CRYOLIFE INC
Form DEFA14A
May 12, 2003

SCHEDULE 14A INFORMATION
Proxy Statement Pursuant to Section 14(a) of
the Securities Exchange Act of 1934
(Amendment No.)

Filed by the Registrant [X]

Filed by a Party other than the Registrant [_]

Check the appropriate box:

[_] Preliminary Proxy Statement
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[X] Definitive Additional Materials
[_] Soliciting Material Pursuant to (ss.)240.14a-11(c) or (ss.)240.14a-12

[ ] Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))

CRYOLIFE, INC.
(Name of Registrant as Specified In Its Charter)

N/A
(Name of Person(s) Filing Proxy Statement if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

[X] No fee required.

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1) Amount Previously Paid:
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May 12, 2003

Dear CryoLife Shareholder:

I am pleased to report to you that CryoLife's progress and first quarter results were in line with management's expectations. The Company's business performance is improving in several key areas. During the first quarter, BioGlue(R), our surgical adhesive, achieved continued, strong sales growth. There was good revenue growth in human tissues that are used in cardiac and vascular reconstruction surgeries in the first quarter 2003 compared to fourth quarter 2002. Renewed confidence in CryoLife by tissue procurement organizations was evident as the number of human heart donors and vascular donors was significantly higher in April compared to the first quarter monthly averages.

This letter will provide you with further details on these important positive developments, as well as an update on our regulatory issues with the FDA, our international business, and certain BioGlue research and development projects.

Overview of Financial Results

Revenues for first quarter 2003 were $15.9 million compared to $25.5 million in first quarter 2002 and $12.2 million in the fourth quarter of 2002. This was an increase of 31% compared to the fourth quarter of 2002. Net loss for first quarter 2003 was $434,000 compared to net income of $3.1 million in first quarter 2002. On a fully diluted basis, loss per common share for first quarter 2003 was $0.02 compared to net income per share of $0.16 for the same period in 2002. Total revenues of $15.1 million, excluding a favorable adjustment to estimated tissue recall returns of $848,000, increased 24%, compared to $12.2 million in the fourth quarter of 2002. In first quarter 2003, there was an estimated $2.3 million that was not included in the cost of tissue preservation services because it related to tissues shipped during the quarter that were written-down in prior periods. If not for these two items, the fully diluted pro forma net loss per share would have been $0.12.*

BioGlue, an Innovative Surgical Adhesive

We are pleased with the strong performance of BioGlue in the U.S. and internationally. BioGlue revenues were $6.5 million in the first quarter, up 33% as compared to the first quarter of 2002 and 16% over the fourth quarter of 2002.

*The effect of these two items of $0.10 per share is calculated as follows: $848,000 (adjustment to estimated tissue recalls) plus $2.3 million (amount that would have been included in cost of preservation services had tissue shipped not previously been written-down) less tax effect of $1.1 million divided by diluted weighted average shares outstanding of 19,634,000. This information is included to provide information comparable to prior periods.

BioGlue is an innovative surgical adhesive that is approved in the U.S. for use in adult patients as an adjunct to standard methods, such as sutures and staples, to control bleeding in open surgical repair of large vessels. It is approved in the European Community and Canada as an adjunct to surgical repair for soft tissues such as vascular, cardiac, dura, pulmonary, and gastrointestinal.

BioGlue, a simple, easy-to-use, unique product, is available in pre-filled cartridges that require no heating, refrigeration, or reconstitution prior to being used. It begins to polymerize in 20 to 30 seconds, when applied by the surgeon, and reaches full bonding strength within two minutes.

BioGlue broadens our revenue and customer base. It is utilized by many cardiovascular surgeons who routinely implant CryoLife processed human tissues, and is being accepted by surgeons who implant other cardiovascular devices. Our technical representatives have effectively leveraged the synergy between our human cardiovascular tissues and our medical device business. We expect the strong performance of BioGlue to continue, with full-year 2003 sales of $26-27 million, a 25% increase over last year.

Update on BioGlue R&D Projects

We have scheduled an Investigational Device Exemption (IDE) filing with the FDA to begin clinical trials for the use of BioGlue in the sealing of dura mater in cranial and spinal surgery for fourth quarter 2003. Management believes that the 2006 market for a dura sealant in the U.S. will approach $63 million. This is based on a total of 193,000 projected cranial and spinal procedures that potentially could include the use of BioGlue.

At the International Intradiscal Therapy Society meeting in Chicago on April 2-6, two papers were presented on the use of BioDisc, a protein hydrogel, in spinal disc replacement. The two presenters were Dr. Philip Benton, past President of the Society, and Dr. Umit Yuksel of CryoLife's staff. The papers were titled, "Use of a Polymerized Protein Hydrogel for Post-Discectomy Augmentation" and "Restoration of the Biomechanical Properties of Calf Spinal Discs Using BioDisc - a Protein Hydrogel Nucleus Pulposus Replacement." Plans for a CE Mark submission for a spinal disc nucleus replacement are ongoing and currently scheduled for first quarter 2004. The IDE submission for a spinal disc nucleus replacement is scheduled for second quarter 2004.

There are approximately 349,000 spinal procedures performed annually in the U.S. that may potentially include the use of BioDisc. Based on this large number of procedures, we believe there is a potential annual market of about $150 million for BioDisc.

Regulatory Affairs Update

As previously announced, the FDA completed an inspection of CryoLife headquarters facility on February 14, 2003. Most of the Form #483 Observations from the April 2002 inspection were corrected as of that date. A new Form #483 Notice of Observations was issued to the Company. The Company responded to the February Form #483 on March 25th. We are engaged in ongoing discussions with the FDA.

We are also in discussions with the FDA regarding the reclassification of certain SynerGraft-processed human heart valves and vascular grafts. The FDA has advised the Company that its SynerGraft heart valves and CryoVein grafts used for AV access will be regulated as medical devices. The Company is in discussions with the FDA about the type of clearances necessary for these products. The Company is not processing tissues using the SynerGraft process at this time.

International Sales Update

International sales continue to show good progress this year. International BioGlue sales were up 43% during the first quarter 2003 compared to the first quarter 2002. The primary reasons for the increase were the conversion of the

U.K. sales force to a direct sales force, seven additional marketing approvals, an expanded approval for BioGlue that was CE marked in January 2002 and approved in Canada in February 2003, as well as several presentations of our clinical data given throughout the year at various meetings.

Sales of the O'Brien porcine stentless heart valve are up 68% over last year. Portions of the manufacturing process for this valve have been moved overseas with the final steps being completed here at our facility in Georgia. We have been able to realize substantial cost savings with this decision that should convert into improved profitability for this product line.

The Model 100 SynerGraft vascular graft, made from a bovine ureter for arterial vascular access, continues to be well accepted in Europe. More than 80 of the SG Model 100 grafts have been implanted in Europe. At the vascular access surgery meeting in Lisbon, Portugal, on May 21-23, Mr. Chris Darby of The John Radcliff Hospital, Oxford, England will present a series of twelve patients many of whom have had the SG Model 100 implanted over one year. Mr. Kamal Abusin, of Queen Alexander Hospital, Portsmouth, England will present a poster on ten patients who have SG Model 100 implants.

Positive Trend in Human Tissue Processing

Tissue processing revenues in the first quarter of 2003 were $9.1 million, as reported, and $8.3 million excluding a favorable adjustment to estimated tissue recall returns of $848,000, as compared to $6.3 million in the fourth quarter 2002. Tissue processing revenues, as reported, increased 45%. Excluding the adjustment to recall returns, the increase was 31% in first quarter 2003 compared to the fourth quarter 2002.

Cardiac revenues, as reported, were $4.7 million for the first quarter, up 44% over the fourth quarter of 2002. Cardiac revenues, excluding a favorable adjustment to estimated tissue recall returns of $92,000 were $4.6 million compared to $3.3 million for the fourth quarter 2002, achieving significant growth of 41% in sequential quarterly revenues.

Vascular revenues, as reported, were $4.3 million for the first quarter, up 46% over the fourth quarter of 2002. Vascular revenues, excluding a favorable adjustment to estimated recall returns of $711,000 were $3.5 million compared to $2.9 million for the fourth quarter 2002. This represents a 22% increase in sequential quarterly revenues.

Procurement of Tissues from Donors Increased in April

Procurement of tissues is accelerating nicely as tissue procurement organizations have shown their confidence in CryoLife. Heart procurement in April was over 300 compared to the first quarter 2003 monthly average of 275. Vein procurement for April was over 325 compared to the first quarter monthly average of 268.

Please remember that it takes about 6 to 8 weeks for tissue to go through our diligent quality assurance and process controls before it can be distributed. Therefore, the increases in procurement that we had in the first quarter and that have continued throughout April suggest that we should have a strong second quarter. The summer months are our busiest months, so the increase in procurement during April, where total tissues processed daily averaged 15% higher than those processed on a daily basis in March, indicates a procurement trend that suggests a strong third quarter as well. We are now processing

tissues from about 90% of the tissue banks and organ procurement groups that we were working with prior to the recall.

Guidance for Second Quarter and Full-Year

We expect revenues in the second quarter of between $16.2 and $16.8 million. Human tissue revenues are expected to be between $9.0 and $9.6 million, and BioGlue revenues are expected to be between $6.8 and $7.0 million.

Revenues for full-year 2003 are expected to be approximately $70 million. Selling, general, and administrative expenses are expected to be at the high end of the $42 to $46 million range.

The positive trends we are experiencing in tissue procurement and processing revenues, along with continued strong growth of BioGlue revenues, lead us to believe that we will meet our business and financial objectives this year. We are confident in the Company's outlook and its ability to maintain its leadership position in processing human tissues implanted for cardiac and vascular surgeries.

Annual Meeting

ATTENDANCE AT THE ANNUAL MEETING WILL BE LIMITED TO SHAREHOLDERS AS OF THE RECORD DATE, THEIR AUTHORIZED PROXY HOLDERS AND GUESTS OF CRYOLIFE. ADMISSION WILL BE BY TICKET ONLY. IF YOU ARE A REGISTERED SHAREHOLDER (YOUR SHARES ARE HELD IN YOUR NAME) AND PLAN TO ATTEND THE MEETING, PLEASE VOTE YOUR PROXY AND DETACH YOUR ANNUAL MEETING TICKET FROM THE BOTTOM PORTION OF THE PROXY CARD. IF YOU ARE A BENEFICIAL OWNER (YOUR SHARES ARE HELD IN THE NAME OF A BANK, BROKER OR OTHER HOLDER OF RECORD) AND PLAN TO ATTEND THE MEETING, YOU CAN OBTAIN AN ADMISSION TICKET IN ADVANCE BY WRITING TO SUZANNE GABBERT, CRYOLIFE, INC. 1655 ROBERTS BLVD, NW, KENNESAW, GEORGIA 30144, 770-419-3355. PLEASE BE SURE TO ENCLOSE PROOF OF OWNERSHIP SUCH AS A BANK OR BROKERAGE ACCOUNT STATEMENT. SHAREHOLDERS WHO DO NOT OBTAIN TICKETS IN ADVANCE MAY OBTAIN THEM UPON VERIFICATION OF OWNERSHIP AT THE RECEPTION DESK ON THE DAY OF THE MEETING. I LOOK FORWARD TO PERSONALLY GREETING THOSE SHAREHOLDERS WHO ARE ABLE TO ATTEND OUR ANNUAL MEETING.

Thank you for your interest and investment in CryoLife, a business dedicated to saving human lives and limbs through human tissue transplantation and innovative surgical devices.

Very truly yours,

Steven G. Anderson,
President and Chief Executive Officer

Attachment: Financial Highlights

Statements made in this letter that look forward in time or that express management's beliefs, expectations or hopes are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These future events may not occur as and when expected, if at all, and, together with the Company's business, are subject to various risks and uncertainties. Such risks and uncertainties include that revenues may not meet expectations, that the Company may not commence distribution of orthopaedic tissue in the

second quarter of 2003, that demand for CryoLife preserved tissues, particularly orthopaedic tissues, may never return to prior levels and physicians and hospital risk managers may be unwilling to approve the use of Company-processed tissues, the possibility that the FDA could impose additional restrictions on the Company's distribution of orthopaedic tissues, FDA regulation of the Company's CryoValve SG and CryoVein SG or other tissues and products may require premarketing approvals that the Company does not have and may not be able to obtain without great time and expense, if at all, the Company may not have sufficient borrowing or other capital availability to fund its business over the long-term, current and future litigation may not be resolved within the limits of the Company's insurance policies or may otherwise be resolved in a matter that is materially adverse to the Company, the possibility that current severe decreases in the Company's revenues and working capital will continue, the possibility that CryoLife will not satisfactorily address the observations contained in the most recent Form 483 issued by the FDA, changes in laws and governmental regulations applicable to CryoLife and other risk factors detailed in CryoLife's Securities and Exchange Commission filings, including CryoLife's Form 10-K filing for the year ended December 31, 2002, and the Company's other SEC filings.

CRYOLIFE, INC.
Unaudited Financial Highlights
(In thousands, except share data)

	Three Months Ended March 31,	
	2003	2002
Revenues:		
Human tissue preservation services	$ 9,130	$ 20,238
Products	6,599	5,065
Distribution and grant	191	168
Total revenues	15,920	25,471
Costs and expenses:		
Human tissue preservation services	2,443	8,063
Products	1,641	2,235
General, administrative, and marketing	11,592	9,478
Research and development	917	1,153
Interest expense	132	192
Interest income	(131)	(298)
Other expense, net	(26)	(56)
Total costs and expenses	16,568	20,767
(Loss) earnings before income taxes	(648)	4,704
Income tax (benefit) expense	(214)	1,600
Net (loss) income	$ (434)	$ 3,104

(Loss) earnings per share:		
Basic	$ (0.02)	$ 0.16
Diluted	$ (0.02)	$ 0.16
Weighted average shares outstanding:		
Basic	19,634	19,096
Diluted	19,634	19,796
Revenues from:		
Cardiovascular	$ 4,725	$ 7,307
Vascular	4,255	7,017
Orthopaedic	150	5,914
Total cryopreservation	9,130	20,238
BioGlue	6,494	4,873
Implantable medical devices	105	192
Distribution and grant	191	168
Total revenues	$ 15,920	$ 25,471
International revenues	$ 1,710	$ 1,662
Domestic revenues	14,210	23,809
Total revenues	$ 15,920	$ 25,471

CRYOLIFE, INC.
Financial Highlights
(In thousands)

	Unaudited March 31 2003	Audited Dec. 31 2002
Cash and cash equivalents and marketable securities, at market	$ 20,225	$ 24,860
Trade receivables, net	7,769	6,930
Other receivables, net	9,090	11,824
Deferred preservation costs, net	7,564	4,332
Inventories	4,703	4,585
Total assets	100,548	106,414
Shareholders' equity	79,326	79,800

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