac valve shipments, partially offset by increases in the volume of lower fee cardiac patch tissues. The Company believes that the decrease in unit shipments of cardiac valves was primarily due to increasing pressure from lower cost competitive products and to continuing cost containment practices at certain hospitals, and that this trend could continue into the fourth quarter of 2011.

Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 47% and 40% of total cardiac preservation services revenues for the three and nine months ended September 30, 2011, respectively, and 37% and 33% of total cardiac preservation services revenues for the three and nine months ended September 30, 2010, respectively. Domestic revenues accounted for 91% of total cardiac preservation services revenues for both the three and nine months ended September 30, 2011 and 93% of total cardiac preservation services revenues for both the three and nine months ended September 30, 2010.

Vascular Preservation Services

Revenues from vascular preservation services for the three months ended September 30, 2011 did not change significantly from revenues for the three months ended September 30, 2010. A 1% decrease in unit shipments of vascular tissues was largely offset by an increase in average service fees.

Revenues from vascular preservation services increased 1% for the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010, primarily due to an increase in average service fees.

Products

Revenues from products increased 13% for the three months and 6% for the nine months ended September 30, 2011 as compared to the three and nine months ended September 30, 2010, respectively. These increases were primarily due to revenues from revascularization technology as a result of the Company's acquisition of Cardiogenesis in the second quarter of 2011 and due to an increase in PerClot and BioGlue revenues, partially offset by a decrease in HemoStase revenues. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; PerClot and HemoStase; and revascularization technology is presented below.

BioGlue and BioFoam

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, increased 10% for the three months ended September 30, 2011 as compared to the three months ended September 30, 2010. This increase was primarily due to a 14% increase in the volume of milliliters sold, which increased revenues by 9% and the favorable impact of foreign exchange rates, which increased revenues by 1%.

Revenues from the sale of BioGlue and BioFoam increased 5% for the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010. This increase was primarily due to a 5% increase in the volume of milliliters sold, which increased revenues by 3%, the favorable impact of foreign exchange rates, which increased revenues by 1%, and an increase in average selling prices, which increased revenues by 1%.

The increase in sales volume for BioGlue and BioFoam for the three and nine months ended September 30, 2011 was primarily due to an increase in shipments of BioGlue in certain international markets, primarily Japan. The Company began shipping BioGlue to Japan in late April 2011, as BioGlue was recently approved in Japan for use in the repair of aortic dissections. Revenues from shipments to Japan for the three and nine months ended September 30, 2011 were \$651,000 and \$1.2 million, respectively. For the year to date period, this increase was partially offset by a volume decrease in the Company's more mature domestic market.

The impact of foreign exchange rates was due to changes in the exchange rates between the U.S. Dollar and both the British Pound and the Euro in both the three and nine months ended September 30, 2011 as compared to the respective periods in 2010. The Company's sales of BioGlue and BioFoam through its direct sales force to United Kingdom hospitals are denominated in British Pounds, and its sales to German hospitals and certain distributors are denominated in Euros.

Management believes that the decrease in BioGlue shipments in its domestic markets is a result of various factors, including: the U.S. market introduction of sealant products with approved indications for use in clinical applications in which BioGlue has been used off label previously, poor economic conditions and their constraining effect on hospital budgets, the resulting attempts by hospitals to control costs by reducing spending on consumable items such as BioGlue, and the efforts of some large competitors in imposing and enforcing contract purchasing requirements for competing non-CryoLife products.

Sales of BioGlue and BioFoam for the three and nine months ended September 30, 2011 included international sales of BioFoam following receipt of the CE Mark approval during the third quarter of 2009. BioFoam sales accounted for less than 1% of total BioGlue and BioFoam sales for the three and nine months ended September 30, 2011. Domestic revenues accounted for 63% and 64% of total BioGlue revenues for the three and nine months ended September 30, 2011, respectively, and 70% and 69% of total BioGlue revenues for the three and nine months ended September 30, 2010, respectively.

BioGlue is a mature product that has experienced increasing competitive pressures. Management believes that BioGlue revenues in future periods will be impacted by price increases and smaller volume increases in international markets and that BioGlue sales in domestic markets will continue to be impacted by the factors discussed above. As a result of these forces, management expects the decline in domestic sales to continue in the fourth quarter of 2011 as compared with the corresponding prior year period.

PerClot and HemoStase

Revenues from the sale of hemostats, consisting of PerClot and HemoStase, decreased 71% for the three months ended September 30, 2011 as compared to the three months ended September 30, 2010. Revenues from the sale of PerClot and HemoStase decreased 40% for the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010. The revenue decreases in the three and nine months ended September 30, 2011 were primarily due to a decrease in hemostat sales volume in domestic markets, partially offset by an increase in sales volume in international markets. The revenue decrease in the nine months ended September 30, 2011 was also impacted by a decrease in average selling prices, which decreased revenues by 6%.

International hemostat revenues increased 24% for the three months ended September 30, 2011 and 55% for the nine months ended September 30, 2011 as compared to the three and nine months ended September 30, 2010, respectively. This increase is primarily due to an increase in international sales of PerClot in the 2011 periods over the international sales of HemoStase in the corresponding 2010 periods. Management believes that international PerClot revenues have been favorably impacted by the Company's ability to market PerClot for all surgical specialties, expanding the direct European sales force into Austria, and PerClot's product performance when compared to other hemostatic agents.

The decrease in domestic sales volume for the three and nine months ended September 30, 2011 was due to the Company's planned discontinuation of sales of HemoStase in late March 2011. The Company recognized no domestic hemostat sales in the second or third quarters of 2011, subsequent to the discontinuance of HemoStase sales, as PerClot is not yet approved for commercial distribution in domestic markets. The Company anticipates this loss of domestic hemostat sales to result in a decrease in total hemostat sales for the remainder of 2011 when compared to the corresponding 2010 periods.

The decrease in average selling prices for the nine months ended September 30, 2011 was primarily due to discounting of HemoStase inventory in an attempt to sell off the Company's remaining inventory balances in the first quarter of 2011.

The Company will not be able to sell PerClot in the U.S. in future years until U.S. Food and Drug Administration (FDA) approval is granted. On March 31, 2011 CryoLife filed an Investigational Device Exemption (IDE) with the FDA seeking approval to begin clinical trials for the purpose of obtaining Premarket Approval to distribute PerClot in the U.S. On April 29, 2011 the FDA disapproved CryoLife's IDE filing with numerous comments and questions. CryoLife is currently addressing those comments and questions and anticipates refiling its IDE for PerClot in the fourth quarter of 2011.

Revascularization Technology

Revenues from revascularization technology for the three and nine months ended September 30, 2011 were a result of the Company's acquisition of Cardiogenesis in the second quarter of 2011. Revascularization technology includes revenues related to the sale of laser consoles, handpieces, and related products. Revascularization technology revenues for the three and nine months ended September 30, 2011 consisted primarily of handpiece sales.

The Company expects that revenues from revascularization technology will have a favorable impact on revenues in the fourth quarter of 2011 as compared to the prior year period.

Other Revenues

Other revenues for the three and nine months ended September 30, 2011 and 2010 included revenues related to funding allocated from U.S. Congress Defense Appropriations Conference Reports in 2005 through 2008, collectively the (DOD Grants). As of September 30, 2011 CryoLife has been awarded \$6.1 million and has received a total of \$5.4 million for the development of protein hydrogel technology, which the Company is currently developing for use in organ sealing. At September 30, 2011 CryoLife had \$1.8 million included in deferred income on the Company's Summary Consolidated Balance Sheet from the DOD Grants, of which \$1.4 million remains in unspent cash advances recorded as cash and cash equivalents.

Cost of Preservation Services and Products

Cost of Preservation Services

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|----------|------------------------------------|-----------|
| | 2011 | 2010 | 2011 | 2010 |
| Cost of preservation services | \$ 8,349 | \$ 8,911 | \$ 25,709 | \$ 27,322 |
| Cost of preservation services as a percentage of preservation service revenues | 57% | 59% | 57% | 60% |

Cost of preservation services decreased 6% for both the three and nine months ended September 30, 2011 as compared to the three and nine months ended September 30, 2010. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

The decrease in cost of preservation services and the decrease in cost of preservation services as a percentage of preservation services revenues in the three and nine months ended September 30, 2011 were primarily due to a decrease in the per unit cost of processing tissues. The decrease in the per unit cost of processing tissues in 2011 was largely a result of increased processing and packaging throughput, as fixed costs were allocated to a greater volume of processed tissues. To a lesser extent, the decrease in cost of preservation services was also due to a decrease in cardiac tissues shipped in the 2011 periods as compared to the corresponding 2010 periods.

Cost of Products

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|----------|------------------------------------|----------|
| | 2011 | 2010 | 2011 | 2010 |
| Cost of products | \$ 2,393 | \$ 4,310 | \$ 7,051 | \$ 9,318 |
| Cost of products as a percentage of product revenues | 16% | 33% | 16% | 23% |

Cost of products decreased 44% for the three months and 24% for the nine months ended September 30, 2011 as compared to the three and nine months ended September 30, 2010, respectively. Cost of products in 2011 includes costs related to BioGlue, BioFoam, PerClot, and revascularization technology, distributed by CryoLife's subsidiary Cardiogenesis, and includes HemoStase for the year to date period. Cost of products in 2010 includes costs related to BioGlue, BioFoam, and HemoStase.

Cost of products for the three and nine months ended September 30, 2010 included a \$1.6 million write-down of HemoStase inventory. The decrease in cost of products in the three and nine months ended September 30, 2011 was primarily due to the write-down of HemoStase in the prior year periods. To a lesser extent, cost of products decreased in 2011 from the prior year periods due to a decrease in shipments of HemoStase, partially offset by increased shipments of PerClot, which the Company began distributing in the third quarter of 2010, and revascularization technology handpieces, which the Company began distributing in the second quarter of 2011 through Cardiogenesis. The decrease in cost of products as a percentage of product revenues for the three and nine months ended September 30, 2011 was primarily due to

Edgar Filing: CRYOLIFE INC - Form 10-Q

the write-down of HemoStase in the prior year periods. To a lesser extent, the decrease was due to decreased revenues from HemoStase, partially offset by increased revenues from PerClot, as both of these hemostats have higher costs as a percentage of revenue than BioGlue and handpieces.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|-----------|------------------------------------|-----------|
| | 2011 | 2010 | 2011 | 2010 |
| General, administrative, and marketing expenses | \$ 14,726 | \$ 11,376 | \$ 42,676 | \$ 36,863 |
| General, administrative, and marketing expenses as a percentage of total revenues | 50% | 40% | 48% | 42% |

General, administrative, and marketing expenses increased 29% for the three months and 16% for the nine months ended September 30, 2011 as compared to the three and nine months ended September 30, 2010, respectively.

The increase in general, administrative, and marketing expenses for the three and nine months ended September 30, 2011 was primarily due to expenses for business development activities and additional expenses related to the sales personnel and ongoing operations of Cardiogenesis, which the Company acquired in the second quarter of 2011. The Company's business development activities included transaction and integration expenses related to the Company's acquisition of Cardiogenesis and additional business development activities that are not currently ongoing and that the Company does not currently expect to result in completed transactions. The Company's business development expenses, including outgoing personnel costs, exit activities, legal, professional and regulatory fees, were \$1.1 million and zero for the three months ended September 30, 2011 and 2010, respectively, and \$4.1 million and \$542,000 for the nine months ended September 30, 2011 and 2010, respectively.

The Company's general, administrative, and marketing expenses included \$615,000 and \$398,000 for the three months ended September 30, 2011 and 2010, respectively, and \$1.9 million and \$1.7 million for the nine months ended September 30, 2011 and 2010, respectively, related to the grant of stock options, restricted stock awards, and restricted stock units.

The Company expects that its expenses associated with lawsuits, including lawsuits with Medafor, Inc. (Medafor), will continue to have a material impact on the Company's general, administrative, and marketing expenses during the fourth quarter of 2011. The Company does not anticipate that it will incur significant additional acquisition related expenses in the fourth quarter of 2011 related to the acquisition of Cardiogenesis. The Company expects that its general, administrative, and marketing expenses will continue to be higher than in prior years due to the additional expenses related to the sales personnel and ongoing operations of Cardiogenesis. The Company continues to evaluate potential business development opportunities and may incur costs related to these activities; however, due to the early stage of these discussions, the Company does not believe that these additional costs will be material in the fourth quarter of 2011.

Research and Development Expenses

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|----------|------------------------------------|----------|
| | 2011 | 2010 | 2011 | 2010 |
| Research and development expenses | \$ 1,690 | \$ 1,590 | \$ 5,099 | \$ 4,122 |
| Research and development expenses as a percentage of total revenues | 6% | 6% | 6% | 5% |

Research and development spending in 2011 was primarily focused on PerClot; the Company's SynerGraft tissues and products, including: CryoValve SGPV, CryoValve SG aortic heart valves, CryoPatch SG, and xenograft SynerGraft tissue products; and the Company's BioGlue family of products, including: BioGlue and BioFoam. Research and development spending in 2010 was primarily focused on the Company's SynerGraft tissues and products and the BioGlue family of products.

Acquired In-Process Research and Development

Edgar Filing: CRYOLIFE INC - Form 10-Q

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|----------|------------------------------------|----------|
| | 2011 | 2010 | 2011 | 2010 |
| Acquired in-process research and development | \$ -- | \$ 3,513 | \$ -- | \$ 3,513 |
| Acquired in-process research and development as a percentage of total revenues | --% | 12% | --% | 4% |

As part of the consideration paid to SMI, the Company allocated \$3.5 million to an intangible asset for PerClot distribution and manufacturing rights in the U.S. and certain other countries which do not have current regulatory approvals. This \$3.5 million is considered in-process research and development as it is dependent upon regulatory approvals which have not yet been obtained. Therefore, CryoLife expensed the \$3.5 million as in-process research and development upon acquisition.

Other Income and Expenses

Interest expense was \$49,000 and \$116,000 for the three and nine months ended September 30, 2011, respectively, and \$29,000 and \$145,000 for the three and nine months ended September 30, 2010, respectively. Interest expense for the three and nine months ended September 30, 2011 and 2010 included interest incurred related to the Company's debt, capital leases, and interest related to uncertain tax positions.

Interest income was \$1,000 and \$13,000 for the three and nine months ended September 30, 2011, respectively, and \$6,000 and \$16,000 for the three and nine months ended September 30, 2010, respectively. Interest income for the three and nine months ended September 30, 2011 and 2010 was primarily due to interest earned on the Company's cash and investments.

The gain on valuation of derivative was zero for both the three and nine months ended September 30, 2011 and \$143,000 and \$1.3 million for the three and nine months ended September 30, 2010, respectively. The gain on valuation of derivative in the 2010 periods was due to the decrease in the value of embedded derivatives related to Medafor common stock previously purchased by the Company.

The other than temporary investment impairment was zero for both the three and nine months ended September 30, 2011 and \$3.6 million for both the three and nine months ended September 30, 2010. This was due to the impairment in the value of the Company's investment in Medafor common stock during the third quarter of 2010.

Earnings

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|------------|------------------------------------|----------|
| | 2011 | 2010 | 2011 | 2010 |
| Income (loss) before income taxes | \$ 2,289 | \$ (4,588) | \$ 8,603 | \$ 3,819 |
| Income tax expense (benefit) | 270 | (1,557) | 3,098 | 1,990 |
| Net income (loss) | \$ 2,019 | \$ (3,031) | \$ 5,505 | \$ 1,829 |
| Diluted income (loss) per common share | \$ 0.07 | \$ (0.11) | \$ 0.20 | \$ 0.06 |
| Diluted weighted-average common shares outstanding | 27,850 | 27,783 | 27,765 | 28,356 |

Income before income taxes increased 150% for the three months and 125% for the nine months ended September 30, 2011 as compared to the three and nine months ended September 30, 2010, respectively. Income before income taxes for the three and nine months ended September 30, 2011 was primarily impacted by costs related to the acquisition of Cardiogenesis and an increase in other costs and expenses as discussed above. Income (loss) before income taxes for the three and nine months ended September 30, 2010 was negatively impacted primarily by the write-down of acquired in-process research and development, the other than temporary investment impairment, and the write-down of HemoStase inventory, partially offset by the gain on valuation of derivative for the nine months ended September 30, 2010.

The Company's effective income tax rate was approximately 12% and 36% for the three and nine months ended September 30, 2011, respectively, as compared to a benefit of 34% for the three months ended September 30, 2010 and expense of 52% for the nine months ended September 30, 2010. The significant change in the Company's effective income tax rate for the three months ended September 30, 2011 was due to the discrete and favorable effect of deductions taken on the Company's 2010 federal tax returns, which were filed in the third quarter of 2011. For the nine months ended September 30, 2011, this favorable effect was largely offset by the unfavorable tax treatment, recognized in the second quarter of 2011, of certain acquisition related expenses, which the Company incurred related to its acquisition of Cardiogenesis.

Edgar Filing: CRYOLIFE INC - Form 10-Q

Net income and diluted income per common share for the three and nine months ended September 30, 2011 increased compared to the corresponding periods in 2010 due to the increase in income before income taxes, adjusted by the effect of income tax expense, as discussed above.

Basic and diluted income per common share could be impacted in future periods unfavorably by the issuance of additional shares of common stock and favorably by the Company's repurchase of its common stock. Stock repurchases are impacted by many factors,

including: stock price, available funds, and competing demands for such funds, and as a result, may be suspended or discontinued at any time.

Seasonality

The Company's demand for its cardiac preservation services has traditionally been seasonal, with peak demand generally occurring in the third quarter. Management believes this trend for cardiac preservation services is primarily due to the high number of surgeries scheduled during the summer months for school-aged patients. Management believes that this trend is lessening in recent years as the Company is distributing a higher percentage of its tissues to adult populations.

The Company believes the demand for its vascular preservation services is seasonal, with lowest demand generally occurring in the fourth quarter. Management believes this trend for vascular preservation services is primarily due to fewer surgeries being scheduled during the winter holiday months.

The Company believes the demand for BioGlue is seasonal, with a decline in demand generally occurring in the third quarter followed by stronger demand in the fourth quarter. Management believes that this trend for BioGlue may be due to the summer holiday season in Europe and fewer surgeries being performed on adult patients in the summer months in the U.S.

The Company is uncertain whether the demand for PerClot will be seasonal. As PerClot is in a growth phase generally associated with a recently introduced product that has not fully penetrated the marketplace, the nature of any seasonal trends in PerClot sales may be obscured.

The Company is uncertain whether the demand for revascularization technology will be seasonal, as the Company only recently acquired this product line in May 2011 and the historical data does not indicate a significant trend.

Liquidity and Capital Resources

Net Working Capital

At September 30, 2011 net working capital (current assets of \$88.9 million less current liabilities of \$22.3 million) was \$66.6 million, with a current ratio (current assets divided by current liabilities) of 4 to 1, compared to net working capital of \$82.2 million and a current ratio of 5 to 1 at December 31, 2010.

Overall Liquidity and Capital Resources

The Company's largest cash requirement for the nine months ended September 30, 2011 was the acquisition of all of the outstanding common stock of Cardiogenesis and related transaction costs. On May 17, 2011 CryoLife completed its acquisition of all of the outstanding shares of Cardiogenesis for \$0.457 per share or approximately \$21.7 million. CryoLife used cash on hand to fund the transaction and will operate Cardiogenesis as a wholly owned subsidiary. In July 2011 the Company paid \$3.5 million to purchase an equity investment in ValveXchange, a private medical device company that was spun off from Cleveland Clinic to develop a lifetime heart valve replacement technology platform featuring exchangeable bioprosthetic leaflets. CryoLife used cash on hand to fund this investment. The Company's other cash requirements included cash for general working capital needs, the payment of legal and professional fees, and repurchases of the Company's common stock. Legal and professional fees during the three and nine months ended September 30, 2011 included business development costs, primarily costs associated with the Company's acquisition of Cardiogenesis, other business development activities, and costs associated with the Company's litigation with Medafor. The Company funded its cash requirements primarily through its existing cash reserves and its operating activities, which generated cash during the period.

CryoLife entered into a credit agreement with GE Capital in March of 2008, as amended (the "GE Credit Agreement"), which provides for up to \$15.0 million in revolving credit for working capital, acquisitions, and other corporate purposes, of which \$14.8 million was available for borrowing as of September 30, 2011. As of September 30, 2011 the outstanding balance under this agreement was zero. As required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least \$5.0 million in accounts in which GE Capital has a first priority perfected lien. As a result, these funds will not be available to meet the Company's liquidity needs during the term of the GE Credit Agreement and, as such, have been recorded in restricted securities on the Company's Summary Consolidated Balance Sheets. Also, the GE Credit Agreement requires that after giving effect to a stock repurchase the Company maintain liquidity, as defined in the agreement, of at least \$20.0 million. During the third quarter of 2011, the Company amended the GE Credit Agreement to extend the expiration date of the credit facility to October 31, 2011. CryoLife anticipates entering into a new credit agreement with GE Capital in the fourth quarter of 2011; however, there is no guarantee that a new or extended line of credit can be obtained.

The Company's cash equivalents include advance funding received under the DOD Grants for the continued development of protein hydrogel technology. As of September 30, 2011 \$1.4 million of the Company's cash equivalents were related to these DOD Grants, which must be used for the specified purposes.

The Company has agreed to provide funding of up to \$2.0 million in debt financing to ValveXchange through a revolving credit facility. The Company cannot currently anticipate if or when ValveXchange may draw funding from this credit facility.

The Company believes that its anticipated cash from operations and existing cash and cash equivalents will enable the Company to meet its current operational liquidity needs for at least the next twelve months. The Company's future cash requirements may include cash to fund clinical trials, including the PerClot and Cardiogenesis clinical trials, to fund other business development activities, to purchase license agreements, for general working capital needs, to fund the Medafor litigation, to fund the ValveXchange revolving credit facility, to repurchase the Company's common stock, and for other corporate purposes. The Company expects that these items will have a significant impact on its cash flows in the remainder of 2011. The Company expects to seek additional borrowing capacity to fund additional business development activities or other future cash requirements, and will be required to obtain such funding to finance any significant future business development activities. The Company acquired net operating loss carryforwards from its acquisition of Cardiogenesis that the Company believes will reduce required cash payments for federal income taxes by approximately \$500,000 for the 2011 tax year.

Net Cash from Operating Activities

Net cash provided by operating activities was \$13.7 million for the nine months ended September 30, 2011 as compared to \$13.8 million for the nine months ended September 30, 2010. The Company uses the indirect method to prepare its cash flow statement and, accordingly, the operating cash flows are based on the Company's net income, which is then adjusted to remove non-cash items and for changes in operating assets and liabilities from the prior year end. For the nine months ended September 30, 2011 these non-cash items included a favorable \$3.6 million in depreciation and amortization expense and \$2.1 million in non-cash stock based compensation.

The Company's working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the nine months ended September 30, 2011 these changes included a favorable \$2.3 million due to decreases in deferred preservation costs and inventory balances and a favorable \$644,000 due to the timing differences between the recording of accounts payable, accrued expenses, and other liabilities and the actual payment of cash, partially offset by an unfavorable \$968,000 due to the timing difference between making cash payments and the expensing of assets, including prepaid insurance policy premiums.

Net Cash from Investing Activities

Net cash used in investing activities was \$27.1 million for the nine months ended September 30, 2011 as compared to \$9.9 million for the nine months ended September 30, 2010. The current year cash used was primarily due to the payment of \$21.1 million for the acquisition of Cardiogenesis, net of cash acquired, the investment of \$3.6 million for ValveXchange preferred stock, and \$2.0 million in capital expenditures.

Net Cash from Financing Activities

Net cash used in financing activities was \$1.0 million for the nine months ended September 30, 2011 as compared to \$3.0 million for the nine months ended September 30, 2010. The current year cash used was primarily due to \$1.6 million in purchases of treasury stock, largely related to the Company's publicly announced stock repurchase plan.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Scheduled Contractual Obligations and Future Payments

Scheduled contractual obligations and the related future payments as of September 30, 2011 are as follows (in thousands):

| | Total | Remainder of 2011 | 2012 | 2013 | 2014 | 2015 | Thereafter |
|--------------------------------------|------------------|------------------------------|-----------------|-----------------|-----------------|-----------------|-------------------|
| Operating leases | \$ 27,558 | \$ 441 | \$ 2,695 | \$ 2,631 | \$ 2,604 | \$ 2,589 | \$ 16,598 |
| Purchase commitments | 9,743 | 1,556 | 2,506 | 3,554 | 2,127 | -- | -- |
| Research obligations | 4,955 | 1,796 | 1,304 | 554 | 1,301 | -- | -- |
| PerClot contingent payments | 2,000 | -- | 500 | -- | 1,500 | -- | -- |
| Compensation payments | 1,985 | -- | -- | 993 | 992 | -- | -- |
| Total contractual obligations | \$ 46,241 | \$ 3,793 | \$ 7,005 | \$ 7,732 | \$ 8,524 | \$ 2,589 | \$ 16,598 |

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

The Company's purchase commitments include minimum purchase requirements for PerClot related to the Company's transaction with SMI. These minimum purchases are included through 2014, as the Company expects to receive FDA approval for PerClot no later than 2014. Upon FDA approval, the Company may terminate its minimum purchase requirements, which it expects to do. However, if the Company does not terminate this provision, it will have minimum purchase obligations of \$1.75 million per year through the end of the contract term in 2025. The Company's purchase commitments also include obligations from agreements with suppliers and contractual payments for licensing computer software and telecommunication services.

The Company's research obligations represent commitments for ongoing studies and payments to support research and development activities, which will be partially funded by the advances received under the DOD Grants.

The obligation for PerClot contingent payments represents the contingent milestone payments that the Company will pay if certain FDA regulatory approvals and other commercial milestones are achieved. The schedule excludes one contingent milestone payment of \$500,000, as the Company cannot make a reasonably reliable estimate of timing of this future payment.

The Company's compensation payment obligations represent estimated payments for post-employment benefits for the Company's Chief Executive Officer (CEO). The timing of the CEO's post-employment benefits is based on the December 2012 expiration date of the CEO's employment agreement. Payment of this benefit may be accelerated by a change in control or by the voluntary retirement of the CEO.

The schedule of contractual obligations above excludes (i) obligations for estimated liability claims unless they are due as a result of a pending settlement agreement or other contractual obligation and (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be \$1.9 million, because the Company cannot make a reasonably reliable estimate of the amount and period of related future payments as no specific assessments have been made for specific litigation or by any taxing authorities.

Capital Expenditures

Capital expenditures for the nine months ended September 30, 2011 were \$2.0 million compared to \$1.5 million for the nine months ended September 30, 2010. Capital expenditures in the nine months ended September 30, 2011 were primarily related to the routine purchases of tissue processing, manufacturing, computer, and office equipment; computer software; and renovations to the Company's corporate headquarters needed to support the Company's business.

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 Exchange Act. Forward-looking statements give the Company's current expectations or forecasts of future events. The words could, may, might, will, would, shall, should, pro forma, potential, pending, intend, believe, expect, anticipate, and similar expressions generally identify forward-looking statements. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements, which are made as of the date of this Form 10-Q. Such forward-looking statements reflect the views of management at the time such statements are made and are subject to a number of risks, uncertainties, estimates, and assumptions, including, without limitation, in addition to those identified in the text surrounding such statements, those identified under Risks and Uncertainties and elsewhere in this Form 10-Q.

All statements, other than statements of historical facts, included herein that address activities, events, or developments that the Company expects or anticipates will or may occur in the future, are forward-looking statements, including statements regarding:

Beliefs regarding BioGlue revenues in future periods and the factors that may impact domestic and international BioGlue sales;

Expectations regarding revenues from PerClot and HemoStase and total hemostat sales for 2011;

Expectations regarding when CryoLife will commence manufacturing PerClot;

Expectations regarding revenues from revascularization technology and the resultant impact on CryoLife's revenues for the remainder of 2011;

Expectations regarding unit shipments of cardiac valves in the fourth quarter of 2011;

Expectations regarding transaction and integration expenses associated with the acquisition of Cardiogenesis;

Expectations regarding acquisition related expenses in the remainder of 2011;

Expectations regarding business development activities and related costs;

Expectations regarding the Company's tax treatment of items related to acquisitions;

Anticipated uses of cash in the remainder of 2011 and the resulting impact on cash flows;

The adequacy of the Company's financial resources;

The Company's belief that it may seek additional borrowing capacity and that it anticipates that it will enter into a new credit agreement with GE Capital in the fourth quarter of 2011;

Edgar Filing: CRYOLIFE INC - Form 10-Q

The Company's belief that it will have sufficient cash to meet its operational liquidity needs for at least the next twelve months;

Issues that may impact the Company's future financial performance and cash flows;

Expectations regarding net operating loss carryforwards;

Expectations regarding general, administrative, and marketing expenses;

Expectations regarding the timing of future payments to SMI and the accounting treatment of those payments;

Plans and costs related to regulatory approval for the distribution of PerClot in the U.S. and international markets;

Anticipated timing of CryoLife's refiling of the IDE for PerClot and anticipated timing of obtaining FDA approval of the IDE;

Expectations regarding minimum purchase requirements related to PerClot;

The Company's expectations regarding the timing of court rulings in its legal proceedings and the length of various stages of legal proceedings;

The Company's estimated future liability for existing tissue processing and product liability lawsuits and for claims incurred but not yet reported;

Expectations regarding unreported loss liability and any related recoverable insurance amounts;

The Company's intentions with respect to lawsuits and the expected impact of current litigation;

The Company's beliefs regarding the seasonal nature of the demand for some of its preservation services and products;

Anticipated impact of changes in interest rates and foreign currency exchange rates;

The Company's expectations regarding the renewal of certain contracts;

Expectations regarding the impact of new accounting pronouncements; and

Other statements regarding future plans and strategies, anticipated events, or trends.

These statements are based on certain assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions, and expected future developments as well as other factors it believes are appropriate in the circumstances. However, whether actual results and developments will conform with the Company's expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from the Company's expectations, including, without limitation, in addition to those specified in the text surrounding such statements, the risk factors set forth below, the risks set forth under Part II, Item 1A of the Company's Form 10-Q for the quarters ended March 31, 2011 and June 30, 2011, the risk factors set forth under Part I, Item 1A of the Company's Form 10-K for the year ended December 31, 2010, and other factors, many of which are beyond the control of the Company. 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 the Company will be realized or, even if substantially realized, that they will have the expected consequences to or effects on the Company or its business or operations. The Company assumes no obligation to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

Risks and Uncertainties

The risks and uncertainties which might impact the forward-looking statements and the Company, its ability to continue as a going concern, and the trading value of its common stock include concerns that:

We are significantly dependent on our revenues from BioGlue and are subject to a variety of risks affecting this product;

Our tissues and products allegedly have caused and may in the future cause injury to patients, and we have been and may be exposed to tissue processing and product liability claims, including one currently outstanding product liability lawsuit, and additional regulatory scrutiny as a result;

Demand for our tissues and products could decrease in the future, which could have a material adverse impact on our business;

We are currently involved in significant litigation with Medafor and that litigation cost may have a material adverse impact on our profitability;

Our investment in Medafor may have been impaired due to Medafor's termination of the EDA, which could have a material adverse impact on our financial condition and profitability;

Medafor has filed counterclaims against us with respect to our lawsuit against Medafor, and if Medafor is successful in its claims, our revenues and profitability may be materially, adversely impacted;

We are subject to stringent domestic and foreign regulation which may impede the approval process of our tissues and products, hinder our development activities and manufacturing processes, and, in some cases, result in the recall or seizure of previously cleared or approved tissues and products;

Uncertainties related to patents and protection of proprietary technology may adversely impact the value of our intellectual property;

Intense competition may impact our ability to operate profitably;

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

If we are not successful in expanding our business activities in international markets, we may be unable to increase our revenues;

We are dependent on the availability of sufficient quantities of tissue from human donors;

The loss of any of our sole-source suppliers could have a material adverse impact on our revenues, financial condition, profitability, and cash flows;

Edgar Filing: CRYOLIFE INC - Form 10-Q

We may be unsuccessful in our efforts to market and sell PerClot in the U.S. and internationally;

Our short-term liquidity and earnings in 2011 will be impacted by our substantial investment in our distribution and license and manufacturing agreements with SMI, and we will not fully realize the benefit of our investment in future years unless we are able to obtain FDA approval for PerClot in the U.S., which will require an additional commitment of funds;

Key growth strategies may not generate the anticipated benefits;

Investments in new technologies and acquisitions of products or distribution rights may not be successful;

We may expand through acquisitions or licenses of, or investments in, other companies or technologies, which may result in additional dilution to our stockholders and consume resources that may be necessary to sustain our business;

We may find it difficult to integrate recent acquisitions of technology and potential future acquisitions of technology or business combinations, which could disrupt our business, dilute stockholder value, and adversely impact our operating results;

We may not realize the anticipated benefits from an acquisition;

Regulatory action outside of the U.S. has affected our business in the past and may affect our business in the future;

Extensive government regulation may adversely impact our ability to develop and market services and products;

Healthcare policy changes, including recent federal legislation to reform the U.S. healthcare system, may have a material adverse impact on us;

Consolidation in the healthcare industry could lead to demands for price concessions, limits on the use of our tissues and products, or eliminate our ability to sell to certain of our significant market segments;

The success of many of our tissues and products depends upon strong relationships with physicians;

Our CryoValve SGPV post-clearance study may not provide expected results;

Our existing insurance policies may not be sufficient to cover our actual claims liability;

We may not be able to obtain adequate insurance at a reasonable cost, if at all;

We are not insured against all potential losses. Natural disasters or other catastrophes could adversely affect our business, financial condition, and profitability;

Our credit facility which expires on October 31, 2011 limits our ability to pursue significant acquisitions;

Our ability to borrow under our credit facility which expires on October 31, 2011 may be limited;

We may not be able to enter into a new credit facility after our current credit facility expires on October 31, 2011;

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

Rapid technological change could cause our services and products to become obsolete;

We are dependent on our key personnel; and

The integration of Cardiogenesis business into our business may be slower than expected or unsuccessful, and our revenues and operating expenses may be materially adversely impacted as a result.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

The Company's 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 the Company's cash and cash equivalents of \$21.1 million and restricted securities of \$5.0 million and interest paid on the Company's variable rate line of credit as of September 30, 2011. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the nine months ended September 30, 2011, affecting the Company's cash and cash equivalents, restricted securities, and line of credit would not have a material impact on the Company's financial position, profitability, or cash flows.

Foreign Currency Exchange Rate Risk

The Company has 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 the Company will receive in payment for assets or that the Company would have to pay to settle liabilities. As a result, the Company could be required to record these changes as gains or losses on foreign currency translation.

The Company has revenues and expenses that are denominated in foreign currencies. Specifically, a significant portion of the Company's international BioGlue revenues are denominated in British Pounds and Euros, and a portion of the Company's general, administrative, and marketing expenses are denominated in British Pounds and Euros. 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, the Company could recognize a reduction in revenues or an increase in expenses related to a change in exchange rates.

An additional 10% adverse change in exchange rates from the exchange rates in effect on September 30, 2011 affecting the Company's balances denominated in foreign currencies would not have had a material impact on the Company's financial position or cash flows. An additional 10% adverse change in exchange rates from the weighted-average exchange rates experienced by the Company for the nine months ended September 30, 2011 affecting the Company's revenue and expense transactions denominated in foreign currencies, would not have had a material impact on the Company's financial position, profitability, or cash flows.

Item 4. Controls and Procedures.

The Company maintains disclosure controls and procedures (Disclosure Controls) as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934. 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 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.

The Company's management, including the Company's President and CEO and the Company's Executive Vice President of Finance, Chief Operating Officer, and CFO, does not expect that its 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 its stated goals under all potential future conditions. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdown can occur because of simple error or mistake. The Company's Disclosure Controls have been designed to provide reasonable assurance of achieving their objectives.

Based upon the most recent Disclosure Controls evaluation conducted by management with the participation of the CEO and CFO, as of September 30, 2011 the CEO and CFO have concluded that the Company's Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by the Company in its 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.

The Securities and Exchange Commission's general guidance permits the exclusion of an assessment of the effectiveness of a registrant's disclosure controls and procedures as they relate to its internal control over financial reporting for an acquired business during the first year following such acquisition if, among other circumstances and factors, there is not adequate time between the acquisition date and the date of assessment. As previously noted in the Form 10-Q, the Company completed the acquisition of Cardiogenesis Corporation (Cardiogenesis) during the second quarter of 2011. Management's assessment and conclusion on the effectiveness of the Company's disclosure controls and procedures as of September 30, 2011 excludes an assessment of the internal control over financial reporting of Cardiogenesis.

During the quarter ended September 30, 2011, there were no other changes in the Company's internal control over financial reporting that materially affected or that are reasonably likely to materially affect the Company's internal control over financial reporting.

Part II - OTHER INFORMATION

Item 1. Legal Proceedings.

Medafor

As previously reported, CryoLife filed a lawsuit against Medafor, Inc. (Medafor) in 2009 in the U.S. District Court for the Northern District of Georgia (Georgia Court). In 2010 Medafor filed counterclaims against CryoLife. On August 2, 2011 Medafor withdrew, without prejudice, its Motion for Partial Summary Judgment with respect to its contention that CryoLife owes Medafor approximately \$1.3 million plus prejudgment interest for product Medafor shipped to CryoLife, stating that it would renew its motion at a later date. On September 30, 2011 the Georgia Court denied CryoLife's motion for partial summary judgment regarding Medafor's alleged wrongful termination of the Exclusive Distribution Agreement (EDA). The Georgia Court found that, at this early stage of discovery, CryoLife had not established as a matter of law that the parties drafted a certain section of the EDA clearly so as to supplant a specific aspect of the Georgia Uniform Commercial Code. The Georgia Court also found that the evidence submitted did not establish as a matter of law that the letter on which Medafor based its termination of the EDA failed to comport with the Georgia Uniform Commercial Code.

As previously reported, on July 5, 2011 the Georgia Court appointed a Discovery Special Master to manage and supervise discovery pursuant to a Joint Motion for Appointment of Special Master filed by the parties. Pursuant to the appointment, the parties have met repeatedly with the Special Master since July regarding discovery issues. Both parties filed motions to compel certain discovery, and on October 14, 2011, the Special Master granted in part and denied in part both parties' motions. The Georgia Court has scheduled a status conference for November 29, 2011, at which the parties will discuss various discovery-related issues and deadlines. CryoLife expects discovery to continue for a significant period of time. CryoLife believes that the trial will not occur until 2013.

As previously reported, on July 14, 2011 Medafor filed a lawsuit against CryoLife in the U.S. District Court for the District of Minnesota (Minnesota Court). Medafor's lawsuit requests that the Minnesota Court grant a declaratory judgment that Medafor's reverse stock split on December 31, 2010 reduced the number of Medafor shareholders to below 500 and that, therefore, Medafor is not required to comply with the registration requirements of Section 12(g) of the Securities Exchange Act of 1934 (i.e., not required to register as a public company with the U.S. Securities and Exchange Commission). Medafor's lawsuit also requests that the Minnesota Court award Medafor its costs and expenses in the lawsuit. On August 5, 2011 CryoLife filed a Motion to Dismiss Medafor's claims arguing that there was no private right cause of action under Section 12(g) of the Securities Exchange Act of 1934. The parties argued the Motion to Dismiss in front of the Minnesota Court on October 11, 2011. As of October 25, 2011 the Minnesota Court had not ruled on the Motion to Dismiss. At this time CryoLife is unable to predict the outcome of this matter. The Company believes that the outcome of this Minnesota Court matter will not have a material adverse effect on its financial position, result of operations, or cash flow. However, as this matter is ongoing, there is no assurance that this matter will be resolved in the Company's favor.

CardioFocus

As previously reported, in February 2008 CardioFocus, Inc. (CardioFocus) filed a complaint in the U.S. District Court for the District of Massachusetts (the Massachusetts Court) against Cardiogenesis Corporation, a wholly owned subsidiary of CryoLife, acquired on May 17, 2011 and a number of other companies. In the complaint CardioFocus alleges that Cardiogenesis and the other defendants had previously violated patent rights allegedly held by CardioFocus directed to the use of holmium-doped

YAG lasers in connection with low-hydroxyl content silica fibers for use in performing surgery. All of the asserted patents have now expired and the Company is the sole remaining defendant in the action. CardioFocus seeks a royalty for Cardiogenesis sales of the products in question, namely, the Solargen, TMR, and New Star lasers and lasers systems, during the period 2002 to 2007.

Since the filing of the lawsuit in February of 2008, Cardiogenesis has filed numerous requests for reexamination of the patents being asserted against Cardiogenesis with the U.S. Patent and Trademark Office (USPTO). Through these reexaminations three claims from two patents of CardioFocus have survived. Claim 2 of U.S. Patent No. 6,547,780 (the 780 Patent) and Claims 2 and 7 of U.S. Patent No. 5,843,073 (the Patent) were confirmed by the USPTO. CryoLife and Cardiogenesis believe that the reinstatement of these claims supports their position of non-infringement and that significant issues concerning the validity of the asserted patents continue to exist. On March 24, 2011 the Massachusetts Court ordered a stay. In addition, Cardiogenesis recently filed additional reexamination requests for the three claims, based on additional new prior art, which the USPTO has not yet determined whether to grant.

On August 15, 2011, at the request of both parties, the Massachusetts Court lifted the stay and entered a Scheduling Order. Pursuant to the Scheduling Order, the claims construction hearing or so-called Markman Hearing occurred on October 21, 2011. The court has not yet ruled on the claims construction. Trial is scheduled for May 14, 2012.

The Company intends to defend itself vigorously in this action. At this time, the Company is unable to predict the outcome of this matter and believes that the outcome of this matter will not have a material adverse effect on the Company's result of operations or cash flow. However, as this matter is ongoing, there is no assurance that this matter will be resolved favorably by the Company or will not result in a material liability to the Company, which could materially affect its results of operations and cash flows.

Item 1A. Risk Factors.

There have been no material changes to the Risk Factors as previously disclosed in Part I, Item 1A, Risk Factors in our 10-K for the year ended December 31, 2010, as updated by Part II, Item 1A, Risk Factors in our Form 10-Q for the quarters ended March 31, 2011 and June 30, 2011.

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

- (c) The following table provides information about purchases by the Company during the quarter ended September 30, 2011 of equity securities that are registered by the Company pursuant to Section 12 of the Exchange Act:

Issuer Purchases of Equity Securities

Common Stock

| Period | Total Number of Common Shares Purchased as of Publicly Announced Plans or Programs | Average Price Paid per Common Share | Total Number of Common Shares Purchased as of Publicly Announced Plans or Programs | Dollar Value of Common Shares That May Yet Be Purchased Under the Plans or Programs |
|---------------------|--|-------------------------------------|--|---|
| 07/01/11 - 07/31/11 | 41,510 | \$ 5.83 | -- | \$ 7,739,911 |
| 08/01/11 - 08/31/11 | 77,635 | 5.33 | -- | 7,739,911 |
| 09/01/11 - 09/30/11 | -- | -- | -- | 7,739,911 |
| Total | 119,145 | 5.50 | -- | 7,739,911 |

On June 1, 2010 the Company announced that its Board of Directors authorized the purchase of up to \$15.0 million of its common stock over the course of the following two years. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions, on such terms as management deems appropriate, and will be dependent upon various factors, including: price, regulatory requirements, and other market conditions. From June 1, 2010 to September 30, 2011 the Company had purchased a total of 1.3 million shares of its common stock for an aggregate purchase price of \$7.3 million. The common shares purchased that were not part of a publically announced plan or program were tendered to the Company in payment of the exercise price of outstanding options and taxes on stock compensation.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. (Removed and Reserved).**Item 5. Other information.**

None.

Item 6. Exhibits.

The exhibit index can be found below.

| Exhibit | |
|-----------|---|
| Number | Description |
| 2.1*+ | Series A Preferred Stock Purchase Agreement Among CryoLife, Inc., The Cleveland Clinic Foundation, and ValveXchange, Inc. dated July 6, 2011. |
| 3.1 | Amended and Restated Articles of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Form 10-K for the year ended December 31, 2007.) |
| 3.2 | Amended and Restated By-Laws. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed July 27, 2011.) |
| 4.1 | Form of Certificate for the Company's 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 | First Amended and Restated Rights Agreement, dated as of November 2, 2005, between CryoLife, Inc. and American Stock Transfer & Trust Company. (Incorporated herein by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K filed November 3, 2005.) |
| 10.1*+ | Loan and Security Agreement by and between ValveXchange, Inc., and CryoLife, Inc. dated July 6, 2011. |
| 10.2* | Seventh Amendment, dated August 30, 2011, to the Credit Agreement by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, letter of credit issuer, and agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner. |
| 31.1* | Certification by Steven G. Anderson 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.LAB** | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE** | XBRL Taxonomy Extension Presentation Linkbase Document |

* Filed herewith.

Edgar Filing: CRYOLIFE INC - Form 10-Q

- ** Furnished herewith. Pursuant to applicable securities laws and regulations, the Company is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Company has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these interactive data files are deemed not filed and otherwise are not subject to liability.

- + The Registrant has requested confidential treatment for certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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.

/s/ STEVEN G. ANDERSON

STEVEN G. ANDERSON
Chairman, President, and
Chief Executive Officer
(Principal Executive Officer)

CRYOLIFE, INC.
(Registrant)

/s/ D. ASHLEY LEE

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

October 27, 2011

DATE