CRYOLIFE INC
Form DEFA14A
May 07, 2002

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	[ ]	Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))
[_]	Definitive Proxy Statement		
[X]	Definitive Additional Materials		
[_]	Soliciting Material Pursuant to section 240.14a-11(c) or section 240.14a-12		

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.

[ ] Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

1) Title of each class of securities to which transaction applies:
2) Aggregate number of securities to which transaction applies:
3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (Set forth the amount on which the filing fee is calculated and state how it was determined):
4) Proposed maximum aggregate value of transaction:
5) Total fee paid:

[_] Fee paid previously with preliminary materials.

[_] Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

1) Amount Previously Paid:
2) Form, Schedule or Registration Statement No.:
3) Filing Party:
4) Date Filed:

April 30, 2002

Dear CryoLife Shareholder:

I am pleased to report that CryoLife, Inc. achieved record revenues and record earnings in the first quarter of 2002.

Revenues for the three months ended March 31, 2002 were $25.5 million, a 19 percent increase over the previous record of $21.4 million set in the first quarter of 2001 and an all time quarterly revenue record for CryoLife, Inc. Net income for the quarter was a record of $3.1 million, compared to a net income of $2.0 million for the first quarter ended March 31, 2001. On a fully diluted basis, earnings per common share for the first quarter ended March 31, 2002 were $0.16, compared to $0.10 for the same period in 2001. First quarter 2001 earnings were restated to include a $747,000 operating charge which reduced diluted per share earnings by $0.03.

Record revenues and record earnings performance in the first quarter of 2002, as compared to first quarter 2001 results, benefited from across the board increases in all four of the Company's major businesses. Revenues from cardiovascular tissue processing rose 6 percent to $7.3 million, vascular tissue processing revenues rose 9 percent to $7.0 million and orthopaedic tissue processing revenues rose 13 percent to $5.9 million. The leading revenue performer in the first quarter of 2002, in terms of percentage increase, was BioGlue(R) surgical adhesive, rising 100 percent to $4.9 million, reflecting the December 2001 approval by the Food and Drug Administration (FDA) for use of BioGlue in certain vascular repair.

The financial highlights for the first quarter are attached for your review.

BIOGLUE UPDATE

The increase in BioGlue revenues for the first quarter represents sales of 105,000 ml, compared to the sales of 76,000 ml recorded in the fourth quarter of 2001. According to field reports, BioGlue is being used in, among other procedures, abdominal aortic aneurysms, endarterectomy surgeries, sealing of suture lines, aortic dissections and aortic root replacements, repair of aortic aneurysms, gluing/sealing of organs, sealing of Dura, sealing of A-V access devices, femoral popliteal bypasses, sealing of LVAD cannulas, prosthetic valve suture lines, sealing of synthetic conduit suture lines, gunshot wounds, coronary artery anastomoses and Bentall procedures. Prior to the PMA approval by the FDA of BioGlue in December 2001, CryoLife had approximately 600 accounts using BioGlue in the U.S. Since then the Company has added approximately 170 new accounts. Approximately 61% of our BioGlue accounts re-ordered during the first quarter of this year. The Company estimates the total U.S. market that BioGlue addresses is about $700 million annually.

Internationally, on February 12, 2002 we announced that BioGlue was awarded a third CE (product certification) Mark allowing its use in general surgical procedures in Europe. This latest product certification in the European Union extends application of BioGlue to include soft tissue repair. The Company believes that, as a result of this additional CE certification, BioGlue may now be used in the European Union for most surgical procedures throughout the human body. Presently, BioGlue is approved for cardiac, vascular and pulmonary repair in 36 countries outside the U. S.

SYNERGRAFT(R) VALVES AND VASCULAR GRAFTS UPDATE

There have been a total of 37 SynerGraft porcine tissue based heart valves implanted in the world since August 1999. Valves have been implanted on both the right and left side of the heart. To the Company's knowledge, twenty-five of these valves remain implanted. An analysis of the explanted valves indicated that they were repopulated with the recipient's own cells, similar to the results experienced with the animal implants. Implants included both infants and adults.

There have been a total of 27 documented bovine tissue-based SynerGraft vascular grafts implanted in Europe since November 2001. However, the Company estimates closer to 100 of the SynerGraft vascular grafts have been implanted in Europe since not all have been documented with implant cards. These vascular grafts have been implanted for peripheral vascular reconstruction and A-V access devices for dialysis patients. To the Company's knowledge, none have been removed.

On the human tissue allograft side of the business, since February 2000, there have been 987 SynerGraft processed allograft heart valves implanted in people throughout North America. Of these valves, to the Company's knowledge, 982 remain implanted at this time and five have been removed. Histological examination of some of these valves indicated that all valves examined had repopulated with the patient's own cells in vivo.

Examinations also confirmed that the PRA (Panel Reactive Antibodies) levels were significantly reduced in the patients that were implanted with a SynerGraft processed allograft valve.

Since January of 2001, a total of 262 SynerGraft processed allograft vascular grafts have been implanted in North America as A-V access devices for dialysis patients and for peripheral vascular reconstruction purposes. We believe that all of these grafts remain implanted at this time.

PROCUREMENT UPDATE

The allograft preservation business is dependent upon procurement. The number of donors CryoLife processed was up 43% in the first quarter of 2002 as compared to the first quarter of 2001. The increase is attributable to several factors, including the Company's formation of new strategic alliances with large tissue procurement groups and the addition of procurement liaison staff that have had an immediate impact in increasing procurement across the board. CryoLife anticipates that the significant procurement increases in the first quarter will have a favorable impact on revenues in the second quarter, as it takes 45 to 90 days to move tissue through CryoLife's processing system.

April results to date indicate that it will be another record month in revenues. The Company estimates that April revenues will be about 25% ahead of revenues recorded in April 2001.

FULL YEAR AND SECOND QUARTER 2002 GUIDANCE

We continue to support our previously issued earnings guidance of between $0.74 and $0.80 per fully diluted common share for fiscal year 2002.

- BioGlue revenues are expected to be between $4.9 million and $5.3 million for the second quarter.
- Cardiovascular tissue processing revenues for the second quarter are expected to increase between 8% and 12% over the second quarter of 2001.
- Vascular tissue processing revenues for the second quarter are expected to

increase between 12% and 15% over the second quarter of 2001.

- Orthopaedic tissue processing revenues for the second quarter are expected to grow between 14% and 20% over the second quarter of 2001.
- Total revenues are expected to be between $26 million and $27 million for the second quarter.
- Gross margins are expected to be between 58.5% and 59.5% for the second quarter.
- General, administrative and marketing expenses are anticipated to be between 36.5 % and 37.5% of revenues for the second quarter.
- R&D expenses are expected to approximate between 4.5% and 5.5% of revenues in the second quarter of 2002.
- Earnings per share are expected to be between $0.17 and $0.19 for the second quarter.

REGULATORY AFFAIRS UPDATE

In response to recent publicity that may have caused concern among shareholders, tissue donors and recipients about the safety of preserved human tissue, CryoLife reiterates the benefits of the availability of human tissue for transplants, and the accomplishments of the industry in providing safe and viable solutions in the treatment of various diseases. In many cases, the only viable, life-saving alternative is the availability of preserved human tissue.

CryoLife continues its ongoing commitment to tissue safety by expanding its long-standing quality assurance programs, educational efforts, ongoing training for our staff and those involved in the recovery process as well as providing hands-on training for surgeons and others in the medical community. The incidence of infections occurring with implants of cryopreserved human tissue is dramatically below that experienced with other implants such as mechanical heart valves, pacemakers or synthetic tissue substitute implants. We intend to maintain our position as an industry leader in setting the highest standards in tissue processing.

CryoLife continues to work closely with the CDC and the FDA in relation to the recent reports of infected allograft tissues that were distributed by four or five tissue banks throughout the U.S. The recent reports of allograft infections make it appear that there has been a sudden appearance of a large number of serious infections associated with implantable human tissues. This is not true, as reported infections from implantable tissues have occurred at very low rates over many years. The CDC and the FDA have been aware of these risks and reported infection rates throughout the last decade. I believe this risk is generally understood within the community of implanting surgeons. Regulatory oversight or certification may not guarantee freedom from the possibility of infection.

I would like to provide some perspective on this situation. Typical infection rates for the implantation of mechanical orthopaedic devices are reported as being between 0.6% and 2.2%. We have previously stated that the rate of reported infection of CryoLife orthopaedic allografts is about 0.2%. Infections directly associated with cardiac pacemaker implantation are said to be as high as 20 to 25%. Our reported infection rate for allograft heart valves is less than 0.16%. Despite this safety record, CryoLife is constantly working to lower these reported rates.

Since the implantation of allografts is usually major surgery, there are inherent risks associated with these operations. Patients can and do react badly to anesthesia, there are errors that occur on the part of health care providers, and hospitals are common environments for contracting infections. Sometimes patients are non-compliant in taking their post-operative medications.

The CDC and the FDA have made reasonable recommendations during investigations of CryoLife and other tissue banks regarding standards for the testing and handling of tissues, and CryoLife is committed to implementing these recommendations as quickly as they can be validated.

CryoLife will continue to cooperate with regulatory agencies to enhance, if possible, procedures and testing to help assure that the tissues are as safe as possible while ensuring a continuing supply. The Company will continue its extensive educational programs that it sponsors for procurement agencies and their personnel. We will continue to expand our programs for training hospital personnel and surgeons on the risks relative to the benefits of implantable human tissues. Finally, CryoLife has initiated a major research effort into potential methods of sterilizing soft tissues in a manner that does not adversely affect the clinical benefits of implanting allograft tissues.

ANNUAL MEETING OF SHAREHOLDERS

The 2001 Annual Report and Corporate Profile Booklet will be mailed to all shareholders on April 30, 2002, along with proxy solicitation materials for the Annual Meeting of Shareholders. The meeting is scheduled to be held at the CryoLife headquarters facility, located at 1655 Roberts Boulevard, NW, Kennesaw, Georgia, at 10:00 a.m., on Wednesday, May 29, 2002.

I look forward to personally greeting those shareholders who are able to attend and participate in the Annual Meeting.

Your continued interest in CryoLife operations and progress is appreciated.

Very truly yours,

/s/ Steven G. Anderson
Steven G. Anderson,
President and Chief Executive Officer

Attachment: Financial Highlights

Forward-Looking Statements. Statements made in this letter that look forward in time or that express management's beliefs, expectations or hopes regarding anticipated operating performance and expenditures during the first quarter and full year of 2002 and other matters are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These future events may not occur when expected, if at all, and are subject to various risks and uncertainties. Such risks and uncertainties include the Company's dependence on cryopreservation of human tissue, the possibility that SynerGraft treated heart valves will not have the expected long-term functionality, repopulate with human recipient cells or reduce immune response, that orthopedic tissue revenues could be adversely impacted due to the recent death of a knee surgery patient and a recent CDC report, potential loss of relationships with tissue providers, that future clinical SynerGraft or BioGlue test results will prove less encouraging than current results, that SynerGraft, BioGlue, or other regulatory submissions will not be ready when planned or that anticipated regulatory approvals will not be obtained when expected, if at all, that surgeons will not continue to accept and use BioGlue, competition from other wound closure products, that the Company will be unable to find an investor in its proprietary light-activated drug delivery systems or that such systems will prove ineffective in oncology applications, that pending legal proceedings against the Company will not be resolved in its favor, the possibility of rapid technological change, uncertainties regarding products in development,

uncertainties related to patents and protection of proprietary technology, changes in economic cycles, competition from other companies, changes in laws and governmental regulations applicable to the Company and other risk factors detailed in the Company's Securities and Exchange Commission filings, including the Company's Form 10-K filing for the year ended December 31, 2001.

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

	Three Mon Marc
	2002
Revenues:	
Human tissue preservation services	$ 20,238
Products	5,065
Distribution and grant	168
Total Revenues	25,471
Costs and Expenses:	
Human tissue preservation services	8,063
Products	2,235
General, administrative and marketing	9,478
Research and development	1,153
Interest expense	192
Interest income	(298)
Other (income) expense, net	(56)
Total Costs and Expenses	20,767
Earnings before income taxes	4,704
Income tax expense	1,600
Net Income	$ 3,104
Earnings per share:	
Basic	$ 0.16
Diluted	$ 0.16
Weighted average shares outstanding:	
Basic	19,096
Diluted	19,796
Revenues from:	
Cardiovascular	$ 7,307
Vascular	7,017

Orthopaedic	5,914
Total Cryopreservation	20,238
BioGlue	4,873
Bioprosthetic valves	192
Distribution and grant	168
Total Revenues	$ 25,471

[GRAPHIC OMITTED]

NEWS RELEASE

FOR IMMEDIATE RELEASE

CONTACT: D. ASHLEY LEE
VICE PRESIDENT, CHIEF FINANCIAL OFFICER
(800) 438-8285

CRYOLIFE, INC. APPOINTS NEW ACCOUNTING FIRM

Atlanta, GA ...(May 7, 2002)...CryoLife, Inc. (NYSE: CRY), a life-science company involved in the development and commercialization of cryopreserved and tissue-engineered implantable heart valves, vascular and orthopaedic grafts, and surgical adhesives, announced that its Board of Directors has appointed the accounting firm of Deloitte & Touche, LLP as the Company's independent auditors.

Founded in 1984, CryoLife, Inc. is the leader in the development and commercialization of implantable living human tissues for use in cardiovascular, vascular and orthopaedic surgeries throughout the United States and Canada. The Company's BioGlue(R) surgical adhesive is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels and is CE marked in the European Community and approved in Canada and Australia for use in vascular and pulmonary sealing and repair. The Company also manufactures the SynerGraft(R) heart valve and the SynerGraft vascular graft, the world's first tissue-engineered heart valve and vascular replacement, respectively, and the CryoLife-O'Brien(R) and CryoLife-Ross(R) stentless porcine heart valves, which are CE marked for distribution within the European Community. The human heart valves and vascular grafts processed by CryoLife using the SynerGraft technology are distributed in the U.S. under the trade names of CryoValve(R)SG and CryoVein(R)SG, respectively.

For additional information about the company, visit CryoLife's web site: http://www.cryolife.com.

-END-

1468943v1