

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
**FORM 10-Q**

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

For the Quarterly Period Ended June 30, 2005  
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 30144  
(Address of principal executive offices)  
(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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

YES  NO

The number of shares of common stock, par value \$0.01 per share, outstanding on August 2, 2005 was 24,174,811.

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<br>June 30, |          | Six Months Ended<br>June 30, |           |
|--|--------------------------------|----------|------------------------------|-----------|
|  | 2005                           | 2004     | 2005                         | 2004      |
|  | (Unaudited)                    |          | (Unaudited)                  |           |
| Revenues:  |                                |          |                              |           |
| Products   | \$ 9,846                       | \$ 9,203 | \$ 19,973                    | \$ 18,062 |
| Human tissue preservation services   | 7,352                          | 6,054    | 14,890                       | 12,279    |
| Research grants  | --                             | 57       | --                           | 59        |
| Total revenues   | 17,198                         | 15,314   | 34,863                       | 30,400    |
| Costs and expenses:  |                                |          |                              |           |
| Products   | 2,079                          | 1,894    | 4,195                        | 3,841     |
| Human tissue preservation services<br>(Including write-downs of \$392 for the<br>three months and \$672 for the six months<br>ended June 30, 2005 and \$1,508 for the<br>three months and \$5,158 for the six months<br>ended June 30, 2004) | 6,070                          | 7,543    | 11,969                       | 16,646    |
| General, administrative, and marketing   | 21,585                         | 9,693    | 31,641                       | 19,841    |
| Research and development   | 929                            | 891      | 1,850                        | 1,812     |
| Interest expense   | 88                             | 59       | 143                          | 102       |
| Interest income  | (167)                          | (64)     | (242)                        | (130)     |

|   |                   |                   |                   |                   |
|---|-------------------|-------------------|-------------------|-------------------|
| Change in valuation of derivative           | 902               | --                | 784               | --                |
| Other expense, net                          | 45                | 21                | 175               | 37                |
| Total costs and expenses                    | <u>31,531</u>     | <u>20,037</u>     | <u>50,515</u>     | <u>42,149</u>     |
| Loss before income taxes                    | (14,333)          | (4,723)           | (15,652)          | (11,749)          |
| Income tax expense (benefit)                | 46                | (1,371)           | 84                | (1,371)           |
| Net loss                                    | <u>\$(14,379)</u> | <u>\$ (3,352)</u> | <u>\$(15,736)</u> | <u>\$(10,378)</u> |
| Effect of preferred stock                   | (244)             | --                | (290)             | --                |
| Net loss applicable to common shares        | <u>\$(14,623)</u> | <u>\$ (3,352)</u> | <u>\$(16,026)</u> | <u>\$(10,378)</u> |
| Loss per common share:                      |                   |                   |                   |                   |
| Basic                                       | <u>\$ (0.61)</u>  | <u>\$ (0.14)</u>  | <u>\$ (0.68)</u>  | <u>\$ (0.46)</u>  |
| Diluted                                     | <u>\$ (0.61)</u>  | <u>\$ (0.14)</u>  | <u>\$ (0.68)</u>  | <u>\$ (0.46)</u>  |
| Weighted average common shares outstanding: |                   |                   |                   |                   |
| Basic                                       | <u>23,905</u>     | <u>23,252</u>     | <u>23,676</u>     | <u>22,747</u>     |
| Diluted                                     | <u>23,905</u>     | <u>23,252</u>     | <u>23,676</u>     | <u>22,747</u>     |

See accompanying notes to summary consolidated financial statements.

Item 1. Financial Statements

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

|   | June 30,<br>2005  | December 31,<br>2004 |
|---|-------------------|----------------------|
|   | (Unaudited)       |                      |
| <b>ASSETS</b>                                   |                   |                      |
| Current Assets:                                 |                   |                      |
| Cash and cash equivalents                       | \$ 4,189          | \$ 4,713             |
| Marketable securities, at market                | 17,382            | 3,956                |
| Restricted securities                           | 552               | 563                  |
| Trade receivables, net                          | 10,550            | 8,293                |
| Other receivables                               | 18,069            | 3,957                |
| Deferred preservation costs, net                | 10,425            | 8,822                |
| Inventories                                     | 4,267             | 4,767                |
| Prepaid expenses and other assets               | 3,824             | 2,590                |
| Total current assets                            | <u>69,258</u>     | <u>37,661</u>        |
| Property and equipment, net                     | 26,631            | 28,724               |
| Patents, net                                    | 4,929             | 4,978                |
| Other long-term assets                          | 2,550             | 1,898                |
| TOTAL ASSETS                                    | <u>\$ 103,368</u> | <u>\$ 73,261</u>     |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>     |                   |                      |
| Current Liabilities:                            |                   |                      |
| Accounts payable                                | \$ 2,394          | \$ 2,569             |
| Accrued expenses and other current liabilities  | 34,442            | 9,615                |
| Accrued compensation                            | 1,615             | 1,835                |
| Accrued procurement fees                        | 2,938             | 2,634                |
| Derivative liability                            | 1,125             | --                   |
| Notes payable                                   | 1,727             | --                   |
| Current maturities of capital lease obligations | 1,078             | 1,319                |
| Total current liabilities                       | <u>45,319</u>     | <u>17,972</u>        |

|  |                   |                  |
|--|-------------------|------------------|
| Capital lease obligations, less current maturities                     | 387               | 530              |
| Other long-term liabilities  | 5,094             | 5,099            |
|  | <u>50,800</u>     | <u>23,601</u>    |
| Shareholders' Equity:  |                   |                  |
| Preferred stock (335 issued shares in 2005)                            | 3                 | --               |
| Common stock (25,476 issued shares in 2005 and 24,805 shares in 2004)  | 255               | 248              |
| Additional paid-in capital   | 113,812           | 94,846           |
| Retained deficit   | (54,283)          | (38,257)         |
| Deferred compensation  | (87)              | (222)            |
| Accumulated other comprehensive income                                 | 188               | 361              |
| Treasury stock at cost (1,390 shares in 2005 and 1,390 shares in 2004) | (7,320)           | (7,316)          |
|  | <u>52,568</u>     | <u>49,660</u>    |
| Total shareholders' equity   |                   |                  |
|  | <u>52,568</u>     | <u>49,660</u>    |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY                             | \$ 103,368        | \$ 73,261        |
|  | <u>\$ 103,368</u> | <u>\$ 73,261</u> |

See accompanying notes to summary consolidated financial statements.

Item 1. Financial Statements

CRYOLIFE, INC.  
SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS  
(IN THOUSANDS)

|  | Six Months Ended<br>June 30, |                |
|--|------------------------------|----------------|
|  | 2005                         | 2004           |
|  | (Unaudited)                  |                |
| Net cash from operating activities:                                      |                              |                |
| Net loss   | \$ (15,736)                  | \$ (10,378)    |
| Adjustments to reconcile net loss to net cash from operating activities: |                              |                |
| Loss on sale of assets   | 151                          | 19             |
| Depreciation and amortization  | 2,571                        | 2,711          |
| Provision for doubtful accounts  | 48                           | 48             |
| Write-down of deferred preservation costs                                | 672                          | 5,158          |
| Other non-cash adjustments to income                                     | (48)                         | 6              |
| Non-cash employee compensation   | 115                          | --             |
| Change in valuation of derivative  | 784                          | --             |
| Changes in operating assets and liabilities:                             |                              |                |
| Receivables  | (2,415)                      | (4,241)        |
| Income taxes   | 178                          | 2,457          |
| Deferred preservation costs and inventories                              | (1,775)                      | (3,851)        |
| Prepaid expenses and other assets  | 869                          | 1,287          |
| Accounts payable, accrued expenses, and other liabilities                | 10,022                       | 1,741          |
|  | <u>(4,564)</u>               | <u>(5,043)</u> |
| Net cash used in operating activities                                    |                              |                |
|  | <u>(4,564)</u>               | <u>(5,043)</u> |
| Net cash from investing activities:                                      |                              |                |
| Capital expenditures   | (490)                        | (439)          |
| Other assets   | (114)                        | 125            |
| Purchases of marketable securities                                       | (14,792)                     | (558)          |
| Sales and maturities of marketable securities                            | 1,390                        | 2,000          |
|  | <u>(14,006)</u>              | <u>1,128</u>   |
| Net cash (used in) provided by investing activities                      |                              |                |
|  | <u>(14,006)</u>              | <u>1,128</u>   |
| Net cash from financing activities:                                      |                              |                |
| Proceeds from debt issuance  | 265                          | --             |
| Principal payments of debt   | (265)                        | --             |
| Payment of obligations under capital leases                              | (384)                        | (342)          |
| Principal payments on short-term note payable                            | (754)                        | (1,000)        |
| Proceeds from exercise of stock options and issuance of common stock     | 235                          | 241            |

|  |          |           |
|--|----------|-----------|
| Proceeds from equity offerings                   | 19,098   | 19,364    |
| Net cash provided by financing activities        | 18,195   | 18,263    |
| (Decrease) increase in cash and cash equivalents | (375)    | 14,348    |
| Effect of exchange rate changes on cash          | (149)    | (54)      |
| Cash and cash equivalents, beginning of period   | 4,713    | 5,672     |
| Cash and cash equivalents, end of period         | \$ 4,189 | \$ 19,966 |

See accompanying notes to summary consolidated financial statements.

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CRYOLIFE, INC. AND SUBSIDIARIES  
NOTES TO SUMMARY CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

**Note 1 — Basis of Presentation**

The accompanying unaudited summary consolidated financial statements have been prepared in accordance with (i) accounting principles generally accepted in the United States for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the United States Securities and Exchange Commission (“SEC”). Accordingly, the statements do not include all of the information and disclosures required by accounting principles generally accepted in the United States for a complete presentation of financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the six months ended June 30, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005. For further information, refer to the consolidated financial statements and notes thereto included in the CryoLife Form 10-K for the year ended December 31, 2004.

The Company expects that the following factors will continue to have an adverse impact on cash flows during 2005:

- o The anticipated lower preservation services revenues as compared to preservation revenues prior to the FDA Order, subsequent FDA activities, and related events (discussed in Note 2),
- o The high cost of human tissue preservation services as a percent of revenue, as compared to the period prior to the FDA Order, as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue and have decreased yields of implantable tissue per donor,
- o An expected use of cash related to the defense and resolution of lawsuits and claims, and
- o The legal and professional costs related to ongoing FDA compliance.

The Company believes the following factors should have a favorable impact on cash flows from operations during the remainder of 2005, although there can be no assurance that the Company’s efforts will be successful:

- o Expected increases in revenues due to increases in BioGlue® Surgical Adhesive (“BioGlue”) list prices implemented in January 2005,
- o Expected increases in the service fees for cardiovascular and vascular tissues due to fee increases implemented in July 2004 and January 2005, to reflect the higher cost of processing these tissues,
- o Anticipated improvements in yields of implantable tissues per donor over the levels experienced in 2003 and 2004 through process changes and process directives,
- o Expected increases in procurement of human tissues for processing during the second half of 2005 as compared to the first half of 2005, and
- o Anticipated decreases in cash payments related to insurance premiums.

The Company believes that its existing cash, cash equivalents, marketable securities, and available borrowings under its credit agreement, discussed in Note 6, will enable the Company to meet its liquidity needs through at least June 30, 2006.

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The Company’s long term liquidity and capital requirements will depend upon numerous factors, including:

- o The success of BioGlue and other products using related technology,
- o The Company's ability to increase the level of tissue procurement and demand for its tissue preservation services,
- o The Company’s ability to reestablish sufficient margins on its tissue preservation services in the face of increased processing costs by improving yields and increasing prices,

- o The Company's spending levels on its research and development activities, including research studies, to develop and support its product and service pipeline,
- o The resolution of the remaining outstanding product liability lawsuits and other claims (see Note 13),
- o The final outcome of other litigation against the Company (see Note 13), and
- o To a lesser degree, the Company's success at resolving the issues with the FDA regarding processing of human tissue using the SynerGraft® technology.

If the Company is unable to address these issues and continues to experience negative cash flows, the Company anticipates that it may require additional financing or seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements beyond June 30, 2006. Additional funds may not be available when needed or on terms acceptable to the Company, which could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows.

## **Note 2 — FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices**

### ***FDA Order***

The FDA inspected the Company's tissue processing operations in December 2001, after it was reported that a Minnesota man had died after receiving an implant of orthopaedic tissue processed by the Company. The FDA conducted another inspection in March 2002. In April 2002 the FDA issued a Form 483 Notice of Observations ("April 2002 483") and an FDA Warning Letter was issued, dated June 17, 2002 ("Warning Letter"). On August 13, 2002 the Company received an order from the Atlanta district office of the FDA regarding the non-valved cardiac, vascular, and orthopaedic tissues processed by the Company since October 3, 2001 (the "FDA Order"). Pursuant to the FDA Order, the Company placed non-valved cardiac, vascular, and orthopaedic tissue subject to the FDA Order (i.e. processed since October 3, 2001) on quality assurance quarantine and recalled the portion of those tissues that had been distributed but not implanted. In addition the Company ceased processing non-valved cardiac, vascular, and orthopaedic tissues.

On September 5, 2002 the Company entered into an agreement with the FDA (the "FDA Agreement") that supplemented the FDA Order and allowed non-valved cardiac and vascular tissues subject to the recall (processed between October 3, 2001 and September 5, 2002) to be released for distribution after the Company had completed steps to ensure that the tissue was used for approved purposes and that patients were notified of risks associated with tissue use. The FDA Agreement had a renewable 45-business day term and the final renewal expired on September 5, 2003. The Company is no longer shipping tissue subject to the recall (processed between October 3, 2001 and September 5, 2002). A renewal of the FDA Agreement that expired on September 5, 2003 was not needed in order for the Company to continue to distribute non-valved cardiovascular, vascular, and orthopaedic tissues processed after September 5, 2002.

In addition, pursuant to the FDA Agreement, the Company agreed to perform additional procedures in the processing of non-valved cardiac and vascular tissues and subsequently resumed processing these tissues. The Company also agreed to establish a corrective action plan within 30 days from September 5, 2002 with steps to validate processing procedures. The corrective action plan was submitted on October 5, 2002, and executed thereafter. The corrective actions taken have been reviewed by the FDA during three subsequent inspections as discussed in "Other FDA Correspondence and Notices" below.

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### ***Other FDA Correspondence and Notices***

FDA Form 483 Notices of Observations ("483") were issued in connection with the FDA inspections of the Company's facilities in February 2003, October 2003, and February 2004. The Company responded to the February 2003 483 in March 2003, responded to the October 2003 483 in October 2003, November 2003, and April 2004, and responded to the February 2004 483 in March 2004, April 2004, and June 2004. On September 24, 2004 CryoLife received an inquiry from the FDA Atlanta District Office seeking additional information on four items submitted by CryoLife in response to the February 2004 483 to which CryoLife responded on November 8, 2004. In response to the Form 483 Notice of Observations, the Company has implemented new and revised existing processing, preservation, and testing procedures. On July 11, 2005 the FDA began an inspection of the Company's tissue processing facilities. The FDA may require the Company to implement additional corrective actions, perform additional validation testing, or supply additional information related to the inspections. The Company has and will continue to work with the FDA to review process improvements and address any outstanding observations.

On February 20, 2003 the Company received a letter from the FDA stating that a 510(k) premarket notification should be filed for the Company's SynerGraft processed human cardiac tissues ("CryoValve® SG") and that premarket approval marketing authorization should be obtained for the Company's SynerGraft processed human vascular tissues ("CryoVein® SG") when marketed or labeled as an arteriovenous ("A-V") access graft. The agency's position is that use of the SynerGraft technology in the processing of allograft heart valves represents a modification to the Company's legally marketed CryoValve allograft and that vascular allografts labeled for use as A-V access grafts are medical devices that require premarket approval.

On November 3, 2003 the Company filed a 510(k) premarket notification with the FDA for the CryoValve SG. On February 4, 2004 the Company received a letter from the FDA requesting additional information. On August 24, 2004, the Company submitted an amendment to its original 510(k) submission providing clarification and additional information. The FDA requested further additional information in November 2004. On June 8, 2005 CryoLife responded to some of these additional requests. CryoLife also has initiated an appeal of others through administrative procedures. The FDA may still require that additional studies be undertaken and may never clear the 510(k) premarket notification. Clearance of the 510(k) premarket notification with the FDA will be required before the Company can resume distribution of SynerGraft processed CryoValve SG.

On December 8, 2003 the Company received a letter from the FDA stating that it was the agency's position that cardiovascular tissues processed with the SynerGraft technology should be regulated as medical devices. On September 14, 2004, the Company met with the FDA to discuss the data to be used to support a formal Request for Designation ("RFD") filing for SynerGraft processed cardiovascular tissue, including the CryoVein SG. An RFD submission establishes the regulatory status of the tissue. The Company submitted the RFD on October 5, 2004. The FDA affirmed its original decision in letters received in December 2004. That decision is currently subject to an administrative appeal. Unless this appeal is successful, CryoLife will be unable to distribute tissues with the SynerGraft technology until further submissions and FDA clearances are granted. In the event that the Company is not successful in appealing the FDA's decision to regulate SynerGraft vascular tissue as a medical device, the Company will evaluate whether it will file and seek a premarket

approval for CryoVein SG or discontinue the CryoVein SG.

In 2003 the Company suspended the use of the SynerGraft technology in the processing of allograft tissue and the distribution of tissues on hand previously processed with the SynerGraft technology until the regulatory issues associated with these tissues are resolved. Additionally, the Company discontinued labeling its vascular grafts for use as A-V access grafts. Until such time as the issues surrounding SynerGraft are resolved, the Company will employ its traditional processing methods on these tissues. During the year ended December 31, 2004, the Company wrote down \$353,000 in SynerGraft processed cardiovascular and vascular tissues. As of June 30, 2005 the Company had no deferred preservation costs related to SynerGraft processed tissues on its Summary Consolidated Balance Sheet.

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### Note 3 — Cash Equivalents and Marketable Securities

The Company maintains cash equivalents and investments in several large, well-capitalized financial institutions, and the Company's policy disallows investment in any securities rated less than "investment-grade" by national rating services. Management determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designations quarterly.

Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Held-to-maturity securities are stated at amortized cost. Trading securities are securities that are acquired principally for the purpose of generating a profit from short-term fluctuations in price. Trading securities are stated at their fair values, with the realized and unrealized gains and losses, interest, and dividends included in investment income. Debt securities not classified as held-to-maturity or trading and marketable equity securities not classified as trading are classified as available-for-sale. Available-for-sale securities are stated at their fair values, with the unrealized gains and losses, net of applicable taxes, reported in a separate component of shareholders' equity. Interest, dividends, realized gains and losses, and declines in value judged to be other than temporary are included in investment income. The cost of securities sold is based on the specific identification method.

As of June 30, 2005 \$17.4 million of marketable securities were designated as available-for-sale, and \$552,000 of marketable securities were designated as held-to-maturity. These securities were designated held-to-maturity due to a contractual commitment to hold the securities as pledged collateral relating to one of the Company's product liability insurance policies, and, therefore, they are reported in the restricted securities line of the June 30, 2005 Summary Consolidated Balance Sheet. As of December 31, 2004 \$4.0 million of marketable securities were designated as available-for-sale, and \$563,000 of marketable securities were designated as held-to-maturity.

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

|   | Cost Basis       | Unrealized<br>Holding<br>(Losses) Gains | Estimated<br>Market<br>Value |
|---|------------------|---|------------------------------|
| <b>June 30, 2005</b>                        |                  |   |                              |
| Cash equivalents:                           |                  |   |                              |
| Money market funds                          | \$ 2,442         | \$ --                                   | \$ 2,442                     |
| Marketable securities:                      |                  |   |                              |
| US Treasury debt securities                 | \$ 1,989         | \$ --                                   | \$ 1,989                     |
| Government sponsored entity debt securities | 10,921           | (5)                                     | 10,916                       |
| Municipal obligations                       | 3,134            | 13                                      | 3,147                        |
| Variable rate demand notes                  | 1,330            | --                                      | 1,330                        |
| Total marketable securities                 | <u>\$ 17,374</u> | <u>\$ 8</u>                             | <u>\$ 17,382</u>             |
| Restricted securities:                      |                  |   |                              |
| Government sponsored entity debt securities | \$ 552           | \$ --                                   | \$ 552                       |
| <b>December 31, 2004</b>                    |                  |   |                              |
| Cash equivalents:                           |                  |   |                              |
| Money market funds                          | \$ 2,290         | \$ --                                   | \$ 2,290                     |
| Marketable securities:                      |                  |   |                              |
| Municipal obligations                       | \$ 3,138         | \$ 43                                   | \$ 3,181                     |
| Variable rate demand notes                  | 775              | --                                      | 775                          |
| Total marketable securities                 | <u>\$ 3,913</u>  | <u>\$ 43</u>                            | <u>\$ 3,956</u>              |
| Restricted securities:                      |                  |   |                              |
| Government sponsored entity debt securities | \$ 563           | \$ --                                   | \$ 563                       |

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Gross realized gains on sales of available-for-sale securities totaled zero for the six months ended June 30, 2005 and the twelve months ended December 31, 2004. Differences between cost and market listed above, consisting of a net unrealized holding gain of \$8,000 less deferred taxes of zero at June 30, 2005 and a net unrealized holding gain of \$43,000 less deferred taxes of \$11,000 at December 31, 2004, are included as a separate component of other comprehensive income in the shareholders' equity section of the Summary Consolidated Balance Sheets.

At June 30, 2005 approximately \$9.0 million of marketable securities had a maturity date within 90 days, approximately \$7.1 million had a maturity date between 90 days and 1 year, zero had a maturity date between 1 and 5 years, and approximately \$1.3 million had a maturity date greater than 5 years. At December 31, 2004 zero marketable securities had a maturity date within 90 days, approximately \$2.2 million had a maturity date between 90 days and 1 year, approximately \$1.0 million had a maturity date between 1 and 5 years, and approximately \$775,000 had a maturity date of greater than 5 years.

#### Note 4 — Inventories

Inventories are comprised of the following (in thousands):

|                 | June 30<br>2005 | December 31,<br>2004 |
|-----------------|-----------------|----------------------|
|                 | (Unaudited)     |                      |
| Raw materials   | \$ 2,856        | \$ 2,780             |
| Work-in-process | 307             | 246                  |
| Finished goods  | 1,104           | 1,741                |
|                 | <u>\$ 4,267</u> | <u>\$ 4,767</u>      |

#### Note 5 — 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 generated deferred tax assets beginning in 2002 primarily as a result of write-downs of deferred preservation costs, accruals for product liability claims, and operating losses, reflecting reductions in revenues and additional professional fees, as a result of the FDA Order, subsequent FDA activities, and related events. The Company continued to generate deferred tax assets for the six months ended June 30, 2005 primarily as a result of operating losses. The Company periodically assesses the recoverability of its deferred tax assets and provides a valuation allowance when management believes it is more likely than not that its deferred tax assets will not be realized.

In assessing the recoverability of its deferred tax assets, the Company reviewed its historical operating results, including the reasons for its operating losses, uncertainties regarding projected future operating results due to the effects of the FDA Order and subsequent FDA activity, and the uncertainty of the outcome of litigation. Based on the results of this analysis, at December 31, 2004 the Company determined that it was more likely than not that the Company's deferred tax assets would not be realized. Therefore, as of December 31, 2004 the Company had a total of \$18.8 million in valuation allowances against deferred tax assets and a net deferred tax asset balance of zero.

For the six months ended June 30, 2005 the Company did not experience any changes that would materially affect the Company's analysis of and valuation of its deferred tax assets. As of June 30, 2005 the Company had a total of \$24.0 million in valuation allowances against deferred tax assets and a net deferred tax asset balance of zero.

As of June 30, 2005 the Company had income tax receivables related to federal income tax losses from the year ended December 31, 2004 that can be carried back to prior years to offset income taxes paid and should result in approximately \$1.3 million in refunds to the Company.

#### Note 6 — Debt

On February 8, 2005 CryoLife and its subsidiaries entered into a new credit agreement with Wells Fargo Foothill, Inc. as lender. The credit agreement provides for a revolving credit facility in an aggregate amount equal to the lesser of \$15.0 million (including a letter of credit subfacility of up to an aggregate of \$2.0 million) or a borrowing base determined in accordance with the terms of the credit agreement. Generally, the borrowing base is 20% of the appraised value of the business of CryoLife, reduced by specified lender reserves. The 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 maintain quarterly (i) a minimum aggregate borrowing capacity plus cash and cash equivalents, as defined, of \$12.5 million or (ii) achieve an increasing level of minimum earnings before interest, taxes, depreciation, and amortization ("EBITDA"), BioGlue gross margins greater than 70% for the preceding twelve months, and cash and cash equivalents, as defined, of \$5.0 million. While the Company currently expects that its aggregate borrowing availability under the credit agreement will equal \$15.0 million, there can be no assurance that the availability will remain at this level. The credit agreement also includes customary conditions on incurring new indebtedness and limitations on cash dividends. Cash dividends on any class of capital stock are prohibited; provided that cash dividends on preferred stock may be paid so long as the Company maintains \$7.5 million, in the aggregate, of cash, cash equivalents, and borrowing capacity, as defined. There is no restriction on the payment of stock dividends. Commitment fees are paid based on the unused portion of the facility. The credit agreement expires on February 7, 2008, at which time the outstanding principal balance will be due. Amounts borrowed under the revolving credit facility bear interest at the bank's prime rate plus 1%. Amounts borrowed under the credit facility are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries. During the first quarter of 2005, CryoLife borrowed approximately \$265,000 against the \$15.0 million then available under its revolving credit facility, and used such borrowings to pay certain expenses of the transaction and related interest expenses and fees. As of June 30, 2005, the outstanding balance of the credit agreement was zero and the borrowing capacity was \$15 million.

In the quarter ended June 30, 2005 the Company entered into two agreements to finance approximately \$1.7 million and \$760,000, respectively, in insurance premiums associated with the yearly renewal of certain Company insurance policies. The amounts financed accrue interest at a 4.98% and 5.02% rate, respectively, and are payable in equal monthly payments over a nine month period and an eight month period, respectively. As of June 30, 2005 the aggregate outstanding balance of the agreements was \$1.7 million.

In April 2004 the Company entered into two agreements to finance approximately \$1.9 million and \$1.5 million, respectively, in insurance premiums associated with the yearly renewal of certain Company insurance policies. The amounts financed accrue interest at a 3.25% rate and are payable in equal monthly payments over a nine month period and an eight month period, respectively. As of June 30, 2005 the outstanding balance under the agreements was zero.

## Note 7 — Private Equity Placement

On January 7, 2004 the Company's Board of Directors authorized an agreement with a financial advisory company to sell shares of the Company's common stock in a private investment in public equity transaction (the "PIPE"). The PIPE was consummated on January 27, 2004, and resulted in the sale of approximately 3.4 million shares of stock at a price of \$6.25 per share. The sale generated net proceeds of approximately \$19.4 million, after commissions, filing fees, late registration fees, and other related charges, which was used for general corporate purposes. The Company filed a registration statement on Form S-3 with the SEC covering the resale of the shares sold in the PIPE by the investors. The Company paid a total of \$466,000 in late registration penalties to the investors through May 18, 2004, the date the registration statement was declared effective. This amount was deducted from the PIPE proceeds in recording net proceeds from the PIPE in shareholders' equity.

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## Note 8 — Convertible Preferred Stock

On December 17, 2004 the Company announced that it had filed a shelf registration statement on Form S-3 with the SEC covering the sale from time to time of up to \$50 million of its common stock, preferred stock, depositary shares, or any combination of these securities for its own account in one or more offerings.

On March 18 and April 19, 2005 the Company completed a public offering of 417,000 shares of 6% convertible preferred stock ("Preferred Stock") at a price to the public of \$50.00 per share. Net proceeds from the offering, after deducting underwriting discounts and offering-related expenses, totaled approximately \$19.1 million.

Dividends on the Preferred Stock are cumulative from the date of original issue at the annual rate of 6% of the liquidation preference of the Preferred Stock, payable quarterly on the first day of January, April, July, and October, commencing July 1, 2005. Any dividends must be declared by the Company's board of directors and must come from funds that are legally available for dividend payments. On June 2, 2005 the Company declared a dividend of \$0.8667 per share on its 6% convertible preferred stock. The dividend of approximately \$290,000 was paid on July 1, 2005 in cash to shareholders of record on June 20, 2005.

The Preferred Stock is convertible at the option of the holder at any time into the Company's common stock at a conversion rate of approximately 6.2189 shares of common stock for each share of Preferred Stock, based on an initial conversion price of \$8.04. The initial conversion price is subject to adjustment in certain events. The Company reserved 4,600,000 shares of common stock for issuance upon conversion. At June 30, 2005 holders had voluntarily converted 82,500 shares of Preferred Stock into 513,052 shares of common stock.

The Company may automatically convert the Preferred Stock into common stock if the closing price of the Company's common stock has exceeded \$12.06, which is 150% of the conversion price of the Preferred Stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion.

If the Company elects to automatically convert, or the holder elects to voluntarily convert, some or all of the Preferred Stock into common stock prior to April 1, 2008, the Company will make an additional payment on the Preferred Stock equal to the aggregate amount of dividends that would have been payable on the Preferred Stock through and including April 1, 2008, less any dividends already paid on the Preferred Stock, the "Dividend Make-Whole Payment". The Dividend Make-Whole Payment is payable in cash or, at the Company's option, in shares of the Company's common stock, or a combination of cash and shares of common stock. At June 30, 2005, the Company had issued 107,539 shares of common stock to converting holders in satisfaction of this additional payment.

In accordance with SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"), the Company is required to separate and account for the Dividend Make-Whole Payment feature of the Preferred Stock, the "Derivative" as an embedded derivative. As an embedded derivative instrument, the Dividend Make-Whole Payment feature must be measured at fair value and reflected as a current liability on the Company's Summary Consolidated Balance Sheets. Changes in the fair value of the Derivative are recognized as the line item change in valuation of derivative as a non-operating income/expense on the Company's Summary Consolidated Statements of Operations. The Company determined the fair value of the Derivative to be \$1.0 million on March 18, 2005, the date of issuance. The Company determined the fair value of the Derivative related to the issuance upon exercise of the underwriter's over allotment option to be \$32,000 on April 19, 2005, the date of issuance. These amounts were allocated from the proceeds of the Preferred Stock to the derivative liability. Due to voluntary conversions, which took place during the period from March 18, 2005 through June 30, 2005, the value of the derivative previously recorded for these shares was increased through other expense of \$503,000 and \$518,000 for the three and six months ended June 30, 2005, respectively, for the fair value of common shares to be issued in excess of the amounts previously recorded as the derivative liability. At June 30, 2005 the derivative liability was valued at \$1.1 million, resulting in the recognition of \$399,000 and \$266,000 in other expense for the three and six months ended June 30, 2005, respectively.

The Preferred Stock has a liquidation preference of \$50 per share, plus accrued and unpaid dividends. The liquidation preference of the Preferred Stock was approximately \$17 million as of June 30, 2005.

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The Company may elect to redeem the Preferred Stock, in whole or in part, at declining redemption prices on or after April 7, 2008.

The Preferred Stock has no maturity date and no voting rights prior to conversion into common stock, except under limited circumstances.

## Note 9 — Comprehensive Income (Loss)

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

| Three Months Ended<br>June 30, |      | Six Months Ended<br>June 30, |      |
|--------------------------------|------|------------------------------|------|
| 2005                           | 2004 | 2005                         | 2004 |



|                                | (Unaudited)       |                   | (Unaudited)       |                   |
|--------------------------------|-------------------|-------------------|-------------------|-------------------|
| Net loss                       | \$ (14,379)       | \$ (3,352)        | \$ (15,736)       | \$ (10,378)       |
| Unrealized loss on investments | (15)              | (28)              | (24)              | (32)              |
| Translation adjustment         | (75)              | 11                | (149)             | (50)              |
|                                | <u>          </u> | <u>          </u> | <u>          </u> | <u>          </u> |
| Comprehensive loss             | \$ (14,469)       | \$ (3,369)        | \$ (15,909)       | \$ (10,460)       |

The tax effect on the change in unrealized gain/loss on investments is zero and a benefit of \$15,000 for the three months ended June 30, 2005 and 2004, respectively. The tax effect on the change in unrealized gain/loss on investments is a benefit of \$11,000 and \$17,000 for the six months ended June 30, 2005 and 2004, respectively. The tax effect on the translation adjustment is zero for each period presented.

Components of accumulated other comprehensive income consist of the following, net of tax (in thousands):

|  | June 30,<br>2005  | December 31,<br>2004 |
|--|-------------------|----------------------|
|  | (Unaudited)       |                      |
| Unrealized gain on investments               | \$ 8              | \$ 32                |
| Translation adjustment                       | 180               | 329                  |
|  | <u>          </u> | <u>          </u>    |
| Total accumulated other comprehensive income | \$ 188            | \$ 361               |

#### Note 10 — Loss per Common Share

The following table sets forth the computation of basic and diluted loss per common share (in thousands, except per share data). The net loss for the three and six months ended June 30, 2005 is adjusted by the effect of the Company's cumulative, convertible Preferred Stock to arrive at net loss applicable to common shares in accordance with SFAS No. 128, "Earnings Per Share" ("SFAS 128"). As discussed in Note 8 the Preferred Stock contains a provision that requires the Company to remit Dividend Make-Whole Payments to converting preferred shareholders. The Company intends to pay these Dividend Make-Whole Payments in shares of its common stock in accordance with the terms of the Preferred Stock.

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|   | Three Months Ended<br>June 30, |                   | Six Months Ended<br>June 30, |                   |
|---|--------------------------------|-------------------|------------------------------|-------------------|
|   | 2005                           | 2004              | 2005                         | 2004              |
|   | (Unaudited)                    |                   | (Unaudited)                  |                   |
| Numerator for basic loss per common share:                  |                                |                   |                              |                   |
| Net loss  | \$ (14,379)                    | \$ (3,352)        | \$ (15,736)                  | \$ (10,378)       |
| Effect of preferred stock <sup>a</sup>                      | (244)                          | --                | (290)                        | --                |
|   | <u>          </u>              | <u>          </u> | <u>          </u>            | <u>          </u> |
| Net loss applicable to common shares                        | \$ (14,623)                    | \$ (3,352)        | \$ (16,026)                  | \$ (10,378)       |
|   | <u>          </u>              | <u>          </u> | <u>          </u>            | <u>          </u> |
| Denominator for basic loss per common share:                |                                |                   |                              |                   |
| Basic weighted-average shares                               | 23,905                         | 23,252            | 23,676                       | 22,747            |
|   | <u>          </u>              | <u>          </u> | <u>          </u>            | <u>          </u> |
| Basic loss per common share                                 | \$ (0.61)                      | \$ (0.14)         | \$ (0.68)                    | \$ (0.46)         |
|   | <u>          </u>              | <u>          </u> | <u>          </u>            | <u>          </u> |
| Numerator for diluted loss per common share:                |                                |                   |                              |                   |
| Net loss  | \$ (14,379)                    | \$ (3,352)        | \$ (15,736)                  | \$ (10,378)       |
| Effect of preferred stock <sup>a, b</sup>                   | (244)                          | --                | (290)                        | --                |
|   | <u>          </u>              | <u>          </u> | <u>          </u>            | <u>          </u> |
| Net loss applicable to common shares                        | \$ (14,623)                    | \$ (3,352)        | \$ (16,026)                  | \$ (10,378)       |
|   | <u>          </u>              | <u>          </u> | <u>          </u>            | <u>          </u> |
| Denominator for diluted loss per common share:              |                                |                   |                              |                   |
| Basic weighted-average shares                               | 23,905                         | 23,252            | 23,676                       | 22,747            |
| Effect of dilutive convertible preferred stock <sup>b</sup> | --                             | --                | --                           | --                |
| Effect of dilutive stock options <sup>c</sup>               | --                             | --                | --                           | --                |
|   | <u>          </u>              | <u>          </u> | <u>          </u>            | <u>          </u> |
| Adjusted weighted-average shares                            | 23,905                         | 23,252            | 23,676                       | 22,747            |
|   | <u>          </u>              | <u>          </u> | <u>          </u>            | <u>          </u> |
| Diluted loss per common share                               | \$ (0.61)                      | \$ (0.14)         | \$ (0.68)                    | \$ (0.46)         |
|   | <u>          </u>              | <u>          </u> | <u>          </u>            | <u>          </u> |

<sup>a</sup> The amount of the accumulated dividend on the Preferred Stock increases the net loss applicable to common shares by \$244,000 and \$290,000 for the three and six months ended June 30, 2005, respectively.

- b The adjustment for the Dividend Make-Whole Payment on preferred shares converted during the period and the change in valuation of the derivative included in the Company's net loss would have decreased the net loss applicable to common shareholders by \$902,000 and \$784,000 for the three and six months ended June 30, 2005, respectively. The common shares that would be issued to shareholders upon conversion of the remaining Preferred Stock and in payment of the remaining Dividend Make-Whole Payment would have increased the weighted-average shares by 2.6 million and 1.6 million for the three and six months ended June 30, 2005, respectively. These adjustments were excluded from the calculation above as they were anti-dilutive pursuant to the provisions of SFAS 128.
- c Outstanding options to purchase the Company's common stock that would have resulted in additional dilutive common shares of 353,000 and 307,000 for the three months ended June 30, 2005 and 2004, respectively, and 377,000 and 363,000 for the six months ended June 30, 2005 and 2004, respectively, were excluded from the calculation, as these items were anti-dilutive pursuant to the provisions of SFAS 128.

In future periods the basic and diluted loss per common share are expected to be affected by the declaration of dividends on preferred stock, the conversion of preferred stock, fluctuations in the fair value of the Company's common stock, and changes in the valuation of the derivative.

#### Note 11 — Stock-Based Compensation

The Company has stock incentive and stock option plans, which provide for grants of shares to employees and grants of options to employees and directors to purchase shares of the Company's common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. The Company has elected to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations ("APB 25") in accounting for its employee stock options because, as discussed below, the alternative fair value accounting provided for under SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123") as amended by SFAS No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure" ("SFAS 148") requires use of option valuation models that were not developed for use in valuing employee stock options.

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Under APB 25, no compensation expense is recognized because the exercise price of the Company's employee stock options equals the market price of the underlying stock on the date of the grant. In accordance with APB 25 the compensation recorded for employee stock grants is equal to the value of the grant on the measurement date, the date of the grant, as determined by the price of the Company's common stock on that date. Some employee stock grants vest in future periods based on a requirement of continued service to the Company. For these stock grants the amount of the stock grant is recorded as deferred compensation in the equity section of the Company's Consolidated Balance Sheets, and is expensed on a straight-line basis over the vesting period.

Pro forma information regarding net loss and loss per share is required by SFAS 123, which requires that this pro forma information be determined as if the Company has accounted for its employee stock options granted under the fair value method of that statement. The fair values for these options were estimated at the dates of grant using a Black-Scholes option-pricing model assuming a 10% annual forfeiture rate in 2005 and a 5% annual forfeiture rate in 2004. The Company periodically reviews its forfeiture rate through a comparison to actual forfeitures experienced by the Company. Additionally, the following weighted-average assumptions were used:

|                                 | Three Months Ended<br>June 30, |           | Six Months Ended<br>June 30, |           |
|---------------------------------|--------------------------------|-----------|------------------------------|-----------|
|                                 | 2005                           | 2004      | 2005                         | 2004      |
|                                 | (Unaudited)                    |           | (Unaudited)                  |           |
| Expected dividend yield         | 0%                             | 0%        | 0%                           | 0%        |
| Expected stock price volatility | .546                           | .594      | .576                         | .598      |
| Risk-free interest rate         | 3.56%                          | 3.39%     | 3.66%                        | 3.22%     |
| Expected life of options        | 3.7 Years                      | 4.2 Years | 4.3 Years                    | 3.9 Years |

For purposes of pro forma disclosures, the estimated fair values of the options are amortized to expense over the options' vesting periods. The Company's pro forma information follows (in thousands, except per share data):

|  | Three Months Ended<br>June 30, |            | Six Months Ended<br>June 30, |             |
|--|--------------------------------|------------|------------------------------|-------------|
|  | 2005                           | 2004       | 2005                         | 2004        |
|  | (Unaudited)                    |            | (Unaudited)                  |             |
| Basic net loss applicable to common shares - as reported                   | \$ (14,623)                    | \$ (3,352) | \$ (16,026)                  | \$ (10,378) |
| Stock-based employee compensation:   |                                |            |                              |             |
| Add expense included in net loss   | 55                             | --         | 115                          | --          |
| Deduct expense determined under the fair value based method for all awards | 783                            | 1,091      | 1,295                        | 1,524       |
| Basic net loss applicable to common shares - pro forma                     | \$ (15,351)                    | \$ (4,443) | \$ (17,206)                  | \$ (11,902) |
| Basic weighted-average shares  | 23,905                         | 23,252     | 23,676                       | 22,747      |
| Basic loss per common share:   |                                |            |                              |             |
| As reported  | \$ (0.61)                      | \$ (0.14)  | \$ (0.68)                    | \$ (0.46)   |

|  |             |            |             |             |
|--|-------------|------------|-------------|-------------|
| Pro forma  | \$ (0.64)   | \$ (0.19)  | \$ (0.73)   | \$ (0.52)   |
| Diluted net loss applicable to common shares - as reported                 | \$ (14,623) | \$ (3,352) | \$ (16,026) | \$ (10,378) |
| Stock-based employee compensation:   |             |            |             |             |
| Add expense included in net loss   | 55          | --         | 115         | --          |
| Deduct expense determined under the fair value based method for all awards | 783         | 1,091      | 1,295       | 1,524       |
| Diluted net loss applicable to common shares - pro forma                   | \$ (15,351) | \$ (4,443) | \$ (17,206) | \$ (11,902) |
| Diluted weighted-average shares  | 23,905      | 23,252     | 23,676      | 22,747      |
| Diluted loss per common share:   |             |            |             |             |
| As reported  | \$ (0.61)   | \$ (0.14)  | \$ (0.68)   | \$ (0.46)   |
| Pro forma  | \$ (0.64)   | \$ (0.19)  | \$ (0.73)   | \$ (0.52)   |

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## Note 12 — Segment Information

The Company has two reportable segments organized according to its products and services: Implantable Medical Devices and Human Tissue Preservation Services.

The Implantable Medical Devices segment includes external revenue from product sales of BioGlue and bioprosthetic devices, including stentless porcine heart valves, SynerGraft processed porcine heart valves, and SynerGraft processed bovine vascular grafts. The Human Tissue Preservation Services segment includes external services revenue from cryopreservation of cardiac, vascular, and orthopaedic allograft tissues. 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 products and preservation services. 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 products and preservation services, and gross margins for the Company's operating segments (in thousands):

|   | Three Months Ended<br>June 30, |                 | Six Months Ended<br>June 30, |                 |
|---|--------------------------------|-----------------|------------------------------|-----------------|
|   | 2005                           | 2004            | 2005                         | 2004            |
|   | (Unaudited)                    |                 | (Unaudited)                  |                 |
| Revenue:                                    |                                |                 |                              |                 |
| Implantable medical devices                 | \$ 9,846                       | \$ 9,203        | \$ 19,973                    | \$ 18,062       |
| Human tissue preservation services          | 7,352                          | 6,054           | 14,890                       | 12,279          |
| All other <sup>a</sup>                      | --                             | 57              | --                           | 59              |
|   | <u>17,198</u>                  | <u>15,314</u>   | <u>34,863</u>                | <u>30,400</u>   |
| Cost of Products and Preservation Services: |                                |                 |                              |                 |
| Implantable medical devices                 | 2,079                          | 1,894           | 4,195                        | 3,841           |
| Human tissue preservation services          | 6,070                          | 7,543           | 11,969                       | 16,646          |
| All other <sup>a</sup>                      | --                             | --              | --                           | --              |
|   | <u>8,149</u>                   | <u>9,437</u>    | <u>16,164</u>                | <u>20,487</u>   |
| Gross Margin (Loss):                        |                                |                 |                              |                 |
| Implantable medical devices                 | 7,767                          | 7,309           | 15,778                       | 14,221          |
| Human tissue preservation services          | 1,282                          | (1,489)         | 2,921                        | (4,367)         |
| All other <sup>a</sup>                      | --                             | 57              | --                           | 59              |
|   | <u>\$ 9,049</u>                | <u>\$ 5,877</u> | <u>\$ 18,699</u>             | <u>\$ 9,913</u> |

<sup>a</sup> The "All other" designation includes grant revenue.

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

|                                     | Three Months Ended<br>June 30, |           | Six Months Ended<br>June 30, |           |
|-------------------------------------|--------------------------------|-----------|------------------------------|-----------|
|                                     | 2005                           | 2004      | 2005                         | 2004      |
|                                     | (Unaudited)                    |           | (Unaudited)                  |           |
| BioGlue                             | \$ 9,552                       | \$ 8,962  | \$ 19,423                    | \$ 17,605 |
| Human tissue preservation services: |                                |           |                              |           |
| Cardiovascular tissue               | 3,518                          | 2,831     | 7,268                        | 6,261     |
| Vascular tissue                     | 2,740                          | 2,649     | 5,456                        | 5,135     |
| Orthopaedic tissue                  | 1,094                          | 574       | 2,166                        | 883       |
| Total preservation services         | 7,352                          | 6,054     | 14,890                       | 12,279    |
| Bioprosthetic devices               | 294                            | 241       | 550                          | 457       |
| Research grants                     | --                             | 57        | --                           | 59        |
|                                     | \$ 17,198                      | \$ 15,314 | \$ 34,863                    | \$ 30,400 |

### Note 13 — Commitments and Contingencies

#### Product Liability Claims

In the normal course of business as a medical device and services company, the Company has product liability complaints filed against it. Following the FDA Order, a greater number of lawsuits than has historically been experienced were filed. As of August 2, 2005 the Company was aware of eight pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, two allege product liability claims arising out of the Company's orthopaedic tissue services, four allege product liability claims arising out of the Company's allograft heart valve tissue services, one alleges a product liability claim arising from BioGlue, and one alleges a product liability claim arising out of the non-tissue products made by Ideas for Medicine, Inc. when it was a subsidiary of the Company.

As of August 2, 2005 there were two outstanding product liability lawsuits against the Company that are covered by two separate insurance policies in the 2000/2001 and 2004/2005 policy years. The Company believes its insurance policies to be adequate to defend against the covered lawsuits in each of these time periods. Additionally, the Company has six outstanding product liability lawsuits against the Company that are not covered by insurance policies, as either the Company has used all of its insurance coverage related to that policy year, or the claims were asserted against the Company in periods after the coverage in the related incident year had lapsed. Additional uninsured claims may be filed in the future. Other product liability claims have been asserted against the Company that have not resulted in lawsuits. The Company is monitoring these claims.

The Company performed an analysis as of June 30, 2005 of the settled but unpaid claims and the pending product liability claims based on settlement negotiations to date and advice from counsel. As of June 30, 2005 the Company had accrued a total of approximately \$933,000 for settled but unpaid claims and pending product liability claims and recorded zero representing amounts to be recovered from the Company's insurance carriers. The \$933,000 accrual is included as a component of accrued expenses and other current liabilities on the June 30, 2005 Summary Consolidated Balance Sheet. This amount represents the Company's estimate of the probable losses related to one settled but unpaid claim and four of the eight pending product liability claims. The Company has not recorded an accrual for the remaining four product liability claims because management has concluded that either a loss is remote or that, although a loss is reasonably possible or probable, a reasonable estimate of that loss or the range of losses cannot be made at this time.

The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. The Company is currently unable to reasonably estimate the maximum amount of the possible loss related to these claims, as many of the claims do not specify the damages sought and the Company does not have a reasonable method for estimating the amount of compensatory or punitive damages that could be assessed by a trial jury. Additionally, if the Company is unable to settle the outstanding claims for amounts within its ability to pay or one or more of the product liability claims in which the Company is a defendant should be tried with a substantial verdict rendered in favor of the plaintiff(s), there can be no assurance that such verdict(s) would not exceed the Company's available insurance coverage and liquid assets. Failure by the Company to meet required future cash payments to resolve the outstanding product liability claims would have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

On April 1, 2005 the Company bound coverage for the 2005/2006 insurance policy year. This policy is a three-year claims made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2006 and reported during the period April 1, 2005 through March 31, 2006 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

The Company maintains claims-made insurance policies to mitigate its financial exposure to product liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period. The Company periodically evaluates its exposure to unreported product liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. In July 2005 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of June 30, 2005. The independent firm estimated the unreported product loss liability using a frequency-severity approach, whereby projected losses were calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims were calculated based on the reported claim development method and the Bornhuetter-Ferguson method using a blend of the Company's historical claim experience and industry data. The estimated cost per claim was calculated using a lognormal claims model blending the Company's historical average

cost per claim with industry claims data. The independent actuarial firm used a number of assumptions in order to estimate the unreported product loss liability including:

- o A ceiling of \$5 million was selected for actuarial purposes in determining the liability per claim given the uncertainty in projecting claim losses in excess of \$5 million,
- o The future claim reporting lag time would be a blend of the Company's experiences and industry data,
- o The frequency of unreported claims for accident years 2001 through 2005 would be lower than the Company's experience since the 2002/2003 policy year, but higher than the Company's historical claim frequency prior to the 2002/2003 policy year,
- o The average cost per claim would be lower than the Company's experience since the 2002/2003 policy year, but higher than the Company's historical cost per claim prior to the 2002/2003 policy year,
- o The average cost per BioGlue claim would be consistent with the Company's overall historical exposures until adequate historical data is available on this product line, and
- o The number of BioGlue claims per million dollars of BioGlue revenue would be 30% lower than non-BioGlue claims per million dollars of revenue. The 30% factor was selected based on BioGlue claims experience to-date and the actuary's judgment.

The Company believes that these assumptions provide a reasonable basis for the calculation of the unreported product liability loss, but actual developments could differ materially from the assumptions above. The accuracy of the actuarial firm's estimates is limited by the general uncertainty that exists for any estimate of future activity, uncertainties surrounding the assumptions used, and Company specific conditions including the FDA Order, the Company's recent levels of litigation activity, the Company's low volume of pre-FDA Order historical claims, and the scarcity of industry data directly relevant to the Company's business activities. Due to these factors, actual results may differ significantly from the amounts accrued.

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Based on the actuarial valuation performed in July 2005 as of June 30, 2005, the Company estimated that its liability for unreported product liability claims was \$8.0 million. The \$8.0 million balance is included as a component of accrued expenses and other current liabilities of \$4.1 million and other long-term liabilities of \$3.9 million on the June 30, 2005 Summary Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as \$14.3 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. Based on the actuarial valuation, the Company estimated that as of June 30, 2005, \$2.3 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$2.3 million insurance recoverable is included as a component of other receivables of \$950,000 and other long-term assets of \$1.4 million on the June 30, 2005 Summary Consolidated Balance Sheet. These amounts represent management's estimate of the probable losses and anticipated recoveries for unreported product liability claims related to services performed and products sold prior to June 30, 2005. Actual results may differ from this estimate.

#### *Class Action Lawsuit*

Several putative class action lawsuits were filed in July through September 2002 against the Company and certain officers of the Company, alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 based on a series of purportedly materially false and misleading statements to the market. The suits were consolidated, and a consolidated amended complaint filed, that principally alleges that the Company made misrepresentations and omissions relating to product safety and the Company did not comply with certain FDA regulations regarding the handling and processing of certain tissues and other product safety matters. The consolidated complaint seeks certification of a class of purchasers between April 2, 2001 and August 14, 2002, compensatory damages, and other expenses of litigation. The Company and the other defendants filed a motion to dismiss the consolidated complaint on February 28, 2003, which motion the U.S. District Court for the Northern District of Georgia denied in part and granted in part on May 27, 2003. The discovery phase of the case commenced on July 16, 2003. On December 16, 2003 the Court certified a class of individuals and entities who purchased or otherwise acquired CryoLife stock from April 2, 2001 through August 14, 2002. On March 11, 2005 defendants moved for summary judgment on all of plaintiffs' claims, and plaintiffs moved for partial summary judgment as to some of their claims against certain defendants. On June 17, 2005 the court denied plaintiffs' motion for partial summary judgment and granted in part and denied in part defendants' motion for summary judgment.

On July 21, 2005 the Company reached an agreement in principle to settle the securities class action lawsuit. The settlement will resolve all claims asserted against the Company and the individual defendants in this case. The terms of the settlement, which must be approved by the court following notice to the class, include a total settlement of \$23.25 million, approximately \$11.5 million of which is expected to be paid from insurance proceeds. The remainder of the settlement is comprised of a cash payment from the Company of approximately \$8.0 million, expected to be paid in the third or fourth quarter of 2005, and common stock with a stipulated value of approximately \$3.75 million. The Company and the individual defendants have denied any wrongdoing and liability whatsoever, and the settlement does not contain any admission of liability.

As a result of this settlement as of June 30, 2005, the Company has accrued \$23.25 million as a component of accrued expense and other current liabilities, recorded a receivable from its insurance company of \$11.5 million as a component of other receivables, and recorded an expense of \$11.75 million in general, administrative, and marketing expenses. Additionally, as of June 30, 2005 the Company had accrued \$701,000 for legal fees incurred but unpaid related to this case and recorded an asset of \$701,000 representing the anticipated recovery of these fees from the Company's insurance carrier. The \$701,000 accrual is included as a component of accrued expenses and other current liabilities and the \$701,000 insurance receivable is included as a component of other receivables on the June 30, 2005 Summary Consolidated Balance Sheet. The Company believes that the receivable will be fully collectible.

#### *Shareholder Derivative Action*

On August 30, 2002 a purported shareholder derivative action was filed by Rosemary Lichtenberger against Steven G. Anderson, Albert E. Heacox, John W. Cook, Ronald C. Elkins, Virginia C. Lacy, Ronald D. McCall, Alexander C. Schwartz, and Bruce J. Van Dyne in the Superior Court of Gwinnett County, Georgia. The suit, which names the Company as a nominal defendant, alleges that the individual defendants breached their fiduciary duties to the Company by causing or allowing the Company to engage in certain inappropriate practices that caused the Company to suffer damages. The complaint was preceded by one day by a letter written on behalf of Ms. Lichtenberger demanding that the Company's Board of Directors take certain actions in response to her allegations. On January 16, 2003 another purported derivative suit alleging claims similar to those of the Lichtenberger suit was filed in the Superior Court of

Fulton County by complainant Robert F. Frailey. As in the Lichtenberger suit, the filing of the complaint in the Frailey action was preceded by a demand letter sent on Frailey's behalf to the Company's Board of Directors. Both complaints seek undisclosed damages, costs and attorney's fees, punitive damages, and prejudgment interest against the individual defendants derivatively on behalf of the Company. As previously disclosed, the Company's Board of Directors established an independent committee to investigate the allegations of Ms. Lichtenberger and Mr. Frailey. The independent committee engaged independent legal counsel to assist in the investigation, which culminated in a report by the committee concluding that no officer or director breached any fiduciary duty. In October 2003 the two derivative suits were consolidated into one action in the Superior Court of Fulton County, and a consolidated amended complaint was filed. The independent committee, along with its independent legal counsel, evaluated the consolidated amended complaint and concluded that its prior report and determination addressed the material allegations contained in the consolidated amended complaint. The committee reiterated its previous conclusions and determinations, including that maintaining the derivative litigation is not in the best interests of the Company. The Company filed a motion to dismiss, which was denied by the Superior Court of Fulton County in an order dated December 1, 2004.

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The Company has been in settlement discussions with the respect to the shareholder derivative lawsuit. A settlement has been agreed to by the parties, approved by the board, and submitted to the court. It remains subject to final court approval. Pursuant to the proposed settlement, the Company anticipates that the fees and expenses of the plaintiffs' counsel will be approximately \$3.5 million. Therefore, the Company accrued a total of \$3.5 million as a component of accrued expenses and other current liabilities as of June 30, 2005. Additionally, the Company has recorded \$3.5 million in other receivables as of June 30, 2005 representing amounts the Company expects to recover from the insurance carriers. Additionally, as part of the settlement, the Company and its management have also agreed to several changes in corporate governance, including the identification and appointment of a new director with regulatory experience, the formation of a regulatory affairs and quality assurance committee, and the adoption of SFAS 123 Revised "Share-Based Payment" ("SFAS 123-R") in the quarter preceding the quarter in which expensing of share-based payments is required, which is expected to be fourth quarter of 2005.

#### *SEC Investigation*

On August 19, 2002 the Company issued a press release announcing that on August 17, 2002, the Company received a letter from the Atlanta District Office of the SEC inquiring about certain matters relating to the Company's August 14, 2002 announcement of the FDA Order. The SEC notified the Company in July 2003 that the inquiry became a formal investigation in June 2003. CryoLife has cooperated with this investigation both before and after the issuance of the formal order of investigation in June 2003 and intends to continue doing so. CryoLife voluntarily reported the names of six employees and former employees to the SEC in December 2002 after discovering they had apparently sold CryoLife shares on August 14, 2002, before trading was halted pending CryoLife's press release reporting the FDA Order. These individuals were not and are not executive officers of CryoLife. The formal order of investigation indicates that the SEC's scope includes whether, during 2002, among other things, CryoLife or others may have traded while in possession of material nonpublic information, made (or caused to be made) false or misleading statements or omissions in press releases and SEC filings, and failed to maintain accurate records and adequate controls. The investigation could also encompass matters not specifically identified in the formal order. As of the date hereof, the SEC has had no discussions with CryoLife representatives as to whether or against whom it will seek relief, or the nature of any relief that may be sought. At present, CryoLife is unable to predict the ultimate focus or outcome of the investigation, or when it will be completed. An unfavorable outcome could have a material adverse effect on CryoLife's reputation, business, financial position, results of operations, and cash flows.

#### **Note 14 — Subsequent Events**

At August 2, 2005 the Company had issued shares or accrued amounts equivalent to approximately 10,987 common shares for Dividend Make-Whole Payments on the conversion of 10,000 shares of Preferred Stock that took place subsequent to June 30, 2005, which will result in a non-operating expense of approximately \$53,000 in the third quarter of 2005.

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## **PART I — FINANCIAL INFORMATION**

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

#### **Overview**

For CryoLife, Inc. ("CryoLife" or the "Company") the quarter ended June 30, 2005 focused on continued revenue growth and improved margins over the prior year quarter. In the second quarter of 2005 the Company experienced a 12% growth in revenues over the prior year quarter, which consisted of growth in both BioGlue and tissue preservation services. This revenue growth was accompanied by improved tissue yields, which reduced the cost of tissue processing as a percentage of tissue service revenues. On July 21, 2005 the Company agreed in principle to settle the class action lawsuit for \$23.25 million, approximately \$11.5 million of which is expected to be paid from insurance proceeds. The remainder of the settlement is comprised of a cash payment of \$8.0 million, expected to be paid in the third or fourth quarter of 2005, and common stock with a stipulated value of approximately \$3.75 million. See the "Results of Operations" section below for additional analysis of the second quarter results.

#### **FDA Order on Human Tissue Preservation**

On August 13, 2002 the Company received an order from the Atlanta district office of the FDA regarding the non-valved cardiac, vascular, and orthopaedic tissues processed by the Company since October 3, 2001 (the "FDA Order"). The FDA Order followed an April 2002 FDA Form 483 Notice of Observations ("April 2002 483") and an FDA Warning Letter dated June 17, 2002, ("Warning Letter"). Pursuant to the FDA Order, the Company placed non-valved cardiac, vascular, and orthopaedic tissue subject to the FDA Order (i.e. processed since October 3, 2001) on quality assurance quarantine and recalled the portion of those tissues that had been distributed but not implanted. In addition the Company ceased processing non-valved cardiac, vascular, and orthopaedic tissues.

On September 5, 2002 the Company entered into an agreement with the FDA (the "Agreement") that supplemented the FDA Order and allowed non-valved cardiac and vascular tissues subject to the recall (processed between October 3, 2001 and September 5, 2002) to be released for distribution after the Company had completed steps to ensure that the tissue was used for approved purposes and that patients were notified of risks associated with tissue use. The Agreement had a renewable 45-business day term, and the final renewal expired on September 5, 2003. The Company is no longer shipping tissue subject to the recall (processed between October 3, 2001 and September 5, 2002). A renewal of the Agreement that expired on September 5, 2003 was not needed in

order for the Company to continue to distribute non-valved cardiovascular, vascular, and orthopaedic tissues processed after September 5, 2002.

In addition, pursuant to the Agreement, the Company agreed to perform additional procedures in the processing of non-valved cardiac and vascular tissues and subsequently resumed processing these tissues. The Company also agreed to establish a corrective action plan within 30 days from September 5, 2002 with steps to validate processing procedures. The corrective action plan was submitted on October 5, 2002, and executed thereafter. The corrective actions taken have been reviewed by the FDA during three subsequent inspections as discussed in "Other FDA Correspondence and Notices" below.

#### **Other FDA Correspondence and Notices**

FDA Form 483 Notices of Observations ("483") were issued in connection with the FDA inspections of the Company's facilities in February 2003, October 2003, and February 2004. The Company responded to the February 2003 483 in March 2003, responded to the October 2003 483 in October 2003, November 2003, and April 2004, and responded to the February 2004 483 in March 2004, April 2004, and June 2004. On September 24, 2004 CryoLife received an inquiry from the FDA Atlanta District Office seeking additional information on four items submitted by CryoLife in response to the February 2004 483 to which CryoLife responded on November 8, 2004. In response to the Form 483 Notice of Observations, the Company has implemented new and revised existing processing, preservation, and testing procedures. On July 11, 2005 the FDA began an inspection of the Company's tissue processing facilities. The FDA may require the Company to implement additional corrective actions, perform additional validation testing, or supply additional information related to the inspections. The Company has and will continue to work with the FDA to review process improvements and address any outstanding observations.

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On February 20, 2003 the Company received a letter from the FDA stating that a 510(k) premarket notification should be filed for the Company's SynerGraft processed human cardiac tissues ("CryoValve® SG") and that premarket approval marketing authorization should be obtained for the Company's SynerGraft processed human vascular tissues ("CryoVein® SG") when marketed or labeled as an arteriovenous ("A-V") access graft. The agency's position is that use of the SynerGraft® technology in the processing of allograft heart valves represents a modification to the Company's legally marketed CryoValve allograft and that vascular allografts labeled for use as A-V access grafts are medical devices that require premarket approval.

On November 3, 2003 the Company filed a 510(k) premarket notification with the FDA for the CryoValve SG. On February 4, 2004 the Company received a letter from the FDA requesting additional information. On August 24, 2004 the Company submitted an amendment to its original 510(k) submission providing clarification and additional information. The FDA requested further additional information in November 2004. On June 8, 2005 CryoLife responded to some of these additional requests. CryoLife also has initiated an appeal of others through administrative procedures. The FDA may still require that additional studies be undertaken and may never clear the 510(k) premarket notification. Clearance of the 510(k) premarket notification with the FDA will be required before the Company can resume distribution of SynerGraft processed CryoValve SG.

On December 8, 2003 the Company received a letter from the FDA stating that it was the agency's position that cardiovascular tissues processed with the SynerGraft technology should be regulated as medical devices. On September 14, 2004 the Company met with the FDA to discuss the data to be used to support a formal Request for Designation ("RFD") filing for SynerGraft processed cardiovascular tissue, including the CryoVein SG. An RFD submission establishes the regulatory status of the tissue. The Company submitted the RFD on October 5, 2004. The FDA affirmed its original decision in letters received in December 2004. That decision is currently subject to an administrative appeal. Unless this appeal is successful, CryoLife will be unable to distribute tissues with the SynerGraft technology until further submissions and FDA clearances are granted. In the event that the Company is not successful in appealing the FDA's decision to regulate SynerGraft vascular tissue as a medical device, the Company will evaluate whether it will file and seek a premarket approval for CryoVein SG or discontinue the CryoVein SG.

In 2003 the Company suspended the use of the SynerGraft technology in the processing of allograft tissue and the distribution of tissues on hand previously processed with the SynerGraft technology until the regulatory issues associated with these tissues are resolved. Additionally, the Company discontinued labeling its vascular grafts for use as A-V access grafts. Until such time as the issues surrounding SynerGraft are resolved, the Company will employ its traditional processing methods on these tissues. During the year ended December 31, 2004, the Company wrote down \$353,000 in SynerGraft processed cardiovascular and vascular tissues. As of June 30, 2005 the Company had no deferred preservation costs related to SynerGraft processed tissues on its Summary Consolidated Balance Sheet.

#### **Critical Accounting Policies**

A summary of the Company's significant accounting policies is included in Note 1 to the summary consolidated financial statements, as filed in the Form 10-K for the fiscal year ended December 31, 2004. 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 United States for interim financial information, which require the Company to make estimates and assumptions. The following are accounting policies that management believes are most important to the portrayal of the Company's financial condition and results and may involve a higher degree of judgment and complexity.

**Product Liability Claims:** In the normal course of business as a medical device and services company, the Company has product liability complaints filed against it. Following the FDA Order, a greater number of lawsuits than has historically been experienced were filed. As of August 2, 2005 the Company was aware of eight pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, two allege product liability claims arising out of the Company's orthopaedic tissue services, four allege product liability claims arising out of the Company's allograft heart valve tissue services, one alleges product liability claims arising from BioGlue, and one alleges product liability claims arising out of the non-tissue products made by Ideas for Medicine, Inc. when it was a subsidiary of the Company.

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As of August 2, 2005 there were two outstanding product liability lawsuits against the Company that are covered by two separate insurance policies in the 2000/2001 and 2004/2005 policy years. The Company believes its insurance policies to be adequate to defend against the covered lawsuits in each of these time periods. Additionally, the Company has six outstanding product liability lawsuits against the Company that are not covered by insurance policies, as either the Company has used all of its insurance coverage related to that policy year, or the claims were asserted against the Company in periods after the coverage in the related incident year had lapsed. Additional uninsured claims may be filed in the future. Other product liability claims have been asserted

against the Company that have not resulted in lawsuits. The Company is monitoring these claims.

The Company performed an analysis as of June 30, 2005 of the settled but unpaid claims and the pending product liability claims based on settlement negotiations to date and advice from counsel. As of June 30, 2005 the Company had accrued a total of \$933,000 for settled but unpaid claims and pending product liability claims and recorded zero representing amounts to be recovered from the Company's insurance carriers. The \$933,000 accrual is included as a component of accrued expenses and other current liabilities on the June 30, 2005 Summary Consolidated Balance Sheet. This amount represents the Company's estimate of the probable losses related to one settled but unpaid claim and four of the eight pending product liability claims. The Company has not recorded an accrual for the remaining four product liability claims because management has concluded that either a loss is remote or that, although a loss is reasonably possible or probable, a reasonable estimate of that loss or the range of losses cannot be made at this time.

The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. The Company is currently unable to reasonably estimate the maximum amount of the possible loss related to these claims, as many of the claims do not specify the damages sought and the Company does not have a reasonable method for estimating the amount of compensatory or punitive damages that could be assessed by a trial jury. Additionally, if the Company is unable to settle the outstanding claims for amounts within its ability to pay or one or more of the product liability claims in which the Company is a defendant should be tried with a substantial verdict rendered in favor of the plaintiff(s), there can be no assurance that such verdict(s) would not exceed the Company's available insurance coverage and liquid assets. Failure by the Company to meet required future cash payments to resolve the outstanding product liability claims would have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

On April 1, 2005 the Company bound coverage for the 2005/2006 insurance policy year. This policy is a three-year claims made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2006 and reported during the period April 1, 2005 through March 31, 2006 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

The Company maintains claims-made insurance policies to mitigate its financial exposure to product liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period. The Company periodically evaluates its exposure to unreported product liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. In July 2005, the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of June 30, 2005. The independent firm estimated the unreported product loss liability using a frequency-severity approach, whereby projected losses were calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims were calculated based on the reported claim development method and the Bornhuetter-Ferguson method using a blend of the Company's historical claim experience and industry data. The estimated cost per claim was calculated using a lognormal claims model blending the Company's historical average cost per claim with industry claims data. The independent actuarial firm used a number of assumptions in order to estimate the unreported product loss liability including:

- o A ceiling of \$5 million was selected for actuarial purposes in determining the liability per claim given the uncertainty in projecting claim losses in excess of \$5 million,

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- o The future claim reporting lag time would be a blend of the Company's experiences and industry data,
  - o The frequency of unreported claims for accident years 2001 through 2005 would be lower than the Company's experience since the 2002/2003 policy year, but higher than the Company's historical claim frequency prior to the 2002/2003 policy year,
  - o The average cost per claim would be lower than the Company's experience since the 2002/2003 policy year, but higher than the Company's historical cost per claim prior to the 2002/2003 policy year,
  - o The average cost per BioGlue® Surgical Adhesive ("BioGlue") claim would be consistent with the Company's overall historical exposures until adequate historical data is available on this product line, and
  - o The number of BioGlue claims per million dollars of BioGlue revenue would be 30% lower than non-BioGlue claims per million dollars of revenue. The 30% factor was selected based on BioGlue claims experience to-date and the actuary's judgment.

The Company believes that these assumptions provide a reasonable basis for the calculation of the unreported product liability loss, but actual developments could differ materially from the assumptions above. The accuracy of the actuarial firm's estimates is limited by the general uncertainty that exists for any estimate of future activity and uncertainties surrounding the assumptions used and due to Company specific conditions including the FDA Order, the Company's recent levels of litigation activity, the Company's low volume of pre-FDA Order historical claims, and the scarcity of industry data directly relevant to the Company's business activities. Due to these factors, actual results may differ significantly from the amounts accrued.

Based on the actuarial valuation performed in July 2005 as of June 30, 2005, the Company estimated that its liability for unreported product liability claims was \$8.0 million. The \$8.0 million balance is included as a component of accrued expenses and other current liabilities of \$4.1 million and other long-term liabilities of \$3.9 million on the June 30, 2005 Summary Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as \$14.3 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. Based on the actuarial valuation, the Company estimated that as of June 30, 2005, \$2.3 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$2.3 million insurance recoverable is included as a component of other receivables of \$950,000 and other long-term assets of \$1.4 million on the June 30, 2005 Summary Consolidated Balance Sheet. These amounts represent management's estimate of the probable losses and anticipated recoveries for unreported product liability claims related to services performed and products sold prior to June 30, 2005. Actual results may differ from this estimate.

**Deferred Preservation Costs:** Tissue is procured from deceased human donors by organ and tissue procurement agencies, which consign the tissue to the Company for processing and preservation. Preservation costs related to tissue held by the Company are deferred until revenue is recognized upon shipment of the tissue to the implanting facilities. Deferred preservation costs consist primarily of direct labor and materials including laboratory expenses, tissue procurement fees, freight-in charges, and fringe benefits, indirect costs including allocations of costs from departments that support processing activities, and



facility allocations. Deferred preservation costs are stated on a first-in, first-out basis.

The calculation of deferred preservation costs includes a high degree of judgment and complexity. The costs included in deferred preservation costs contain several estimates due to the timing differences between the occurrence of the cost and receipt of final bills for services. Costs that contain estimates include tissue procurement fees, which are estimated based on the Company's contracts with independent procurement agencies, and freight-in charges, which are estimated based on the Company's prior experiences with these charges. These costs are adjusted for differences between estimated and actual fees when invoices for these services are received. Management believes that its estimates approximate the actual costs of these services, but estimates could differ from actual costs. Total deferred preservation costs are then allocated among the different tissues processed during the period based on specific cost drivers such as the number of donors and the number of tissues processed. At each balance sheet date a portion of the deferred preservation costs relates to tissues currently in active processing or held in quarantine pending release to implantable status. The Company applies a yield estimate to all tissues in process and in quarantine to estimate the portion of tissues that will ultimately become implantable. Management determines this estimate of quarantine yields based on its experience in prior periods and reevaluates this estimate periodically. Due to the nature of this estimate and the length of the processing times experienced by the Company, actual yields could differ from the Company's estimates. A significant change in quarantine yields could materially affect the deferred preservation costs per tissue, which could impact the amount of deferred preservation costs on the Company's Summary Consolidated Balance Sheet and the cost of preservation services, including the lower of cost or market write-down, described below, on the Company's Summary Consolidated Statement of Operations.

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During 2002 the Company recorded impairment write-downs of deferred preservation costs totaling \$32.7 million as a result of the FDA Order. The amount of these write-downs reflected management's estimates based on information available to it at the time the estimates were made and actual results did differ from these estimates. The write-down created a new cost basis, which cannot be written back up if and when these tissues become available for distribution. The cost of human tissue preservation services in the six months ended June 30, 2004 was favorably affected by tissue shipments that were related to previously written-down deferred preservation costs. The cost of human tissue preservation services was not materially affected by these write-downs in the six months ended June 30, 2005 and is not expected to be materially affected by these write-downs in future periods.

The Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value. The Company recorded \$392,000 and \$672,000, respectively, in the three and six months ended June 30, 2005 and \$1.2 million and \$4.8 million, respectively, in the three and six months ended June 30, 2004 as an increase to cost of preservation services to write-down the value of certain deferred tissue preservation costs that exceeded market value. The amount of these write-downs reflects management's estimates of market value based on recent average service fees. Actual results may differ from these estimates. The three and six months ended June 30, 2004 also included \$353,000 in costs related to the write-down of SynerGraft processed tissues.

As of June 30, 2005 deferred preservation costs consisted of \$2.9 million for allograft heart valve tissues, \$372,000 for non-valved cardiac tissues, \$4.1 million for vascular tissues, and \$3.1 million for orthopaedic tissues.

**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 generated deferred tax assets beginning in 2002 primarily as a result of write-downs of deferred preservation costs, accruals for product liability claims, and operating losses, reflecting reductions in revenues and additional professional fees, as a result of the FDA Order, subsequent FDA activities, and related events. The Company continued to generate deferred tax assets for the six months ended June 30, 2005 primarily as a result of operating losses. The Company periodically assesses the recoverability of its deferred tax assets and provides a valuation allowance when management believes it is more likely than not that its deferred tax assets will not be realized.

In assessing the recoverability of its deferred tax assets, the Company reviewed its historic operating results, including the reasons for its operating losses, uncertainties regarding projected future operating results due to the effects of the FDA Order and subsequent FDA activity, and the uncertainty of the outcome of litigation. Based on the results of this analysis, at December 31, 2004 the Company determined that it was more likely than not that the Company's deferred tax assets would not be realized. Therefore, as of December 31, 2004 the Company had a total of \$18.8 million in valuation allowances against deferred tax assets and a net deferred tax asset balance of zero.

For the six months ended June 30, 2005 the Company did not experience any changes that would materially affect the Company's analysis of and valuation of its deferred tax assets. As of June 30, 2005 the Company had a total of \$24.0 million in valuation allowances against deferred tax assets and a net deferred tax asset balance of zero.

**Valuation of Long-lived and Intangible Assets and Goodwill:** The Company assesses the impairment of its long-lived, identifiable intangible assets and related goodwill annually and whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that management considers important that could trigger an impairment review include the following:

- o Significant underperformance relative to expected historical or projected future operating results,
- o Significant negative industry or economic trends,

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- o Significant decline in the Company's stock price for a sustained period, and
  - o Significant decline in the Company's market capitalization relative to net book value.

Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"), requires the write-down of a long-lived asset to be held and used if the carrying value of the asset or the asset group to which the asset belongs is not recoverable. The carrying value of the asset or asset group is not recoverable if it exceeds the sum of the undiscounted future cash flows expected to result from the use and eventual disposition of the asset or asset group. In applying SFAS 144, the Company defined the specific asset groups used to perform the cash flow analysis. The Company defined the asset groups at the lowest level possible, by identifying the cash flows from groups of assets that could be segregated from the cash flows of other assets and liabilities. Using this methodology, the Company determined that its asset groups consisted of the long-lived assets related to the

Company's two reporting segments. As the Company does not segregate assets by segment, the Company allocated assets to the two reporting segments based on factors including facility space and revenues. The Company used an eleven-year period for the undiscounted future cash flows. This period of time was selected based upon the approximate remaining life of the primary assets of the asset groups, which are leasehold improvements. The undiscounted future cash flows related to these asset groups exceeded their carrying values as of December 31, 2004 and, therefore, management concluded that there was not an impairment of the Company's long-lived intangible assets and tangible assets related to the tissue preservation business or medical device business. However, depending on the Company's ability to rebuild demand for its tissue preservation services and the future effects of events surrounding the FDA Order, these assets may become impaired. Management will continue to evaluate the recoverability of these assets in accordance with SFAS 144. For the three and six months ended June 30, 2005 the Company did not experience any changes that would materially affect the Company's analysis of and recoverability of its long-lived assets.

SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"), requires goodwill resulting from business acquisitions and other intangible assets be subject to periodic impairment testing. The Company's intangible assets consist of patent costs, which are amortized over the expected useful lives of the patents (primarily 17 years) using the straight-line method, trademarks, which are non-amortizing, and other intangibles, which consist primarily of manufacturing rights and agreements and are amortized over the expected useful lives of the related assets (primarily five years). As of December 31, 2004 the Company did not believe that an impairment existed related to the other intangible assets that were assessed in accordance with SFAS No. 144.

**Derivative Instruments:** The terms of the Company's first quarter 6% convertible Preferred Stock offering include a Dividend Make-Whole Payment. If the Company elects to automatically convert, or the holder elects to voluntarily convert, some or all of the Preferred Stock into common stock prior to April 1, 2008, the Company will make an additional payment on the Preferred Stock equal to the aggregate amount of dividends that would have been payable on the Preferred Stock through and including April 1, 2008, less any dividends already paid on the Preferred Stock. The Dividend Make-Whole Payment is payable in cash or, at the Company's option, in shares of the Company's common stock, or a combination of cash and shares of common stock. In accordance with SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"), the Company is required to separate and account for, as an embedded derivative, the Dividend Make-Whole Payment feature of the Preferred Stock, the "Derivative". As an embedded derivative instrument, the Dividend Make-Whole Payment feature must be measured at fair value and reflected as a current liability on the Company's Summary Consolidated Balance Sheets. Changes in the fair value of the Derivative are recognized as the line item change in valuation of derivative as a non-operating income/expense on the Company's Summary Consolidated Statements of Operations.

The accounting for derivatives is complex, and requires significant judgments and estimates in determining the fair value in the absence of quoted market values. These estimates are based on valuation methodologies and assumptions deemed appropriate in the circumstances. The fair value of the dividend make-whole payment feature is based on various assumptions, including the estimated market volatility and discount rates used in determination of fair value. The use of different assumptions may have a material effect on the estimated fair value amount, which is reflected in the Company's results of operations and financial position.

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#### New Accounting Pronouncements

The Company will be required to adopt SFAS 123 Revised "Share-Based Payment" ("SFAS 123-R") as amended by SEC Rule 2005-57 "Commission Amends Compliance Dates For FASB Statement No. 123R on Employee Stock Options" for the fiscal year beginning January 1, 2006 per the SFAS 123-R. However, pursuant to the agreement in principle in the shareholder derivative action settlement, as discussed in Part I, Item 1, "Note 13 of the Notes to Summary Consolidated Financial Statements", upon finalization and court approval of the settlement the Company will be required to adopt of SFAS 123-R in the quarter preceding the quarter in which expensing of share-based payments is required, which is expected to be fourth quarter of 2005. SFAS 123-R requires companies to recognize the cost of all share-based payments in the financial statements using a fair-value based measurement method. Based on its preliminary analysis, the Company anticipates that the effect of implementing SFAS 123-R on its results of operations will be less than the amounts in the pro forma footnote disclosures currently required, but will have a significant impact on the Company's results of operations, assuming that the Company's stock price, option terms, and amounts of 2005 option grants are comparable with 2004. The Company anticipates it will adopt SFAS 123-R using the modified version of prospective application, as defined in SFAS 123-R. However, the Company is continuing to evaluate the adoption of SFAS 123-R.

The Company will be required to adopt SFAS 151 "Inventory Costs" ("SFAS 151") for the fiscal year ending December 31, 2006. SFAS 151 requires current period expensing of items such as idle facility expense, excessive spoilage, double freight, and rehandling costs and requires allocation of fixed production overheads to be based on the normal capacity of the production facilities. The Company is currently evaluating the impact of the adoption of SFAS 151 on its results of operations and financial position.

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#### Results of Operations (In thousands)

##### Revenues

|          | Three Months Ended<br>June 30, |           | Six Months Ended<br>June 30, |           |
|----------|--------------------------------|-----------|------------------------------|-----------|
|          | 2005                           | 2004      | 2005                         | 2004      |
| Revenues | \$ 17,198                      | \$ 15,314 | \$ 34,863                    | \$ 30,400 |

Revenues increased 12% and 15%, respectively, for the three and six months ended June 30, 2005 as compared to the three and six months ended June 30, 2004 due to increases in sales of BioGlue and increases in human tissue preservation service revenues.

Further discussion of the increases in BioGlue revenues and preservation service revenues for each of the three major tissue types processed by the Company continues in the detailed sections below.

## BioGlue

|  | Three Months Ended<br>June 30, |          | Six Months Ended<br>June 30, |           |
|--|--------------------------------|----------|------------------------------|-----------|
|  | 2005                           | 2004     | 2005                         | 2004      |
| Revenues   | \$ 9,552                       | \$ 8,962 | \$ 19,423                    | \$ 17,605 |
| BioGlue revenues as a<br>percentage of total revenue | 56%                            | 59%      | 56%                          | 58%       |

Revenues from the sale of BioGlue increased 7% for the three months ended June 30, 2005 as compared to the three months ended June 30, 2004. The 7% increase in revenues for the three months ended June 30, 2005 was primarily due to an increase in average selling prices, which increased revenues by 6%, and an increase in BioGlue sales volume, which increased revenues by 1%, primarily due to an increase in demand at the Company's European subsidiary.

Revenues from the sale of BioGlue increased 10% for the six months ended June 30, 2005 as compared to the six months ended June 30, 2004. The 10% increase in revenues for the six months ended June 30, 2005 was primarily due to an increase in average selling prices, which increased revenues by 6%, and an increase in BioGlue sales volume, which increased revenues by 4%, primarily due to an increase in demand at the Company's European subsidiary.

The price increase was primarily due to an increase in average selling prices, due to list price increases that went into effect on January 1, 2005 domestically. The volume increase was primarily due to demand for the new BioGlue syringe product, which was introduced in mid 2004, partially offset by decreases in other BioGlue products as customers transitioned to the syringe product line. Domestic revenues accounted for 74% and 76% of total BioGlue revenues for the three and six months ended June 30, 2005, and 78% and 79% of total BioGlue revenues for the three and six months ended June 30, 2004.

The Company anticipates that revenues from BioGlue will continue to grow for the full year 2005 when compared to 2004 primarily due to the price increase that went into effect on January 1, 2005.

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## Cardiovascular Preservation Services

|   | Three Months Ended<br>June 30, |          | Six Months Ended<br>June 30, |          |
|---|--------------------------------|----------|------------------------------|----------|
|   | 2005                           | 2004     | 2005                         | 2004     |
| Revenues  | \$ 3,518                       | \$ 2,831 | \$ 7,268                     | \$ 6,261 |
| Cardiovascular revenues as a<br>percentage of total revenue | 20%                            | 18%      | 21%                          | 21%      |

Revenues from cardiovascular preservation services increased 24% for the three months ended June 30, 2005 as compared to the three months ended June 30, 2004. The 24% increase in revenues for the three months ended June 30, 2005 was due to an increase in average service fees, which increased revenues by 27%, partially offset by a decrease in cardiovascular volume, which reduced revenues by 3%.

Revenues from cardiovascular preservation services increased 16% for the six months ended June 30, 2005 as compared to the six months ended June 30, 2004. The 16% increase in revenues for the six months ended June 30, 2005 was due to an increase in average service fees, which increased revenues by 28%, partially offset by a decrease in cardiovascular volume, which reduced revenues by 12%.

The price increase reflected the fee increases that went into effect in July 2004 and January 2005. The fee increases primarily increased revenues for traditionally processed pulmonary valves and aortic valves. The decrease in cardiovascular volume is primarily due to reduced amount of tissues available for implantation as a result of a decline in procurement levels as discussed below.

The Company's procurement of cardiac tissues, from which heart valves and non-valved cardiac tissues are processed, decreased 21% during the three months ended June 30, 2005 as compared to the three months ended June 30, 2004 and decreased 3% during the three months ended June 30, 2005 as compared to the three months ended March 31, 2005. Procurement levels of cardiac tissues remain significantly below procurement levels in the second quarter of 2002, prior to the FDA Order.

The Company anticipates that cardiovascular service revenues will benefit in the remainder of 2005, if and to the extent tissues available for implantation increase due to expected improvements in procurement and in the Company's tissue processing yields. Process changes were implemented during 2004 and 2005 and others are being evaluated for future implementation. Cardiovascular revenues for 2005 should also be favorably affected by the fee increases implemented in July 2004 and January 2005.

As discussed in "Other FDA Correspondence and Notices" the Company has suspended the use of the SynerGraft technology in the processing of allograft cardiovascular tissue and in late September 2003 suspended the distribution of tissues on hand that were processed with the SynerGraft technology until the regulatory status of the CryoValve SG is resolved. At this time, the Company cannot estimate when or if it will resume processing allograft cardiovascular tissue using the SynerGraft technology.

## Vascular Preservation Services

|   | Three Months Ended<br>June 30, |          | Six Months Ended<br>June 30, |          |
|---|--------------------------------|----------|------------------------------|----------|
|   | 2005                           | 2004     | 2005                         | 2004     |
| Revenues  | \$ 2,740                       | \$ 2,649 | \$ 5,456                     | \$ 5,135 |
| Vascular revenues as a<br>percentage of total revenue | 16%                            | 17%      | 16%                          | 17%      |

Revenues from vascular preservation services increased 3% for the three months ended June 30, 2005 as compared to the three months ended June 30, 2004. The 3% increase in revenues for the three months ended June 30, 2005 was due to an increase in average service fees, which increased revenues by 24%, largely offset by a decrease in vascular volume, which reduced revenues by 21%.

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Revenues from vascular preservation services increased 6% for the six months ended June 30, 2005 as compared to the six months ended June 30, 2004. The 6% increase in revenues for the six months ended June 30, 2005 was due to an increase in average service fees, which increased revenues by 25%, largely offset by a decrease in vascular volume, which reduced revenues by 19%.

The price increase reflected the fee increases that went into effect in July 2004 and January 2005 on all vascular tissues. The decrease in vascular volume is primarily due to reduced amount of tissues available for implantation as a result of a decline in procurement levels during the first half of 2005 as compared to the first half of 2004.

The Company's procurement of vascular tissues increased 1% during the three months ended June 30, 2005 as compared to the three months ended June 30, 2004 and increased 33% during the three months ended June 30, 2005 as compared to the three months ended March 31, 2005. Procurement levels of vascular tissues remain significantly below procurement levels in the second quarter of 2002, prior to the FDA Order.

The Company anticipates that vascular service revenues will benefit in the remainder of 2005, if and to the extent tissues available for implantation increase through expected improvements in procurement and in the Company's tissue processing yields, as well as from the fee increases implemented in July 2004 and January 2005.

#### ***Orthopaedic Preservation Services***

|  | Three Months Ended<br>June 30, |        | Six Months Ended<br>June 30, |        |
|--|--------------------------------|--------|------------------------------|--------|
|  | 2005                           | 2004   | 2005                         | 2004   |
| Revenues   | \$ 1,094                       | \$ 574 | \$ 2,166                     | \$ 883 |
| Orthopaedic revenues as a<br>percentage of total revenue | 6%                             | 4%     | 6%                           | 3%     |

Revenues from orthopaedic preservation services increased 91% for the three months ended June 30, 2005 as compared to the three months ended June 30, 2004. The 91% increase in revenues for the three months ended June 30, 2005 was due to an increase in orthopaedic volume, which increased revenues by 94%, partially offset by a decrease in average service fees, which decreased revenues by 3%.

Revenues from orthopaedic preservation services increased 145% for the six months ended June 30, 2005 as compared to the six months ended June 30, 2004. The 145% increase in revenues for the six months ended June 30, 2005 was due to an increase in orthopaedic volume, which increased revenues by 145%.

The volume increase was primarily due to an increase in shipments of non-boned tendons and osteochondral grafts. The increase in orthopaedic tissue shipments is directly related to the low volume of shipments in 2004 due to low levels of orthopaedic tissues available for shipment due to lower yields of implantable tissue per donor as a result of process changes implemented subsequent to the FDA Order and increased tissue processing and release times.

The Company's procurement of orthopaedic tissues decreased 30% during the three months ended June 30, 2005 as compared to the three months ended June 30, 2004 and increased 20% during the three months ended June 30, 2005 as compared to the three months ended March 31, 2005. Procurement levels of orthopaedic tissues remain significantly below procurement in the second quarter of 2002, prior to the FDA Order.

The Company anticipates that orthopaedic service revenues will benefit in the remainder of 2005 due to the reintroduction of osteochondral grafts in February 2005, which have not been part of the Company's service offerings since the FDA Order was issued in August 2002. Revenues will additionally benefit, if and to the extent tissues available for implantation increase through expected improvements in procurement and in the Company's tissue processing yields.

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#### ***Grant Revenues***

Grant revenues were zero and \$57,000, respectively, for the three months ended June 30, 2005 and 2004. Grant revenues were zero and \$59,000, respectively, for the six months ended June 30, 2005 and 2004.

The 2005 Defense Appropriations Conference Report included \$1 million for the development of BioFoam™. In February 2005 CryoLife submitted a proposal to the Department of Defense for the use of these funds. These funds are expected to result in an increase in grant revenues in the second half of 2005.

#### ***Cost of Products***

Cost of products aggregated \$2.1 million and \$4.2 million, respectively, for the three and six months ended June 30, 2005, representing 21% of total product revenues during each such period. Cost of products aggregated \$1.9 million and \$3.8 million, respectively, for the three and six months ended June 30, 2004, representing 21% of total product revenues during such periods.

#### ***Cost of Human Tissue Preservation Services***

Cost of human tissue preservation services decreased to \$6.1 million and \$12.0 million for the three and six months ended June 30, 2005, respectively, as compared to \$7.5 million and \$16.6 million for the three and six months ended June 30, 2004, respectively. The decrease in cost of human tissue preservation services is primarily due to improvements in the Company's tissue processing yields. Cost of human tissue preservation services for the three and six months ended June 30, 2005 includes the write-down of \$392,000 and \$672,000, respectively, as compared to \$1.2 million and \$4.8 million for the three and six months ended June 30, 2004, respectively, of certain deferred preservation costs that exceeded market value. The three and six months ended June 30, 2004 also included \$353,000 in costs related to the write-down of SynerGraft processed tissues. See "Critical Accounting Policies—Deferred Preservation Costs" above. The write-down of deferred tissue preservation costs in both the three and six months ended June 30, 2005 and 2004 is primarily due to higher overhead cost allocations per unit associated with lower tissue processing volumes and changes in processing methods subsequent to the FDA Order.

Cost of human tissue preservation services as a percentage of tissue preservation service revenues was 83% and 80% for the three and six months ended June 30, 2005, respectively, as compared to 125% and 136% for the three and six months ended June 30, 2004, respectively. The decrease in cost of human tissue preservation services as a percentage of tissue preservation service revenues is primarily due to improvements in the Company's tissue processing yields. Cost of human tissue preservation services as a percentage of tissue preservation service revenues was favorably affected by shipments of tissue with a zero cost basis for which revenues were recognized but costs, estimated to be \$173,000 and \$530,000 for the three and six months ended June 30, 2004, had already been recorded in previous periods primarily related to write-downs of deferred preservation costs in 2002. The write-downs of deferred preservation costs during 2002 created a new cost basis, which cannot be written back up when these tissues are shipped or become available for shipment.

The Company anticipates that cost of human tissue preservation services as a percentage of tissue preservation service revenues will benefit in the remainder of 2005 from any increases in the amount of tissues processed, or any increases in yields of implantable tissue per donor, as well as increases in average service fees due to fee increases implemented in July 2004 and January 2005. The cost of human tissue preservation services as a percentage of revenue will likely continue to be high compared to pre-FDA Order levels as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue.

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

General, administrative, and marketing expenses increased 123% to \$21.6 million for the three months ended June 30, 2005, compared to \$9.7 million for the three months ended June 30, 2004, representing 126% and 63%, respectively, of total revenues during such periods. General, administrative, and marketing expenses increased to \$31.6 million for the six months ended June 30, 2005, compared to \$19.8 million for the six months ended June 30, 2004, representing 91% and 65%, respectively, of total revenues during such periods. General, administrative, and marketing expenses increased due to \$11.8 million in expense related to the settlement of the shareholder class action lawsuit as discussed in Part I, Item 1, "Note 13 of the Notes to Summary Consolidated Financial Statements." General, administrative, and marketing expenses also includes a favorable adjustment to the unreported product liability accruals of approximately \$800,000 and \$1.1 million for the three and six months ended June 30, 2005, respectively, and approximately \$800,000 for both the three and six months ended June 30, 2004. The remaining increase in expenses for the six months ended June 30, 2005 was primarily due to an increase in expenses at the Company's European subsidiary related to the relocation of that facility in April 2005 and due to increases in expenses necessary to support increasing revenues.

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#### ***Research and Development Expenses***

Research and development expenses were \$929,000 for the three months ended June 30, 2005, compared to \$891,000 for the three months ended June 30, 2004, representing 5% and 6%, respectively, of total revenues during such periods. Research and development expenses were \$1.9 million for the six months ended June 30, 2005, compared to \$1.8 million for the six months ended June 30, 2004, representing 5% and 6%, respectively, of total revenues during such periods. Research and development spending in 2005 and 2004 was primarily focused on the Company's tissue preservation, SynerGraft, and Protein Hydrogel Technologies ("PHT"), which include BioGlue and related products.

The 2005 Defense Appropriations Conference Report included \$1 million for the development of BioFoam. In February 2005 CryoLife submitted a proposal to the Department of Defense for the use of these funds. Depending on the timing of the release of funds, research and development expenses may increase in the second half of 2005 due to additional expenditures related to BioFoam.

#### ***Other Costs and Expenses***

Interest expense increased to \$88,000 for the three months ended June 30, 2005, compared to \$59,000 for the three months ended June 30, 2004. Interest expense increased to \$143,000 for the six months ended June 30, 2005, compared to \$102,000 for the six months ended June 30, 2004. Interest expense for the three and six months ended June 30, 2005 included interest incurred related to the Company's credit agreement, short term notes payable, and capital leases. Interest expense for the three and six months ended June 30, 2004 included interest incurred related to the Company's short term notes payable and capital leases.

Interest income increased to \$167,000 for the three months ended June 30, 2005, compared to \$64,000 for the three months ended June 30, 2004. Interest income increased to \$242,000 for the six months ended June 30, 2005, compared to \$130,000 for the six months ended June 30, 2004. Interest income in both periods was primarily due to interest earned on the Company's cash, cash equivalents, and marketable securities.

The change in valuation of the derivative was a \$902,000 and \$784,000 expense for the three and six months ended June 30, 2005 compared to zero for the three and six months ended June 30, 2004. The change in valuation of derivative in the three and six months ended June 30, 2005 reflects the amount of the Dividend Make-Whole Payment on preferred shares converted during the period and the amount of the change in valuation of the derivative.

The Company's income tax expense of \$46,000 and \$84,000 for the three and six months ended June 30, 2005 is related to foreign taxes on income of the Company's wholly owned European subsidiary. The Company's income tax benefit of \$1.4 million for the three and six months ended June 30, 2004 was due to the receipt of tax refunds related to product liability expenses incurred in 2003.

#### ***Seasonality***

The demand for BioGlue appears to experience some seasonality, with a flattening or slight 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 fewer surgeries being performed on adult patients in the summer months. The Company will continue to evaluate the seasonal nature of BioGlue sales.

The demand for the Company's cardiovascular tissue preservation services is seasonal, with peak demand generally occurring in the second and third quarters. Management believes this trend for cardiovascular tissue preservation services is primarily due to the high number of surgeries scheduled during the summer months for school aged patients, who drive the demand for a large percentage of CryoLife's cardiovascular tissues.

The demand for the Company's human vascular and orthopaedic tissue preservation services and bioprosthetic cardiovascular and vascular devices does not appear to experience seasonal trends.

## **Liquidity and Capital Resources**

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

At June 30, 2005 net working capital (current assets of \$69.3 million less current liabilities of \$45.3 million) was \$24.0 million, with a current ratio (current assets divided by current liabilities) of 2 to 1, compared to net working capital of \$19.7 million, with a current ratio of 2 to 1 at December 31, 2004. The Company's primary capital requirements historically arose out of general working capital needs, capital expenditures for facilities and equipment, and funding of research and development projects, and the Company funded those requirements through cash generated by operations, equity offerings, and bank credit facilities.

In recent years the Company's primary requirements for capital have arisen out of working capital needs created by increasing costs of operations and settlements of litigation combined with losses incurred in the Company's tissue preservation services business. Operating results have also been negatively impacted by increases in general, administrative, and marketing costs over pre-FDA Order levels, as a result of legal and professional fees and litigation costs. For the six months ended June 30, 2005 the Company funded these requirements primarily through existing cash, cash equivalents, and marketable securities and through the proceeds from its equity financing, as discussed below.

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

The Company expects that the following factors will continue to have an adverse impact on cash flows during 2005:

- o The anticipated lower preservation services revenues as compared to preservation revenues prior to the FDA Order, subsequent FDA activities, and related events (discussed in "FDA Order on Human Tissue Preservation" and "Other FDA Correspondence and Notices" above),
- o The high cost of human tissue preservation services as a percent of revenue, as compared to the period prior to the FDA Order, as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue and have decreased yields of implantable tissue per donor,
- o An expected use of cash related to the defense and resolution of lawsuits and claims, and
- o The legal and professional costs related to ongoing FDA compliance.

The Company believes the following factors should have a favorable impact on cash flows from operations during the remainder of 2005, although there can be no assurance that the Company's efforts will be successful:

- o Expected increases in revenues due to increases in BioGlue list prices implemented in January 2005,
- o Expected increases in the service fees for cardiovascular and vascular tissues due to fee increases implemented in July 2004 and January 2005, to reflect the higher cost of processing these tissues,
- o Anticipated improvements in yields of implantable tissues per donor over the levels experienced in 2003 and 2004 through process changes and process directives,

- o Expected increases in procurement of human tissues for processing during the second half of 2005 as compared to the first half of 2005, and
- o Anticipated decreases in cash payments related to insurance premiums.

The Company believes that its existing cash, cash equivalents, marketable securities, and available borrowings under its credit agreement, will enable the Company to meet its liquidity needs through at least June 30, 2006.

The Company's long term liquidity and capital requirements will depend upon numerous factors, including:

- o The success of BioGlue and other products using related technology,
- o The Company's ability to increase the level of tissue procurement and demand for its tissue preservation services,
- o The Company's ability to reestablish sufficient margins on its tissue preservation services in the face of increased processing costs by improving yields and increasing prices,
- o The Company's spending levels on its research and development activities, including research studies, to develop and support its product and service pipeline,

- o The resolution of the remaining outstanding product liability lawsuits and other claims (see Part I, Item 1, “Note 13 of the Notes to Summary Consolidated Financial Statements”),
- o The final outcome of other litigation against the Company (see Part I, Item 1, “Note 13 of the Notes to Summary Consolidated Financial Statements”), and
- o To a lesser degree, the Company’s success at resolving the issues with the FDA regarding processing of human tissue using the SynerGraft technology.

If the Company is unable to address these issues and continues to experience negative cash flows, the Company anticipates that it may require additional financing or seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements beyond June 30, 2006. Additional funds may not be available when needed or on terms acceptable to the Company, which could have a material adverse effect on the Company’s business, financial condition, results of operations, and cash flows.

#### *Product Liability Claims*

As discussed in Part I, Item 1, “Note 13 of the Notes to Summary Consolidated Financial Statements”, as of June 30, 2005 the Company had accrued a total of \$933,000 for pending product liability claims and recorded a receivable of zero representing amounts to be paid by the Company’s insurance carriers. The \$933,000 accrual is an estimate of the Company’s portion of the costs required to resolve outstanding claims, and does not reflect actual settlement arrangements or actual judgments, including punitive damages, which may be assessed by the courts. The \$933,000 accrual is not a cash reserve. The timing and amount of actual future payments is dependent on when and if judgments are rendered, and/or settlements are reached. Should payments related to the accrual be required, the Company’s portion of these monies would have to be paid from liquid assets. The Company continues to attempt to reach resolution of these outstanding claims in order to minimize the potential cash payout.

If the Company is unable to settle the outstanding claims for amounts within its ability to pay or one or more of the product liability lawsuits in which the Company is a defendant should be tried with a substantial verdict rendered in favor of the plaintiff(s), such verdict(s) could exceed the Company’s liquid assets. There is a possibility that significant punitive damages could be assessed in one or more lawsuits which would have to be paid out of the liquid assets of the Company, if available. As discussed in Part I, Item 1, “Note 13 of the Notes to Summary Consolidated Financial Statements”, at June 30, 2005 the Company had accrued a total \$8.0 million for the estimated costs of unreported product liability claims related to services performed and products sold prior to June 30, 2005 and had recorded a receivable of \$2.3 million representing amounts to be paid by the Company’s insurance carriers. The \$8.0 million accrual does not represent cash set aside. The timing of future payments related to the accrual is dependent on when and if claims are asserted, judgments are rendered, and/or settlements are reached. Should payments related to the accrual be required, these monies would have to be paid from insurance proceeds and liquid assets. Since the amount accrued is based on actuarial estimates, actual amounts required could vary significantly from this estimate.

#### *Shareholder Derivative Action*

As discussed in Part I, Item 1, “Note 13 of the Notes to Summary Consolidated Financial Statements”, the Company has been in settlement discussions with respect to the shareholder derivative lawsuit. A settlement has been agreed to by the parties, approved by the board, and submitted to the court. It remains subject to final court approval. Pursuant to proposed settlement, the Company anticipates that the fees and expenses of the plaintiffs’ counsel will be approximately \$3.5 million and will be covered by insurance. There can be no assurance that court approval will be obtained and the terms could change.

#### *Class Action Lawsuit*

As discussed in Part I, Item 1, “Note 13 of the Notes to Summary Consolidated Financial Statements”, the Company has agreed in principle to settle the class action lawsuit for \$23.25 million, approximately \$11.5 million of which is expected to be paid from insurance proceeds. The remainder of the settlement is comprised of a cash payment of \$8.0 million, expected to be paid in the third or fourth quarter of 2005, and common stock with a stipulated value of approximately \$3.75 million. This settlement is subject to court approval. There can be no assurance that court approval will be obtained, and the terms could change. As of June 30, 2005 the Company has accrued \$23.25 million as a component of accrued expense and other current liabilities, recorded a receivable from its insurance company of \$11.5 million as a component of other receivables, and recorded an expense of \$11.75 million in general, administrative, and marketing expenses.

The Company and the individual defendants have denied any wrongdoing and liability whatsoever, and the settlement does not contain any admission of liability. While the court previously dismissed a number of plaintiffs’ claims in a ruling on the Company’s motion for summary judgment, the court also ruled that several claims could proceed to trial. Plaintiffs intended to seek damages at trial in excess of \$150 million. Although the Company believes plaintiffs’ claims lacked merit, in light of the inherent risks and uncertainties of litigation, the Company determined to resolve the matter short of trial rather than expose the Company and its current shareholders to these costs and the risk of a potentially catastrophic award at trial.

#### *Net Cash from Operating Activities*

Net cash used in operating activities was \$4.6 million for the six months ended June 30, 2005, as compared to \$5.0 million for the six months ended June 30, 2004. The \$4.6 million in cash used in the six months ended June 30, 2005 was primarily due to a net loss. The net loss is due to the Company’s cryopreservation services business, which has failed to generate margins sufficient to cover operating expenses since the second half of 2002 as a result of the FDA Order, subsequent FDA activity, and related events, as discussed in “FDA Order on Human Tissue Preservation” and “Other FDA Correspondence and Notices” above.

The Company uses the indirect method to prepare its cash flow statement, and as such the operating cash flows are based on the Company’s net loss, which is then adjusted to remove non-cash items included that generated a book gain or loss during the period and for changes in operating assets and liabilities. For the six months ended June 30, 2005, the Company’s \$15.7 million net loss included significant recurring non-cash items that generated favorable and unfavorable adjustments to the net loss. For the six months ended June 30, 2005 these adjustments included a favorable \$2.6 million in depreciation and amortization, a favorable \$672,000 in write-downs for impairment of deferred preservation costs, and a favorable \$784,000 in non-cash gains related to the revaluation of the Derivative. The Company’s working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the six months ended June 30, 2005 these changes included, an unfavorable \$2.4 million due to the timing differences between the recording of receivables and the actual receipt of cash, an unfavorable \$1.8 million due to the buildup of deferred preservation costs and inventories for which vendors and employees

have already been paid, and a favorable \$10.0 million due to the timing differences between the recording of accounts payable, accrued expenses, and other current liabilities and the actual payment of cash.

The Company expects that its operations will continue to generate negative cash flows from operating activities during 2005. Cash used will primarily be a result of the Company's projected net loss for 2005 and settlement payments related to the class action lawsuit. Cash used in operations may be negatively affected in addressing any notices of observation or other actions taken by the FDA as a result of the inspection it began on July 11, 2005.

**Net Cash from Investing Activities**

Net cash used by investing activities was \$14.0 million for the six months ended June 30, 2005, as compared to cash provided of \$1.1 million for the six months ended June 30, 2004. The \$14.0 million in current year cash used was primarily due to \$14.8 million in purchases of marketable securities, partially offset by \$1.4 million in sales and maturities of marketable securities. Investments were purchased using the proceeds of the equity offering discussed below. In addition capital expenditures used \$490,000 in cash during the period.

**Net Cash from Financing Activities**

Net cash provided by financing activities was \$18.2 million for the six months ended June 30, 2005, as compared to \$18.3 million for the six months ended June 30, 2004. The \$18.2 million in current year cash provided was primarily due to \$19.1 million in net proceeds from the Company's offering of Preferred Stock in March and April of 2005, partially offset by \$1.1 million in principal payments on capital leases and short-term notes payable used to finance certain of the Company's insurance policies.

**Scheduled Contractual Obligations and Future Payments**

Scheduled contractual obligations and the related future payments are as follows (in thousands):

|                                      | Total           | Remainder<br>of<br>2005 | 2006           | 2007           | 2008           | 2009           | Thereafter      |
|--------------------------------------|-----------------|-------------------------|----------------|----------------|----------------|----------------|-----------------|
| Operating leases                     | \$22,438        | \$ 1,067                | \$2,185        | \$2,198        | \$2,154        | \$2,061        | \$12,773        |
| Shareholder class action settlement  | 11,750          | 11,750                  | --             | --             | --             | --             | --              |
| Insurance premium obligations        | 1,868           | 1,868                   | --             | --             | --             | --             | --              |
| Capital lease obligations            | 1,568           | 442                     | 860            | 266            | --             | --             | --              |
| Purchase commitments                 | 568             | 543                     | 25             | --             | --             | --             | --              |
| Preferred stock dividends            | 290             | 290                     | --             | --             | --             | --             | --              |
| Other obligations                    | 1,375           | 389                     | 404            | 409            | 173            | --             | --              |
| <b>Total contractual obligations</b> | <b>\$39,857</b> | <b>\$16,349</b>         | <b>\$3,474</b> | <b>\$2,873</b> | <b>\$2,327</b> | <b>\$2,061</b> | <b>\$12,773</b> |

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 rented by the Company, leases on Company vehicles, and leases on a variety of office equipment.

The shareholder class action settlement is the net liability that the Company must satisfy in stock and cash related to the settlement agreement for the class action litigation discussed above.

The Company's insurance premium obligations are required installment payments related to payment plans and notes payable from the renewal and financing of certain Company insurance policies.

The Company's capital lease obligations result from the financing of certain of the Company's equipment and leasehold improvements primarily purchased during the renovation of the corporate headquarters and manufacturing facilities in previous years. Additional capital lease obligations result from the lease of a building related to Company's Ideas for Medicine ("IFM") manufacturing business, which the Company sold in 2000. The Company has a sublease agreement with a wholly owned subsidiary of LeMaitre Vascular, Inc., the current parent of IFM, to sublet the building housing the IFM manufacturing facilities, which effectively reduces the Company's future obligations under this capital lease to zero.

The Company's purchase commitments result from agreements with suppliers to stock certain custom raw materials needed for the Company's processing and production.

The Company has a commitment to pay dividends on its 6% convertible preferred stock, if and when these dividends are declared by the Board of Directors of CryoLife. In addition the Company will have a commitment related to the Preferred Stock's Dividend Make-Whole Payment provision, which requires the Company to remit cumulative unpaid dividends to converting preferred stock holders. The Company intends to satisfy any required Dividend Make-Whole Payments by issuing shares of its common stock in lieu of making cash payments. The amount included in the table above represents dividends declared and payable on July 1, 2005. As the timing of payments or stock issuances related to undeclared preferred stock dividends and Dividend Make-Whole Payments cannot be determined at this time, the Company did not include these items in the table above.

The Company's other obligations contain various items including minimum required royalty payments, payments to support research and development activities, litigation settlement obligations, and other items as appropriate.

**Capital Expenditures**



The Company expects that its capital expenditures for the full year 2005 may show a modest increase over its expenditures in 2004, which were approximately \$1.0 million. Planned expenditures for 2005 are primarily related to routine purchases of tissue processing, manufacturing, computer, and office equipment needed to support the Company's business needs. The Company expects to have the flexibility to increase or decrease the majority of its planned capital expenditures depending on its ability to generate cash flows.

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### FORWARD-LOOKING STATEMENTS

This Form 10-Q contains forward-looking statements and information made or provided by the Company that are based on the beliefs of its management as well as estimates and assumptions made by and information currently available to management. The words "could," "may," "will," "would," "should," "pro forma," "potential," "pending," "intend," "believe," "expect," "anticipate," "estimate," "plan," "future," and other similar expressions generally identify forward-looking statements, including, in particular, statements regarding anticipated revenues, cost savings, insurance coverage, regulatory activity, available funds and capital resources, and pending litigation. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned not to place undue reliance on these forward-looking statements, which are as of their respective dates. Such forward-looking statements reflect the views of our 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 filing.

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:

- o The impact of recent accounting pronouncements;
- o The impact of adoption of SFAS 123 Revised "Share-Based Payment;"
- o Adequacy of product liability insurance to defend against lawsuits;
- o The outcome of lawsuits filed against the Company;
- o The impact of the FDA Order, subsequent FDA activity, and measures taken by the Company as a result, on anticipated future revenues, profits and business operations;
- o The effect of the FDA Order and subsequent FDA activity on sales of BioGlue;
- o Future tissue procurement levels;
- o Expected future impact of BioGlue on revenues and gross margins;
- o The impact of the FDA's Form 483 Notices of Observation;
- o The estimates of the amounts accrued for the retention levels under the Company's product liability and directors' and officers' insurance policies, as well as the estimates of the amounts accrued for product liability claims incurred but not reported;
- o Future costs of human tissue preservation services;
- o Changes in liquidity and capital resources;
- o Statements regarding the expected 2005 performance of the Company relative to that of 2004;
- o The Company's expectations regarding the adequacy of current financing arrangements;
- o Product demand and market growth;
- o The impact on net loss of future fluctuations in the value of the dividend make-whole payment feature of the Company's 6% convertible preferred stock; and
- o 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 "Risk Factors" in Part I, Item 1 of the Company's Form 10-K for the year ended December 31, 2004 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.

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

- o The August 2002 FDA Order on human tissue and subsequent FDA activity continue to adversely impact CryoLife's business, including demand for its services and processing costs;
- o The FDA Order and subsequent activity have had and continue to have an adverse impact on liquidity and capital resources;
- o The Company may be unable to reduce costs of processing tissues, to obtain increased yields of implantable tissue, and to increase fees for tissue preservation services;
- o Revenue from orthopaedic tissue preservation services is minimal and may not return;
- o Physicians may be reluctant to implant CryoLife's preserved tissues;
- o Products and services not included in the FDA recall may come under increased scrutiny;
- o Demand for heart valves processed by CryoLife has decreased and may continue to decrease;
- o Adverse publicity may reduce demand for products and services not affected by the FDA recall;
- o The Company may be unable to address the concerns raised by the FDA in its Form 483 notices of observations;
- o Depending on the nature and extent of any observations provided or other actions taken by the FDA, as a result of the inspection it began on July 11, 2005, the Company may incur significant additional expenses to address those observations or other actions;
- o The FDA may provide observations, including by means of a new Form 483 notice of observations, or take other actions, as a result of the inspection it began on July 11, 2005, and the Company may be unable to address the FDA's concerns in a timely or cost-effective manner, if at all;
- o The FDA has notified CryoLife of its belief that marketing of CryoValve SG and CryoVein SG require additional regulatory submissions and/or approvals;
- o Regulatory action outside of the United States may also affect CryoLife's business;
- o CryoLife is the subject of an ongoing SEC investigation;
- o CryoLife's insurance coverage may be insufficient;
- o Insurance coverage may be difficult or impossible to obtain in the future and if obtained, the cost of insurance coverage is likely to be much more expensive than in the past;
- o Intense competition may affect CryoLife's ability to recover from the FDA Order;
- o CryoLife may not be successful in obtaining necessary clinical results and regulatory approvals for products and services in development, and such products and services may not achieve market acceptance;
- o Investments in new technologies or distribution rights may not be successful;
- o CryoLife is dependent on its key personnel;
- o Extensive government regulation may adversely affect the ability to develop and sell products and services;
- o Uncertainties related to patents and protection of proprietary technology may adversely affect the value of intellectual property;
- o Uncertainties regarding future health care reimbursement may affect the amount and timing of revenues;
- o Rapid technological change could cause services and products to become obsolete;
- o Sales prices for CryoLife shares on the New York Stock Exchange have been, and may continue to be, volatile;
- o Future fluctuations in the value of the dividend make-whole payment feature of the Company's 6% convertible preferred stock may have a material impact on the Company's results of operations;
- o Dividends on the Company's common stock are not likely to be paid in the foreseeable future; and
- o The Company may not be able to borrow against its credit agreement; and
- o CryoLife may be unable to raise funds if they are needed to continue operations after June 30, 2006.

## Interest Rate Risk

The Company's interest income and expense are sensitive to changes in the general level of United States interest rates. In this regard, changes in United States interest rates affect the interest earned on the Company's cash and cash equivalents of \$4.2 million as of June 30, 2005. The Company's short-term investments in marketable securities of \$17.4 million as of June 30, 2005 can also be affected by changing interest rates to the extent that these items contain variable interest rates or are subject to maturity or sale during a period of changing interest rates. A 10% adverse change in interest rates affecting the Company's cash equivalents and short-term investments would not have a material impact on the Company's financial position, results of operations, or cash flows.

## Derivative Valuation Risk

The terms of the Company's March 18, 2005 6% convertible preferred stock offering include a dividend make-whole payment feature. This feature is considered an embedded derivative instrument, and the Company determined the fair value of this derivative to be \$1.0 million on March 18, 2005, the date of issuance. At June 30, 2005 the derivative liability was valued at \$1.1 million, and a net total of \$902,000 and \$784,000, respectively, in non-operating expense was recorded related to this derivative and the dividend make-whole payment feature for the three and six months ended June 30, 2005. The fair value of this derivative is based on various factors, including the market price of the Company's common stock and discount rates used in determination of fair value. Changes in these factors could cause the fair value of this derivative to fluctuate significantly from period to period. These resulting changes in valuation may have a significant impact on the Company's results of operations.

## Item 4. Controls and Procedures.

The Company's management, including the Company's President and Chief Executive Officer ("CEO") and the Company's Executive Vice President, Chief Operating Officer, and Chief Financial Officer ("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. Because of 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.

Based upon the Company's most recent Disclosure Controls evaluation as of June 30, 2005, 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 United States Securities and Exchange Commission's rules and forms.

During the quarter ended June 30, 2005, there were no 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.

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## Part II — OTHER INFORMATION

### Item 1. Legal Proceedings.

See Note 13 of Notes to Summary Consolidated Financial Statements at Part I, Item 1 "Financial Statements", which is incorporated herein by reference.

### 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 June 30, 2005 of equity securities that are registered by the Company pursuant to Section 12 of the Exchange Act:

#### Issuer Purchases of Equity Securities

| Period              | Total Number of Common Shares Purchased | Average Price Paid per Common Share | Common Stock   |  |
|---------------------|---|-------------------------------------|--|--|
|                     |   |                                     | Total Number of Common Shares Purchased as Part of Publicly Announced Programs | Maximum Number of Common Shares That May Yet Be Purchased Under the Programs |
| 04/01/05 - 04/30/05 | --                                      | \$ --                               | --   | --   |
| 05/01/05 - 05/31/05 | 262                                     | 7.28                                | --   | --   |
| 06/01/05 - 06/30/05 | --                                      | --                                  | --   | --   |
| Total               | 262                                     | \$ 7.28                             | --   | --   |

The Company currently has no stock repurchase program, publicly announced or otherwise. The common shares shown were tendered to the Company in payment of the exercise price of outstanding options.

#### 6% Convertible Preferred Stock

The Company did not repurchase any shares of its 6% convertible preferred stock in the quarter ended June 30, 2005.

Item 3. Defaults Upon Senior Securities.  
None

Item 4. Submission of Matters to a Vote of Security Holders.

- (a) The Annual Meeting of Shareholders was held on June 2, 2005.
- (b) Management's nominees for director were elected at the meeting by the holders of common stock. The election was uncontested.

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The following table shows the results of voting in the election of Directors:

|                        | Shares Voted For | Authority Withheld | Abstained | Broker Non-Votes |
|------------------------|------------------|--------------------|-----------|------------------|
| Steven G. Anderson     | 20,960,394       | 260,231            | --        | --               |
| John M. Cook           | 21,007,858       | 212,767            | --        | --               |
| Ronald C. Elkins, M.D  | 21,005,645       | 214,980            | --        | --               |
| Virginia C. Lacy       | 21,055,004       | 165,621            | --        | --               |
| Ronald D. McCall, Esq  | 20,957,182       | 263,443            | --        | --               |
| Bruce J. Van Dyne, M.D | 21,050,406       | 170,219            | --        | --               |
| Thomas F. Ackerman     | 21,055,004       | 165,621            | --        | --               |
| Daniel J. Bevevino     | 20,996,880       | 186,245            | --        | --               |

Item 5. Other information.  
None.

Item 6. Exhibits.

The exhibit index can be found below.

| <u>Exhibit Number</u> | <u>Description</u>  |
|-----------------------|---|
| 3.1                   | Restated Certificate of Incorporation of the Company, as amended. (Incorporated by reference to Exhibit 3.1 to Form 10-Q for the quarter ended March 31, 2003.)   |
| 3.2                   | ByLaws of the Company, amendments adopted on December 8, 2004. (Incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed on December 10, 2004.)  |
| 3.3                   | Articles of Amendment to the Articles of Incorporation of the Company. (Incorporated by reference to Exhibit 3.3 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.) |
| 4.1                   | Form of Certificate for the Company's Common Stock. (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).  |
| 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.   |

\* Filed herewith.

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## SIGNATURES

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

CRYOLIFE, INC.  
(Registrant)

/s/ STEVEN G. ANDERSON

/s/ DAVID ASHLEY LEE

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

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

August 4, 2005  
DATE

**CERTIFICATIONS**

I, Steven G. Anderson, Chairman, President, and Chief Executive Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CryoLife, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: August 4, 2005

/s/ STEVEN G. ANDERSON  
Chairman, President, and  
Chief Executive Officer

I, David Ashley Lee, Executive Vice President, Chief Operating Officer, and Chief Financial Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CryoLife, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: August 4, 2005

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

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

In connection with the Quarterly Report of CryoLife Inc. (the "Company") on Form 10-Q for the quarter ending June 30, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of Steven G. Anderson, the Chairman, President, and Chief Executive Officer of the Company, and David Ashley Lee, the Executive Vice President, Chief Operating Officer, and Chief Financial Officer of the Company, hereby certifies, pursuant to and for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ STEVEN G. ANDERSON  
STEVEN G. ANDERSON  
Chairman, President, and  
Chief Executive Officer  
August 4, 2005

/s/ DAVID ASHLEY LEE  
DAVID ASHLEY LEE  
Executive Vice President,  
Chief Operating Officer, and  
Chief Financial Officer  
August 4, 2005