

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

Current Report
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 4, 2003

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

Florida
(State or other jurisdiction of incorporation)

1-13165
(Commission File Number)

59-2417093
(IRS Employer Identification No.)

1655 Roberts Boulevard N.W., Kennesaw, Georgia 30144

(Address of principal executive offices, including zip code)

(770) 419-3355
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS.

(a) Financial Statements.

Not applicable.

(b) Pro Forma Financial Information.

Not applicable.

(c) Exhibits.

| Exhibit Number | Description |
|----------------|--------------------------------------|
| 99.1 | Press Release dated November 4, 2003 |

ITEM 12. RESULTS OF OPERATIONS AND FINANCIAL CONDITION

The information provided pursuant to this Item 12 is to be considered "filed" under the Securities Exchange Act of 1934 ("Exchange Act") and incorporated by reference into those filings of CryoLife, Inc. ("CryoLife") that provide for the incorporation of all reports and documents filed by CryoLife under the Exchange Act.

On November 4, 2003, CryoLife issued a press release announcing its results for the quarter ended September 30, 2003. CryoLife hereby incorporates by reference herein the information set forth in its Press Release dated November 4, 2003, a copy of which is attached hereto as Exhibit 99.1. Except as otherwise provided in the press release, the press release speaks only as of the date of such press release and such press release shall not create any implication that the affairs of CryoLife have continued unchanged since such date.

Except for the historical information contained in this report, the statements made by CryoLife are forward-looking statements that involve risks and uncertainties. All such statements are subject to the safe harbor created by the Private Securities Litigation Reform Act of 1995. CryoLife's future financial performance could differ significantly from the expectations of management and from results expressed or implied in the Press Releases. For further information on other risk factors, please refer to the "Risk Factors" contained in CryoLife's Form 10-K/A for the year ended December 31, 2002, as filed with the Securities and Exchange Commission. CryoLife disclaims any obligation or duty to update or modify these forward-looking statements.

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SIGNATURES

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

CRYOLIFE, INC.

Date: November 4, 2003

By: /s/ D. Ashley Lee

Name: D. Ashley Lee
Title: Vice President, Chief Financial
Officer and Treasurer

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EXHIBIT INDEX

| Exhibit Number | Description | Page |
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| 99.1 | Press Release dated November 4, 2003 | 5 |

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[COMPANY LOGO]

FOR IMMEDIATE RELEASE

CONTACT: JOSEPH T. SCHEPERS
VICE PRESIDENT, CORPORATE COMMUNICATIONS
(770) 419-3355

CRYOLIFE(R) REPORTS THIRD QUARTER 2003 FINANCIAL RESULTS

BIOGLUE(R) REVENUES ON TRACK TO REACH \$26-27 MILLION FOR 2003

Files Application for AATB Accreditation

Submits 510k to the FDA for Decellurized, SynerGraft Processed Heart Valves
Restates 2nd Quarter 2003 Results to Reflect Additional \$2.4 Million Tax Refund

ATLANTA...(November 4, 2003)...CryoLife, Inc. (NYSE: CRY), a human tissue processing and bio-surgical device company today reported financial results for the third quarter 2003.

Revenues for the third quarter 2003 were \$15.1 million compared to \$16.9 million in the third quarter of 2002. Net loss in the third quarter of 2003 was \$4.7 million compared to \$19.6 million in the third quarter of 2002. On a fully diluted basis, net loss per common share for the third quarter was \$0.24 compared to a net loss of \$1.01 per share for the same period in 2002.

Revenues for the first nine months of 2003 were \$46.7 million compared to \$65.6 million in the first nine months of 2002. The net loss for the first nine months of 2003 was \$25.1 million compared to a net loss of \$22.1 million in the same period last year. On a fully diluted basis, the net loss per common share was \$1.27 compared to a \$1.14 net loss in the first nine months of 2002.

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Separately, the Company is reporting a restatement of previously reported financial results for the second quarter 2003, reflecting an additional \$2.4 million of anticipated income tax refunds resulting from tax loss carrybacks. Accordingly, restated results of operations reflect a \$2.4 million decrease in income tax expense for the three and six months ended June 30, 2003. Basic and diluted net loss per share for the three and six months, as restated, is \$1.01 and \$1.04, respectively, reflecting a favorable impact of \$0.13 per share. A summary of the previously reported and restated amounts is attached. The Company expects to receive the tax refund in the first half of 2004.

In the third quarter of 2003, worldwide BioGlue sales increased 29% to \$6.7 million compared to \$5.2 million in the third quarter of 2002. BioGlue revenues increased 31% for the first nine months of 2003 to \$20.0 million from \$15.3 million in the same period last year. BioGlue is on track to reach \$26-27 million in sales for the full-year 2003.

BioGlue is now approved in 48 countries and achieved 48% growth internationally to \$1.7 million in the third quarter of 2003 compared to \$1.1 million in the same period last year. "International BioGlue sales growth was driven by the success of the UK direct sales team, strong distribution support throughout Europe, increased usage of BioGlue in the core applications of cardiac and large vessel vascular surgery, and expanded usage in neuro, pulmonary and general surgery," stated Steven G. Anderson, CryoLife President and CEO.

Tissue processing revenues were \$8.1 million in the third quarter of 2003 compared to \$11.3 million in the third quarter of 2002. Cardiac tissue processing revenues were \$4.5 million in the third quarter of 2003 compared to \$5.5 million in the third quarter of 2002. Vascular tissue processing revenues were \$3.1 million in the third quarter 2003 compared to \$3.3 million in the third quarter of 2002. The Company is processing boned and non-boned orthopaedic tissue and distributing non-boned orthopaedic tissue. Tissue revenues were affected in the third quarter 2003 by limited availability of processed tissue, the discontinuance of the processing and distribution of decellurized, SynerGraft ("SG") processed tissues, and discontinued labeling of its vascular tissue for use as arteriovenous access grafts.

1 For the three months ended Sept. 30, 2003, vascular revenues as reported include a \$41,000 favorable adjustment, orthopaedic revenues as reported include a favorable adjustment of \$18,000 and cardiac revenues as reported include a \$7,000 unfavorable adjustment. These adjustments were due to a difference in actual tissue returns compared to earlier estimates.

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Procurement of cardiac and vascular tissue continues to increase. Procurement of vascular tissues increased 12% and cardiac tissues increased 4% in the third quarter of 2003 compared to the second quarter of 2003.

CryoLife filed its application for accreditation with the American Association of Tissue Banks (AATB) on October 13, 2003. The AATB is a scientific, not-for-profit, peer group organization founded in 1976. Its mission is to facilitate the provision of high quality transplantable human tissue in quantities sufficient to meet national needs.

On November 3, 2003 CryoLife submitted a 510k premarket notification to the FDA for decellurized, SG processed heart valves. The Company is currently processing vascular and cardio vascular tissues without the decellurized, SG process.

Regarding insurance coverage, CryoLife recently announced that the Company and an insurer have mutually agreed to resolve their coverage dispute on a \$10 million products liability policy previously issued to CryoLife, representing the last layer of insurance in place for the 2002-2003 insurance policy year. The full amount of this policy will be placed in escrow for CryoLife to use, together with other funds provided by the Company and another insurer, for the purpose of defending and resolving certain products liability litigation. Since August 5, 2003, the Company has resolved, or reached agreements in principle to resolve, 15 product liability matters.

Full year 2003 total revenues for the Company are projected to be approximately \$60 million. CryoLife made a payment of \$4.5 million paying off the balance of a term loan in August 2003. As of September 30, 2003 the Company had approximately \$8.2 million in cash and cash equivalents, and approximately \$9.7 million in marketable securities, for a total of \$17.9 million. The Company expects to receive a tax refund of approximately \$2.4 million in the first half of 2004 related to tax losses incurred in 2003.

Founded in 1984, CryoLife, Inc. is a leader in the processing and distribution of implantable living human tissues for use in cardiovascular and vascular 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 for use in soft tissue repair and approved in Australia for use in vascular and pulmonary sealing and repair. The Company also manufactures the SynerGraft(R) Vascular Graft, which is CE marked for distribution within the European Community.

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Statements made in this press release 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. These risks and uncertainties include that revenues may not meet expectations, that demand for CryoLife preserved tissues may not return to prior levels, the possibility that the FDA could impose additional restrictions on the Company's distribution of tissues, require a recall, or prevent the Company from distributing tissues, as could occur if the Company is unable to satisfactorily address the concerns raised in the FDA's most recent Form 483s, that the Company's 510k application for SG processed heart valves may require significant time and expense and may not be cleared on a timely basis or at all, that FDA regulation of the Company's CryoValve SG and CryoVein SG may require significant time and expense, that the Company may not have sufficient borrowing or other capital availability to fund its business, that present and future litigation

may be resolved only by substantial payments by the Company in excess of available insurance coverage and amounts to be set aside for products liability cases by CryoLife since the outcomes of products liability securities class action, and derivative cases are inherently uncertain, that pending litigation cannot be settled on terms acceptable to the Company, that the Company may not have sufficient resources to pay punitive damages which are not covered by insurance or liabilities in excess of available insurance, that the company may not receive all or a portion of the expected tax refunds, the possibility of severe decreases in the Company's revenues and working capital, that to the extent the Company does not have sufficient resources to pay the existing and future claims against it, it may be forced to cease operations or to obtain protection under applicable bankruptcy or insolvency laws, 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. The Company does not undertake to update its forward-looking statements.

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

| | Three Months Ended | | Nine Months Ended | |
|---|--------------------|-------------|-------------------|-------------|
| | September 30, | | September 30, | |
| | 2003 | 2002 | 2003 | 2002 |
| Revenues: | | | | |
| Human tissue preservation services | \$ 8,097 | \$ 11,300 | \$ 25,842 | \$ 49,074 |
| Products | 6,831 | 5,354 | 20,362 | 15,892 |
| Distribution and grant | 169 | 235 | 526 | 658 |
| | ----- | ----- | ----- | ----- |
| Total revenues | 15,097 | 16,889 | 46,730 | 65,624 |
| Costs and expenses: | | | | |
| Human tissue preservation services | 7,481 | 27,978 | 15,084 | 53,244 |
| Products | 1,782 | 4,739 | 5,429 | 8,817 |
| General, administrative, and marketing | 10,575 | 11,193 | 45,706 | 32,118 |
| Research and development | 823 | 1,347 | 2,828 | 3,696 |
| Goodwill impairment | -- | 1,399 | -- | 1,399 |
| Interest expense | 87 | 155 | 366 | 543 |
| Interest income | (101) | (188) | (348) | (725) |
| Other (income) expense, net | (94) | 35 | 46 | (37) |
| | ----- | ----- | ----- | ----- |
| Total costs and expenses | 20,553 | 46,658 | 69,111 | 99,055 |
| Loss before income taxes | (5,456) | (29,769) | (22,381) | (33,431) |
| Income tax (benefit) expense | (761) | (10,123) | 2,669 | (11,367) |
| | ----- | ----- | ----- | ----- |
| Net loss | \$ (4,695) | \$ (19,646) | \$ (25,050) | \$ (22,064) |
| | ===== | ===== | ===== | ===== |
| Net loss per share: | | | | |
| Basic | \$ (0.24) | \$ (1.01) | \$ (1.27) | \$ (1.14) |
| | ===== | ===== | ===== | ===== |
| Diluted | \$ (0.24) | \$ (1.01) | \$ (1.27) | \$ (1.14) |
| | ===== | ===== | ===== | ===== |
| Weighted average shares outstanding: | | | | |
| Basic | 19,701 | 19,526 | 19,669 | 19,388 |
| | ===== | ===== | ===== | ===== |
| Diluted | 19,701 | 19,526 | 19,669 | 19,388 |
| | ===== | ===== | ===== | ===== |
| Revenues from: | | | | |
| Cardiovascular | \$ 4,547 | \$ 5,487 | \$ 14,308 | \$ 20,131 |
| Vascular | 3,083 | 3,260 | 10,637 | 14,918 |
| Orthopaedic | 467 | 2,553 | 897 | 14,025 |
| | ----- | ----- | ----- | ----- |
| Total cryopreservation | 8,097 | 11,300 | 25,842 | 49,074 |
| | ----- | ----- | ----- | ----- |
| BioGlue | 6,694 | 5,183 | 20,027 | 15,308 |
| Implantable medical devices | 137 | 171 | 335 | 584 |
| Distribution and grant | 169 | 235 | 526 | 658 |
| | ----- | ----- | ----- | ----- |
| Total revenues | \$ 15,097 | \$ 16,889 | \$ 46,730 | \$ 65,624 |
| | ===== | ===== | ===== | ===== |
| International revenues | \$ 1,951 | \$ 1,565 | \$ 5,508 | \$ 5,155 |
| Domestic revenues | 13,146 | 15,324 | 41,222 | 60,469 |
| | ----- | ----- | ----- | ----- |
| Total revenues | \$ 15,097 | \$ 16,889 | \$ 46,730 | \$ 65,624 |
| | ===== | ===== | ===== | ===== |

CRYOLIFE, INC.
Financial Highlights
(In thousands)

| | Unaudited September 30, 2003 | Audited December 31, 2002 |
|---|------------------------------------|---------------------------------|
| | ----- | ----- |
| Cash and cash equivalents and marketable securities, at market | \$ 17,882 | \$ 24,860 |
| Trade receivables, net | 7,336 | 6,930 |
| Other receivables, net | 3,360 | 11,824 |
| Deferred preservation costs, net | 9,666 | 4,332 |
| Inventories | 4,935 | 4,585 |
| Total assets | 86,523 | 106,414 |
| Shareholders' equity | 55,319 | 79,800 |

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

| | Restated | | Originally Reported | |
|--|----------------------------|------------------|----------------------------|------------------|
| | Three and Six Months Ended | | Three and Six Months Ended | |
| | June 30, 2003 | June 30, 2003 | June 30, 2003 | June 30, 2003 |
| | ----- | ----- | ----- | ----- |
| Revenues: | | | | |
| Human tissue preservation services | \$ 8,615 | \$ 17,745 | \$ 8,615 | \$ 17,745 |
| Products | 6,932 | 13,531 | 6,932 | 13,531 |
| Distribution and grant | 166 | 357 | 166 | 357 |
| | ----- | ----- | ----- | ----- |
| Total revenues | 15,713 | 31,633 | 15,713 | 31,633 |
| Costs and expenses: | | | | |
| Human tissue preservation services | 5,160 | 7,603 | 5,160 | 7,603 |
| Products | 2,006 | 3,647 | 2,006 | 3,647 |
| General, administrative, and marketing | 23,539 | 35,131 | 23,539 | 35,131 |
| Research and development | 1,088 | 2,005 | 1,088 | 2,005 |
| Interest expense | 147 | 279 | 147 | 279 |
| Interest income | (116) | (247) | (116) | (247) |
| Other expense, net | 166 | 140 | 166 | 140 |
| | ----- | ----- | ----- | ----- |
| Total costs and expenses | 31,990 | 48,558 | 31,990 | 48,558 |
| Loss before income taxes | (16,277) | (16,925) | (16,277) | (16,925) |
| Income tax expense | 3,644 | 3,430 | 6,069 | 5,855 |
| | ----- | ----- | ----- | ----- |
| Net loss | \$ (19,921) | \$ (20,355) | \$ (22,346) | \$ (22,780) |
| | ===== | ===== | ===== | ===== |
| Net loss per share: | | | | |
| Basic | \$ (1.01) | \$ (1.04) | \$ (1.14) | \$ (1.16) |
| | ===== | ===== | ===== | ===== |
| Diluted | \$ (1.01) | \$ (1.04) | \$ (1.14) | \$ (1.16) |
| | ===== | ===== | ===== | ===== |
| Weighted average shares outstanding: | | | | |
| Basic | 19,675 | 19,654 | 19,675 | 19,654 |
| | ----- | ----- | ----- | ----- |
| Diluted | 19,675 | 19,654 | 19,675 | 19,654 |
| | ----- | ----- | ----- | ----- |
| Revenues from: | | | | |
| Cardiovascular | \$ 5,036 | \$ 9,761 | \$ 5,036 | \$ 9,761 |
| Vascular | 3,299 | 7,554 | 3,299 | 7,554 |
| Orthopaedic | 280 | 430 | 280 | 430 |
| | ----- | ----- | ----- | ----- |
| Total cryopreservation | 8,615 | 17,745 | 8,615 | 17,745 |
| | ----- | ----- | ----- | ----- |
| BioGlue | 6,839 | 13,333 | 6,839 | 13,333 |

| | | | | |
|-----------------------------|-----------|-----------|-----------|-----------|
| Implantable medical devices | 93 | 198 | 93 | 198 |
| Distribution and grant | 166 | 357 | 166 | 357 |
| | ----- | ----- | ----- | ----- |
| Total revenues | \$ 15,713 | \$ 31,633 | \$ 15,713 | \$ 31,633 |
| | ===== | ===== | ===== | ===== |
| International revenues | \$ 1,847 | \$ 3,557 | \$ 1,847 | \$ 3,557 |
| Domestic revenues | 13,866 | 28,076 | 13,866 | 28,076 |
| | ----- | ----- | ----- | ----- |
| Total revenues | \$ 15,713 | \$ 31,633 | \$ 15,713 | \$ 31,633 |
| | ===== | ===== | ===== | ===== |

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CRYOLIFE, INC.
Financial Highlights
(In thousands)

| | Unaudited June 30, 2003 Restated | Unaudited June 30, 2003 Originally Reported |
|---|--|---|
| | ----- | ----- |
| Cash and cash equivalents and marketable securities, at market | \$ 25,908 | \$ 25,908 |
| Trade receivables, net | 8,260 | 8,260 |
| Other receivables, net | 1,196 | 616 |
| Deferred preservation costs, net | 9,559 | 9,559 |
| Inventories | 4,535 | 4,535 |
| Total assets | 96,861 | 95,006 |
| Shareholders' equity | 59,875 | 57,450 |

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

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