

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, 2002  
Commission File Number 1-13165

CRYOLIFE, INC.  
(Exact name of registrant as specified in its charter)

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Florida 59-2417093  
(State or other jurisdiction (I.R.S. Employer  
of incorporation or organization) 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 X NO \_\_\_\_\_

The number of shares of common stock, par value \$0.01 per share, outstanding on August 30, 2002 was 19,502,371.

Part I - FINANCIAL INFORMATION

INFORMATION WITH RESPECT TO FINANCIAL STATEMENTS

On April 11, 2002 CryoLife, Inc. filed a Form 8-K, indicating that the Board of Directors, upon the recommendation of the audit committee, had dismissed the accounting firm Arthur Andersen LLP as the Company's independent auditors effective April 9, 2002. On May 10, 2002 CryoLife, Inc. filed a Form 8-K, indicating that the Board of Directors, upon the recommendation of the audit committee, had appointed Deloitte & Touche LLP as the Company's independent auditors effective May 7, 2002.

CryoLife, Inc.'s Form 10-Q for the quarterly period ended March 31, 2002 was previously filed without a review of the financial statements for the quarterly period ended March 31, 2002, by an independent public accountant in accordance with Rule 10-01(d) of Regulation S-X promulgated by the Securities and Exchange Commission. CryoLife, Inc. elected not to obtain such a review from its prior auditor, Arthur Andersen LLP.

Deloitte & Touche LLP has subsequently reviewed the financial statements for the quarterly period ended March 31, 2002 in accordance with Rule 10-01(d).

## Item 1. Financial statements

CRYOLIFE, INC. AND SUBSIDIARIES  
SUMMARY CONSOLIDATED STATEMENTS OF OPERATIONS  
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
	(Unaudited)		(Unaudited)	
Revenues:				
Human tissue preservation services, net	\$ 17,536	\$ 18,765	\$ 37,774	\$ 37,331
Products	5,473	2,789	10,538	5,430
Distribution and grant	255	143	423	368
	23,264	21,697	48,735	43,129
Costs and expenses:				
Human tissue preservation services (including write-down of \$10,023 in 2002)	17,203	7,697	25,266	15,370
Products	1,843	1,423	4,078	2,855
General, administrative, and marketing	11,447	8,120	20,925	16,279
Research and development	1,196	1,286	2,349	2,372
Interest expense	196	16	388	16
Interest income	(239)	(576)	(537)	(1,138)
Other (income) expense, net	(16)	(5)	(72)	742
	31,630	17,961	52,397	36,496
Income (loss) before income taxes	(8,366)	3,736	(3,662)	6,633
Income tax (benefit) expense	(2,844)	1,196	(1,244)	2,123
Net (loss) income	\$ (5,522)	\$ 2,540	\$ (2,418)	\$ 4,510
Net (loss) earnings per share:				
Basic	\$ (0.28)	\$ 0.14	\$ (0.13)	\$ 0.24
Diluted	\$ (0.28)	\$ 0.13	\$ (0.13)	\$ 0.23
Weighted average shares outstanding:				
Basic	19,538	18,780	19,318	18,761
Diluted	19,538	19,622	19,318	19,575

See accompanying notes to summary consolidated financial statements.

## Item 1. Financial Statements

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

	June 30, 2002	December 31, 2001
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 12,290	\$ 7,204
Marketable securities, at market	18,659	26,483

Trade receivables, net	13,800	13,305
Other receivables, net	3,727	2,820
Note receivable, net	--	1,169
Deferred preservation costs, net	21,039	24,199
Inventories	7,352	6,259
Prepaid expenses and other assets	2,976	2,341
Deferred income taxes	3,457	688
Total current assets	83,300	84,468
Property and equipment, net	39,574	39,246
Goodwill	1,399	1,399
Patents, net	4,998	2,919
Other, net	1,087	1,278
TOTAL ASSETS	\$ 130,358	\$ 129,310
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LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,826	\$ 555
Accrued expenses and other current liabilities	2,784	1,491
Accrued compensation	1,233	2,560
Accrued procurement fees	8,224	6,592
Current maturities of capital lease obligations	628	609
Current maturities of long-term debt	6,400	1,600
Convertible debenture	--	4,393
Total current liabilities	21,095	17,800
Capital lease obligations, less current maturities	2,821	3,140
Bank loan, less current maturities	--	5,600
Deferred income taxes	199	449
Other long-term liabilities	961	882
Total liabilities	25,076	27,871
Shareholders' equity:		
Preferred stock	--	--
Common stock (issued 20,864 shares in 2002 and 20,172 shares in 2001)	208	202
Additional paid-in capital	73,336	66,828
Retained earnings	38,129	40,547
Deferred compensation	(27)	(33)
Accumulated other comprehensive income (loss)	137	(145)
Less: Treasury stock at cost (1,309 shares in 2002 and 1,286 shares in 2001)	(6,501)	(5,960)
Total shareholders' equity	105,282	101,439
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 130,358	\$ 129,310
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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 June 30,	
	2002	2001
	(Unaudited)	
Net cash from operating activities:		
Net (loss) income	\$ (2,418)	\$ 4,510

Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Loss on sale of marketable equity securities	228	--
Depreciation and amortization	2,526	2,169
Provision for doubtful accounts	48	47
Write-down of deferred preservation costs	10,023	--
Other non-cash adjustments to income	--	748
Deferred income taxes	(3,048)	(578)
Tax effect of nonqualified option exercises	481	114
Changes in operating assets and liabilities:		
Receivables	90	(1,645)
Income taxes	(1,540)	926
Deferred preservation costs and inventories	(7,956)	(2,053)
Prepaid expenses and other assets	(635)	(814)
Accounts payable, accrued expenses, and other liabilities	2,951	889
Net cash flows provided by operating activities	750	4,313
Net cash flows from investing activities:		
Capital expenditures	(2,735)	(9,072)
Other assets	(1,980)	(257)
Purchases of marketable securities	(11,725)	(9,307)
Sales and maturities of marketable securities	19,391	10,664
Proceeds from note receivable	1,169	1,605
Net cash flows provided by (used in) investing activities	4,120	(6,367)
Net cash flows from financing activities:		
Principal payments of debt	(800)	(133)
Proceeds from debt issuance	--	1,165
Payment of obligations under capital leases	(300)	(85)
Proceeds from exercise of stock options and issuance of common stock	1,099	540
Net cash (used in) provided by financing activities	(1)	1,487
Increase (decrease) in cash	4,869	(567)
Effect of exchange rate changes on cash	217	(124)
Cash and cash equivalents, beginning of period	7,204	17,480
Cash and cash equivalents, end of period	\$ 12,290	\$ 16,789

See accompanying notes to summary consolidated financial statements.

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

NOTE 1 - BASIS OF PRESENTATION

The accompanying unaudited condensed 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 Securities and Exchange Commission ("SEC"). Accordingly, they 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 and estimated write-downs and accruals resulting from an order received from the United States Food and Drug Administration ("FDA")) considered necessary for a fair presentation have been included. Certain prior year balances have been reclassified to conform to the 2002 presentation. CryoLife, Inc.'s ("CryoLife" or the "Company") unaudited June 30, 2001 year to date results of operations have been revised from the amounts previously reported in the Form 10-Q for the quarter ended June 30, 2001, as indicated in Note 20 to the consolidated financial statements included in the CryoLife, Inc Form 10-K for the year ended December 31, 2001. Operating results for the three and six months ended June 30,

2002 are not necessarily indicative of the results that may be expected for the year ending December 31, 2002. For further information, refer to the consolidated financial statements and notes thereto included in the CryoLife, Inc. Form 10-K for the year ended December 31, 2001.

The Company anticipates that the FDA Order, defined in Note 2, will have significant adverse effects on its financial position, results of operations and cash flows. The Company expects its liquidity to decrease significantly over the remainder of the year due to the anticipated significant decrease in revenues as a result of the FDA Order and an expected use of cash due to the increased legal and professional costs relating to the defense of lawsuits and to addressing the FDA Order. As a result, the Company plans to reduce the number of personnel it employs in several areas, as needed, based in part on the Company's success in its efforts to appeal or obtain a modification of the FDA Order. On September 3, 2002 the Company announced a reduction in employee force of approximately 105 employees. The Company anticipates that severance and related costs will be approximately \$625,000, which will be recorded in the third quarter of 2002. As a result of the employee reduction, management anticipates personnel costs will be reduced by approximately \$360,000 per month. The Company anticipates that after it has reduced the number of employees in response to the reduction in revenues, the savings in resources will enable the Company to meet its liquidity needs through June 30, 2003. Even if the Company is able to obtain a favorable outcome of its appeal or requested modification of the FDA Order, there is no assurance that the Company would experience a return to the current level of demand for its tissue services as a result of the adverse publicity or as a result of customers and tissue banks switching to competitors.

The Company's long term liquidity and capital requirements will depend upon numerous factors, including the resolution of the Company's appeal of the FDA Order as described in Note 2, the extent of the anticipated revenue decreases, the costs associated with becoming compliant with the FDA requirements as outlined in the FDA Order, the outcome of litigation against the Company as described in Note 11, the level of demand for tissue based on adverse publicity in the event the FDA Order is resolved in a manner favorable to the Company, the default on the Term Loan as described in Note 6, and the Company's inability to borrow on its line of credit as described in Note 12. The Company 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, 2003. 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. These are factors that indicate that the Company may be unable to continue operations.

#### NOTE 2 - 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 tissue processed by the Company since October 3, 2001 (the "FDA Order"). Revenue from human tissue preservation services accounted for 78% of the Company's revenues for the six months ended June 30, 2002, and of those revenues 67% or \$26.9 million are derived from preservation of tissues subject to the FDA Order. The Company announced the receipt of the FDA Order in a press release dated August 14, 2002. The FDA Order follows an FDA warning letter dated June 17, 2002, which the Company announced in a press release dated June 24, 2002. Subsequently, the Company responded to the warning letter and requested a meeting with the FDA. The FDA Order contains the following principal provisions:

- o The FDA alleges that, based on its inspection of the Company's facility on March 25 through April 12, 2002, certain human tissue received and distributed by the Company may be in violation of 21 Code of Federal Regulations ("CFR") Part 1270. (Part 1270 requires persons or entities engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue to perform certain medical screening and testing on human tissue intended for transplantation. The rule also imposes requirements regarding procedures for the prevention of contamination or cross-contamination of tissues during processing and the maintenance of certain records related to these activities.)

- o The FDA alleges that the Company has not validated procedures for the prevention of infectious disease contamination or cross-contamination of tissue during processing at least since October 3, 2001.
- o Non-valved cardiac, vascular, and orthopaedic tissue processed by the Company since October 3, 2001 must be retained until it is recalled, destroyed, the safety is confirmed, or an agreement is reached with the FDA for its proper disposition under the supervision of an authorized official of the FDA.
- o The FDA strongly recommends that CryoLife perform a retrospective review of all tissue in inventory (i.e. currently in storage at CryoLife) that is not referenced in the FDA Order to assure that it was recovered, processed, stored, and distributed in conformance with 21 CFR 1270
- o The Center for Devices and Radiological Health ("CDRH"), a division of the FDA, is evaluating whether there are similar risks that may be posed by CryoLife's allograft heart valves, and will take further regulatory action if appropriate.

Pursuant to the FDA Order, the Company has placed all non-valved cardiac, vascular, and orthopaedic tissue subject to the FDA Order on quality assurance quarantine and is recalling all non-valved cardiac, vascular, and orthopaedic tissues subject to the FDA Order (i.e. processed since October 3, 2001) that have been distributed but not implanted. After the FDA issued its order regarding the recall, Health Canada also issued a recall on the same types of tissue and the United Kingdom Department of Health has begun investigating tissue exported by the Company.

The Company appealed the FDA Order on August 14, 2002 and requested a hearing with the FDA. No dates have been set for the hearing. In addition, the Company has requested a modification of the FDA Order to allow distribution of certain non-valved cardiac tissues and vascular tissues which are used in life saving or limb salvaging surgical procedures. The Company has met with the FDA and is holding on-going discussions regarding its request for modification of the FDA Order to accommodate distribution of non-valved cardiac and vascular tissue in life saving and limb salvaging situations. The Company is unable to predict if it will obtain a favorable outcome to its appeal or request for modification of the FDA Order or the timing of the resolution of these matters.

After receiving the FDA Order, the Company met with representatives of the FDA's CDRH division regarding CDRH's review of the Company's processed allograft heart valves, which are not required to be recalled pursuant to the FDA Order. On August 21, 2002 the FDA publicly stated that allograft heart valves have not

been included in the FDA recall order as these devices are essential for the correction of congenital cardiac lesions in neonate and pediatric patients and no satisfactory alternative device exists. However, the FDA also publicly stated that it still has serious concerns regarding the processing and handling of allograft heart valves. The FDA also recommended that surgeons carefully consider using processed allografts from alternative sources, that surgeons inform prospective patients of the FDA's concerns with the Company's allograft heart valves, and that patients be carefully monitored for both fungal and bacterial infections.

Management has determined that, with respect to tissue subject to the FDA Order, product liability claims and shareholder litigation, the FDA Order received on August 13, 2002 is a type one subsequent event, as defined by generally accepted auditing standards in the United States, which requires adjustment to the second quarter financial statements. A type one subsequent event provides additional evidence about conditions which existed at the balance sheet date, and results in changes to the estimates used to prepare the financial statements. Management has made this determination because the FDA Order clarified the accounting estimates surrounding the June 17, 2002 FDA warning letter, which stated a recall was a possible course of action for the FDA if the warning letter issues were not resolved promptly. The Company was working with the FDA to correct the issues and did not believe a recall would be instated. Therefore, the Company previously estimated that there was no material accounting impact from the FDA

warning letter. This estimate was revised due to the receipt of the FDA Order. Management has determined that the negative implications of the FDA Order to its revenues generated from tissue not subject to the FDA Order and any resulting impairments of other assets or incurrence of liabilities do not represent a type one subsequent event and therefore any necessary adjustments will be recorded in future periods.

As a result of the FDA Order, the Company has recorded a reduction to pretax income of \$12.6 million, in the quarter ended June 30, 2002. The reduction was comprised of a net \$8.9 million increase to cost of human tissue preservation services, a \$2.4 million reduction to revenues (and accounts receivable) for the estimated return of the tissues subject to recall by the FDA Order, and a \$1.3 million accrual recorded in general, administrative, and marketing expenses for retention levels under the Company's product liability and directors' and officers' insurance policies of \$1.2 million (see Note 11) and for estimated expenses of \$75,000 for packaging and handling for the return of affected tissues under the FDA Order.

The net increase of \$8.9 million to cost of preservation services is comprised of a \$10.0 million write-down of deferred preservation costs for tissues subject to the FDA Order, offset by a \$1.1 million decrease in cost of preservation services due to the estimated tissue returns resulting from the FDA Order (the costs of such recalled tissue are included in the \$10.0 million write-down). The Company evaluated many factors in determining the magnitude of impairment to deferred preservation costs, including the impact of the current FDA Order, the possibility of continuing action by the FDA or other United States and foreign government agencies, and the possibility of unfavorable actions by physicians, customers, procurement organizations, and others. As a result of this evaluation, management believes that since all non-valved cardiac, vascular, and orthopaedic allograft tissues processed since October 3, 2001 are under recall pursuant to the FDA Order, and the Company does not know if it will obtain a favorable resolution of its appeal and request for modification of the FDA Order, the deferred preservation costs for tissues subject to the FDA Order have been significantly impaired. The Company has estimated that this impairment approximates the full balance of the deferred preservation costs of the tissues subject to the FDA Order, which includes the tissues stored by the Company and the tissues to be returned to the Company, and has therefore recorded a write-down of \$10.0 million for these assets.

As of June 30, 2002 deferred preservation costs of tissues not subject to the FDA Order (i.e. tissue processed prior to October 3, 2001) were \$829,000 for non-valved cardiac tissues, \$7.3 million for vascular tissues, and \$4.7 million for orthopaedic tissues. Deferred preservation costs for allograft heart valves, which are not subject to the FDA Order, were \$8.5 million as of June 30, 2002. The Company is continuing to ship these tissues.

The Company evaluated many factors in determining the potential impairment of the deferred preservation costs for non-valved cardiac, vascular, and orthopaedic tissues processed prior to October 3, 2001 and all of the Company's

allograft heart valves, as these tissue populations are not subject to the FDA Order. The allograft heart valve, non-valved cardiac, and vascular tissues are principally used in life saving and limb salvaging surgical procedures and are often used after all other avenues of treatment have been exhausted. Therefore, the Company believes that non-valved cardiac tissues and vascular tissues processed prior to October 3, 2001 and allograft heart valves will continue to be in demand. Although management believes that the demand for non-valved cardiac and vascular tissues processed prior to October 3, 2001 and all allograft heart valves stored by the Company will be affected by the adverse publicity surrounding the FDA Order, the Company cannot estimate the degree to which these tissues have been impaired. The Company may determine in the future that a write-down of the deferred preservation costs for these tissues is necessary. Management will continue to monitor the Company's progress in satisfying the FDA's requirements and the effect of the FDA Order and the related adverse publicity on the demand for these tissues to determine if additional write-downs of deferred preservation costs are required.

Management has reviewed the current circumstances relating to orthopaedic tissues not subject to the FDA order (i.e. processed prior to October 3, 2001), including whether there were indications of impairment of deferred preservation costs for such tissues as of June 30, 2002. Management has determined that the

demand for orthopaedic tissues had not been affected sufficiently as of June 30, 2002 to cause an impairment in the deferred preservation costs related to these tissues (i.e., cost was not in excess of market). Accordingly, the Company has not recorded a write-down in the deferred preservation costs related to the orthopaedic tissue processed prior to October 3, 2001 in the June 30, 2002 financial statements. However, the adverse publicity following the FDA Order has resulted in a significant decrease in orthopaedic tissue revenues since August 13, 2002. As a result, management believes that the deferred preservation costs for orthopaedic tissues not subject to the FDA Order have been impaired in the third quarter of 2002 and expects that it will record a substantial write-down of such costs in the third quarter of 2002.

As noted above, the FDA Order strongly recommends that the Company perform a retrospective review of all tissue in inventory not subject to the FDA Order. The Company is having ongoing discussions with the FDA to establish the procedures to be followed in the retrospective review and therefore is currently unable to reasonably estimate the costs for such review. Once the Company and the FDA agree on these procedures the Company will evaluate the costs associated with performing the review and record an appropriate accrual for these costs.

The Company periodically evaluates the recoverability of noncurrent tangible and intangible assets and measures the amount of impairment, if any. Management does not believe an impairment of the Company's tangible and intangible assets relating to the tissue preservation business had occurred as of June 30, 2002. However, depending on the outcome of the FDA Order and the future effects of adverse publicity surrounding the FDA Order and reported infections on preservation revenues, these assets may become impaired. Management will continue to evaluate the recoverability of these assets.

The Company anticipates that the FDA Order will also affect the financial position, results of operations, and cash flows of the Company for the quarter ended September 30, 2002. In addition to the anticipated write-down of deferred preservation costs for orthopaedic tissue, the Company expects a \$1.0 million reversal of revenues recorded in July and August, due to the estimated returns of tissues subject to the FDA Order, which were shipped in July and August. The deferred preservation costs of tissues processed during the third quarter of 2002 that are subject to the FDA Order approximate \$3.9 million as of August 14, 2002. The deferred preservation costs of these tissues processed during the third quarter are anticipated to be fully impaired and the Company expects to record a write-down approximating their full cost in the third quarter.

#### NOTE 3 - CASH EQUIVALENTS AND MARKETABLE SECURITIES

The Company maintains cash equivalents, which consist primarily of highly liquid investments with maturity dates of 90 days or less at the time of acquisition, and marketable securities 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.

9

Management determines the appropriate classification of debt securities at the time of purchase and reevaluates such designations as of each balance sheet date. 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. Debt securities not classified as held-to-maturity or trading and marketable equity securities not classified as trading are classified as available-for-sale. At June 30, 2002 and December 31, 2001, all marketable equity securities and debt securities were designated as available-for-sale.

Available-for-sale securities are stated at their fair values, with the unrealized gains and losses, net of tax, reported in a separate component of shareholders' equity. Interest income, 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.

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



June 30, 2002	Cost Basis	Adjustments to Cost Basis	Adjusted Cost Basis	Unrealized Holding Gains/(Losses)	Estimated Market Value
Cash equivalents:					
Money market funds	\$ 6,061	\$ --	\$ 6,061	\$ --	\$ 6,061
Municipal obligations	3,454	--	3,454	--	3,454
	<u>\$ 9,515</u>	<u>\$ --</u>	<u>\$ 9,515</u>	<u>\$ --</u>	<u>\$ 9,515</u>
Marketable securities:					
Municipal obligations	\$ 17,642	\$ --	\$ 17,642	\$ 269	\$ 17,911
Equity securities	1,075	(284)	791	(43)	748
	<u>\$ 18,717</u>	<u>\$ (284)</u>	<u>\$ 18,433</u>	<u>\$ 226</u>	<u>\$ 18,659</u>
December 31, 2001	Cost Basis	Adjustments to Cost Basis	Adjusted Cost Basis	Unrealized Holding Gains/(Losses)	Estimated Market Value
Cash equivalents:					
Money market funds	\$ 1,301	\$ --	\$ 1,301	\$ --	\$ 1,301
Municipal obligations	500	--	500	--	500
	<u>\$ 1,801</u>	<u>\$ --</u>	<u>\$ 1,801</u>	<u>\$ --</u>	<u>\$ 1,801</u>
Marketable securities:					
Municipal obligations	\$ 17,696	\$ --	\$ 17,696	\$ 147	\$ 17,843
Debt securities	6,227	(1,217)	5,010	--	5,010
Equity securities	3,900	(343)	3,557	10	3,567
Certificates of deposit	63	--	63	--	63
	<u>\$ 27,886</u>	<u>\$ (1,560)</u>	<u>\$ 26,326</u>	<u>\$ 157</u>	<u>\$ 26,483</u>

The Adjustments to Cost Basis column includes a \$284,000 loss as of June 30, 2002 recorded for an other than temporary decline in the market value of equity securities, and a \$1.6 million loss as of December 31, 2001 recorded for an other than temporary decline in the market value of debt and equity securities. Differences between cost and market listed above, consisting of a net unrealized holding gain less deferred taxes of \$77,000 at June 30, 2002 and \$50,000 as of December 31, 2001, are included in the accumulated other comprehensive income account of shareholders' equity.

At June 30, 2002 and December 31, 2001 approximately \$2.0 million and \$3.4 million, respectively, of marketable securities had a maturity date between 90 days and 1 year, approximately \$4.6 million and \$14.5 million, respectively of marketable securities matured between 1 and 5 years, and approximately \$12.1 million and \$8.6 million of marketable securities matured in more than 5 years or did not have a maturity date.

10

#### NOTE 4 - INVENTORIES

Inventories are comprised of the following (in thousands):

	June 30, 2002	December 31, 2001
Raw materials	\$ 2,402	\$ 1,987
Work-in-process	961	1,183
Finished goods	3,989	3,089
	<u>\$ 7,352</u>	<u>\$ 6,259</u>

#### NOTE 5 - EARNINGS PER SHARE

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

Three Months Ended June 30,		Six Months Ended June 30,	
2002	2001	2002	2001

The effects of stock options of 674,000 and 692,000 shares for the three and six months ended June 30, 2002, respectively, were excluded from the calculation because the amounts are antidilutive for the period presented.

On April 25, 2000 the Company entered into a loan agreement permitting the Company to borrow up to \$8 million under a line of credit during the expansion of the Company's corporate headquarters and manufacturing facilities. Borrowings under the line of credit accrued interest equal to Adjusted LIBOR plus 2% adjusted monthly. On June 1, 2001, the line of credit was converted to a term loan (the "Term Loan") to be paid in 60 equal monthly installments of principal plus interest computed at Adjusted LIBOR plus 1.5% (3.34% at June 30, 2002). At June 30, 2002 the principal balance of the Term Loan was \$6.4 million. The Term Loan is secured by substantially all of the Company's assets. The Term Loan contains certain restrictive covenants including, but not limited to, maintenance of certain financial ratios, a minimum tangible net worth requirement, and the requirement that no materially adverse event has occurred. The lender has notified the Company that the FDA Order, as described in Note 2, and the inquiries of the SEC, as described in Note 12, have had a material adverse effect on the Company that constitute an event of default. As of August

30, 2002 the lender has elected not to declare an event of default, but reserves the right to exercise any such right under the terms of the Term Loan. Therefore, all amounts due under the Term Loan as of June 30, 2002 are reflected as a current liability on the Summary Consolidated Balance Sheet.

In March 1997 the Company issued a \$5.0 million convertible debenture in connection with the Ideas for Medicine, Inc. acquisition. The debenture accrued interest at 7% and was convertible into common stock of the Company at any time prior to the due date of March 5, 2002 at \$8.05 per common share. On March 30, 1998 \$607,000 of the convertible debenture was converted into 75,000 shares of the Company's common stock, and on March 4, 2002 the remaining \$4.4 million was converted into 546,000 shares of the Company's common stock.

The Company's Term Loan, which accrues interest computed at Adjusted LIBOR plus 1.5%, exposes the Company to changes in interest rates going forward. On March 16, 2000, the Company entered into a \$4 million notional amount forward-starting interest swap agreement, which took effect on June 1, 2001 and expires in 2006. This swap agreement was designated as a cash flow hedge to effectively convert a portion of the Term Loan balance to a fixed rate basis, thus reducing the impact of interest rate changes on future income. This agreement involves the receipt of floating rate amounts in exchange for fixed rate interest payments over the life of the agreement, without an exchange of the underlying principal amounts. The differential to be paid or received is recognized in the period in which it

accrues as an adjustment to interest expense on the Term Loan.

On January 1, 2001 the Company adopted SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133") as amended. SFAS 133 requires the Company to recognize all derivative instruments on the balance sheet at fair value, and changes in the derivative's fair value must be recognized currently in earnings or other comprehensive income, as applicable. The adoption of SFAS 133 impacts the accounting for the Company's forward-starting interest rate swap agreement. Upon adoption of SFAS 133, the Company recorded an unrealized loss of approximately \$175,000 related to the interest rate swap, which was recorded as part of long-term liabilities and accumulated other comprehensive income as the cumulative effect of adopting SFAS 133 within the Statement of Shareholders' Equity.

At June 30, 2002 the notional amount of this swap agreement was \$3.2 million, and the fair value of the interest rate swap agreement, as estimated by the bank based on its internal valuation models, was a liability of \$269,000. The fair value of the swap agreement is recorded as part of long-term liabilities and is recorded net of tax as part of accumulated other comprehensive income within shareholders' equity.

#### NOTE 8 -COMPREHENSIVE INCOME

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Net (loss) income	\$ (5,522)	\$ 2,540	\$ (2,418)	\$ 4,510
Unrealized gain/(loss) on investments	128	115	42	817
Change in fair value of interest rate swap (including cumulative effect of adopting SFAS 133 in 2001)	15	5	23	(158)
Translation adjustment	250	(121)	217	(124)
Comprehensive income	\$ (5,129)	\$ 2,539	\$ (2,136)	\$ 5,045

The tax effect on the change in unrealized gain/loss on investments is \$66,000 and \$59,000 for the three months ended June 30, 2002 and 2001, respectively. The tax effect for the six months ended June 30, 2002 and 2001 is \$27,000 and \$398,000, respectively. The tax effect on the change in fair value of the interest rate swap is \$7,000 and \$3,000 for the three months ended June 30, 2002 and 2001, respectively. The tax effect for the six months ended June 30, 2002 and 2001 is \$2,000 and a tax benefit of \$81,000, respectively. The translation adjustment is not currently adjusted for income taxes as it relates to a permanent investment in a foreign subsidiary.

#### NOTE 9 - ACCOUNTING PRONOUNCEMENTS

On January 1, 2002 the Company was required to adopt SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"), and SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"). SFAS 142 specifies that goodwill and certain other intangible assets will no longer be amortized but instead will be subject to periodic impairment testing. SFAS 144 clarifies accounting and reporting for assets held for sale, scheduled for abandonment or other disposal, and recognition of impairment loss related to the carrying value of long-lived assets. The Company has completed its impairment testing as required by FAS 142, and has determined that the recognition of an impairment loss on intangible assets is not required. The adoption of these statements did not have a material effect on the consolidated financial statements of the Company. However, the adoption of SFAS 142 will increase the Company's pretax income by approximately \$100,000 in 2002 due to the cessation of goodwill amortization.

The Company will be required to adopt SFAS No. 143, "Accounting for Asset Retirement Obligations" ("SFAS 143") on January 1, 2003. SFAS 143 addresses

accounting and reporting for asset retirement costs of long-lived assets resulting from legal obligations associated with acquisition, construction, or development transactions. The Company has determined that the adoption of SFAS 143 will not have a material effect on the results of operations or financial position of the Company.

The Company will be required to adopt SFAS No. 145, "Rescission of FASB Statements 4, 44 and 64, Amendment to FASB Statement 13, and Technical Corrections" ("SFAS 145") on January 1, 2003. SFAS 145 changes the accounting for the classification of gains and losses from the extinguishment of debt. The Company is currently evaluating the impact of this Statement.

The Company will be required to adopt SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146") on January 1, 2003. SFAS 146 requires that costs associated with exit or disposal activities be recorded at their fair values when a liability has been incurred. Under previous guidance, certain exit costs were accrued upon management's commitment to an exit plan, which is generally before an actual liability has been incurred. The Company is currently evaluating the impact of this Statement.

#### NOTE 10 - SEGMENT INFORMATION

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

The HUMAN TISSUE PRESERVATION SERVICES segment includes external revenue from cryopreservation services of cardiac, vascular, and orthopaedic allograft tissues. The IMPLANTABLE MEDICAL DEVICES segment includes external revenue from product sales of BioGlue Surgical Adhesive and bioprosthetic devices, including stentless porcine heart valves, SynerGraft treated porcine heart valves, and SynerGraft treated bovine vascular grafts. There are no intersegment revenues.

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

13

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Revenue:				
Human tissue preservation services, net a	17,536	18,765	37,774	37,331
Implantable medical devices	5,473	2,789	10,538	5,430
All other b	255	143	423	368
	<u>\$ 23,264</u>	<u>\$ 21,697</u>	<u>\$ 48,735</u>	<u>\$ 43,129</u>
Cost of Preservation Services and Products:				
Human tissue preservation services c	17,203	7,697	25,266	15,370
Implantable medical devices	1,843	1,423	4,078	2,855
All other b	--	--	--	--
	<u>19,046</u>	<u>9,120</u>	<u>29,344</u>	<u>18,225</u>
Gross Margin (Loss):				
Human tissue preservation services	333	11,068	12,508	21,961
Implantable medical devices	3,630	1,366	6,460	2,575
All other b	255	143	423	368
	<u>\$ 4,218</u>	<u>\$ 12,577</u>	<u>\$ 19,391</u>	<u>\$ 24,904</u>

a Revenue from human tissue preservation services includes the estimated effect of the return of tissues subject to recall by the FDA Order of \$2.4 million in the three and six months ended June 30, 2002.

- b The "All other" designation includes 1) grant revenue and 2) distribution revenue.
- c Cost of human tissue preservation services includes the write-down of deferred preservation costs for tissues subject to the FDA Order of \$10.0 million in the three and six months ended June 30, 2002.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Revenue:				
Human tissue preservation services, net a:				
Cardiovascular tissue	\$ 7,336	\$ 7,182	\$ 14,644	\$ 14,093
Vascular tissue	4,641	6,017	11,658	12,429
Orthopaedic tissue	5,559	5,566	11,472	10,809
Total preservation services	17,536	18,765	37,774	37,331
BioGlue surgical adhesive	5,251	2,631	10,124	5,074
Bioprosthetic devices	222	158	414	356
Distribution and grant	255	143	423	368
	\$ 23,264	\$ 21,697	\$ 48,735	\$ 43,129

- a Revenue from tissue preservation services includes the estimated effect of the return of tissues subject to recall by the FDA Order of \$340,000 in cardiovascular tissue, \$1.7 million in vascular tissue, and \$380,000 in orthopaedic tissue, totaling \$2.4 million, for the three and six months ended June 30, 2002.

#### NOTE 11 - COMMITMENTS AND CONTINGENCIES

In the normal course of business as a medical device and services company the Company has product liability complaints filed against it. As of August 30, 2002 fifteen product liability cases had been filed against the Company between May 18, 2000 and August 15, 2002. The cases are currently in the pre-discovery or discovery stages. Of these cases, nine allege product liability claims arising out of the Company's orthopaedic tissue, four allege product liability claims arising out of the Company's allograft heart valve tissue and one alleges product liability claims arising out of the non-tissue products made by Ideas for Medicine, when it was a subsidiary of the Company.

Included in these cases is the complaint filed against the Company in the Superior Court of Cobb County, Georgia, on July 12, 2002 by Steve Lykins, as Trustee for the benefit of next of kin of Brian Lykins. This complaint alleges strict liability, negligence, professional negligence, and breach of warranties related to tissue implanted in November of 2001. The plaintiff seeks unspecified compensatory and punitive damages.

The Company maintains product liability insurance policies, which the Company believes to be adequate to defend against these suits. The Company's insurance company has been notified of these actions. The Company intends to vigorously defend against these claims. Nonetheless, an adverse judgment in excess of the Company's insurance coverage could have a material adverse effect on the Company's financial position, results of operations, and cash flows.

Several putative class action lawsuits were filed in July 2002, one of which was amended in August of 2002, against the Company and certain officers of the Company alleging that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, by issuing a series of materially false and misleading statements to the market throughout the Class Period of August of 2000 through August of 2002, which statements had the effect of artificially inflating the market price of the Company's securities. The principal allegations of the complaints are that the Company failed to disclose its alleged lack of compliance with certain FDA regulations regarding the handling and processing of certain tissues and other

product safety matters. The plaintiffs seek unspecified compensatory damages in an amount to be proven at trial. The Company believes these cases will be consolidated into one putative class action lawsuit. The Company believes the claims made in the lawsuits are without merit and intends to vigorously defend against these claims. Management has retained the services of the Atlanta based law firm of King & Spalding to defend the Company. The Company carries director's and officer's liability insurance which the Company believes to be adequate to defend against these suits. Nonetheless, an adverse judgment in excess of the Company's insurance coverage could have a material adverse effect on the Company's financial position, results of operations, and cash flows.

The Company has concluded that it is probable that it will incur losses relating to claims and litigation of at least \$1.2 million; which represents the aggregate amount of the Company's deductibles under its product liability and directors and officer's insurance policies. Therefore the Company has recorded an accrual of \$1.2 million as of June 30, 2002.

#### NOTE 12 - SUBSEQUENT EVENTS

On July 23, 2002 the Company's Board of Directors authorized the purchase of up to \$10 million of its Common Stock. As of August 13, 2002 the Company had repurchased 68,000 shares of its Company stock for \$666,000. No further purchases are anticipated in the near term.

On July 30, 2002 the Company entered into a line of credit agreement with the lender that made the Term Loan, as discussed in Note 6, permitting the Company to borrow up to \$10 million. Borrowings under the line of credit agreement accrue interest equal to Adjusted LIBOR plus 1.25% adjusted monthly. This loan is secured by substantially all of the Company's assets. As of August 30, 2002 \$6,900 has been drawn on the line of credit. As a result of the FDA Order, as discussed in Note 2, the Company is not in compliance with the lender's requirements for advances of funds under the line of credit. On August 21, 2002 the lender notified the Company that it was not entitled to any further advances under the line of credit.

15

On August 7, 2002 the Company announced the settlement of its ongoing litigation with Colorado State University Foundation ("CSURF") over the ownership of the Company's SynerGraft technology. The settlement resolves all disputes between the parties and extinguishes all CSURF ownership claims to any aspect of CryoLife's SynerGraft technology. The settlement includes an unconditional assignment to CryoLife of CSURF tissue engineering patents, trade secrets and know-how relating to tissue decellularization and recellularization. The technology assignment supercedes the 1996 technology license, which was terminated by the terms of the settlement. Payment terms include a nonrefundable advance of \$400,000 paid by the Company to CSURF that will be applied to earned royalties as they accrue through March 2011. The Company will record these amounts as prepaid royalties and will expense the amounts as the royalties accrue. The earned royalty rate is a maximum of 0.75% of net revenues from products or tissue services utilizing the SynerGraft technology. Royalties earned under the agreement for revenues through June 30, 2002 were approximately \$27,000.

On August 14, 2002 the compensation committee determined to pay bonuses to Steven G. Anderson, Chairman, President and CEO, of \$225,000 and Sidney B. Ashmore, Vice President Marketing, of \$15,000. On August 16, 2002 the compensation committee determined to pay a bonus to James Vander Wyk, Vice President Regulatory Affairs and Quality Assurance, of \$60,000. In each case the compensation committee determined to grant the mid-year bonus in recognition of the officer's efforts on behalf of the Company in addressing important Company issues in difficult times, the officer's long term service to the Company, and to accommodate the economic needs of the officers arising from their desire to retain Company shares rather than permit them to be sold pursuant to margin calls. These officers now have no margin loans against their shares.

On Saturday, August 17, 2002 the Company received a letter from the United States Securities and Exchange Commission (the "SEC Letter") that stated that the Company was subject to an investigation related to the Company's August 14, 2002 announcement of the FDA Order and requesting information from the Company from the period between September 1, 2001 through the date of the Company's response to the SEC Letter. The SEC Letter stated, in part, that "We are trying to determine whether there have been any violations of the federal securities

laws. The investigation and the subpoena do not mean that we have concluded that anyone has broken the law. Also, the investigation does not mean that we have a negative opinion of any person, entity or security." The staff of the SEC subsequently confirmed that its investigation is informal in nature, and that it does not have subpoena power at this time. At the present time, the Company is unable to predict the outcome of this matter.

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

RECENT EVENTS

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 tissue processed by the Company since October 3, 2001 (the "FDA Order"). Revenue from human tissue preservation services accounted for 78% of the Company's revenues for the six months ended June 30, 2002, and of those revenues 67% or \$26.9 million are derived from preservation of tissues subject to the FDA Order. The Company announced the receipt of the FDA Order in a press release dated August 14, 2002. The FDA Order follows an FDA warning letter dated June 17, 2002, which the Company announced in a press release dated June 24, 2002. Subsequently, the Company responded to the warning letter and requested a meeting with the FDA. The FDA Order contains the following principal provisions:

- o The FDA alleges that, based on its inspection of the Company's facility on March 25 through April 12, 2002, certain human tissue received and distributed by the Company may be in violation of 21 Code of Federal Regulations ("CFR") 1270. Code 21, 1270 (PROVIDE A BRIEF DESCRIPTION OF WHAT THIS IS)
- o The FDA alleges that the Company has not validated procedures for the prevention of infectious disease contamination or cross-contamination of tissue during processing at least since October 3, 2001.
- o Non-valved cardiac, vascular, and orthopaedic tissue processed by the Company since October 3, 2001 must be retained until it is recalled, destroyed, the safety is confirmed, or an agreement is reached with the FDA for its proper disposition under the supervision of an authorized official of the FDA.
- o The FDA strongly recommends that CryoLife perform a retrospective review of all tissue in inventory that is not referenced in the FDA Order to assure that it was recovered, processed, stored, and distributed in conformance with 21 CFR 1270
- o The Center for Devices and Radiological Health ("CDRH") is evaluating whether there are similar risks that may be posed by CryoLife's allograft heart valves, and will take further regulatory action if appropriate.

Pursuant to the FDA Order, the Company has placed all non-valved cardiac, vascular, and orthopaedic tissue subject to the FDA Order on quality assurance quarantine and is recalling all non-valved cardiac, vascular, and orthopaedic tissues subject to the FDA Order that have been distributed but not implanted. After the FDA issued its order regarding the recall, Health Canada also issued a recall on the same types of tissue and the United Kingdom Department of Health has begun investigating tissue exported by the Company.

The Company appealed the FDA Order on August 14, 2002 and requested a hearing with the FDA. No dates have been set for the hearing. In addition, the Company has requested a modification of the FDA Order to allow distribution of certain non-valved cardiac tissues and vascular tissues which are used in life saving or limb salvaging surgical procedures. The Company has met with the FDA and is holding on-going discussions regarding its request for modification of the FDA Order to accommodate distribution of non-valved cardiac and vascular tissue in life saving and limb salvaging situations. The Company is unable to predict if it will obtain a favorable outcome to its appeal or request for modification of the FDA Order or the timing of the resolution of these matters.

After receiving the FDA Order, the Company met with representatives of the FDA's CDRH division regarding CDRH's review of the Company's processed allograft heart valves, which are not required to be recalled pursuant to the FDA Order. On August 21, 2002 the FDA publicly stated that allograft heart valves have not

17

been included in the FDA recall order as these devices are essential for the correction of congenital cardiac lesions in neonate and pediatric patients and no satisfactory alternative device exists. However, the FDA also publicly stated that it still has serious concerns regarding the processing and handling of allograft heart valves. The FDA also recommended that surgeons carefully consider using processed allografts from alternative sources, that surgeons inform prospective patients of the FDA's concerns with the Company's allograft heart valves, and that patients be carefully monitored for both fungal and bacterial infections.

Management has determined that, with respect to tissue subject to the FDA Order, product liability claims and shareholder litigation, the FDA Order received on August 13, 2002 is a type one subsequent event, as defined by generally accepted auditing standards in the United States, which requires adjustment to the second quarter financial statements. A type one subsequent event provides additional evidence about conditions which existed at the balance sheet date, and results in changes to the estimates used to prepare the financial statements. Management has made this determination because the FDA Order clarified the accounting estimates surrounding the June 17, 2002 FDA warning letter, which stated a recall was a possible course of action for the FDA if the warning letter issues were not resolved promptly. The Company was working with the FDA to correct the issues and did not believe a recall would be instated. Therefore, the Company previously estimated that there was no material accounting impact from the FDA warning letter. This estimate was revised due to the receipt of the FDA Order. Management has determined that the negative implications of the FDA Order to the tissue revenues not subject to the FDA Order and any resulting impairments of other assets or incurrence of liabilities do not represent a type one subsequent event and therefore any necessary adjustments will be recorded in future periods.

As a result of the FDA Order, the Company has recorded a reduction to pretax income of \$12.6 million, in the quarter ended June 30, 2002. The reduction was comprised of a net \$8.9 million increase to cost of human tissue preservation services, a \$2.4 million reduction to revenues (and accounts receivable) for the estimated return of the tissues subject to recall by the FDA Order, and a \$1.3 million accrual recorded in general, administrative, and marketing expenses for retention levels under the Company's product liability and directors' and officers' insurance policies of \$1.2 million (see Note 11) and for estimated expenses of \$75,000 for packaging and handling for the return of affected tissues under the FDA Order.

The net increase of \$8.9 million to cost of preservation services is comprised of a \$10.0 million write-down of deferred preservation costs for tissues subject to the FDA Order, offset by a \$1.1 million decrease in cost of preservation services due to the estimated tissue returns resulting from the FDA Order. The Company evaluated many factors in determining the magnitude of impairment to deferred preservation costs, including the impact of the current FDA Order, the possibility of continuing action by the FDA or other United States and foreign government agencies, and the possibility of unfavorable actions by physicians, customers, procurement organizations, and others. As a result of this evaluation, management believes that since all non-valved cardiac, vascular, and orthopaedic allograft tissues processed since October 3, 2001 are under recall pursuant to the FDA Order, and the Company does not know if it will obtain a favorable resolution of its appeal and request for modification of the FDA Order, the deferred preservation costs for tissues subject to the FDA Order have been significantly impaired. The Company has estimated that this impairment approximates the full balance of the deferred preservation costs of the tissues subject to the FDA Order, which includes the tissues stored by the Company and the tissues to be returned to the Company, and has therefore recorded a write-down of \$10.0 million for these assets.

As of June 30, 2002 deferred preservation costs of tissues not subject to the FDA Order (i.e. tissue processed prior to October 3, 2001) were \$829,000 for non-valved cardiac tissues, \$7.3 million for vascular tissues, and \$4.7 million for orthopaedic tissues. Deferred preservation costs for allograft heart valves,



which are not subject to the FDA Order, were \$8.5 million as of June 30, 2002. The Company is continuing to ship these tissues.

The Company evaluated many factors in determining the potential impairment of the deferred preservation costs for non-valved cardiac, vascular, and orthopaedic tissues processed prior to October 3, 2001 and all of the Company's allograft heart valves, as these tissue populations are not subject to the FDA

Order. The allograft heart valve, non-valved cardiac, and vascular tissues are principally used in life saving and limb salvaging surgical procedures and are often used after all other avenues of treatment have been exhausted. Therefore, the Company believes that non-valved cardiac tissues and vascular tissues processed prior to October 3, 2001 and allograft heart valves will continue to be in demand. Although management believes that the demand for non-valved cardiac and vascular tissues processed prior to October 3, 2001 and all allograft heart valves stored by the Company will be affected by the adverse publicity surrounding the FDA Order, the Company cannot estimate the degree to which these tissues have been impaired. The Company may determine in the future that a write-down of the deferred preservation costs for these tissues is necessary. Management will continue to monitor the Company's progress in satisfying the FDA's requirements and the effect of the FDA Order and the related adverse publicity on the demand for these tissues to determine if additional write-downs of deferred preservation costs are required.

Management has reviewed the current circumstances relating to orthopaedic tissues not subject to the FDA order (i.e. processed prior to October 3, 2001), including whether there were indications of impairment of deferred preservation costs for such tissues as of June 30, 2002. Management has determined that the demand for orthopaedic tissues had not been affected sufficiently as of June 30, 2002 to cause an impairment in the deferred preservation costs related to these tissues (i.e., cost was not in excess of market). Accordingly, the Company has not recorded a write-down in the deferred preservation costs related to the orthopaedic tissue processed prior to October 3, 2001 in the June 30, 2002 financial statements. However, the adverse publicity following the FDA Order has resulted in a significant decrease in orthopaedic tissue revenues since August 13, 2002. As a result, management believes that the deferred preservation costs for orthopaedic tissues not subject to the FDA Order have been impaired in the third quarter of 2002 and expects that it will record a substantial write-down of such costs in the third quarter of 2002.

As noted above, the FDA Order strongly recommends that the Company perform a retrospective review of all tissue in inventory not subject to the FDA Order. The Company is having ongoing discussions with the FDA to establish the procedures to be followed in the retrospective review and therefore is currently unable to reasonably estimate the costs for such review. Once the Company and the FDA agree on these procedures the Company will evaluate the costs associated with performing the review and record an appropriate accrual for these costs.

The Company periodically evaluates the recoverability of noncurrent tangible and intangible assets and measures the amount of impairment, if any. Management does not believe an impairment of the Company's tangible and intangible assets relating to the tissue preservation business has occurred as of June 30, 2002. However, depending on the outcome of the FDA Order and the future effects of adverse publicity surrounding the FDA Order and reported infections on preservation revenues, these assets may become impaired. Management will continue to evaluate the recoverability of these assets.

The Company anticipates that the FDA Order will also affect the financial position, results of operations, and cash flows of the Company for the quarter ended September 30, 2002. In addition to the anticipated write-down of deferred preservation costs for orthopaedic tissue, the Company expects a \$1.0 million reversal of revenues recorded in July and August, due to the estimated returns of tissues subject to the FDA Order, which were shipped in July and August. The deferred preservation costs of tissues processed during the third quarter of 2002 that are subject to the FDA Order approximate \$3.9 million as of August 14, 2002. The deferred preservation costs of these tissues processed during the third quarter are anticipated to be fully impaired and the Company expects to record a write-down approximating their full cost in the third quarter.

On July 23, 2002 the Company's Board of Directors authorized the purchase of up to \$10 million of its Common Stock. As of August 13, 2002 the Company had

repurchased 68,000 shares of its Company stock for \$666,000. No further purchases are anticipated in the near term.

On August 7, 2002 the Company announced the settlement of its ongoing litigation with Colorado State University Foundation ("CSURF") over the ownership of the Company's SynerGraft technology. The settlement resolves all disputes between the parties and extinguishes all CSURF ownership claims to any aspect of CryoLife's SynerGraft technology. The settlement includes an unconditional assignment to CryoLife of CSURF tissue engineering patents, trade secrets and

19

know-how relating to tissue decellularization and recellularization. The technology assignment supercedes the 1996 technology license, which was terminated by the terms of the settlement. Payment terms include a nonrefundable advance of \$400,000 paid by the Company to CSURF that will be applied to earned royalties as they accrue through March 2011. The Company will record these amounts as prepaid royalties and will expense the amounts as the royalties accrue. The earned royalty rate is a maximum of 0.75% of net revenues from products or tissue services utilizing the SynerGraft technology. Royalties earned under the agreement for revenues through June 30, 2002 were approximately \$27,000.

On August 14, 2002 the compensation committee determined to pay bonuses to Steven G. Anderson, Chairman, President and CEO, of \$225,000 and Sidney B. Ashmore, Vice President Marketing, of \$15,000. On August 16, 2002 the compensation committee determined to pay a bonus to James Vander Wyk, Vice President Regulatory Affairs and Quality Assurance, of \$60,000. In each case the compensation committee determined to grant the mid-year bonus in recognition of the officer's efforts on behalf of the Company in addressing important Company issues in difficult times, the officer's long term service to the Company, and to accommodate the economic needs of the officers arising from their desire to retain Company shares rather than permit them to be sold pursuant to margin calls. The officers now have no margin loans against their shares.

On Saturday, August 17, 2002 the Company received a letter from the United States Securities and Exchange Commission (the "SEC Letter") that stated that the Company was subject to an investigation related to the Company's August 14, 2002 announcement of the FDA Order and requesting information from the Company from the period between September 1, 2001 through the date of the Company's response to the SEC Letter. The SEC Letter stated, in part, that "We are trying to determine whether there have been any violations of the federal securities laws. The investigation and the subpoena do not mean that we have concluded that anyone has broken the law. Also, the investigation does not mean that we have a negative opinion of any person, entity or security." The staff of the SEC subsequently confirmed that the investigation is informal in nature, and that it does not have subpoena power at this time. At the present time, the Company is unable to predict the outcome of this matter.

On September 3, 2002 the Company announced a reduction in employee force of approximately 105 employees. The Company anticipates that severance and related costs will be approximately \$625,000, which will be recorded in the third quarter of 2002. As a result of the employee reduction, management anticipates personnel costs will be reduced by approximately \$360,000 per month.

#### CRITICAL ACCOUNTING POLICIES

A summary of the Company's significant accounting policies is included in Note 1 to the consolidated financial statements, as filed in the Form 10-K for the fiscal year ended December 31, 2001. 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 consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States, 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.

**REVENUE RECOGNITION:** The Company recognizes revenue in accordance with SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"), which provides guidance on applying generally accepted accounting

principles to revenue recognition issues. Revenues for human tissue preservation services are recognized when services are completed and tissue is delivered to the customer. The Company accepts returned human tissue within 72 hours of

original shipment. The Company has recorded the estimated revenues of tissues to be recalled pursuant to the FDA Order as a service revenue return. Revenues for products are recognized at the time the product is shipped, at which time title passes to the customer. There are no further performance obligations and delivery occurs upon shipment. Revenues from research grants are recognized in the period the associated costs are incurred. The Company assesses the likelihood of collection based on a number of factors, including past transaction history with the customer and the credit-worthiness of the customer.

**DEFERRED PRESERVATION COSTS:** Tissue is procured from deceased human donors by organ procurement agencies and tissue banks, 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 hospital. Deferred preservation costs consist primarily of laboratory expenses, tissue procurement fees, fringe and facility allocations, and freight-in charges, and are stated, net of reserve, on a first-in, first-out basis. As of June 30, 2002 the deferred preservation costs were \$8.5 million for allograft heart valve tissues, \$829,000 for non-valved cardiac tissues, \$7.3 million for vascular tissues, and \$4.7 million for orthopaedic tissues, excluding valuation allowances of \$300,000. At June 30, 2002 the Company recorded a write-down of deferred preservation costs of \$1.6 million for non-valved cardiac tissues, \$5.0 million for vascular tissues, and \$3.4 million for orthopaedic tissue totaling \$10.0 million. These write-downs were recorded as a result of the FDA Order as discussed in the Recent Events section. The amount of these write-downs reflects management's estimate based on information currently available to it. These estimates may prove inaccurate, as the scope and impact of the FDA Order are determined. Management will continue to evaluate the recoverability of these deferred preservation costs based on the factors discussed in the Recent Events section and record additional write-downs if it becomes clear that additional impairments have occurred.

**INTANGIBLE ASSETS:** Goodwill resulting from business acquisitions is not amortized, but is instead subject to periodic impairment testing in accordance with FAS 142. Patent costs are amortized over the expected useful lives of the patents (primarily 17 years) using the straight-line method. Other intangibles, which consist primarily of manufacturing rights and agreements, are amortized over the expected useful lives of the related assets (primarily five years). The Company periodically evaluates the recoverability of noncurrent tangible and intangible assets and measures the amount of impairment, if any. Management does not believe an impairment exists to the intangible assets relating to the tissue preservation business. However, depending on outcome of the FDA Order and the future effects adverse publicity surrounding the FDA Order and reported infections on preservation revenues, these assets may become impaired. Management will continue to evaluate the recoverability of these intangible assets.

#### NEW ACCOUNTING PRONOUNCEMENTS

On January 1, 2002 the Company was required to adopt SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"), and SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"). SFAS 142 specifies that goodwill and certain other intangible assets will no longer be amortized but instead will be subject to periodic impairment testing. SFAS 144 clarifies accounting and reporting for assets held for sale, scheduled for abandonment or other disposal, and recognition of impairment loss related to the carrying value of long-lived assets. The Company has completed its impairment testing as required by FAS 142, and has determined that the recognition of an impairment loss on intangible assets is not required. The adoption of these statements did not have a material effect on the consolidated financial statements of the Company. However, the adoption of SFAS 142 will increase the Company's pretax income by approximately \$100,000 in 2002 due to the cessation of goodwill amortization.

The Company will be required to adopt SFAS No. 143, "Accounting for Asset Retirement Obligations" ("SFAS 143") on January 1, 2003. SFAS 143 addresses accounting and reporting for asset retirement costs of long-lived assets resulting from legal obligations associated with acquisition, construction, or

development transactions. The Company has determined that the adoption of SFAS 143 will not have a material effect on the financial position, results of operations, and cash flows of the Company.

The Company will be required to adopt SFAS No. 145, "Rescission of FASB Statements 4, 44 and 64, Amendment to FASB Statement 13, and Technical Corrections" ("SFAS 145") on January 1, 2003. SFAS 145 changes the accounting for the classification of gains and losses from the extinguishment of debt. The Company is currently evaluating the impact of this Statement.

The Company will be required to adopt SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146") on January 1, 2003. SFAS 146 requires that costs associated with exit or disposal activities be recorded at their fair values when a liability has been incurred. Under previous guidance, certain exit costs were accrued upon management's commitment to an exit plan, which is generally before an actual liability has been incurred. The Company is currently evaluating the impact of this Statement.

## RESULTS OF OPERATIONS

### REVENUES

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Revenues	\$ 23,264	\$ 21,697	\$ 48,735	\$ 43,129
Revenues excluding recall	\$ 25,697	\$ 21,697	\$ 51,168	\$ 43,129

Revenues increased 7% and 13%, respectively, for the three and six months ended June 30, 2002. Revenues were adversely impacted by the estimated effect of the return of tissues subject to recall by the FDA Order, which resulted in an estimated decrease of \$2.4 million in preservation service revenues during the three and six months ended June 30, 2002.

Excluding the effect of the FDA Order, revenues increased 18% and 19%, respectively, for the three and six months ended June 30, 2002. This increase in revenues for the three month and six month periods ended June 30, 2002 was primarily due to increased sales of BioGlue Surgical Adhesive and growth in the Company's preservation businesses. The increases are primarily attributable to the receipt of FDA approval for BioGlue in December 2001, a greater acceptance of these products by the surgical community and the Company's ability to procure greater amounts of tissue. Management currently believes the FDA Order will have an adverse impact on these trends.

The Company has not yet determined the full impact of the FDA Order on future revenues. In the event the Company is not successful in its appeal of the FDA Order or is unable to reach a satisfactory agreement with the FDA, future revenues can be expected to decrease significantly. Revenues from human tissue preservation services accounted for 78% of the Company's revenues for the six months ended June 30, 2002, and of those revenues 67% were derived from preservation of tissues subject to the FDA Order. In 2001 revenues for human tissue preservation services were 87% of the Company's revenues, or \$75.6 million, and of those revenues 68%, or \$51.6 million, were derived from preservation of tissues subject to the FDA Order.

### BIOGLUE SURGICAL ADHESIVE

Three Months Ended June 30,	Six Months Ended June 30,
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	2002	2001	2002	2001
Revenues	\$ 5,251	\$ 2,631	\$ 10,124	\$ 5,074
Percentage of total revenue	23%	12%	21%	12%
Percentage of total revenue excluding recall	20%	12%	20%	12%

Revenues from the sale of BioGlue Surgical Adhesive increased 100% for the three and six month periods ended June 30, 2002. The increase in revenues for the three month and six month periods ended June 30, 2002 was due to an increase in

the milliliters of BioGlue shipped of 81% and 79%, respectively, and an increase in the average selling price of the BioGlue shipped. The increase in shipments was primarily due to the receipt of FDA approval in December 2001 for the use of BioGlue in the United States as an adjunct in open surgical repair of large vessels for adult patients. Domestic revenues accounted for 77% and 64% of total BioGlue revenues for the three months ended June 30, 2002 and 2001, respectively. Domestic revenues accounted for 78% and 65% of total BioGlue revenues for the six months ended June 30, 2002 and 2001, respectively.

Although BioGlue was not included in the FDA Order, future sales of BioGlue could be adversely affected due to the adverse publicity surrounding the FDA's review of and correspondence with the Company. Additionally, there is a possibility the Company's BioGlue operations could come under increased scrutiny from the FDA as a result of their review of the Company's tissue processing laboratories.

#### PRESERVATION SERVICE REVENUES

Quarter over quarter statistics presented for tissues procured and processed for human tissue preservation services are from the period February through April, as such procurement and processing of tissues received during this time period is the primary generator of second quarter revenues. Year-to-date over year-to-date statistics presented for tissues procured and processed for human tissue preservation services are from the period beginning in November of the prior year through April of the year presented, as such procurement and processing of tissues received during this time period is the primary generator of year-to-date revenues. During the time period for which procurement statistics are discussed, the Company benefited from significant increases in procurement due to new relationships with tissue banks and competitive wins of tissue bank contracts. Additionally, the Company changed certain tissue acceptance guidelines, which resulted in an increase in tissues procured and processed. Tissue acceptance and processing guidelines include donor age, gender, manner of death, time of procurement, and other factors. These guidelines are under constant review to allow the most recipients to benefit from donated tissues, while preserving the quality of tissue procured and processed. Tissue acceptance guidelines are changed periodically through the general course of business based on the demand for certain types or sizes of tissue and based on the scientific analysis of the viability of tissues procured under the guidelines. More stringent guidelines have recently been implemented for certain tissues.

The increases in procurement surpassed the Company's expectations during this period. However, the Company expects that future procurement levels of all tissues will decrease as a result of the uncertainties surrounding the Company's inability to continue to ship non-valved cardiac, vascular and orthopaedic grafts as a result of the FDA Order and due to the uncertainties as to whether tissue banks will continue to send tissues to the Company to process as a result of the adverse publicity surrounding the FDA's review and the FDA Order. As of August 14, 2002 the Company reduced its acceptance of orthopaedic and vascular tissues for processing to minimal levels until it receives resolution of its request for modification or appeal of the FDA Order. The Company is continuing to accept cardiac tissues for processing from tissue banks. As of August 30, 2002 the Company estimates approximately 50% of its cardiovascular procurement has been suspended due to the FDA Order and the surrounding publicity.

Due to a variety of factors, primarily the FDA Order, but including the time required to process the greater amounts of tissue, the increase in processing time and complexity for tissues processed using the SynerGraft technology, the focus of the Company on the marketing and rollout of BioGlue, and adverse publicity resulting from certain tissue infections and lawsuits during this

period, the increases in tissues procured and processed did not translate into equivalent increases in revenues from preservation services. As a result of this increased procurement, the level of deferred preservation costs prior to write-downs increased in all of the Company's main tissue service categories: cardiac, vascular, and orthopaedic. These higher levels of deferred preservation costs are expected to result in some revenue growth for allograft heart valve tissues in the short term as the Company provides services related to the more critical implant needs. The Company expects that the majority of this increase in procurement will generate more modest increases in service revenues over a longer period of time for cardiac tissues, as less critical need tissues and tissues of various sizes are properly matched with recipients.

#### CARDIOVASCULAR PRESERVATION SERVICES

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Revenues	\$ 7,336	\$ 7,182	\$ 14,644	\$ 14,093
Percentage of total revenue	32%	33%	30%	33%
Revenues excluding recall	\$ 7,676	\$ 7,182	\$ 14,984	\$ 14,093
Percentage of total revenue	30%	33%	29%	33%

Revenues from cardiovascular preservation services increased 2% and 4%, respectively, for the three and six months ended June 30, 2002. The revenues from cardiovascular preservation services were adversely impacted by the estimated effect of the tissues returned subject to the FDA Order on service revenues for non-valved cardiac tissues, which resulted in an estimated decrease of \$340,000 in service revenues during the three and six months ended June 30, 2002. At June 30, 2002 \$9.3 million of cardiac deferred preservation costs related to tissue not subject to the FDA Order was available for shipment.

Excluding the effect of the FDA Order, revenues from cardiovascular preservation services increased 7% and 6%, respectively, for the three and six months ended June 30, 2002. This increase in revenues for the three month and six month periods ended June 30, 2002 was in part due to an increase in the number of cardiovascular allograft shipments of 3% in each such period as a result of a 20% and 23% increase in cardiovascular tissues procured and processed quarter over quarter and year-to-date over year-to-date, respectively. Additionally, average service fees were higher by 4% and 3%, during the three and six months ended June 30, 2002, respectively, due to an increase in shipments during 2002 as compared to 2001 of SynerGraft processed cardiovascular grafts, which have higher service fees than non-SynerGraft cardiovascular grafts.

The Company anticipates a future decrease in cardiovascular preservation revenues as a result of the uncertainties regarding the Company's inability to ship non-valved cardiac tissue processed since October 3, 2001 pursuant to the FDA Order and the adverse publicity surrounding the FDA's review of and correspondence with the Company.

#### VASCULAR PRESERVATION SERVICES

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Revenues	\$ 4,641	\$ 6,017	\$ 11,658	\$ 12,429

Percentage of total revenue		20%		28%		24%		29%
Revenues excluding recall	\$	6,354	\$	6,017	\$	13,371	\$	12,429
Percentage of total revenue		25%		28%		26%		29%

Revenues from human vascular tissue preservation services decreased 23% and 6%, respectively, for the three and six months ended June 30, 2002. The revenues from vascular tissue preservation services were adversely impacted by the estimated effect of the return of tissues subject to recall by the FDA Order, which resulted in an estimated decrease of \$1.7 million in service revenues during the three and six months ended June 30, 2002. At June 30, 2002 \$7.3 million of vascular deferred preservation costs related to tissue not subject to the FDA Order was available for shipment.

24

Excluding the effect of the FDA Order, revenues from human vascular tissue preservation services increased 6% and 8%, respectively, for the three and six months ended June 30, 2002. This increase in revenues for the three month and six month periods ended June 30, 2002 was due to an increase in the number of vascular allograft shipments of 8% and 3%, respectively, which resulted from a 17% increase in vascular tissues procured and processed year-to-date over year-to-date.

The Company anticipates a future decrease in vascular preservation revenues due to the Company's inability to ship vascular grafts processed subsequent to October 2, 2001 pursuant to the FDA Order and the adverse publicity surrounding the FDA's review of and correspondence with the Company. If the Company is unable to obtain a favorable decision from its appeal or request for modification of the FDA Order and/or to clear the issues as outlined in the FDA's warning letter and the FDA Order, future vascular preservation revenues, if any, may be immaterial.

#### ORTHOPAEDIC PRESERVATION SERVICES

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Revenues	\$ 5,559	\$ 5,566	\$ 11,472	\$ 10,809
Percentage of total revenue	24%	26%	24%	25%
Revenues excluding recall	\$ 5,939	\$ 5,566	\$ 11,852	\$ 10,809
Percentage of total revenue	23%	26%	23%	25%

Revenues from human orthopaedic tissue preservation services increased 0% and 6% for the three and six months ended June 30, 2002. The revenues from orthopaedic tissue preservation services were adversely impacted by the estimated effect of the return of tissues subject to recall by the FDA Order, which resulted in an estimated decrease of \$380,000 in service revenues during the three and six months ended June 30, 2002. At June 30, 2002 \$4.7 million of orthopaedic deferred preservation costs related to tissue not subject to the FDA Order was available for shipment; see discussion of impairment of this asset in the Recent Events section.

Excluding the effect of the FDA Order, revenues from human orthopaedic tissue preservation services increased 7% and 10% for the three and six months ended June 30, 2002. This increase in revenues for the three month and six month periods ended June 30, 2002 was primarily due to an increase in the number of allograft shipments of 6% and 8%, respectively. The increase in orthopaedic shipments, primarily boned tendons, resulted from a 76% and 62% increase in orthopaedic allograft tissues procured and processed quarter over quarter and year-to-date over year-to-date, respectively, and an increasing acceptance of these tissues in the orthopaedic surgeon community. Shipments of boned tendons increased 42% and 52% in the three and six months ended June 30, 2002, respectively, due to increased availability of these higher demand tissues,

which resulted in an increase of \$400,000 and \$1 million in revenues with respect to these tissues for the three and six months ended June 2002 as compared to the same periods in 2001, partially offset by a decrease in shipments of non-boned tendons. Additional increases in revenues in the six-month period were due to a more favorable product mix, with increased shipments of hemi-osteochondral grafts, which carry higher average service fees than other orthopaedic tissues. The increases in orthopaedic revenues were smaller than anticipated, due to the effects of adverse publicity surrounding the reports of infections in some orthopaedic allograft recipients.

The Company anticipates a substantial decrease in the orthopaedic preservation revenues in the future due to the Company's inability to ship orthopaedic grafts processed since October 3, 2001 pursuant to the FDA Order, the adverse publicity surrounding the FDA's review of and correspondence with the Company, and the reported infections in some orthopaedic allograft recipients. If the Company is unable to clear the issues as outlined in the FDA's warning letter and FDA Order or obtain a favorable appeal of the FDA Order, future orthopaedic preservation revenue, if any, may be immaterial. These factors would be likely to result in a substantial decrease of revenues from tissues preserved both prior to and since October 3, 2001.

#### BIOPROSTHETIC DEVICES

Revenues from bioprosthetic cardiovascular devices increased 41% to \$222,000 for the three months ended June 30, 2002 from \$158,000 for the three months ended June 30, 2001, representing 1% of total revenues during each such period. Revenues from bioprosthetic cardiovascular devices increased 16% to \$414,000 for the six months ended June 30, 2002 from \$356,000 for the six months ended June 30, 2001, representing 1% of total revenues during each such period.

#### DISTRIBUTION AND GRANT REVENUES

Distribution and grant revenues increased to \$255,000 for the three months ended June 30, 2002 from \$143,000 for the three months ended June 30, 2001. Distribution and grant revenues increased to \$423,000 for the six months ended June 30, 2002 from \$368,000 for the six months ended June 30, 2001. Grant revenues of \$104,000 and \$143,000, for the three and six months ended June 30, 2002 and 2001, respectively, and \$131,000 and \$368,000, for the six months ended June 30, 2002 and 2001, respectively, are primarily attributable to the SynerGraft research and development programs.

#### COSTS AND EXPENSES

Cost of human tissue preservation services aggregated \$17.2 million for the three months ended June 30, 2002 as compared to \$7.7 million for the three months ended June 30, 2001, representing 98% and 41%, respectively, of total human tissue preservation service revenues for each such period. Cost of human tissue preservation services aggregated \$25.3 million for the six months ended June 30, 2002 as compared to \$15.4 million for the six months ended June 30, 2001, representing 67% and 41%, respectively of total human tissue preservation service revenues for each period. The cost of human tissue preservation services for the three and six months ended June 30, 2002 includes a \$10.0 million write-down of deferred preservation costs related to the FDA Order, as discussed in Recent Events. The Company anticipates a reduction in the cost of human tissue preservation services due to a reduction in shipments of tissues as a result of the FDA Order; however the cost of human tissue preservation services as a percent of revenue may increase due to potential write-downs of deferred preservation costs if the Company is unable to meet the requirements of the FDA as outlined in the FDA Order and if there is a significant decline in the demand for the tissues.

Cost of products aggregated \$1.8 million for the three months ended June 30, 2002 as compared to \$1.4 million for the three months ended June 30, 2001, representing 34% and 51%, respectively, of product revenues for each such period. Cost of products aggregated \$4.1 million for the six months ended June 30, 2002 as compared to \$2.9 million for the six months ended June 30, 2001, representing 39% and 53%, respectively, of total product revenues for each period. The decrease in the 2002 cost of products as a percentage of total product revenues is due to a more favorable product mix during 2002. The product mix was impacted by an increase in revenues from BioGlue Surgical Adhesive, which carries higher gross margins than bioprosthetic devices.



General, administrative, and marketing expenses increased 41% to \$11.4 million for the three months ended June 30, 2002, compared to \$8.1 million for the three months ended June 30, 2001, representing 49% and 37%, respectively of total revenues during each such period. General, administrative, and marketing expenses increased 29% to \$20.9 million for the six months ended June 30, 2002, compared to \$16.3 million for the six months ended June 30, 2001, representing 43% and 38%, respectively, of total revenues during each such period. The increase in expenditures for the three and six months ended June 30, 2002 was primarily due to an increase in marketing and general expenses to support planned revenue growth, increased overhead costs in connection with the expansion of the corporate headquarters and manufacturing facility, which was substantially completed in the first quarter of 2002, an increase in insurance premiums, an increase in legal costs and a \$1.3 million accrual for retention levels under the Company's product liability and directors' and officers' insurance policies of \$1.2 million (see Legal Proceedings under Item 1) and for estimated expenses of \$75,000 for packaging and handling fees for the return of affected tissues subject to the FDA Order. The Company expects to incur significant increases in legal costs and professional fees over the remainder of the year as a result of defending the lawsuits filed against the Company and the

26

Company's appeal of the FDA Order. Additional marketing expenses may be incurred to address the effects of the adverse publicity surrounding the FDA Order.

Research and development expenses decreased 7% to \$1.2 million for the three months ended June 30, 2002, compared to \$1.3 million for the three months ended June 30, 2001, representing 5% and 6%, respectively, of total revenues for each such period. Research and development expenses decreased 1% to \$2.3 million for the six months ended June 30, 2002, compared to \$2.4 million for the six months ended June 30, 2001, representing 5% of total revenues for each such periods. Research and development spending for the three and six months ended June 30, 2002 was primarily focused on the Company's SynerGraft and Protein Hydrogel Technologies.

Interest income, net of interest expense, was \$43,000 and \$560,000 for the three months ended June 30, 2002 and 2001, respectively. Interest income, net of interest expense, was \$149,000 and \$1.1 million for the six months ended June 30, 2002 and 2001, respectively. The 2002 decrease in net interest income is due to reduced interest rates in 2002 as compared to 2001 and the lack of interest expense capitalized in 2002 in connection with the expansion of the corporate headquarters and manufacturing facility, which was substantially completed in the first quarter of 2002.

The effective income tax rate was 34% and 32% for the three and six months ended June 30, 2002 and 2001, respectively.

#### SEASONALITY

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

#### LIQUIDITY AND CAPITAL RESOURCES

At June 30, 2002 net working capital was \$62.2 million, with a current ratio of 4 to 1, compared to \$66.7 million at December 31, 2001. 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. The Company funded these requirements through bank credit facilities, cash generated by operations and equity offerings. Based on the anticipated decrease in revenues resulting from the FDA Order and associated adverse publicity, the Company expects that its cash generated by operations will decrease significantly over the near term, and that net working capital will decrease. The Company anticipates that after it has reduced the number of employees to reflect the reduction in revenues, the savings in resources will enable the Company to meet its liquidity needs through 2002. It is possible that

the Company will not have sufficient funds to meet its primary capital requirements over the long term.

Net cash provided by operating activities was \$750,000 for the six months ended June 30, 2002, as compared to \$4.3 million for the six months ended June 30, 2001. The \$750,000 in current year cash provided was primarily due to \$7.8 million in net income before depreciation, taxes, and excluding non-cash items, partially offset by a decrease in cash of \$7.1 million due to an increase in working capital requirements from current and planned future revenue growth, expansion of product lines, and an increase in tissue procurement. Adjustments to net income for the six months ended June 30, 2002 include a \$10.0 million write-down for the impairment of deferred preservation costs resulting from the FDA Order.

Net cash provided by investing activities was \$4.1 million for the six months ended June 30, 2002, as compared to cash used of \$6.4 million for the six months ended June 30, 2001. The \$4.1 million in current year cash provided was primarily due to a net \$7.7 million increase in cash from marketable securities,

27

primarily due to the maturity of debt securities, and \$1.2 million in proceeds from notes receivable, partially offset by a \$2.7 million decrease due to capital expenditures in 2002, as the expansion and renovation of the Company's corporate headquarters and manufacturing facilities approached completion, and a decrease due to spending on patents of \$2.3 million, primarily relating to costs incurred to defend the SynerGraft technology patents. For further information please refer to the Recent Events section.

Net cash used by financing activities was \$1,000 for the six months ended June 30, 2002, as compared to cash provided of \$1.5 million for the six months ended June 30, 2001. The \$1,000 in current year cash used was primarily due to \$800,000 in principal payments on the Term Loan and \$300,000 in principal payments on capital leases, offset by a \$1.1 million increase due to proceeds from stock option exercises.

The Company's Term Loan, of which the principal balance was \$6.1 million as of August 30, 2002, contains certain restrictive covenants including, but not limited to, maintenance of certain financial ratios and a minimum tangible net worth requirement, and the requirement that no materially adverse event has occurred. The lender has determined that the FDA Order, as described in Note 2 to the Summary Consolidated Financial Statements, and the inquiries of the Securities and Exchange Commission, as described in Note 12 to the Summary Consolidated Financial Statements, have a material adverse effect on the Company that constitutes an event of default. As of August 30, 2002 the lender has elected not to declare an event of default, but reserves the right to exercise any such right under the terms of the Term Loan. Therefore, all amounts due under the Term Loan as of June 30, 2002 are reflected as a current liability on the Consolidated Balance Sheet. In the event the lender calls the Term Loan, the Company at present has adequate funds to pay the principal amount outstanding. The Term Loan is secured by substantially all of the Company's assets.

The Company's Term Loan, which accrues interest computed at Adjusted LIBOR plus 1.5%, exposes the Company to changes in interest rates going forward. On March 16, 2000, the Company entered into a \$4 million notional amount forward-starting interest swap agreement, which took effect on June 1, 2001 and expires in 2006. This swap agreement was designated as a cash flow hedge to effectively convert a portion of the Term Loan balance to a fixed rate basis, thus reducing the impact of interest rate changes on future income. This agreement involves the receipt of floating rate amounts in exchange for fixed rate interest payments over the life of the agreement, without an exchange of the underlying principal amounts. The differential to be paid or received is recognized in the period in which it accrues as an adjustment to interest expense on the Term Loan.

On January 1, 2001 the Company adopted SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133") as amended. SFAS 133 requires the Company to recognize all derivative instruments on the balance sheet at fair value, and changes in the derivative's fair value must be recognized currently in earnings or other comprehensive income, as applicable. The adoption of SFAS 133 impacts the accounting for the Company's forward-starting interest rate swap agreement. Upon adoption of SFAS 133, the Company recorded an unrealized loss of approximately \$175,000 related to the interest rate swap, which was recorded as part of long-term liabilities and accumulated other comprehensive income within

the Statement of Shareholders' Equity.

At June 30, 2002 the notional amount of this swap agreement was \$3.2 million, and the fair value of the interest rate swap agreement, as estimated by the bank based on its internal valuation models, was a liability of \$269,000. The fair value of the swap agreement is recorded as part of long-term liabilities and is recorded net of tax as part of accumulated other comprehensive income within the Statement of Shareholders' Equity.

On July 30, 2002 the Company entered into a line of credit agreement with the lender that made the Term Loan, permitting the Company to borrow up to \$10 million. Borrowings under the line of credit agreement accrue interest equal to Adjusted LIBOR plus 1.25% adjusted monthly. This loan is secured by substantially all of the Company's assets. As of August 30, 2002 \$6,900 has been drawn on the line of credit. As a result of the FDA Order, as discussed in Note 2 to the Summary Consolidated Financial Statements, the Company is not in compliance with the lender's requirements for advances of funds under the line of credit. On August 21, 2002 the lender notified the Company that it was not entitled to any further advances under the line of credit.

28

Since October 1998 management has been seeking to enter into a corporate collaboration or to complete a potential private placement of equity or equity-oriented securities to fund the commercial development of its Activation Control Technology ("ACT"). This technology is now held by the Company's wholly-owned subsidiary AuraZyme Pharmaceutical, Inc., which was formed on February 26, 2001. This strategy, if successful, will allow an affiliated entity to fund the ACT and should expedite the commercial development of its oncology, fibrin lysis (blood clot dissolving), and surgical sealant product applications without additional research and development expenditures by the Company (other than through the affiliated company). This strategy, if successful, will favorably impact the Company's liquidity going forward. However, if the Company is unable to obtain funds for the commercial development of the ACT and/or if the Company decides to fund the technology itself, the expenses required to fund the ACT could adversely impact the Company's liquidity going forward. The Company expects that it will reduce its efforts to fund the commercial development of ACT in the near term until it has evaluated the financial impact of the recent FDA Order.

The Company expects its liquidity to decrease significantly over the remainder of the year due to the anticipated significant decrease in revenues as a result of the FDA Order and an expected decrease in cash due to the increased legal and professional costs relating to the defense of lawsuits and the FDA Order. As a result, the Company plans to reduce the number of personnel it employs in several areas, with the exact number to be based in part on the Company's success in its efforts to appeal or obtain a modification of the FDA Order. On September 3, 2002 the Company announced a reduction in employee force of approximately 105 employees. The Company anticipates that severance and related costs will be approximately \$625,000, which will be recorded in the third quarter of 2002. As a result of the employee reduction, management anticipates personnel costs will be reduced by approximately \$360,000 per month. The Company anticipates that after it has reduced the number of employees to reflect the reduction in revenues, the savings in resources will enable the Company to meet its liquidity needs through the June 30, 2003. Even if the Company is able to obtain a favorable outcome of its appeal of the FDA Order or requested modification, there is no assurance that the Company would be able to return to the current level of demand for its tissue services as a result of the adverse publicity or as a result of customers and tissue banks switching to competitors.

The Company's long term liquidity and capital requirements will depend upon numerous factors, including the resolution of the Company's appeal of the FDA Order, the extent of the anticipated revenue decreases, the costs associated with becoming compliant with the FDA requirements as outlined in the FDA Order, the outcome of litigation against the Company as described in Part II Item 1 of this Form 10-Q, the level of demand for tissue based on adverse publicity in the event the FDA Order is resolved in a manner favorable to the Company, the timing of the Company's receipt of FDA approvals to begin clinical trials for its products currently in development, the availability of resources required to further develop its marketing and sales capabilities if and when those products gain approval, the extent to which the Company's products generate market acceptance and demand and the resolution of the "Risk Factors" discussed below.

The ultimate impact of many of these factors will be affected by the outcome of others. There can be no assurance the Company will not require additional financing or will not seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet future requirements. 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.

#### RISK FACTORS

##### FDA ORDER ON HUMAN TISSUE-DEPENDENCE ON PRESERVATION OF HUMAN TISSUE

On Tuesday, August 13, 2002 the Company received an order from the FDA calling for the retention, recall, and/or destruction of all non-valved cardiac, vascular and orthopaedic tissue processed by the Company at its headquarters since at least October 3, 2001 based upon allegations of FDA violations by the Company of its handling of such tissue and alleged contamination through the Company's processing of such tissue that resulted in 14 post-transplant infections including one death. A significant portion of the Company's current revenues is derived from the preservation of human tissues. Revenues of human tissue preservation services for the six months ended June 30, 2002 were 79% of the Company's revenues. Of those revenues, 67% were derived from preservation of tissues subject to the FDA Order representing \$26.9 million. Revenues for human tissue preservation services for the year ended 2001 were 86% of the Company's revenues. Of those revenues, 68% were derived from preservation of tissues subject to the FDA Order.

The Company expects the FDA Order to have a material adverse effect on the Company's business, financial condition, results of operations and cash flows. As a result of the FDA Order, the Company expects to experience decreases in revenues and profits and there is a possibility that the Company may not generate sufficient cash from operations to fund its operations.

Even if the FDA Order is lifted or modified at some future date such that the Company may resume the processing of the types of human tissue covered by the FDA Order, demand for such tissue may be reduced by the adverse publicity generated from the recall or from implanting physicians' decisions to use human tissue from the Company's competitors. Therefore, even if the FDA Order is lifted or modified, the Company could still experience significant decreases in revenues and profits and there is a possibility that the Company would not generate sufficient cash from operations to fund its operations.

In the event that the Company resumes successful processing of human tissue in accordance with FDA standards, the success of the Company depends upon, among other factors, the availability of sufficient quantities of tissue from human donors. Any material reduction in the supply of donated human tissue could restrict the Company's growth. The Company relies primarily upon the efforts of third party procurement agencies and tissue banks (most of which are not-for-profit) and others to educate the public and foster a willingness to donate tissue. If the Company's relationships with procurement agencies continue to be adversely affected, the Company may be unable to obtain adequate supplies of donated tissues to operate profitably.

##### EFFECTS OF FDA ORDER ON LIQUIDITY AND CAPITAL RESOURCES

Based upon the FDA Order, the Company anticipates a decrease in liquidity. Based upon the anticipated decrease in revenues and profits from the FDA Order and associated adverse publicity, the Company expects that cash generated by operations could decrease over the near term and working capital could decrease. Although the Company anticipates reducing its level of operation and the number of personnel employed in response to the FDA Order, there is a possibility that the Company may not have sufficient funds to fund its primary capital requirements or to meet its operating and development needs.

##### IMPLANTATION OF ORTHOPAEDIC AND OTHER TISSUE MAY BECOME ILLEGAL OR SUBJECT TO SIGNIFICANT ADDITIONAL RESTRICTIONS

As a result of the FDA's and the CDC's ongoing investigation regarding the

safety of cryopreserved orthopaedic tissue, and because orthopaedic tissue is generally not involved in life-saving or limb salvaging procedures, this tissue may no longer be legally available for implantation or may become subject to significant additional restrictions before it is considered safe for use. As a

result, this portion of the Company's business may have to be discontinued or may only continue at an extremely reduced level due to a restricted supply of tissue for transplant or increased costs that render the business unprofitable. Either occurrence would result in a significant decrease in the Company's revenues and profitability. In addition, although the vascular and cardiovascular tissues preserved by the Company are frequently used in lifesaving or limb salvaging operations and the Company has requested a modification of the FDA Order, there is also the possibility that their implantation will be restricted or prohibited. Either of these occurrences would also result in a significant decrease in the Company's revenues and profitability.

#### PHYSICIANS MAY BE RELUCTANT TO IMPLANT CRYOLIFE PRESERVED TISSUES

Even if the FDA Order is lifted or modified, and the Company is allowed to resume shipping the tissues subject to the FDA Order, there is a risk that physicians will be reluctant to choose the Company's preserved tissues for use in implantation, due to a perception that they may not be safe or to a belief that the implanting physician or hospital may be subject to a heightened liability risk if the Company tissues are used. In addition, for similar reasons, hospital risk managers may forbid implanting surgeons to utilize the Company tissues where alternatives are available. If a significant number of implanting hospitals or physicians refused to use tissues preserved by the Company, the Company's revenues and profits would be materially adversely affected.

#### HEART VALVES PROCESSED BY THE COMPANY MAY ALSO BE RECALLED

On August 21, 2002 the FDA publicly stated that allograft heart valves have not been included in the FDA recall order as these devices are essential for the correction of congenital cardiac lesions in neonate and pediatric patients and no satisfactory alternative device exists. However, the FDA also publicly stated that it still has serious concerns regarding the processing and handling of allograft heart valves. The FDA also recommended that surgeons carefully consider using processed allografts from alternative sources, that surgeons should inform prospective patients of the FDA's concerns with the Company's allograft heart valves, and that patients should be carefully monitored for both fungal and bacterial infections. The FDA could institute a recall or other corrective measures if it felt that the Company was not making progress in complying with the FDA Order. Any adverse finding by the FDA regarding allograft heart valves, including a recall, would cause further decreases in the Company's revenue base and profits and significantly reduce the Company's potential for growth. If such a recall occurs, the Company may also be required to write-down all or a portion of the deferred preservation costs for allograft heart valves, which could have a material adverse effect on the results of operations and financial condition of the Company.

#### ESTIMATED COSTS OF RECALL AND RELATED WRITE-DOWNS

The Company's financial statements reflect the estimated cost of recalling tissue pursuant to the FDA Order. The Company has recorded a write-down of \$10.0 million of deferred preservation costs for tissues subject to the FDA Order and anticipates a further write-down of deferred preservation costs in the third quarter of 2002 for additional tissues processed in the third quarter that are subject to the FDA Order and orthopaedic tissue not subject to the FDA Order. Such write-downs could have a material adverse effect on the results of operations and financial condition of the Company. While these estimates are based on the Company's best estimate of the costs associated with the recall and the impairment of deferred preservation costs subject to the FDA Order, there can be no assurance that these costs and write-downs will in fact be limited to the amount estimated.

#### REGULATORY ACTION OUTSIDE OF THE UNITED STATES

After the FDA issued its order regarding the recall, Health Canada also issued a recall on the same types of tissue and the United Kingdom Department of Health

has begun investigating tissue exported by the Company. We expect that such actions will further decrease revenues. Although management is not aware of any reports of contamination in Canada or the United Kingdom of tissues processed by the Company, in the event that any tissue processed by the Company that was exported by the Company to other countries is found to be contaminated, it would have a further material adverse impact on the Company's business and operations.

#### THE COMPANY MAY BE FORCED TO CEASE TISSUE PRESERVATION

If the FDA Order is not reversed or modified in the near future, or if the allograft heart valves processed by the Company are also recalled, the Company may not be able to profitably continue its tissue processing business. In such an event, the Company would attempt to continue as a smaller adhesives and valve manufacturing company; however, in order to do so the Company would be required to divest itself of a number of assets related to its tissue processing business and would have to institute large-scale workforce reductions. There is no guarantee that the resulting entity would be able to generate sufficient revenues to operate profitably, and in any event, the Company would be much smaller and would likely be valued at a reduced level by the marketplace.

#### THE COMPANY'S COMMON STOCK IS POTENTIALLY AT RISK OF BEING DELISTED FROM THE NEW YORK STOCK EXCHANGE

Because of the FDA Order and the current trading price of the Company's common stock, there is a possibility that the Company's common stock could be delisted from the New York Stock Exchange. If the stock is delisted, there is no guaranty that there will be a liquid market for the stock and the trading price of the stock would likely be adversely affected.

#### THE COMPANY IS THE SUBJECT OF AN ONGOING SEC INVESTIGATION

The Company received notice from the Securities and Exchange Commission on Saturday, August 17, 2002 that it is the subject of an investigation with respect to accounting issues and trades in the Company's stock related to the FDA Order. The Company does not know any details of the investigation, but believes that an adverse finding by the SEC could have a material adverse effect on its business financial position, results of operations, and cash flows. The staff of the SEC subsequently confirmed that its investigation is informal in nature, and that it does not have subpoena power at this time. At the present time, the Company is unable to predict the outcome of this matter.

#### EFFECTS OF THE FDA RECALL ON CREDIT FACILITY

The Term Loan contains certain restrictive covenants including, but not limited to, maintenance of certain financial ratios, a minimum tangible net worth requirement, and the requirement that no materially adverse event has occurred. The lender has determined that the FDA Order, as described in Note 2 to the Summary Consolidated Financial Statements, and the inquiries of the Securities and Exchange Commission, as described in Note 12 to the Summary Consolidated Financial Statements, have a material adverse effect on the Company that constitutes an event of default. As of August 30, 2002 the lender has elected not to declare an event of default, but reserves the right to exercise any such right under the terms of the Term Loan. There is no assurance the lender will not exercise its rights, which could have a material adverse effect on the Company's liquidity.

#### THE COMPANY'S PRODUCT LIABILITY AND INSURANCE COVERAGE MAY BE INSUFFICIENT TO COVER CURRENT AND FUTURE CLAIMS AND ADDITIONAL COVERAGE MAY BE DIFFICULT OR IMPOSSIBLE TO OBTAIN IN THE FUTURE

The Company's products are used by health care providers in connection with the treatment of patients, who will, on occasion, sustain injury or die as a result of their condition or medical treatment. As a result, the use of the Company's products and human tissue processed by the Company involves the possibility of adverse effects that could expose the Company to product liability claims, including the lawsuits filed against the Company relating to infection of implanted tissue described below in Item 3 "Legal Proceedings." The recent FDA Order could adversely influence the outcome of current product liability claims relating to infection of tissue processed by the Company.

In addition, a recent United States Supreme Court decision held that product liability may exist despite FDA approval, and future court decisions may also increase the Company's risk of product liability.

Whether or not the Company is ultimately determined to be liable for product liability claims, the Company will incur significant legal expenses. In addition, such litigation could damage the Company's reputation and therefore impair its ability to market its products or obtain product liability insurance and could cause the premiums for such insurance to increase. Although the Company has incurred minimal losses due to product liability claims to date, the Company may incur significant losses in the future. The Company currently maintains product liability insurance in the aggregate amount of \$25 million per year. Management believes that the coverage is adequate to cover any losses due to product claims if actually incurred however, there can be no assurance that such coverage will be adequate. In addition, there can be no assurance that such coverage will continue to be available on terms acceptable to the Company, especially in light of the recent FDA Order. Furthermore, if any product liability claims are successful, it could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows.

Because of the current litigation and the adverse publicity from the FDA Order, the Company may be unable to obtain additional insurance coverage in the future, causing the Company to be subject to additional future exposure from product liability claims.

#### INTENSE COMPETITION

The Company faces competition from other companies that cryopreserve human tissue, as well as companies that market mechanical valves and synthetic and animal tissue for implantation and companies that market wound closure products. During the time that the Company is restricted from processing and marketing human tissue, tissue preservation service customers may be forced to obtain tissue from the Company's competitors, which could lead to permanent substitution when, and if, the Company resumes processing tissues subject to the FDA Order.

Management believes that at least four tissue banks offer preservation services for allograft heart valves and many companies offer processed porcine heart valves and mechanical heart valves. A few companies dominate portions of the mechanical and porcine heart valve markets, including St. Jude Medical, Inc., Medtronic, Inc. and Edwards Life Sciences. The Company is aware that several companies have surgical adhesive products under development. Competitive products may also be under development by other large medical device, pharmaceutical and biopharmaceutical companies. Many of the Company's competitors have greater financial, technical, manufacturing and marketing resources than the Company and are well established in their markets.

There can be no assurance that the Company's products and services will be able to compete successfully with the products of these or other companies. Any products developed by the Company that gain regulatory clearance or approval would have to compete for market acceptance and market share. Failure of the Company to compete effectively could have a material adverse effect on the Company's business, financial condition, results of operations and cash flows. The FDA Order and related adverse publicity will have an adverse effect on the Company's competitive position, which may have material adverse effect on the Company's results of operations. As a result of the FDA Order, the Company's competitors may gain competitive advantages that may be difficult to overcome.

#### RAPID TECHNOLOGICAL CHANGE

The technologies underlying the Company's products and services are subject to rapid and profound technological change. The Company expects competition to intensify as technical advances in each field are made and become more widely known. There can be no assurance that others will not develop products or processes with significant advantages over the products and processes that the Company offers or is seeking to develop. Any such occurrence could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows.

#### UNCERTAINTIES REGARDING PRODUCTS IN DEVELOPMENT

The Company's growth and profitability will depend, in part, upon its ability to complete development of and successfully introduce new products, including additional applications of its BioGlue and SynerGraft technologies and its ACT. The Company may be required to undertake time consuming and costly development activities and seek regulatory clearance or approval for new products. The Company expects that it will have to reduce its development efforts in the near term because of the impact of the FDA Order on the Company's financial condition.

Although the Company has conducted pre-clinical studies on many of its products under development which indicate that such products may be effective in a particular application, there can be no assurance that the results obtained from expanded clinical studies will be consistent with earlier trial results or be sufficient for the Company to obtain any required regulatory approvals or clearances. There can be no assurance that the Company will not experience difficulties that could delay or prevent the successful development, introduction and marketing of new products, that regulatory clearance or approval of these or any new products will be granted on a timely basis, if ever, or that the new products will adequately meet the requirements of the applicable market or achieve market acceptance.

The completion of the development of any of the Company's products remains subject to all of the risks associated with the commercialization of new products based on innovative technologies, including unanticipated technical or other problems, manufacturing difficulties and the possible insufficiency of the funds allocated for the completion of such development. Consequently, the Company's products under development may not be successfully developed or manufactured or, if developed and manufactured, such products may not meet price or performance objectives, be developed on a timely basis or prove to be as effective as competing products.

The inability to complete successfully the development of a product or application, or a determination by the Company, for financial, technical or other reasons, not to complete development of any product or application, particularly in instances in which the Company has made significant capital expenditures, could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows. The Company's porcine heart valve products, including its SynerGraft treated porcine valves, are currently only offered for sale outside of the United States. The Company's porcine heart valves are subject to the risk that the Company may be unable to obtain regulatory approval necessary to permit commercial distribution of these products in the United States. The Company's research and development efforts are time consuming and expensive and there can be no assurance that these efforts will lead to commercially successful products or services. Even the successful commercialization of a new service or product in the medical industry can be characterized by slow growth and high costs associated with marketing, under-utilized production capacity and continuing research, and development and education costs. Generally, the introduction of new human tissue products requires significant physician training and years of clinical evidence derived from follow-up studies on human implant recipients in order to gain acceptance in the medical community.

#### UNCERTAINTIES REGARDING THE FUNDING OF THE ACT TECHNOLOGY

The ACT is a reversible linker technology that has potential uses in the areas of cancer therapy, fibrin lysis (blood clot dissolving) and other drug delivery applications. The Company has formed AuraZyme, a wholly owned subsidiary, in order to seek a corporate collaboration or to complete a potential private placement of equity or equity-oriented securities to fund the commercial development of the ACT.

This strategy is designed to allow the Company to continue development of this technology without incurring additional research and development expenditures, other than through AuraZyme. There can be no guarantee that such funding can be obtained on acceptable terms, if at all, especially in light of the recent FDA Order. If such funding is not obtained, the Company may be unable to effectively test and develop the ACT, and may therefore be unable to determine its effectiveness. Even if such financing is obtained, there is no guarantee that the ACT will in fact prove to be effective in the above applications. Failure to



obtain the desired financing, or failure of the ACT to perform as anticipated in future tests, could have a material adverse effect on the Company's future expansion plans and could limit future growth.

#### UNCERTAINTIES REGARDING THE SYNERGRAFT TECHNOLOGY

The Company processes porcine, bovine and human tissues with the SynerGraft process. In animal studies, explanted porcine heart valves have been shown to repopulate with the hosts' cells. However, should SynerGraft-treated tissues implanted in humans not repopulate with the human host cells, the SynerGraft-treated tissues may not have the longevity that the Company currently expects. This could have a material adverse effect on future expansion plans and could limit future growth.

#### EXTENSIVE GOVERNMENT REGULATION

Government regulation in the United States, the EC and other jurisdictions represents a potentially determinative factor in the success of the Company's efforts to market and develop its products. The allograft heart valves to which the Company applies its preservation services are currently regulated as Class II medical devices by the FDA and are subject to significant regulatory requirements, including Quality System Regulations and record keeping requirements. Changes in regulatory treatment or the adoption of new statutory or regulatory requirements are likely to occur, which could adversely impact the marketing or development of these products or could adversely affect market demand for these products. Other allograft tissues processed and distributed by the Company are currently regulated as "human tissue" under rules promulgated by the FDA pursuant to the Public Health Services Act. These rules establish requirements for donor testing and screening of human tissue and record keeping relating to these activities and impose certain registration and product listing requirements on establishments that process or distribute human tissue or cellular-based products. The FDA has proposed and is refining a regulation that will improve good tissue practices, akin to good manufacturing practices, on tissue banks and processors of human tissue. It is anticipated that these good tissue practices regulations when promulgated will enhance regulatory oversight of the Company and other processors of human tissue.

BioGlue Surgical Adhesive is regulated as a Class III medical device and the Company believes that its ACT may be regulated as a biologic or drug by the FDA. The ACT has not been approved for commercial distribution in the United States. or elsewhere. Fixed porcine heart valve products are classified as Class III medical devices. There can be no assurance that the Company will be able to obtain the FDA approval required to distribute its porcine heart valve products in the United States. Distribution of these products within the EC is dependent upon the Company maintaining its CE Mark and ISO 9001 certifications, of which there can be no assurance.

Most of the Company's products in development, if successfully developed, will require regulatory approvals from the FDA and perhaps other regulatory authorities before they may be commercially distributed. The process of obtaining required regulatory approvals from the FDA normally involves clinical trials and the preparation of an extensive PMA application and often takes many years. The process is expensive and can vary significantly based on the type, complexity and novelty of the product. There can be no assurance that any products developed by the Company, independently or in collaboration with others, will receive the required approvals for manufacturing and marketing.

Delays in obtaining United States or foreign approvals could result in substantial additional cost to the Company and adversely affect the Company's competitive position. The FDA may also place conditions on product approvals that could restrict commercial applications of such products. Product marketing approvals or clearances may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. Delays imposed by the governmental clearance process may materially reduce the period during which the Company has the exclusive right to commercialize patented products.

Also, delays or rejections may be encountered during any stage of the regulatory approval process based upon the failure of the clinical or other data to demonstrate compliance with, or upon the failure of the product to meet, the regulatory agency's requirements for safety, efficacy and quality, and those requirements may become more stringent due to changes in applicable law, regulatory agency policy or the adoption of new regulations. Clinical trials may also be delayed due to unanticipated side effects, inability to locate, recruit and qualify sufficient numbers of patients, lack of funding, the inability to locate or recruit clinical investigators, the redesign of clinical trial programs, the inability to manufacture or acquire sufficient quantities of the particular product candidate or any other components required for clinical trials, changes in the Company's or its collaborative partners' development focus and disclosure of trial results by competitors.

Even if regulatory approval is obtained for any of the Company's products or services, the scope of the approval may significantly limit the indicated usage for which such products or services may be marketed. Products marketed by the Company pursuant to FDA or foreign oversight or approvals are subject to continuing regulation. In the United States, devices and biologics must be manufactured in registered establishments (and, in the case of biologics, licensed establishments) and must be produced in accordance with Quality System Regulations. Manufacturing facilities and processes are subject to periodic FDA inspection. Labeling and promotional activities are also subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The export of devices and biologics is also subject to regulation and may require FDA approval. From time to time, the FDA may modify such regulations, imposing additional or different requirements. Failure to comply with any applicable FDA requirements, which may be ambiguous, could result in civil and criminal enforcement actions, warnings, citations, product recalls or detentions and other penalties and could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows. As noted above, the FDA Order may have such an effect.

In addition, NOTA prohibits the acquisition or transfer of human organs for "valuable consideration" for use in human transplantation. NOTA permits the payment of reasonable expenses associated with the removal, transportation, processing, preservation, quality control and storage of human organs. There can be no assurance that restrictive interpretations of NOTA will not be adopted in the future that will challenge one or more aspects of the Company's methods of charging for its preservation services. The Company's laboratory operations are subject to the United States Department of Labor, Occupational Safety and Health Administration and Environmental Protection Agency requirements for prevention of occupational exposure to infectious agents and hazardous chemicals and protection of the environment. Some states have enacted statutes and regulations governing the processing, transportation and storage of human organs and tissue.

More restrictive state laws or regulations may be adopted in the future and they could have a material adverse effect on the Company's business, financial condition, results of operations and cash flows.

#### UNCERTAINTIES RELATED TO PATENTS AND PROTECTION OF PROPRIETARY TECHNOLOGY

The Company owns several patents, patent applications and licenses relating to its technologies, which it believes provide important competitive advantages. There can be no assurance that the Company's pending patent applications will issue as patents or that challenges will not be instituted concerning the validity or enforceability of any patent owned by the Company, or, if instituted, that such challenges will not be successful. The cost of litigation to uphold the validity and prevent infringement of a patent could be substantial. Furthermore, there can be no assurance that competitors will not independently develop similar technologies or duplicate the Company's technologies or design around the patented aspects of the Company's technologies. There can be no assurance that the Company's proposed technologies will not infringe patents or other rights owned by others.

In addition, under certain of the Company's license agreements, if the Company fails to meet certain contractual obligations, including the payment of minimum royalty amounts, such licenses may become nonexclusive or terminable by the licensor, which could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows. Additionally, the Company protects its proprietary technologies and processes in part by confidentiality agreements with its collaborative partners, employees and consultants. There can be no assurance that these agreements will not be breached, that the Company will have adequate remedies for any breach or that

the Company's trade secrets will not otherwise become known or independently discovered by competitors, any of which could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows.

36

#### UNCERTAINTIES REGARDING FUTURE HEALTH CARE REIMBURSEMENT

Even though the Company does not receive payments directly from third-party health care payors, their reimbursement methods and policies impact demand for the Company's cryopreserved tissue and other services and products. The Company's preservation services may be particularly susceptible to third-party cost containment measures. In particular, the initial cost of a cryopreserved allograft heart valve generally exceeds the cost of a mechanical, synthetic or animal-derived valve. The Company is unable to predict what changes will be made in the reimbursement methods and policies utilized by third-party health care payors or their effect on the Company.

Changes in the reimbursement methods and policies utilized by third-party health care payors, including Medicare, with respect to cryopreserved tissues provided for implant by the Company and other Company services and products, could have a material adverse effect on the Company. Significant uncertainty exists as to the reimbursement status of newly approved health care products and services and there can be no assurance that adequate third-party coverage will be available for the Company to maintain price levels sufficient for realization of an appropriate return on its investment in developing new products.

Government, hospitals, and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new products approved for marketing by the FDA and by refusing in some cases to provide any coverage for uses of approved products for indications for which the FDA has not granted marketing approval. If adequate coverage and reimbursement levels are not provided by government and other third-party payors for uses of the Company's new products and services, market acceptance of these products would be adversely affected, which could have a material adverse effect on the Company's business, financial condition, results of operations and cash flows.

#### DEPENDENCE ON KEY PERSONNEL

The Company's business and future operating results depend in significant part upon the continued contributions of its key technical personnel and senior management, many of who would be difficult to replace. The Company's business and future operating results also depend in significant part upon its ability to attract and retain qualified management, processing, technical, marketing, sales and support personnel for its operation. Competition for such personnel is intense and there can be no assurance that the Company will be successful in attracting and retaining such personnel. The loss of key employees, the failure of any key employee to perform adequately or the Company's inability to attract and retain skilled employees as needed could have a material adverse effect on the Company's business, financial condition, results of operations and cash flows.

#### VOLATILITY OF SECURITIES PRICES

The trading price of the Company's Common Stock has been subject to wide fluctuations recently and may continue to be subject to such volatility in the future. Trading price fluctuations can be caused by a variety of factors, including regulatory actions such as the recent FDA Order, recent product liability claims, quarter to quarter variations in operating results, announcement of technological innovations or new products by the Company or its competitors, governmental regulatory acts, developments with respect to patents or proprietary rights, general conditions in the medical device or service industries, actions taken by government regulators, changes in earnings estimates by securities analysts or other events or factors, many of which are beyond the Company's control. If the Company's revenues or operating results in

37

future quarters fall below the expectations of securities analysts and

investors, the price of the Company's Common Stock would likely decline further, perhaps substantially. Changes in the trading price of the Company's Common Stock may bear no relation to the Company's actual operational or financial results. If the Company's share prices do not meet the requirements of the New York Stock Exchange, the Company's shares may be delisted. The Company's closing stock price since January 1, 2002 has ranged from a high of \$31.31 to a low of \$2.03.

#### ANTI-TAKEOVER PROVISIONS

The Company's Articles of Incorporation and Bylaws contain provisions that may discourage or make more difficult any attempt by a person or group to obtain control of the Company, including provisions authorizing the issuance of preferred stock without shareholder approval, restricting the persons who may call a special meeting of the shareholders and prohibiting shareholders from taking action by written consent. In addition, the Company is subject to certain provisions of Florida law that may discourage or make more difficult takeover attempts or acquisitions of substantial amounts of the Company's Common Stock. Further, pursuant to the terms of a shareholder rights plan adopted in 1995, each outstanding share of Common Stock has one attached right. The rights will cause substantial dilution of the ownership of a person or group that attempts to acquire the Company on terms not approved by the Board and may have the effect of deterring hostile takeover attempts.

#### ABSENCE OF DIVIDENDS

The Company has not paid, and does not presently intend to pay, cash dividends. The Company's major credit agreement contains, and future credit agreements may contain, financial covenants, including covenants to maintain certain levels of net worth and certain leverage ratios, which could have the effect of restricting the amount of dividends that the Company may pay. It is not likely that any cash dividends will be paid in the foreseeable future.

#### FORWARD-LOOKING STATEMENTS

This Form 10-Q includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the Private Securities Litigation Reform Act of 1995.

All statements, other than statements of historical facts, included herein which address activities, events or developments which the Company expects or anticipates will or may occur in the future, including statements regarding the impact of recent accounting pronouncements, adequacy of product liability insurance to defend against lawsuits, the outcome of lawsuits filed against the Company, the impact of the FDA Order on future revenues, profits and business operations, the effect of the FDA Order on sales of BioGlue, future tissue procurement levels resulting from the FDA Order, the outcome of the Company's appeal of the FDA Order, the estimates underlying the charges recorded in the second quarter due to the FDA Order, the estimates underlying the accrual to second quarter earnings established to account for the cost to the Company of the FDA Order and the legal and professional fees necessary because of the FDA Order, the estimates of the amounts accrued for the retention levels under its product liability and directors' and officers' insurance policies, future costs of human tissue preservation services, changes in liquidity and capital resources as a result of the FDA Order, the outcome of any evaluation of allograft heart valves by the FDA, the possible adverse outcome of the SEC investigation referenced in the SEC Letter, future product development plans as a result of the FDA Order, the Company's competitive position, the successful development of its SynerGraft porcine valves, funding available to continue development of the ACT, estimated dates relating to the Company's proposed regulatory submissions, the Company's expectations regarding the adequacy of current financing arrangements, product demand and market growth, the potential of the ACT for use in cancer therapies, fibrin lysis (blood clot dissolving), and other drug delivery applications, the outcome of litigation, the impact on the Company of adverse results of surgery utilizing tissue processed by it, and

other statements regarding future plans and strategies, anticipated events or trends and similar expressions concerning matters that are not historical facts are forward-looking statements.

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 to the Company's expectations and predictions is subject to a number of risks and uncertainties, as is the Company's business. These risks and uncertainties, which could cause actual results to differ materially from the Company's expectations, include the risk factors discussed in this Form 10-Q 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.

39

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

The Company's interest income and expense are most 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 \$12.3 million and short-term investments in municipal obligations of \$18.7 million as of June 30, 2002, as well as interest paid on its debt. 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 interest income for 2002.

The Company manages interest rate risk through the use of fixed debt and an interest rate swap agreement. At June 30, 2002 approximately \$3.2 million of the Company's \$6.4 million in debt charged interest at a fixed rate. This fixed rate debt includes a portion of the Company's outstanding term loan balance that has been effectively converted to fixed rate debt through an interest rate swap agreement. A 10% increase in interest rates affecting the Company's variable rate debt, net of the effect of the interest rate swap agreement, would not have a material increase in the Company's interest expense for 2002.

#### Item 4. Controls and Procedures. Not applicable.

40

## Part II - OTHER INFORMATION

### Item 1. Legal Proceedings.

In the normal course of business as a medical device and services company the Company has product liability complaints filed against it. As of August 30, 2002 fifteen product liability cases had been filed against the Company between May 18, 2000 and August 15, 2002. The cases are currently in the pre-discovery or discovery stages. Of these cases, nine allege product liability claims arising out of the Company's orthopaedic tissue, four allege product liability claims arising out of the Company's allograft heart valve tissue and one alleges product liability claims arising out of the non-tissue products made by Ideas for Medicine, when it was a subsidiary of the Company.

Included in these cases is the complaint filed against the Company in the

Superior Court of Cobb County, Georgia, on July 12, 2002 by Steve Lykins, as Trustee for the benefit of next of kin of Brian Lykins. This complaint alleges strict liability, negligence, professional negligence, and breach of warranties related to tissue implanted in November 2001. The plaintiff seeks unspecified compensatory and punitive damages.

The Company maintains general liability insurance policies, which the Company believes to be adequate to defend against these suits. The Company's insurance company has been notified of these actions. The Company intends to vigorously defend against these claims. Nonetheless, an adverse judgment in excess of the Company's insurance coverage could have a material adverse effect on the Company's results of operations.

Several putative class action lawsuits were filed in July 2002, one of which was amended in August of 2002, against the Company and certain officers of the Company alleging that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, by issuing a series of materially false and misleading statements to the market throughout the Class Period of August of 2000 through August of 2002, which statements had the effect of artificially inflating the market price of the Company's securities. The principal allegations of the complaints are that the Company failed to disclose its alleged lack of compliance with certain FDA regulations regarding the handling and processing of certain tissues and other product safety matters. The plaintiffs seek unspecified compensatory damages in an amount to be proven at trial. The Company believes these cases will be consolidated into one putative class action lawsuit. The Company believes the claims made in the lawsuits are without merit and intends to vigorously defend against these claims. Management has retained the services of the Atlanta based law firm of King & Spalding to defend the Company. The Company carries director's and officer's liability insurance which the Company believes to be adequate to defend against this suit. Nonetheless, an adverse judgment in excess of the Company's insurance coverage could have a material adverse effect on the Company's results of operations.

On August 7, 2002 the Company announced the settlement of its ongoing litigation with Colorado State University Foundation ("CSURF") over the ownership of the Company's SynerGraft technology. The settlement resolves all disputes between the parties and extinguishes all CSURF ownership claims to any aspect of CryoLife's SynerGraft technology. The settlement includes an unconditional assignment to CryoLife of CSURF tissue engineering patents, trade secrets and know-how relating to tissue decellularization and recellularization. The technology assignment supercedes the 1996 technology license, which was terminated by the terms of the settlement. Payment terms include a nonrefundable advance of \$400,000 paid by the Company to CSURF that will be applied to earned royalties as they accrue through March 2011. The Company will record these amounts as prepaid royalties and will expense the amounts as the royalties accrue. The earned royalty rate is a maximum of 0.75% of net revenues from products or tissue services utilizing the SynerGraft technology. Royalties earned under the agreement for revenues through June 30, 2002 were approximately \$27,000.

41

On Saturday, August 17, 2002 the Company received a letter from the United States Securities and Exchange Commission (the "SEC Letter") that stated that the Company was subject to an investigation related to the Company's August 14, 2002 announcement of the FDA Order and requesting information from the Company from the period between September 1, 2001 through the date of the Company's response to the SEC Letter. The SEC Letter stated, in part, that "We are trying to determine whether there have been any violations of the federal securities laws. The investigation and the subpoena do not mean that we have concluded that anyone has broken the law. Also, the investigation does not mean that we have a negative opinion of any person, entity or security." The staff of the SEC subsequently confirmed that its investigation is informal in nature, and that it does not have subpoena power at this time.

Item 2. Changes in Securities.  
None

Item 3. Defaults Upon Senior Securities.

See Note 6 to the Summary Consolidated Financial Statements for information regarding a notification by the Company's lender that the FDA Order and the inquiries of the SEC have had a material adverse effect on the Company, which constitutes an event of default. The lender has elected not to declare an event of default at this time.

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

- (a) The Annual Meeting of Shareholders was held on May 29, 2002.
- (b) Management's nominees for director were elected at the meeting by the holders of common stock. The election was uncontested.

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

	Shares Voted For	Authority Withheld
Steven G. Anderson	16,611,274	875,356
John M. Cook	17,366,243	120,387
Ronald C. Elkins, M.D.	17,351,146	135,484
Virginia C. Lacy	17,366,243	120,387
Ronald D. McCall, Esq.	16,561,274	925,356
Alexander C. Schwartz, Jr.	17,366,243	120,387
Bruce J. Van Dyne, M.D.	17,351,146	135,484

- (c) A proposal was passed which approved the CryoLife, Inc. 2002 Stock Incentive Plan.

The following table shows the results of voting:

	Common Shares
Voting for	16,261,220
Voting against	1,078,559
Abstain from voting	146,851
Total	17,486,630

Item 5. Other information.  
None.

Item 6. Exhibits and Reports on Form 8-K

- (a) The exhibit index can be found below.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Company, as amended. (Incorporated by reference to Exhibit 3.1 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
3.2	ByLaws of the Company, as amended. (Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.)
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).)
10.1*	2002 Stock Incentive Plan
99.1*	Certification Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant

(b) Current Reports on Form 8-K.

The Registrant filed a Current Report on Form 8-K with the Commission on April 11, 2002 with respect to a Change in the Registrant's Certifying Accountant.

The Registrant filed a Current Report on Form 8-K with the Commission on May 10, 2002 with respect to a Change in the Registrant's Certifying Accountant.

\* Filed herewith.

43

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

-----  
DAVID ASHLEY LEE  
Vice President and Chief Financial  
Officer  
(Principal Financial and  
Accounting Officer)

September 3, 2002  
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DATE

44

CERTIFICATIONS

I, Steven G. Anderson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CryoLife, Inc.;
2. Based on my knowledge, this quarterly 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 quarterly report; and
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report.



Date: September 3, 2002

/s/STEVEN G. ANDERSON  
Chief Executive Officer

I, Ashley D. Lee, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CryoLife, Inc.;
2. Based on my knowledge, this quarterly 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 quarterly report; and
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report.

Date: September 3, 2002

/s/DAVID ASHLEY LEE  
Chief Financial Officer

EXPLANATORY NOTE REGARDING CERTIFICATIONS: Representations 4, 5 and 6 of the Certifications as set forth in Form 10-Q have been omitted, consistent with the Transition Provisions of SEC Exchange Act Release No. 34-46427, because this Quarterly Report on Form 10-Q covers a period ending before the Effective Date of Rules 13a-14 and 15d-14.

CRYOLIFE, INC. 2002  
STOCK INCENTIVE PLAN

SECTION 1

GENERAL

1.1 Purpose. The CryoLife, Inc. 2002 Stock Incentive Plan (the "Plan") has been established by CryoLife, Inc. ("CryoLife" or the "Company") to (i) attract and retain persons eligible to participate in the Plan; (ii) motivate Participants (as defined in subsection 1.2 below), by means of appropriate incentives, to achieve long-range goals; (iii) provide incentive compensation opportunities that are competitive with those of other similar companies; and (iv) further identify Participants' interests with those of the Company's other shareholders through compensation that is based on the Company's common stock; and thereby promote the long-term financial interest of the Company and its Subsidiaries, as hereinafter defined, including the growth in value of the Company's equity and enhancement of long-term shareholder return. Pursuant to the Plan, Participants may receive Options, Stock Appreciation Rights, or Stock Awards, as defined herein.

1.2 Participation. Subject to the terms and conditions of the Plan, the Committee (as defined in Section 6) shall determine and designate, from time to time, from among the Eligible Grantees, as hereinafter defined (including transferees of Eligible Grantees to the extent the transfer is permitted by the Plan and the applicable Award Agreement), those persons who will be granted one or more Awards under the Plan, and thereby become "Participants" in the Plan. In the discretion of the Committee, a Participant may be granted any Award permitted under the provisions of the Plan, and more than one Award may be granted to a Participant. Awards may be granted as alternatives to or replacement of awards outstanding under the Plan, or any other plan or arrangement of the Company or a Subsidiary (including a plan or arrangement of a business or entity, all or a portion of which is acquired by the Company or a Subsidiary).

1.3 Operation, Administration, and Definitions. The operation and administration of the Plan, including the Awards made under the Plan, shall be subject to the provisions of Section 4 (relating to operation and administration). Capitalized terms in the Plan shall be defined as set forth in the Plan (including the definition provisions of Section 8 of the Plan).

SECTION 2

OPTIONS AND SARs

2.1 Definitions.

(a) The grant of an "Option" entitles the Participant to purchase shares of Stock at an Exercise Price established by the Committee. Options granted under this Section 2 may either be Incentive Stock Options ("ISOs") or Non-Qualified Options ("NQOs"), as determined in the discretion of the

Committee. An "ISO" is an Option that is intended to satisfy the requirements applicable to an "incentive stock option" described in section 422(b) of the Code. An "NQO" is an Option that is not intended to be an "incentive stock option" as that term is described in section 422(b) of the Code.

(b) A stock appreciation right (an "SAR") entitles the Participant to receive, in cash or Stock (as determined in accordance with subsection 2.5), value equal to (or otherwise based on) the excess of: (a) the Fair Market Value (as defined in Section 8) of a specified number of shares of Stock at the time of exercise; over (b) an Exercise Price established by the Committee.

2.2 Exercise Price. The Exercise Price of each Option and SAR granted under this Section 2 shall be established by the Committee or shall be determined by a method established by the Committee at the time the Option or SAR is granted. The Exercise Price shall not be less than 100% of the Fair Market Value of a share of Stock on the date of grant of the Award.

2.3 Exercise. An Option and an SAR shall be exercisable in accordance with such terms and conditions and during such periods as may be established by the

Committee; provided, however, that if a Participant shall die while in the employ of the Company or a Subsidiary and shall not have fully exercised an Option or SAR, the Option or SAR may be exercised, subject to the condition that no Option or SAR shall be exercisable after the expiration of ten years from the date it is granted or beyond its original term, to the extent that the Participant's right to exercise such Option or SAR had accrued pursuant to this Section 2 of the Plan at the time of his death and had not previously been exercised, at any time within one (1) year after the Participant's death, by the executors or administrators of the Participant or by any person or persons who shall have acquired the Option or SAR directly from the Participant by bequest or inheritance.

2.4 Payment of Option Exercise Price. The payment of the Exercise Price of an Option granted under this Section 2 shall be subject to the following:

(a) Subject to the following provisions of this subsection 2.4, the full Exercise Price for shares of Stock purchased upon the exercise of any Option shall be paid at the time of such exercise (except that, in the case of an exercise arrangement approved by the Committee and described in paragraph 2.4(c), payment may be made as soon as practicable after the exercise).

(b) The Exercise Price shall be payable in cash or by tendering shares of Stock acceptable to the Committee and which have been held by the participant for at least six months, and valued at Fair Market Value as of the day of exercise, or in any combination thereof, as determined by the Committee.

2

(c) The Committee may permit a Participant to elect to pay the Exercise Price upon the exercise of an Option by irrevocably authorizing a third party to sell shares of Stock (or a sufficient portion of the shares) acquired upon exercise of the Option and remit to the Company a sufficient portion of the sale proceeds to pay the entire Exercise Price and any tax withholding resulting from such exercise.

2.5 Settlement of Award. Shares of Stock delivered pursuant to the exercise of an Option or SAR shall be subject to such conditions, restrictions and contingencies as the Committee may establish in the applicable Award Agreement. Settlement of SARs may be made in shares of Stock (valued at their Fair Market Value at the time of exercise), in cash, or in a combination thereof, as determined in the discretion of the Committee. The Committee, in its discretion, may impose such conditions, restrictions and contingencies with respect to shares of Stock acquired pursuant to the exercise of an Option or an SAR as the Committee determines to be desirable.

### SECTION 3

#### OTHER STOCK AWARDS

##### 3.1 Definitions.

(a) A "Stock Unit" Award is the grant of a right to receive shares of Stock in the future.

(b) A "Performance Share" Award is a grant of a right to receive shares of Stock or Stock Units which is contingent on the achievement of performance or other objectives during a specified period.

(c) A "Restricted Stock" Award is a grant of shares of Stock, and a "Restricted Stock Unit" Award is the grant of a right to receive shares of Stock in the future, with such shares of Stock or right to future delivery of such shares of Stock subject to a risk of forfeiture or other restrictions that will lapse upon the achievement of one or more goals relating to completion of service by the Participant, or achievement of performance or other objectives, as determined by the Committee.

3.2 Restrictions on Stock Awards. Each Stock Unit Award, Restricted Stock Award, Restricted Stock Unit Award and Performance Share Award shall be subject to the following:

(a) Any such Award shall be subject to such conditions, restrictions and contingencies as the Committee shall determine.

3

(b) The Committee may designate whether any such Awards being granted to any Participant are intended to be "performance-based compensation" as that term is used in Code Section 162(m) of the Code. Any such Awards designated as intended to be "performance-based compensation" shall be conditioned on the achievement of one or more Performance Measures. The Performance Measures that may be used by the Committee for such Awards shall be based on any one or more of the following, as selected by the Committee: return on capital or increase in pretax earnings of the Company and/or one or more divisions and/or subsidiaries, return on shareholders' equity of the Company, increase in earnings per share of the Company, sales of the Company and/or one or more divisions and/or subsidiaries, pretax earnings of the Company and/or one or more divisions and/or subsidiaries, net earnings of the Company and/or one or more divisions and/or subsidiaries, control of operating and/or non-operating expenses of the Company and/or one or more divisions and/or subsidiaries, margins of the Company and/or one or more divisions and/or subsidiaries, market price of the Company's securities and other objectively measurable factors directly tied to the performance of the Company and/or one or more divisions and/or subsidiaries. For Awards intended to be "performance-based compensation," the grant of the Awards and the establishment of the Performance Measures shall be made during the period required under Code Section 162(m).

#### SECTION 4 OPERATION AND ADMINISTRATION

4.1 Effective Date; Duration. Subject to the approval of the shareholders of the Company at the Company's 2002 annual meeting of its shareholders, the Plan shall be effective as of the date of approval of shareholders (the "Effective Date"). The Plan shall have a duration of ten years from the date the Plan is adopted, or, if earlier, the date the Plan is approved by shareholders; provided that in the event of Plan termination, the Plan shall remain in effect as long as any Awards under it are outstanding; provided, further however, that, no Award may be granted under the Plan on a date that is more than ten years from the date the Plan is adopted or, if earlier, the date the Plan is approved by shareholders.

4.2 Awards Subject to Plan. Awards granted under the Plan shall be subject to the following:

(a) Subject to the following provisions of this subsection 4.2, the maximum number of shares of Stock that may be delivered to Participants and their beneficiaries under the Plan shall be 974,000 shares of Stock.

(b) The following limitations are imposed under the Plan: (i) a maximum of 974,000 shares may be issued under Options intended to be Incentive Stock Options ("ISOs") under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"), (ii) a maximum of 100,000 shares may

4

be issued under Options and SARS to any one individual during any consecutive twelve-month period, (iii) a maximum of 100,000 shares may be issued under other Awards, and (iv) a maximum payment of \$400,000 under other Awards may be made to any one individual for any Performance Goals established for any performance period (including the Fair Market Value of stock subject to Awards denominated in shares). These maximums are subject to adjustment in the event of stock dividends, stock splits, combination of shares, recapitalization, reorganization, merger, consolidation, split-up, spin-off, exchange of shares or other changes in the outstanding Common Stock ("Corporate Transactions"). Any such adjustment will be made by the Committee

(c) To the extent any shares of Stock covered by an Award are not delivered to a Participant or beneficiary because the Award is forfeited or

canceled, or the shares of Stock are not delivered because the Award is settled in cash or used to satisfy the applicable tax withholding obligation, such shares shall not be deemed to have been delivered for purposes of determining the maximum number of shares of Stock available for delivery under the Plan. The maximum number of shares of Stock available for delivery under the Plan shall not be reduced for shares subject to plans assumed by the Company in an acquisition of an interest in another company.

(d) If the exercise price of any Option granted under the Plan is satisfied by tendering shares of Stock to the Company, only the number of shares of Stock issued net of the shares of Stock tendered shall be deemed delivered for purposes of determining the maximum number of shares of Stock available for delivery under the Plan.

(e) Subject to adjustment in accordance with paragraph 4.2(f), no more than 100,000 shares of Stock may be subject to Stock Unit Awards, Restricted Stock Awards, Restricted Stock Unit Awards and Performance Share Awards that are intended to be "performance-based compensation" (as that term is used for purposes of Code section 162(m)) granted to any one individual during any one fiscal-year period (regardless of when such shares are deliverable).

(f) Subject to any required action by the shareholders, the number of shares covered by each outstanding Award, and the price per share in each such Award, shall be proportionately adjusted for any increase or decrease in the number of issued shares of the Company resulting from a Corporate Transaction or any other increase or decrease in the number of such shares effected without receipt of consideration by the Company.

(g) If the Company merges or consolidates with another corporation, whether or not the Company is a surviving corporation, or if the Company is liquidated or sells or otherwise disposes of substantially all of its assets while unexercised Options or other Awards remain outstanding under this Plan, (A) subject to the provisions of clause (C) below, after the effective date of the merger, consolidation, liquidation, sale or other

5

disposition, as the case may be, each holder of an outstanding Option or other Award shall be entitled, upon exercise of that Option or Award or in place of it, as the case may be, to receive, in lieu of shares of Stock, the number and class or classes of shares of Stock or other securities or property to which the holder would have been entitled if, immediately prior to the merger, consolidation, liquidation, sale or other disposition, the holder had been the holder of record of a number of shares of Stock equal to the number of shares of Stock as to which that Option may be exercised or are subject to the Award; (B) if Options or other Awards have not already become exercisable under Section 5 hereof, the Board of Directors may waive any limitations set forth in or imposed pursuant to this Plan so that all Options or other Awards, from and after a date prior to the effective date of that merger, consolidation, liquidation, sale or other disposition, as the case may be, specified by the Board of Directors, shall be exercisable in full; and (C) all outstanding Options or SARs may be cancelled by the Board of Directors as of the effective date of any merger, consolidation, liquidation, sale or other disposition provided that any optionee or SAR holder shall have the right immediately prior to such event to exercise his or her Option or SAR to the extent such optionee or holder is otherwise able to do so in accordance with this Plan (including Section 5 hereof) or his individual Option or SAR agreement.

(h) In the event of a change in the shares of the Company as presently constituted, which is limited to a change of all of its authorized shares with par value into the same number of shares with a different par value or without par value, the shares resulting from any such change shall be deemed to be the shares within the meaning of this Plan.

(i) To the extent that the foregoing adjustments relate to Stock or securities of the Company, such adjustments shall be made by the Committee, whose determination in that respect shall be final, binding and conclusive; provided, that each Option which, upon grant of the Option, is specifically designated as an ISO shall not be adjusted in a manner that causes the Option to fail to continue to qualify as an ISO without the consent of the

Option holder.

(j) Except as hereinbefore expressly provided in this Section 4, a Participant shall have no rights by reason of any subdivision or consolidation of shares of stock of any class or the payment of any stock dividend or any other increase or decrease in the number of shares of stock of any class or by reason of any dissolution, liquidation, merger, or consolidation or spin-off of assets or stock of another corporation, and no issue by the Company of shares of stock of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number or price of shares of Stock subject to an Award, unless the Committee shall otherwise determine.

6

(k) The grant of any Award pursuant to this Plan shall not affect in any way the right or power of the Company (A) to make adjustments, reclassifications, reorganizations or changes of its capital or business structure, (B) to merge or consolidate, (C) to dissolve, liquidate or sell, or transfer all or any part of its business or assets or (D) to issue any bonds, debentures, preferred or other preference stock ahead of or affecting the Stock. If any action described in the preceding sentence results in a fractional share for any Participant under any Award hereunder, such fraction shall be completely disregarded and the Participant shall only be entitled to the whole number of shares resulting from such adjustment.

4.3 General Restrictions. Delivery of shares of Stock or other amounts under the Plan shall be subject to the following:

(a) Notwithstanding any other provision of the Plan, the Company shall have no liability to deliver any shares of Stock under the Plan or make any other distribution of benefits under the Plan unless such delivery or distribution would comply with all applicable laws (including, without limitation, the requirements of the Securities Act of 1933), and the applicable requirements of any securities exchange or similar entity.

(b) To the extent that the Plan provides for issuance of stock certificates to reflect the issuance of shares of Stock, the issuance may be effected on a non-certificated basis, to the extent not prohibited by applicable law or the applicable rules of any stock exchange.

4.4 Tax Withholding. All distributions under the Plan are subject to withholding of all applicable taxes, and the Committee may condition the delivery of any shares or other benefits under the Plan on satisfaction of the applicable withholding obligations. The Committee, in its discretion, and subject to such requirements as the Committee may impose prior to the occurrence of such withholding, may permit such withholding obligations to be satisfied through cash payment by the Participant, through the surrender of shares of Stock which the Participant already owns, or through the surrender of shares of Stock to which the Participant is otherwise entitled under the Plan.

4.5 Use of Shares. Subject to the overall limitation on the number of shares of Stock that may be delivered under the Plan, the Committee may use available shares of Stock as the form of payment for compensation, grants or rights earned or due under any other compensation plans or arrangements of the Company or a Subsidiary, including the plans and arrangements of the Company or a Subsidiary assumed in business combinations.

4.6 Dividends and Dividend Equivalents. An Award (including without limitation an Option or SAR Award) may provide the Participant with the right to receive dividend payments or dividend equivalent payments with respect to Stock subject to the Award (both before and after the Stock subject to the Award is earned, vested, or acquired), which payments may be either made currently or credited to an account for the Participant, and may be settled in cash or Stock

7

as determined by the Committee. Any such settlements, and any such crediting of dividends or dividend equivalents or reinvestment in shares of Stock, may be subject to such conditions, restrictions and contingencies as the Committee shall establish, including the reinvestment of such credited amounts in Stock

equivalents.

4.7 Payments. Awards may be settled through cash payments, the delivery of shares of Stock, the granting of replacement Awards, or any combination thereof as the Committee shall determine. Any Award settlement, including payment deferrals, may be subject to such conditions, restrictions and contingencies as the Committee shall determine. The Committee may permit or require the deferral of any Award payment, subject to such rules and procedures as it may establish, which may include provisions for the payment or crediting of interest, or dividend equivalents, including converting such credits into deferred Stock equivalents. Each Subsidiary shall be liable for payment of cash due under the Plan with respect to any Participant to the extent that such benefits are attributable to the services rendered for that Subsidiary by the Participant. Any disputes relating to liability of a Subsidiary for cash payments shall be resolved by the Committee.

4.8 Transferability. Except as otherwise provided by the Committee, Awards under the Plan are not transferable except as designated by the Participant by will or by the laws of descent and distribution.

4.9 Form and Time of Elections. Unless otherwise specified herein, each election required or permitted to be made by any Participant or other person entitled to benefits under the Plan, and any permitted modification, or revocation thereof, shall be in writing filed with the Committee at such times, in such form, and subject to such restrictions and limitations, not inconsistent with the terms of the Plan, as the Committee shall require.

4.10 Agreement With Company. An Award under the Plan shall be subject to such terms and conditions, not inconsistent with the Plan, as the Committee shall, in its sole discretion, prescribe. The terms and conditions of any Award to any Participant shall be reflected in such form of written document as is determined by the Committee. A copy of such document shall be provided to the Participant, and the Committee may, but need not, require that the Participant shall sign a copy of such document. Such document is referred to in the Plan as an "Award Agreement" regardless of whether any Participant signature is required.

4.11 Action by Company or Subsidiary. Any action required or permitted to be taken by the Company or any Subsidiary shall be by resolution of its board of directors, or by action of one or more members of the board (including a committee of the board) who are duly authorized to act for the board, or (except to the extent prohibited by applicable law or applicable rules of any stock exchange) by a duly authorized officer of such company.

8

4.12 Gender and Number. Where the context admits, words in any gender shall include any other gender, words in the singular shall include the plural and the plural shall include the singular.

4.13 Limitation of Implied Rights.

(a) Neither a Participant nor any other person shall, by reason of participation in the Plan, acquire any right in or title to any assets, funds or property of the Company or any Subsidiary whatsoever, including, without limitation, any specific funds, assets, or other property which the Company or any Subsidiary, in its sole discretion, may set aside in anticipation of a liability under the Plan. A Participant shall have only a contractual right to the Stock or amounts, if any, payable under the Plan, unsecured by any assets of the Company or any Subsidiary, and nothing contained in the Plan shall constitute a guarantee that the assets of the Company or any Subsidiary shall be sufficient to pay any benefits to any person.

(b) The Plan does not constitute a contract of employment, and selection as a Participant will not give any participating employee the right to be retained in the employ of the Company or any Subsidiary, nor any right or claim to any benefit under the Plan, unless such right or claim has specifically accrued under the terms of the Plan. Except as otherwise provided in the Plan, no Award under the Plan shall confer upon the holder thereof any rights as a shareholder of the Company prior to the date on which the individual fulfills all conditions for receipt of such rights.

4.14 Evidence. Evidence required of anyone under the Plan may be by certificate, affidavit, document or other information which the person acting on it considers pertinent and reliable, and shall be signed, made or presented by the proper party or parties.

## SECTION 5

### CHANGE IN CONTROL

Subject to the provisions of paragraph 4.2(f) (relating to the adjustment of shares), and except as otherwise provided in the Plan or the Award Agreement reflecting the applicable Award, upon the occurrence of a Change in Control as defined in Section 8:

(a) All outstanding Options held by executive officers and directors of the Company (regardless of whether in tandem with SARs) shall become fully exercisable.

9

(b) All outstanding SARs held by executive officers and directors of the Company (regardless of whether in tandem with Options) shall become fully exercisable.

(c) All Stock Units, Restricted Stock, Restricted Stock Units, and Performance Shares held by executive officers and directors of the Company shall become fully vested.

## SECTION 6

### COMMITTEE

6.1 Administration. The authority to control and manage the operation and administration of the Plan shall be vested in a committee (the "Committee") in accordance with this Section 6. The Committee shall be selected by the Board, and shall consist solely of two or more members of the Board who are nonemployee directors within the meaning of Rule 16b-3 under the Securities Exchange Act of 1934, as amended, and are outside directors within the meaning of Code Section 162(m). If the Committee does not exist, or for any other reason determined by the Board, the Board may take any action under the Plan that would otherwise be the responsibility of the Committee. Unless otherwise determined by the Board, the Compensation Advisory Committee of the Company shall be designated as the "Committee" hereunder.

6.2 Powers of Committee. The Committee's administration of the Plan shall be subject to the following:

(a) Subject to the provisions of the Plan, the Committee will have the authority and discretion to select from among the Eligible Grantees those persons who shall receive Awards, to determine the time or times of receipt, to determine the types of Awards and the number of shares covered by the Awards, to establish the terms, conditions, performance criteria, restrictions, and other provisions of such Awards, and (subject to the restrictions imposed by Section 7) to cancel or suspend Awards.

(b) To the extent that the Committee determines that the restrictions imposed by the Plan preclude the achievement of the material purposes of the Awards in jurisdictions outside the United States, the Committee will have the authority and discretion to modify those restrictions as the Committee determines to be necessary or appropriate to conform to applicable requirements or practices of jurisdictions outside of the United States.

(c) The Committee will have the authority and discretion to interpret the Plan, to establish, amend, and rescind any rules and regulations relating to the Plan, to determine the terms and provisions of any Award Agreement made pursuant to the Plan, and to make all other determinations that may be necessary or advisable for the administration of the Plan.

10

(d) Any interpretation of the Plan by the Committee and any decision



made by it under the Plan is final and binding on all persons.

(e) In controlling and managing the operation and administration of the Plan, the Committee shall take action in a manner that conforms to the certificate of incorporation and by-laws of the Company, and applicable state corporate law.

6.3 Delegation by Committee. Except to the extent prohibited by applicable law or the applicable rules of a stock exchange, the Committee may allocate all or any portion of its responsibilities and powers to any one or more of its members and may delegate all or any part of its responsibilities and powers to any person or persons selected by it. Any such allocation or delegation may be revoked by the Committee at any time.

6.4 Information to be Furnished to Committee. The Company and Subsidiaries shall furnish the Committee with such data and information as it determines may be required for it to discharge its duties. The records of the Company and Subsidiaries as to an employee's or Participant's employment, termination of employment, leave of absence, reemployment and compensation shall be conclusive on all persons unless determined to be incorrect. Participants and other persons entitled to benefits under the Plan must furnish the Committee such evidence, data or information as the Committee considers desirable to carry out the terms of the Plan.

## SECTION 7

### AMENDMENT AND TERMINATION

The Plan may be terminated or amended by the Board of Directors at any time, except that the following actions may not be taken without shareholder approval: (a) materially increasing the number of shares that may be issued under the Plan (except by certain adjustments provided for under the Plan); or (b) amending the Plan provisions regarding the limitations on the Exercise Price. In addition, no amendment or termination may, in the absence of written consent to the change by the affected Participant (or, if the Participant is not then living, the affected beneficiary) adversely affect the rights of any Participant or beneficiary under any Award granted under the Plan prior to the date such amendment is adopted by the Board. Options may not be granted under the Plan after the date of termination of the Plan, but Options granted prior to that date shall continue to be exercisable according to their terms.

11

## SECTION 8

### DEFINED TERMS

In addition to the other definitions contained herein, the following definitions shall apply:

(a) Award. The term "Award" shall mean any award or benefit granted under the Plan, including, without limitation, the grant of Options, SARs, Stock Unit Awards, Restricted Stock Awards, Restricted Stock Unit Awards and Performance Share Awards.

(b) Board. The term "Board" shall mean the Board of Directors of the Company.

(c) Change in Control. The term "Change in Control" means a change in the beneficial ownership of the Company's voting stock or a change in the composition of the Board which occurs as follows:

(i) Any "person," including a "syndication" or "group" as those terms are used in Section 13(d)(3) of the Securities Exchange Act of 1934, is or becomes the beneficial owner, directly or indirectly, of securities of the Company representing 20% or more of the combined voting power of the Company's then outstanding "Voting Securities," which is any security which ordinarily possesses the power to vote in the election of the Board of Directors of a corporation without the happening of any precondition or contingency;

(ii) The Company is merged or consolidated with another

corporation and immediately after giving effect to the merger or consolidation less than 80% of the outstanding Voting Securities of the surviving or resulting entity are then beneficially owned in the aggregate by (x) the shareholders of the Company immediately prior to such merger or consolidation, or (y) if a record date has been set to determine the shareholders of the Company entitled to vote on such merger or consolidation, the shareholders of the Company as of such record date;

(iii) If at any time the following do not constitute a majority of the Board of Directors of the Company (or any successor entity referred to in clause (ii) above): Persons who, prior to their election as a director of the Company (or successor entity if applicable) were nominated, recommended or endorsed by a formal resolution of the Board of Directors of the Company; or

(iv) The Company transfers substantially all of its assets to another corporation which is a less than 80% owned subsidiary of the Company.

12

(d) Code. The term "Code" means the Internal Revenue Code of 1986, as amended. A reference to any provision of the Code shall include reference to any successor provision of the Code.

(e) Eligible Grantee. The term "Eligible Grantee" shall mean any employee, consultant or director of the Company or a Subsidiary. An Award may be granted to an employee, in connection with hiring, retention or otherwise, prior to the date the employee first performs services for the Company or the Subsidiaries, provided that such Award shall not become vested prior to the date the employee first performs such services.

(f) Fair Market Value. For purposes of determining the "Fair Market Value" of a share of Stock as of any date, then the "Fair Market Value" as of that date shall be the closing price of the Stock on that date on the New York Stock Exchange.

(g) Subsidiaries. The term "Subsidiary" means any subsidiary of the Company, and any business venture designated by the Committee in which the Company has a significant interest, as determined in the discretion of the Committee.

(h) Stock. The term "Stock" shall mean shares of common stock of the Company.

## SECTION 9

### GOVERNING LAW

This Plan shall be governed by, and construed in accordance with, the laws of the State of Georgia, except to the extent that the Florida Business Corporation Act shall be applicable.

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, 2002, 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 Chief Financial Officer of the Company, hereby certify, 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

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STEVEN G. ANDERSON  
Chairman, President, and  
Chief Executive Officer  
September 3, 2002

/s/ DAVID ASHLEY LEE

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DAVID ASHLEY LEE  
Vice President and Chief Financial  
Officer  
September 3, 2002