

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, 1996 Commission File Number 0-21104

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

-----  
 Florida 59-2417093  
 (State or other jurisdiction (I.R.S. Employer  
 of incorporation or organization) Identification No.)

2211 New Market Parkway, Suite 142  
 Marietta, Georgia 30067  
 (Address of principal executive offices)  
 (zip code)

(770) 952-1660  
 (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 July 26, 1996 was 9,515,132.

Part I - FINANCIAL INFORMATION  
 Item 1. Financial statements

CRYOLIFE, INC. AND SUBSIDIARIES  
 SUMMARY CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	1996	1995	1996	1995
	(Unaudited)		(Unaudited)	
Revenues:				
Cryopreservation	\$9,619,346		\$7,104,370	\$17,878,905
Research grants, licenses, lease and interest revenue	78,524		125,390	252,772
	<u>9,697,870</u>	<u>7,229,760</u>	<u>18,131,677</u>	<u>13,834,625</u>
Costs and expenses:				
Preservation	3,289,370		2,706,257	6,168,219
General, administrative and marketing	4,181,360		3,042,545	7,807,029
Research & development	700,423		667,923	1,390,519
Interest expense	--		2,620	--
				2,620

	8,171,153	6,419,345	15,365,767	12,451,080	
Income before income taxes			1,526,717	810,415	2,765,910
Income tax expense			538,278	251,036	994,974
Net income			\$ 988,439	\$ 559,379	\$ 1,770,936
Earnings per share of common stock			\$ 0.10	\$ 0.06	\$ 0.18
Weighted average common and common equivalent shares outstanding	9,932,512	9,503,528	9,876,286	9,462,232	\$ 949,509

See accompanying notes to summary consolidated financial statements.

#### Item 1. Financial Statements

##### CRYOLIFE, INC. AND SUBSIDIARIES SUMMARY CONSOLIDATED BALANCE SHEETS

June 30, December 31,  
1996 1995  
(Unaudited)

#### ASSETS

##### Current assets:

Cash and cash equivalents	\$ 58,061	\$ 166,931
Marketable securities	4,317,254	6,015,158
Receivables (net)	7,465,534	5,369,205
Deferred preservation costs (net)	6,522,387	5,996,201
Inventories (net)	332,885	424,200
Prepaid expenses	584,648	369,594
Deferred income taxes	80,345	--

Total current assets	19,361,114	18,341,289
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Property and equipment (net)	4,580,272	3,279,168
Patents and other intangibles (net)	2,549,508	1,728,262
Other assets	464,943	240,897

TOTAL ASSETS	\$26,955,837	23,589,616
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#### LIABILITIES AND SHAREHOLDERS' EQUITY

##### Current liabilities:

Accounts payable	\$ 1,651,821	\$1,372,862
Accrued expenses	1,866,936	1,474,365
Accrued compensation	305,163	260,709
Current portion of long term debt	198,458	--

Total current liabilities	4,022,378	3,107,936
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Deferred income taxes	--	16,486
Other long term liabilities	445,816	--

Total liabilities	4,468,194	3,124,422
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##### Shareholders' Equity:

Preferred stock	--	--
Common stock (issued 10,058,132 shares in 1996 and 9,974,332 shares in 1995)	100,582	99,744
Additional paid-in capital	16,837,339	6,568,312
Retained earnings	5,745,474	3,974,538
Unrealized gain on investments	4,740	28,092
Less: Treasury stock (543,000 shares)	(179,625)	(179,625)

Notes receivable from shareholders	(20,867)	(25,867)
Total shareholders' equity	22,487,643	20,465,194
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$26,955,837	\$23,589,616

See accompanying notes to summary consolidated financial statements.

Item 1. Financial Statements

CRYOLIFE, INC. AND SUBSIDIARIES  
SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS

Six Months Ended		
June 30,		
1996	1995	
(Unaudited)		
Net cash flows from operating activities:		
Net income	\$1,770,936	\$ 949,509
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	637,620	459,094
Provision for doubtful accounts	28,400	38,000
Deferred income taxes	(96,831)	--
Increase in receivables	(2,124,729)	(773,221)
(Increase) decrease in deferred preservation costs and inventory	(434,871)	540,801
Increase in prepaid expenses and other assets	(1,387,966)	(938,206)
Increase in accounts payable and accrued expenses	715,984	708,226
Net cash flows provided by (used in) operating activities	(891,457)	984,203
Net cash flows used in investing activities:		
Capital expenditures	(1,811,104)	(544,754)
Proceeds from other long term liabilities	644,274	--
Proceeds from the sale of marketable securities	4,128,622	2,176,400
Purchase of marketable securities	(2,430,718)	(3,584,859)
Net cash flows provided by (used in) investing activities	531,074	1,953,213)
Net cash flow from financing activities:		
Proceeds from issuance of common stock and from notes receivable from shareholders	251,513	106,846
Net cash provided by financing activities	251,513	106,846
Decrease in cash	(108,870)	(862,164)
Cash and cash equivalents at beginning of period	166,931	2,592,799
Cash and cash equivalents at end of period	\$ 58,061	\$ 1,730,635

See accompanying notes to summary consolidated financial statements.

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

Note 1 - Basis of Presentation

The accompanying unaudited, summary, consolidated financial statements have been prepared in accordance with (i) generally accepted accounting principles for interim financial information, and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for fair presentation have been included. Operating results for the three and six months ended June 30, 1996 are not necessarily indicative of the results that may be expected for the year ended December 31, 1996. Note 2 below covers events occurring after the latest fiscal year end. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's Form 10-K for the year ended December 31, 1995.

#### Note 2 - Shareholders' equity

On May 16, 1996 the shareholders ratified and approved an amendment to the Company's Articles of Incorporation to increase the number of authorized shares of common stock of the Company from 20,000,000 shares to 50,000,000 shares.

On May 16, 1996 the shareholders approved the Employee Stock Purchase Plan (the "Plan") under which employees who meet certain criteria are eligible to purchase common stock of the Company, through payroll deductions, at 85% of the market value of the shares, determined on either the first or last day of a purchase period, on whichever date the market value is less. No compensation expense is recorded in connection with the Plan. There are a maximum of 600,000 shares eligible for issuance under the Plan.

On May 16, 1996 the shareholders approved an amendment to the Articles of Incorporation of the Company deleting the provision on required voting rights for preferred stock. On May 16, 1996 the Board of Directors declared a two for one stock split, effected in the form of a stock dividend, payable on June 28, 1996 to shareholders of record on June 7, 1996.

#### PART I - FINANCIAL INFORMATION

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

###### Results of Operations

Revenues were \$9.7 million and \$18.1 million for the three and six months ended June 30, 1996, respectively, compared to \$7.2 million and \$13.8 million for the corresponding periods in 1995. Revenues increased 35% and 31% for the three and six months ended June 30, 1996, respectively, compared to the corresponding periods in 1995. Revenue increases are due to greater allograft shipments resulting from increased demand.

Revenues from human heart valve preservation increased 32% to \$6.6 million for the three months ended June 30, 1996 from \$5.0 million for the three months ended June 30, 1995, representing 68% and 69% of total revenues, respectively. For the six months ended June 30, revenues from human heart valve preservation increased 27% to \$12.1 million for 1996 from \$9.5 million for 1995, representing 67% and 69% of total revenue, respectively. Second quarter revenues increased due to a 34% increase in tissue shipments resulting from an increase in demand in the second quarter of 1996 compared to the second quarter of 1995. Six month revenues increased due to a 31% increase in tissue shipments resulting from an increase in demand in the first half of 1996 compared to 1995.

Revenues from vein preservation increased 24% to \$2.1 million for the three months ended June 30, 1996 from \$1.7 million for the three months ended June 30, 1995, representing 22% and 24% of total revenues, respectively. For the six months ended June 30, revenues from vein preservation increased 18% to \$3.9 million for 1996 from \$3.3 million for 1995, representing 21% and 24% of total revenue, respectively. Second quarter

revenues increased due to a 27% increase in tissue shipments resulting from an increase in demand in the second quarter of 1996 compared to the second quarter of 1995. Six month revenues increased due to a 16% increase in tissue shipments resulting from an increase in demand in the first half of 1996 compared to 1995.

Revenues from orthopaedic tissue preservation increased 150% to \$896,000 for the three months ended June 30, 1996 from \$359,000 for the three months ended June 30, 1995, representing 9% and 5% of total revenues, respectively. For the six months ended June 30, revenues from orthopaedic tissue preservation increased 159% to \$1.7 million for 1996 from \$638,000 for 1995, representing 9% and 5% of total revenue, respectively. Second quarter revenues increased due to a 231% increase in tissue shipments resulting from an increase in demand in the second quarter of 1996 compared to the second quarter of 1995. Six month revenues increased due to a 241% increase in tissue shipments resulting from an increase in demand in the first half of 1996 compared to 1995.

Other revenues were \$77,000 for the three months ended June 30, 1996 compared to \$125,000 for the three months ended June 30, 1995, representing 1% and 2% of total revenues, respectively. For the six months ended June 30, other revenues were \$253,000 for 1996 compared to \$265,000 for 1995, representing 1% and 2% of total revenue, respectively. Other revenues consist primarily of research grant award revenues and interest income. Research grant award revenues in 1996 are primarily related to the bioadhesive and synergraft projects.

Preservation costs aggregated \$3.3 million and \$6.2 million, respectively, for the three and six months ended June 30, 1996, representing 34% of total revenues for both periods, compared to \$2.7 million and \$5.1 million, respectively, for the three and six months ended June 30, 1995, representing 38% and 37% of total revenues, respectively. Preservation costs increased 22% for second quarter 1996 compared to second quarter 1995 and increased 22% for the first half of 1996 compared to the first half of 1995 due to increased shipments of human allografts.

General, administrative, and marketing expenses aggregated \$4.2 million and \$7.8 million, respectively, for the three and six months ended June 30, 1996, representing 43% of total revenues for both periods, compared to \$3.0 million and \$6.0 million, respectively, for the three and six months ended June 30, 1995, representing 42% and 43% of total revenues, respectively. This increase reflects the general overhead growth trends, including increased marketing expenses associated with the increase in revenues and the switch from a predominantly independent sales force to a predominantly direct sales force.

Research and development expenses aggregated \$700,000 and \$1.4 million, respectively, for the three and six months ended June 30, 1996, representing 7% and 8% of total revenues, respectively, compared to \$668,000 and \$1.4 million, respectively, for the three and six months ended June 30, 1995, representing 9% and 10% of total revenues, respectively. R & D spending relates principally to the Company's focus on bioadhesives and the synergraft technology.

#### Seasonality

The demand for the Company's human heart valve tissue preservation services is seasonal. Management believes this demand trend for human heart valves is primarily due to the high number of pediatric surgeries scheduled during the summer months.

#### Liquidity and Capital Resources

At June 30, 1996 net working capital was \$15.3 million, compared to \$15.2 million at December 31, 1995, with a current ratio of 4.8 to 1. Shareholders' equity at June 30, 1996 was \$22.5 million. The Company's primary capital requirements arise out of working capital needs, including receivables and deferred preservation costs, and capital expenditures for

facilities and equipment, primarily the new corporate headquarters. The increase in receivables relates to the increase in revenue. The increase in prepaid expenses relates primarily to prepaid lab supplies for the bioadhesives facility. The increase in other assets relates primarily to the purchase of the Bioglue technology. The increase in accounts payable and accrued expenses is due to increased procurement fees pursuant to an increase in tissue procured, and the increase in overhead to support the increased revenues. Other long term liabilities relate to the acquisition of the Bioglue technology. Fixed asset additions of \$1.8 million during the first half of 1996 related principally to the construction of the new corporate headquarters.

The Company believes that available cash, cash equivalents, and marketable securities, along with cash generated from operations, will be sufficient to meet its operating and development needs for the foreseeable future.

Part II - OTHER INFORMATION

Item 1. Legal Proceedings.  
None

Item 2. Changes in Securities.  
None

Item 3. Defaults Upon Senior Securities.  
Not Applicable

Item 4. Submission of Matters to a Vote of Security Holders.  
(a) The Annual Meeting of Shareholders was held on May 16, 1996.  
  
(b) Management's nominees for director were elected at the meeting by the holders of common stock. The election was uncontested.  
  
(c) A proposal to approve the Company's Employee Stock Purchase Plan was approved.

The result of the voting was as follows:

Common shares	
-----	
Voting for	2,679,355
Voting against	29,245
Abstain from voting	8,788
BrokerNon-votes	930,712
Total	3,648,100

A proposal to amend the Company's Articles of Incorporation to increase the number of authorized shares of common stock from twenty million to fifty million shares was approved. The result of the voting was as follows:

Common shares	
-----	
Voting for	3,478,798
Voting against	395,575
Abstain from voting	19,680
Broker Non-votes	0
Total	3,894,053

A proposal to amend the Company's Articles of Incorporation

to delete the requirement that preferred shares have voting rights was approved. The result of the voting was as follows:

Common shares	
Voting for	2,441,238
Voting against	259,984
Abstain from voting	16,166
Broker Non-votes	930,712
<hr/>	
Total	3,648,100
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The following table shows the results of voting in the election of Directors:

Shares Voted For	Authority Withheld	
Steven G. Anderson	3,781,470	112,653
Ronald C. Elkins, M.D.	3,781,470	112,653
Benjamin H. Gray	3,781,470	112,653
Rodney G. Lacy	3,781,470	112,653
Ronald D. McCall, Esq.	3 781,470	112,653

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 Registration Statement on Form S-1 (No. 33-56388).)
- 3.2 Amendment to Articles of Incorporation of the Company dated November 29, 1985. (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 Amendment to the Company's Articles of Incorporation to increase the number of authorized shares of common stock from 20 million to 50 million shares and to delete the requirement that all preferred shares have one vote per share.
- 3.4 ByLaws of the Company, as amended. (Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report of Form 10-K for the fiscal year ended December 31, 1993.)
- 10.1 Research and Option Agreement between the Company and Biocompatibles Limited.
- 11.1 Statement re: computation of earnings per share
- 27.1 Financial Data Schedule

(b) Current Reports on Form 8-K.

The Registrant filed a Current Report on Form 8-K with the Commission on April 23 with respect to a Change in the Registrant's Certifying Accountant.

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)

August 13, 1996  
EDWIN B. CORDELL, JR.

DATE \_\_\_\_\_ EDWIN B. CORDELL, JR.  
Vice President and Chief Financial  
Officer  
(Principal Financial and  
Accounting Officer)



<ARTICLE> 5

<LEGEND>

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL DATA INFORMATION EXTRACTED FROM THE COMPANY'S UNAUDITED FINANCIAL STATEMENTS CONTAINED IN ITS REPORT ON FORM 10-Q FOR THE QUARTERLY PERIOD ENDED JUNE 30, 1996 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

</LEGEND>

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JUN-30-1996

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EXHIBIT 3.3

ARTICLES OF AMENDMENT TO THE ARTICLES OF INCORPORATION  
OF CRYOLIFE, INC.

TO: DEPARTMENT OF STATE  
TALLAHASSEE, FLORIDA 32304

Pursuant to the provisions of Section 607.1006 and Section 607.1007 of the Florida Statutes, the undersigned Corporation adopts the following Amendments to the Articles of Incorporation:

1. The name of the corporation is CRYOLIFE, INC.

2. The following Amendments to the Articles of Incorporation were adopted by the shareholders of the corporation on May 16, 1996, in the manner prescribed by the Florida General Corporation Act:

A. Paragraph a(1) of Article V of the Articles of Incorporation is hereby deleted in its entirety and the following is substituted therefor:

(a) (1) The number of shares of capital stock authorized to be issued by this corporation shall be Fifty Million (50,000,000) shares of common stock, each with a par value of One Cent (\$.01) and Five Million (5,000,000) shares of preferred stock, each with a par value of One Cent (\$.01). The shares of preferred stock may be divided into and issued in series.

B. Paragraph a(3) of Article V of the Articles of Incorporation is hereby deleted in its entirety and the following is substituted therefor:

(a) (3) Each share of issued and outstanding common stock shall entitle the holder thereof to one (1) vote on each matter with respect to which shareholders have the right to vote, to fully participate in all shareholder meetings, and to share ratably in the net assets of the corporation upon liquidation and/or dissolution. Each share of issued and outstanding preferred stock shall have such rights to share in the net assets of the corporation upon liquidation and/or dissolution as are determined and fixed by the Board of Directors pursuant to Florida Statutes Section 607.047. All or any part of said capital stock may be paid for in cash, in property or in labor or services at a fair valuation to be fixed by the Board of Directors at a meeting called for such purposes. All stock when issued shall be paid for and shall be nonassessable.

The other paragraphs of Article V remained unchanged.

3. The total number of shares of common stock of the corporation that have been issued or are outstanding are 4,716,166.

4. The number of each class entitled to vote thereon as a class voted for and against such amendment, respectively was:

NUMBER OF COMMON SHAREHOLDERS VOTED:

AMENDMENT	CLASS	FOR	AGAINST
ARTICLE V-A(1)	Common Shareholders	3,478,798	395,575
ARTICLE V-A(3)	Common Shareholders	2,441,238	259,984

The number of votes cast by the shareholders was sufficient for approval.

IN WITNESS WHEREOF, the foregoing Articles of Amendment to the Articles of Incorporation are hereby executed by the President, STEVEN G. ANDERSON, and attested by RONALD D. McCALL, as Secretary of the Corporation, CRYOLIFE, INC. on this 21st day of June, 1996.

WITNESSES:

STEVEN G. ANDERSON

FELICIA E. TROTT

-----  
STEVEN G. ANDERSON

President & Ceo

Cryolife, Inc.

Printed Name of Witness

-----  
FELICIA E. TROTT

RONALD D. McCALL

JOYCE A. CLARK

-----  
RONALD D. McCALL, Secretary

Cryolife, Inc.

-----  
Printed Name of Witness

-----  
JOYCE A. CLARK

STATE OF GEORGIA

COUNTY OF COBB

I HEREBY CERTIFY that before me the undersigned authority personally appeared STEVEN G. ANDERSON, as President and CEO of Cryolife, Inc., to me well known and who acknowledged that he executed the foregoing instrument this 21st day of June, 1996, for the purposes stated therein.

SUZANNE K. GABBERT

-----  
Notary Public, State of Georgia at Large

SUZANNE K. GABBERT

-----  
Printed Name of Notary Public

My Commission Expires:

Notary Public, Cobb County, Georgia

My Commission Expires Sept. 13, 1996

STATE OF FLORIDA

COUNTY OF HILLSBOROUGH

I HEREBY CERTIFY that before me the undersigned authority personally appeared RONALD D. McCALL, as Secretary of Cryolife, Inc., to me well known and who acknowledged that he executed the foregoing instrument this 14th day of June, 1996, for the purposes stated therein.

JOYCE A. CLARK

-----  
Notary Public, State of Florida at Large

JOYCE A. CLARK

-----  
Printed Name of Notary Public

My Commission Expires:

Joyce A. Clark

My Commission # CC2886 B Expires

May 30, 1997

Bonded thru Troy Fain Insurance, Inc.

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RESEARCH AND OPTION AGREEMENT

This Agreement is made and entered into as of this 29th day of July, 1996 (the "Effective Date"), by and between BIOCOMPATIBLES LIMITED, a United Kingdom company ("Biocompatibles"), and CRYOLIFE, INC., a Florida corporation ("CryoLife").

W I T N E S S E T H:

WHEREAS, CryoLife desires to engage Biocompatibles, and Biocompatibles desires to be engaged, to conduct certain scientific research relating to the development of methods, formulae and processes for applying Biocompatibles' proprietary and patent protected "coating polymers" to preserved animal and human tissue.

NOW THEREFORE, in consideration of the premises and the mutual agreements set forth below, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. DEFINITIONS.

The following terms shall have the following meanings when used in this Agreement:

"Biocompatibles Technology" shall mean the secret and proprietary information, data, formulae, methods, processes, products and techniques of Biocompatibles or its affiliates for coating materials with polymers which improve the biocompatibility of implantable devices. The Biocompatibles Technology includes information, data, formulae, methods, processes, products and techniques developed by Biocompatibles in the course of conducting any Research Project.

"coated" shall refer to tissues to which the Biocompatibles Technology has been applied.

"Confidential Information" shall mean as to each party, its secret information, data, formulae, methods, processes, products and techniques directly related to the patents described in Exhibit B. Confidential Information shall not include any information, data, formulae, methods, processes, products or techniques which (i) are in the public domain, (ii) come into the public domain through no fault of the other party, (iii) were known to the other party prior to its disclosure by the party claiming confidentiality as evidenced by the written records of the other party, (iv) are disclosed by a third party not under an obligation of non-disclosure, (v) is required by law or legal process to be disclosed, or (vi) written permission for disclosure has been granted to the disclosing party by the party claiming confidentiality.

"CryoLife Technology" shall mean the secret and proprietary information, data, formulae, methods, processes, products and techniques of CryoLife for preserving and processing human and animal tissue, but excluding the Biocompatibles Technology.

"Designated Representative" shall mean, as to each party, the individual appointed by the party to fulfill the responsibilities identified for Designated Representatives in

Section 2 of this Agreement. The initial Designated Representative for Biocompatibles is Robert Hanley, Ph.D. The initial Designated Representative for CryoLife is Steven Goldstein, Ph.D.

"Other Tissues" shall mean animal and human tissues types identified on Exhibit A.

"Oversight Team" shall mean the collective Designated Representatives of both parties. Actions of the Oversight Team shall require the agreement of both Designated Representatives.

"Research Project" shall mean research and development work conducted by Biocompatibles pursuant to this Agreement for the purpose of developing commercially feasible methods for applying the Biocompatibles Technology to porcine heart valves and, if designated by CryoLife, Other Tissue, which generates the defined outcomes described on Exhibit A or otherwise identified by the Oversight Team.

## 2. RESEARCH PROJECTS.

2.1 Biocompatibles shall conduct a Research Project relating to the application of Biocompatibles' Technology to porcine heart valves in the manner and on the schedule identified on Exhibit A, which schedule may be revised by the Oversight Team. Biocompatibles shall also conduct Research Projects for Other Tissues designated by CryoLife on schedules agreed to by the Oversight Team. During the term of any Research Project and for a period of 90 days after completion of the last Research Project, Biocompatibles agrees not to conduct research projects involving coating polymers, except pursuant to this Agreement, for preserved porcine tissue or any of the tissue types identified on Exhibit A.

2.2 CryoLife shall provide Biocompatibles with reasonable quantities of tissue for each Research Project, at no cost to Biocompatibles.

2.3 To initiate the porcine heart valve Research Project, the Oversight Team shall meet at CryoLife's headquarters in Atlanta, Georgia, U.S.A. for the purpose of (i) sharing information necessary to the conduct of the Research Project, (ii) adjusting, if necessary, the schedule and the defined outcomes identified in Exhibit A, and (iii) setting the standards by which proof of coating patency and proof of concept are determined for the porcine heart valve Research Project. All travel expenses incurred in connection with this initial meeting and subsequent meetings shall be borne by the party incurring the expenses. Following the initial meeting, CryoLife shall send a representative to Biocompatibles' facilities for approximately one week to assist with the Research Project. The scheduling of meetings shall be determined by the Oversight Committee.

2.4 Biocompatibles shall keep the CryoLife Designated Representative regularly and fully advised of the progress and results of each Research Project, which advice shall include monthly written progress reports. Such reports shall contain reasonable detail and include reports on matters reasonably requested by CryoLife's Designated Representative. Full written reports will also be required for establishing proof of coating patency and proof of concept for each tissue Research Project. Upon completion of each Research Project which includes proof of concept, Biocompatibles shall provide CryoLife with a final report setting forth the results achieved under and pursuant to the Research Project. Such final report shall include: a complete summary of the research carried out and detailed experimental protocols of the research performed in the course of

the Research Project.

2.5 Biocompatibles shall provide to CryoLife copies of all data and other information generated in connection with the Research Project including, without limitation, all raw data obtained as a result of studies conducted in the course of Research Project and all experimental procedures developed under the Research Project in sufficient written detail to permit CryoLife's personnel to employ such procedures in their own research.

2.6 All studies done in connection with the Research Project shall be carried out in strict compliance with any applicable laws, regulations, or guidelines governing the conduct of such research. CryoLife's Designated Representative shall be regularly consulted on all studies and testing conducted in the course of a Research Project.

### 3. PAYMENTS.

3.1 For Biocompatibles' research efforts pursuant to this Agreement, CryoLife agrees to pay Biocompatibles the following sums, subject to the following conditions, in the following manner:

- (a) \$100,000 upon execution of this Agreement,
- (b) \$50,000 upon proof of coating patency for each tissue indication for which CryoLife requests Biocompatibles to develop a coating, initially porcine heart valves,
- (c) \$125,000 upon commencement of animal trials following completion of the porcine valve development program contemplated by the Research Project and proof of concept for the coated porcine valve,
- (d) \$125,000 upon satisfactory completion of animal trials for the coated porcine valves,
- (e) \$250,000 upon European Union acceptance to conduct the first human device clinical trials for a coated tissue group,
- (f) \$250,000 upon CryoLife obtaining its first CE marking approval for a coated tissue group,
- (g) \$200,000 upon CryoLife's first commercial distribution of a coated tissue group product in the European Union,
- (h) \$300,000 upon CryoLife's first commercial distribution of a coated tissue group product in the United States, and
- (i) a percentage royalty (10% of net sales) and minimum royalties for commercial distribution of coated tissues in the amounts set forth in the exclusive license form contained in Exhibit C.

3.2 The payment requirement of subsections (e) through and including (h) of Section 3.1 shall be contingent upon Biocompatibles and CryoLife entering into a license in the form of Exhibit C, pursuant to which CryoLife shall be granted the license to commercialize the application of the Biocompatibles Technology with porcine heart valves or Other Tissues. The payment requirements of subsections (e) through and including (g) of Section 3.1 shall apply only to the first tissue group which meets the criteria of the subsection. In case of any conflict between the terms of this Agreement and the terms of an

outstanding License Agreement as to any tissue group, the terms of the License Agreement shall prevail.

3.3 Payments under the terms of this Agreement shall be made by check or wire transfer and shall be payable in U.S. dollars. In the event that CryoLife should fail to make payment within 30 days of the due date, CryoLife will be liable for interest payments on the outstanding sums at U.S. Prime Rate (as announced in the The Wall Street Journal) plus 4% per annum, calculated on actual number of days elapsed.

#### 4. CONFIDENTIALITY.

Each party agrees that, it will not use, except in furtherance of this Agreement, and will not disclose orally, by written publication, or otherwise, any Confidential Information of the other party. Each party will safeguard and protect the Confidential Information of the other, and only those of its employees whose participation is required to complete the Research Project shall have access to the Confidential Information of the other party.

#### 5. OWNERSHIP AND PATENTS.

5.1 Biocompatibles hereby represents and warrants that it owns all right, title and interest in and to the Biocompatibles Technology which is germane to this Project and is authorized and empowered to enter into and perform its obligations under this Agreement. Biocompatibles represents and warrants that Exhibit B attached hereto lists all of the patents and patent applications relating to the Biocompatibles Technology.

5.2 Biocompatibles shall have sole and exclusive ownership rights to any enhancements to the Biocompatibles' Technology developed by Biocompatibles in connection with the Research Project. CryoLife retains all right, title, and interest in and to the CryoLife Technology.

5.3 No license to make, use or sell any CryoLife Technology or Biocompatibles Technology is granted by this Agreement.

#### 6. OPTION TO LICENSE/RESERVATION OF COATING RIGHTS.

6.1 Biocompatibles hereby grants to CryoLife the exclusive option to receive a worldwide license to make, use and sell the Biocompatibles' Technology as it may be applied to porcine heart valves, and each Other Tissue for which a Research Project is undertaken, on the terms and conditions, and subject to the limitations, set forth on the form License Agreement attached hereto as Exhibit C (the "License Agreement"). Notice of exercise of the option for each tissue group must be given by CryoLife to Biocompatibles in writing on or before the 90th day following CryoLife's receipt of the final report on the Research Project as described in Section 2.4 for such tissue group.

6.2 If CryoLife exercises its option according to the terms of this Agreement, the parties agree after the first exercise thereafter (i) to be bound by the terms and conditions set forth in the License Agreement effective as of the date of CryoLife's notice of exercise for the tissue group identified in the notice, (ii) to sign and deliver the License Agreement within 20 days of exercise of the option, and (iii) to identify the "Product" for which the License Agreement applies to be the tissue group for which CryoLife has exercised the option by adding the description of the tissue group to Exhibit A to the License Agreement (which identifies the tissue groups included within the Products licensed under the License Agreement). For subsequent exercises of the option, CryoLife shall provide the notice required under



Section 6.1 and the parties shall evidence the addition of the tissue group to the License Agreement by adding a description of the notified tissue group to Exhibit A to the License Agreement; provided, however, that failure to complete any of the tasks identified in this Section 6.2 shall not prevent the License Agreement from taking effect as to a tissue group for which proper notice has been given under Section 6.1.

6.3 Notwithstanding the option to license granted herein, Biocompatibles reserves the exclusive right to coat porcine valves with the Biocompatibles Technology outside the United States but agrees not to coat porcine heart valves with the Biocompatibles Technology during the Initial Five Year Term (defined in Section 6(a) of Exhibit C) of a License Agreement for a porcine valve "Product". After execution of such a License Agreement, the parties intend to cooperate in coating porcine valves in the United States through a joint venture or other vehicle organized for the purpose.

## 7. PUBLICATION.

CryoLife shall have the right to publish data generated as a result of the Research Project provided that in no event may CryoLife disclose any Biocompatibles' Technology or other Confidential Information of Biocompatibles. CryoLife agrees, however, that CryoLife will give Biocompatibles 30 days to review any proposed publication prior to submission or publication, and shall obtain Biocompatibles' approval prior to such publication, which approval shall not be unreasonably withheld by Biocompatibles. If Biocompatibles fails to provide CryoLife with a written statement setting forth in detail any objections it has to the proposed publication within the 30-day period, Biocompatibles shall be deemed to have approved of such publication.

## 8. TERM AND TERMINATION.

8.1 The term during which CryoLife can initiate any Research Project shall be two years.

8.2 This Agreement may be cancelled by either party in the event of default by the other party, which default is not cured within 30 days following receipt of written notice describing such default. In the event that either party shall be in default of any of its obligations under this Agreement and shall fail to remedy such default within 30 days after receipt of written notice thereof, the party not in default shall have the option of canceling this Agreement by giving written notice of termination to the other party. If this Agreement is terminated as a result of breach by Biocompatibles, CryoLife shall be entitled to a refund of all amounts paid under Section 3. For the avoidance of doubt, "breach" as used in the preceding sentence shall not refer to a failure of the Research Project to achieve the research objective of CryoLife.

8.3 CryoLife may terminate this Agreement at any time by providing Biocompatibles with at least 60 days advance written notice.

8.4 Termination of this Agreement shall not affect the rights and obligations of the parties, which shall have accrued prior to termination. Sections 4, 5, 7 and 9 through 16 and this Section 8.4 shall survive any termination of this Agreement. Section 6 shall survive any termination except for termination due to breach by CryoLife.

8.5 Upon termination, each party shall be required to deliver back to the other party, all Confidential Information of

such other party. An officer of the delivering party shall be required to certify that this condition has been met.

9. INDEPENDENT CONTRACTORS.

CryoLife and Biocompatibles shall at all times act as independent parties and nothing contained in this Agreement shall be construed or implied to create an agency, joint venture, or partnership. Neither party shall have the authority to contract or incur expenses on behalf of the other except as may be expressly authorized by collateral agreements.

10. CHOICE OF LAW.

Any disputes or claims arising under this Agreement shall be governed by the laws of the United Kingdom.

11. SEVERABILITY.

If any one or more of the provisions of this Agreement shall be held to be invalid, illegal or unenforceable, the validity, legality or enforceability of the remaining provisions of this Agreement shall not in any way be affected or impaired thereby.

12. WAIVER.

The failure of any party hereto to insist upon strict performance of any provision of this Agreement or to exercise any right hereunder will not constitute a waiver of that provision or right.

13. NOTICES.

Any notice or communication required or permitted to be given or made under this Agreement by one of the parties hereto to the other shall be in writing and shall be deemed to have been sufficiently given or made for all purposes if (a) mailed by certified mail, postage prepaid, (b) sent by reputable express courier, including UPS, Federal Express, DHL, or similar service, or (c) sent by telecopy, with a copy sent by one of the methods described in (a) or (b) above, addressed to such other party at its respective address as follows:

If to CryoLife:                   CryoLife, Inc.  
2211 New Market Parkway  
Suite 142  
Marietta, Georgia 30067  
Attention: President  
Facsimile: (770) 850-0762

If to Biocompatibles:       Biocompatibles Limited  
Frensham House  
Farnham Business Park  
Weydon Lane  
Farnham  
Surrey G49 8QL  
England  
Facsimile: 44-1252-732703  
Attention: Alistair H. Taylor,  
President and C.E.O.

14. ASSIGNMENT.

This Agreement may be assigned by either party to any parent, subsidiary, or affiliate of the party or to any successor in interest by reason of any merger or acquisition. This Agreement may not be assigned to any competitor or the other party without the prior written consent of the other party, which

consent shall not be unreasonably withheld.

15. ARBITRATION.

15.1 If any dispute or difference shall arise between the parties to this Agreement, as to the interpretation of this Agreement or any covenants or conditions of this Agreement or as to the rights, duties, or liabilities of any party under this Agreement or as to any act, matter, or thing arising out of or under or relating to this Agreement (even though the Agreement may have been terminated), the same shall be finally settled by arbitration conducted in accordance with the rules of the American Arbitration Association. Whenever any dispute, controversy, claim, or difference which may be submitted to arbitration under this Section 15 arises between the parties, either party hereby may give the other party notice of its intention to submit such dispute, controversy, claim, or difference to arbitration. Such arbitration shall take place in New York, New York, before a single arbitrator agreed upon by the parties to the arbitration. In the event the parties cannot agree upon an arbitrator within 20 days after the effective date of receipt, of either party's notice to arbitrate, such arbitration shall take place in New York, New York, before a single arbitrator appointed by the American Arbitration Association in accordance with its rules.

15.2 The parties further agree that notwithstanding the determination of the arbitrator (i) all costs associated with the arbitration shall be borne equally by each party to the arbitration, and (ii) each party to the arbitration shall be responsible for its own attorneys' fees incurred in connection with the arbitration. The determinations of such arbitrator will be final and binding upon the parties to the arbitration, and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. The arbitrator shall set forth the grounds for his decision in the award.

15.3 The parties hereto stipulate that submission of disputes to arbitration as provided in this Section 15 and arbitration pursuant thereto shall be a condition precedent to any suit, action, or proceeding instituted in any court or before any administrative tribunal with respect to this Agreement or disputes arising out of or regarding this Agreement.

16. ENTIRETY.

This Agreement represents the entire agreement of the parties and it expressly supersedes all previous written and oral communications between the parties. No amendment, alteration, or modification of this Agreement or any exhibits attached hereto shall be valid unless executed in writing by authorized signatories of both parties.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date set forth above.

CRYOLIFE, INC.

BIOCOMPATIBLES LIMITED

By: Steven G. Anderson

By: John Bardwell

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Title: President/CEO

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Title: Director

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EXHIBIT A

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RESEARCH PROJECT

CryoLife will provide Biocompatibles with the following tissues to which Biocompatibles will supply the Biocompatibles Technology and assess such Technology's ability to generate the outcome described below.

Project Scope and Defined Outcomes

A. Tissues

The scope of this research project involves multiple tissues which Cryolife will provide for coating according to the Biocompatibles Technology.

1. Porcine Heart Valves
  - a. Cellular, glutaraldehyde-fixed
    - (1) aortic (including leaflets and aortic conduit)
    - (2) pulmonary (including leaflets and pulmonary artery)
  - b. Acellular, unfixed or glutaraldehyde-fixed
    - (1) aortic
    - (2) pulmonary
2. Porcine (or other xenogenic) Circulatory Vessels
  - a. Acellular vein
  - b. Acellular artery
3. Bovine Ligamentous Grafts
  - a. Ligament
  - b. Tendon
  - c. Fascia Lata
4. Other Xenogenic Tissues
  - a. Dura mater
  - b. Pericardium
  - c. Nerves
5. Cryopreserved Human Allograft Tissues including, but not limited to, Heart Valves, Vessels and Nerves

B. Defined Outcomes

A selection of coated tissues as defined in A. (v.s.) will be assessed according to the following tests to demonstrate the effectiveness of Biocompatibles Technology coatings in providing

the indicated results. These tests will be applied according to the particular requirements for each coated tissue.

1. Coverage - Surface covering of the coated tissues is anticipated. Coverage of the tissue will be demonstrated to be uniform and unbroken.
2. The tissue surface coatings is expected to remain intact and unbroken for an agreed clinically relevant time period; no thinning of the coating is expected. Coating stability will be assessed following exposure of the coated tissues in: 1) static cultures in the presence of tissue culture media, blood, or similar medium; 2) in dynamic (stirred) cultures of similar medium; and 3) in orthotopic or heterotopic in vivo implants of the coated tissues. As in B.1., coating coverage will be demonstrated.
3. Histology and ultrastructure - the matrix protein structure of the coated tissue should appear normal by light and transmission electron microscopic analyses.
4. Nonthrombogenicity/Noninflammatory - limited and nonprogressive platelet and/or white cell adhesion in at least one of the following models: 1) subdermal implant in rat (inflammation); b) in vitro platelet and/or white cell adhesion; c) intravascular or intrasynovial implant in vivo.

5. Biomechanical characteristics

- a. Extensibility - should not change more than 10% relative to a selected standard tissue.
- b. Stress-relaxation - relaxation slope and ultimate relaxation should reflect retention of viscoelastic properties with no more than a 10% change in relaxation slope or ultimate relaxation relative to standard fixed tissue.
- c. Load at Failure and Maximum Stress at Failure - should not change more than 10% relative to a selected standard tissue.

6. Toxicity/Biocompatibility

- a. The coating material should be compatible with cell survival and cell proliferation and function.
- b. The coated tissue should be compatible with cell survival and cell proliferation and function (either non-fixed tissues or tissues fixed with other than glutaraldehyde).
- c. Cytocompatibility of coated tissues will be assessed by supplementing cell culture media with aqueous extracts made from tissues following coating and observing the effect of such supplementation on the growth rates of fibroblast and endothelial cells.

d. Nontoxicity or cytocompatibility will be defined as growth rates of cells in the presence of coating-related materials being within 10% of the growth rates of cells grown under control conditions.

#### 7. Anticalcification

A model of implanting treated tissues subdermally in weanling rats will be used to assess effects of coating(s) on the rate and extent of tissue calcification. At least a 60% reduction in the extent of calcification relative to uncoated control tissue is considered acceptable after 16 weeks of implantation.

### C. Acceptance Parameters

1. Coatings will be screened according to the tests outline in B.(v.s.).

2. Up to seven coating formulations will be screened for each tissue type.

3. Coatings will be selected based on disclosure of known properties to CryoLife.

4. Tests will be selected according to suitability for each tissue type.

#### 5. Parameters:

a. coverage - see B.1.

b. stability - B.2.

c. histology and ultrastructure - see B.3. Various standard stains will be applied to sectioned tissues to facilitate observation of collagens, elastin, glycosaminoglycans, and glycoproteins. Comparisons with untreated tissues will be carried out by a qualified pathologist. Transmission electron microscopy will be used to examine, among other factors, collagen periodicity, collagen fiber crimp, and so on.

d. nonthrombogenicity/noninflammatory - see B.4.

e. biomechanical characteristics - see B.5.

f. toxicity/biocompatibility - see B.6.

g. anticalcification - see B.7. We anticipate the acceptable levels of coated tissue calcium will be no greater than 5 mg/g dry weight of tissue after 16 weeks of implantation.

### D. Schedules

#### 1. Preliminary Screening of Coatings

Initial examinations of coatings will entail analysis of: 1) coating thickness and consistency; 2) cellular and extracellular matrix morphology, 3) appropriate biomechanical parameters; 4) biocompatibility of coating and of treated tissue; and 5) effect of coating on rate and extent of calcification of the coated tissue. It is anticipated that only those coating with

acceptable outcomes for coating properties and tissue morphology (D.1.1. and D.1.2.) will be delivered to CryoLife for further analysis.

## 2. Secondary Screening Outcomes

As indicated, those coating displaying acceptable outcomes in the Preliminary Screenings (D.1.) will be further analyzed by in vivo implants to demonstrate: 1) thrombogenicity/inflammatory response characteristics, and 2) stability of the coating in a functional graft model.

### EXHIBIT B

#### PATENTS

Patent or Application Number	Jurisdiction	Date	Status
PCT/GB92/01215 (BCP 33)	Europe (Austria, Belgium, Switzerland, and Lichstenstein, Germany, Denmark, Spain, France, U.K., Greece, Italy, Luxemborg, Monaco, Netherlands, Portugal and Sweden) Japan U.S.A. Australia Canada Russia	6/7/92	Pending

### EXHIBIT C

#### FORM OF LICENSE AGREEMENT

This License Agreement (the "Agreement") is entered into this \_\_\_\_ day of \_\_\_\_\_, 199 , is between CryoLife, Inc., a Florida corporation ("CryoLife") and Biocompatibles Limited, a United Kingdom company ("Biocompatibles").

WHEREAS, Biocompatibles and CryoLife have previously entered into a Research and Option Agreement dated July , 1996 (the "Research Agreement"), relating to the development of methods, formulae, and processes for applying Biocompatibles' proprietary and patent protected "coating polymers" to preserved animal and human tissues;

WHEREAS, CryoLife desires to license the Biocompatibles Technology (defined below).

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and in consideration of the mutual covenants set forth below, the parties agree as follows:

1. Definitions. Capitalized terms not otherwise defined herein shall have the meanings given to them in the Research Agreement when used in this Agreement.

"Biocompatibles Technology" shall mean the secret and

proprietary information, data, formulae, methods, processes, products and techniques of Biocompatibles or its affiliates for coating materials with polymers which improve the biocompatibility of implantable devices. The Biocompatibles Technology includes information, data, formulae, methods, processes, products and techniques developed by Biocompatibles during or after the course of conducting any Research Project pursuant to the Research Agreement. Biocompatibles Technology includes the Know-How, Patents and Trade Secrets.

"Know-How" shall mean any and all non-Confidential Information heretofore or hereafter owned, developed, acquired or licensed by Biocompatibles relating to the Biocompatibles Technology.

"Patent(s)" shall mean any and all domestic or foreign patents or patent applications owned, acquired or licensed by Biocompatibles, which relate to the Biocompatibles Technology, or which may in the future be filed on the Trade Secrets or Know-How. The term Patent(s) also shall include any and all U.S. or foreign divisions, continuations, continuations-in-part, substitutions, reissues, and extensions of said Patent(s). Schedule A lists all Patents relevant to this License Agreement.

"Processed Tissues" shall mean those tissue groups which have been (i) properly notified to Biocompatibles pursuant to Section 6.1 of the Research Agreement for license under this Agreement and (ii) treated with the Biocompatibles Technology. The parties shall endeavor to maintain a record of Processed Tissues by amending Schedule B attached hereto to include all tissue groups notified for inclusion as and when Biocompatibles receives proper notification.

"Trade Secrets" shall mean any and all Confidential Information heretofore or hereafter owned, developed, acquired or licensed by Biocompatibles, relating to the Biocompatibles Technology.

## 2. License.

(a) License Grant. Biocompatibles hereby grants CryoLife a license to the Biocompatibles Technology to develop, manufacture, use, and distribute Processed Tissues throughout the world. The license is exclusive in the United States and is the sole license Biocompatibles will grant outside the United States; provided, however, that Biocompatibles agrees not to produce or coat porcine heart valves with the Biocompatibles Technology during the Initial Five Year Term (defined in Section 6(a)), except to the extent Biocompatibles participates in a joint venture or partnership with CryoLife for coating valves in the United States.

(b) Sublicense. CryoLife shall have the right to grant sublicenses of any rights granted to it under this license, provided that CryoLife shall have received the prior written approval of Biocompatibles, which shall not be unreasonably withheld.

## 3. Payments by CryoLife.

(a) Non-Royalty Payments. CryoLife shall pay Biocompatibles the sums identified in subsections (d) through and including (h) of Section 3.1 of the Research Agreement upon completion of the conditions set forth in those provisions.

(b) Percentage Royalties. CryoLife shall pay Biocompatibles a royalty on Net Revenues (gross revenues minus sales taxes, reasonable discounts, freight and returns, if any)



from all distribution of Processed Tissues by CryoLife. The amount of the royalty payable for Processed Tissues distributed in countries ("Protected Countries") where the Processed Tissues are protected by a patent or patent application at the time of distribution shall be 10% of Net Revenues. The royalty payable for Processed Tissues distributed outside of Protected Countries shall be 5% of Net Revenues generated outside of Protected Countries.

(c) Minimum Royalties. CryoLife shall pay Biocompatibles minimum royalties commencing on the first day of the first calendar quarter following first commercial distribution of Processed Tissues after approval for unrestricted commercial sale by the European Union or the U.S. Food and Drug Administration as follows:

Year 1	\$100,000
Year 2	\$150,000
Year 3	\$200,000
Year 4	\$300,000
Year 5 and thereafter	\$400,000

Minimum royalties will be payable in equal quarterly installments and shall be credited toward earned royalties due under Subsections (b) and (c) above. The obligation to pay minimum royalties shall expire upon the expiration of patent protection for the Technology in the United States or Europe. Failure to make royalty payments equal to or exceeding minimum royalty obligations in any year shall be deemed a breach or default under this Agreement and may result in its termination by Biocompatibles.

(d) Reports; Audit Rights. Payments of royalties under Section 3(b) shall be made on a monthly basis and shall be payable within 20 days following the end of the preceding month. Such payment shall be accompanied by a statement showing distribution of the Processed Tissues by CryoLife to all parties, and such other particulars as are necessary or which may be reasonably requested by Biocompatibles in order to verify accurate payment of royalties and fees pursuant to this Section 3. CryoLife shall keep complete and accurate records of all distributions by CryoLife of the Processed Tissues and all sublicenses granted hereunder. Biocompatibles and its representatives shall have the right during the term of this Agreement and for a period of two years following any termination of this Agreement to review the books and records of CryoLife relating to distribution of the Processed Tissues and sublicenses granted hereunder in order to verify payments under this Agreement. All costs of such audit shall be borne by Biocompatibles; provided, however, in the event such audit reveals an underpayment of more than 5%, CryoLife shall immediately pay the amount of the underpayment and shall reimburse Biocompatibles for the costs incurred in connection with the audit.

(e) Pricing of Processed Tissues. In the event CryoLife sells the Processed Tissues for use with other products of CryoLife (a "Combined Product"), the purchase price for the Combined Product shall be reasonably allocated between the Processed Tissues and CryoLife's other products. In the event Biocompatibles objects to such allocation, the matter shall be submitted to arbitration in accordance with Section 7(i).

#### 4. Representations of Biocompatibles; Patents.

(a) Title. Biocompatibles hereby represents and warrants that it owns all right, title, and interest in and to the Biocompatibles Technology which is germane to the granting of

the license contained in this Agreement and is authorized to enter into and perform its obligations under this Agreement. Biocompatibles represents and warrants that Schedule B attached hereto lists all of the patents and patent applications relating to the Biocompatibles Technology. Biocompatibles has not granted any other licenses to the Biocompatibles Technology for use with Processed Tissue.

(b) Patents. CryoLife agrees to cooperate with Biocompatibles at Biocompatibles cost in the preparation, filing, and prosecution of domestic and foreign Patent(s) applications and to keep each other fully informed at all times of the status of the Patent(s) and applications.

(c) Prosecution of Patents. Biocompatibles shall have the sole right in the first instance to take appropriate measures, including the bringing or defending of suits throughout the world, to prevent or stop infringement or misappropriation by others in making, using or selling Processed Tissues. CryoLife may participate in such suit through counsel of its own choosing, and in its own name. All costs of any infringement, declaratory judgment or other suit brought or defended by Biocompatibles shall be the obligation of Biocompatibles. In the event of recovery of damages in, or sums and settlement of, a suit or suits for infringement or misappropriation brought or defended by Biocompatibles, Biocompatibles shall be entitled to retain two-thirds of whatever recovery (after costs) of sums for damages or otherwise that might be obtained in such suit or settlement, with one-third of the recovery (after costs) being payable to CryoLife. CryoLife agrees to cooperate with Biocompatibles to prevent or stop such infringement or misappropriation and to provide Biocompatibles with documents, data, and other information as may be reasonably necessary to conduct such suit by Biocompatibles. When such disclosures are identified as Confidential Information, then Biocompatibles undertakes to ensure that the confidentiality of those disclosures is maintained. Should Biocompatibles fail or refuse to take or cause to be taking any such measures against any third party after one month from the date of receipt of written notice to Biocompatibles by CryoLife of such infringement or misappropriation accompanied by reasonable evidence of such infringement or misappropriation, CryoLife may take such legal action in its own name and at its own expense. In such latter case, CryoLife shall be entitled to retain two-thirds of whatever recovery (after costs) of sums for damages or otherwise that it may obtain in such suit or settlement, with one-third of the recovery (after costs) being payable to Biocompatibles. When either party litigates under this paragraph, it shall keep the other party informed of such activities in writing at least every calendar quarter.

5. Indemnification. Biocompatibles shall defend, indemnify, and hold CryoLife and its officers, directors, employees and affiliates harmless from and against any and all damages, liabilities, losses, and expenses (collectively, "Damages"), including reasonable attorneys fees and court costs, incurred by CryoLife as a result of any claim, lawsuit, action, or proceeding (collectively, "Claim") against CryoLife in which it is determined or alleged that the Biocompatibles Technology infringes on any trade secret, patent, copyright, or other proprietary right of any third party. Except as provided above, CryoLife shall indemnify, defend, and hold Biocompatibles and its officers, directors, employees and affiliates harmless from and against any and all Damages incurred by Biocompatibles arising out of any Claim of a third party based upon the production, distribution, or marketing by CryoLife of the Processed Tissues. Any party claiming indemnification pursuant to this Section 5 (the "Indemnitee") shall give prompt notice of any claim,

lawsuit, action or proceeding with respect to which indemnification is claimed and shall cooperate fully, at the cost of the indemnifying party, in the defense or settlement thereof. The indemnifying party shall have sole control of the defense, negotiation, or settlement of any matter with respect to which indemnification is claimed.

## 6. Termination.

(a) Term. This license shall continue in full force and effect for each Processed Tissue for a term ending five years after receipt of regulatory approval in the United States or European Union to commercialize the Processed Tissue (the "Initial Five Year Term") and shall automatically renew for additional one year terms thereafter so long as CryoLife is not in material default hereunder for a period of up to ten years or the life of any Patents, whichever is longer. This Agreement may be earlier terminated by CryoLife by giving 90 days advance written notice.

(b) Breach by CryoLife. In the event CryoLife commits any breach of the material terms and conditions of this Agreement, and if such failure or breach shall continue for a period of 60 days after written notice thereof is delivered by Biocompatibles to CryoLife, Biocompatibles shall have the option to terminate this Agreement.

(c) Breach by Biocompatibles. In the event Biocompatibles commits any breach of the material terms and conditions of this Agreement and if such failure or breach shall continue for a period of 60 days after written notice thereto is delivered by CryoLife to Biocompatibles, CryoLife shall have the option to terminate this Agreement.

(d) Survival. The provisions of Sections 3(e), 5, this Section 6(d) and 7 shall survive any termination of this Agreement. Termination of this Agreement shall not affect or terminate CryoLife's obligation to pay any amounts which were payable pursuant to the terms of Section 3 with respect to sales of Processed Tissues and grants of sublicenses prior to the effective date of such termination.

## 7. General Provisions.

(a) Entire Agreement. This Agreement constitutes the entire agreement and understanding of the parties with respect to the Technology and supersedes and terminates all other prior commitments, arrangements, or understandings, both oral and written between the parties with respect to the Technology.

(b) Amendment. This Agreement may not be modified or amended except by an instrument in writing executed by each of the parties.

(c) Binding. This Agreement shall be binding upon and inure to the benefit of the parties and their respective successors and assigns.

(d) Governing Law. This Agreement shall be governed and construed in accordance with the laws of the United Kingdom.

(e) Notices. Any notices required or permitted hereunder shall be in writing and shall be sent by (a) personal delivery (including delivery by Federal Express or similar overnight courier), (b) mailed by registered or certified mail, return receipt requested, postage prepaid, or (c) transmitted by facsimile, telex, or telecopy to the numbers set forth below and with originals of such transmissions sent by registered or

certified mail. Notices shall be sent to the addresses as set forth below or to such other addresses as may be hereafter furnished by one party to the other party in compliance with the terms hereof.

If to Biocompatibles: Biocompatibles Limited  
Frensham House  
Farnham Business Park  
Weydon Lane  
Farnham  
Surrey G49 8QL England  
Facsimile: 44-1252-732703  
Attention: Alistair H.  
Taylor, President and C.E.O.

If to CryoLife: CryoLife, Inc.  
2211 New Market Parkway  
Suite 142  
Marietta, Georgia 30067  
Attention: President  
Telecopy: (770) 850-0762

Notices shall be effective (a) upon receipt by the addressee, if sent by personal delivery or mail, or (b) upon transmission, if sent by telecopy, telex, or facsimile.

(f) Waiver. None of the provisions of the Agreement shall be deemed to have been waived by any act or acquiescence on the part of either party, their agents or employees, but may be waived only by instruments in writing signed by an authorized officer of the respective party. No waiver of any provision of this Agreement shall constitute a waiver of any other provision or of the same provision on another occasion.

(g) Counterparts. This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute but one and the same instrument.

(h) Assignment. CryoLife shall not assign or transfer any of its duties, rights, interests, or obligations in or under this Agreement, without the prior written approval of Biocompatibles. Any merger, consolidation, or sale of substantially all of the stock of CryoLife shall be considered an assignment hereunder for which Biocompatibles's consent is required.

(i) Arbitration.

(i) Submission to Arbitration. If any dispute or difference shall arise between the parties to this Agreement, as to the interpretation of this Agreement or any covenants or conditions of this Agreement or as to the rights, duties, or liabilities of any party under this Agreement or as to any act, matter, or thing arising out of or under or relating to this Agreement (even though the Agreement may have been terminated), the same shall be finally settled by arbitration conducted in accordance with the rules of the American Arbitration Association. Whenever any dispute, controversy, claim, or difference which may be submitted to arbitration under this Section 7(h) arises between the parties, either party hereby may give the other party notice of its intention to submit such dispute, controversy, claim, or difference to arbitration. Such arbitration shall take place in New York, New York, before a single arbitrator agreed upon by the parties to the arbitration. In the event the parties cannot agree upon an arbitrator within 20 days after the effective date of receipt, of either party's notice to arbitrate, such arbitration shall take place in New

York, New York, before a single arbitrator appointed by the American Arbitration Association in accordance with its rules.

(ii) Costs; Binding. The parties further agree that notwithstanding the determination of the arbitrator (i) all costs associated with the arbitration shall be borne equally by each party to the arbitration, and (ii) each party to the arbitration shall be responsible for its own attorneys' fees incurred in connection with the arbitration. The determinations of such arbitrator will be final and binding upon the parties to the arbitration, and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. The arbitrator shall set forth the grounds for his decision in the award.

(iii) Applicable Law. The arbitrator shall apply the law of the United Kingdom, as to both substantive and procedural questions, but excepting any rule which would result in judicial failure to enforce this arbitration provision or any portion thereof.

(iv) Condition Precedent. The parties hereto stipulate that submission of disputes to arbitration as provided in this Section 7 and arbitration pursuant thereto shall be a condition precedent to any suit, action, or proceeding instituted in any court or before any administrative tribunal with respect to this Agreement or disputes arising out of or regarding this Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date set forth herein by their duly authorized representatives.

CRYOLIFE, INC.

BIOCOMPATIBLES LIMITED

By: \_\_\_\_\_

By: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

SCHEDULE A TO FORM OF LICENSE AGREEMENT

PATENTS

All Patents listed on Exhibit B to the Research Agreement plus:

Patent or Application Number	Jurisdiction	Date	Status
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SCHEDULE B TO FORM OF LICENSE AGREEMENTS

PROCESSED TISSUES

[to be completed in the manner anticipated in the Research Agreement]

## EXHIBIT 11.1

## STATEMENT RE: COMPUTATION OF EARNINGS PER SHARE

	Three Months Ended		Six Months Ended				
	June 30 1996	1995	June 30 1996	1995			
Primary:							
Average shares outstanding			9,490,956	9,359,982	9,462,128	9,355,422	
Net effect of dilutive stock options based on the treasury stock method using average market price			441,556	143,746	414,158	106,810	
Totals			9,932,512	9,503,528	9,876,286	9,462,232	
Net Income			\$988,439	\$559,379	\$1,770,936	\$949,509	
Per share amount			\$.10	\$.06	\$.18	\$.10	
Fully diluted:							
Average shares outstanding			9,490,956	9,359,982	9,462,128	9,355,422	
Net effect of dilutive stock options based on the treasury stock method using quarter-end market price which is greater than average market price				474,326	236,040	498,088	236,040
Totals			9,965,282	9,596,022	9,960,216	9,591,462	
Net Income			\$988,439	\$ 559,379	\$1,770,936	\$949,509	
Per share amount			\$.10	\$.06	\$.18	\$.10	