

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): August 5, 2003

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

Commission File Number: 1-13165

Florida  
(State or other jurisdiction of  
incorporation)

59-2417093  
(IRS Employer Identification  
No.)

1655 Roberts Boulevard N.W.  
Kennesaw, Georgia  
(Address of principal executive offices)

30144  
(Zip Code)

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

(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	Transcript of earnings conference call held August 5, 2003

Item 12. Results of Operations and Financial Condition

The information in this Form 8-K and the Exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as shall be expressly set forth by specific reference in such filing.

On August 5, 2003, CryoLife, Inc. ("CryoLife") held its second quarter 2003 earnings conference call, broadcast live by webcast. A transcript of the call is attached hereto as Exhibit 99.1 and incorporated by reference.

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 earnings conference call. For further information on other risk factors, please refer to the "Risk Factors" contained in CryoLife's press release dated August 5, 2003, and in CryoLife's Form 10-K for the fiscal 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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SIGNATURE

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 hereunto duly authorized.

CRYOLIFE, INC.

Date: August 11, 2003

By: /s/ D. Ashley Lee

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

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EXHIBIT INDEX

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TITLE: Q2 2003 CryoLife, Inc. Financial Conference Call  
DATE: Tuesday, August 5, 2003  
TIME: 11:15 A.M. ET

Conference call coordinator: Good morning, ladies and gentlemen, and welcome to the CryoLife second quarter financial conference call. At this time, all participants have been placed on the "listen only" mode and the floor will be open for your questions following the presentation. It is now my pleasure to turn the floor over to your host, Mr. Steve Anderson, Chief Executive Officer. Sir, the floor is yours.

Steve Anderson: Good morning, everyone. This is Steve Anderson, the CEO of CryoLife, and I would like to welcome you to CryoLife's second quarter and first half conference call. With me today is Ashley Lee, the Company's Vice President of Finance and Chief Financial Officer, and Clinton Richardson, a partner with the Company's legal counsel, Arnall Golden & Gregory. This morning, we will be commenting on the Company's operating results for the second quarter and the first half of '03. The agenda for today's call is as follows: First, Ashley will comment on this morning's press release and we'll get into the detail of the numbers. Second, Mr. Richardson will comment on various litigation and insurance issues. Then, I will follow Mr. Richardson with comments on international operations, BioGlue revenues, SynerGraft's AV access graft results, allograft tissue revenues and certain FDA matters relating to SynerGraft issues. After my comments, Ashley will give some financial guidance going forward and after the guidance comments, we will then open up the conference call for questions. At this time, Ashley will comment on this morning's press release.

Ashley Lee: Thanks, Steve. First of all, I would like to read the following statement in order to comply with the Safe Harbor requirements of the Private Securities Litigation Reform Act of 1995, I would like to make the following statement. Comments made in this call which look forward in time involve risk and uncertainties and are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The forward-looking statements include the statements made as to the Company's or management's intentions, hopes, beliefs, expectations or predictions of the future. All statements made during this call that do not reflect historical results or information should be deemed to be forward-looking statements. It is important to note that the Company's actual results could differ materially from those projected in such forward-looking statements. Additional information concerning risk and uncertainties as contained from time to time in the Company's SEC filings including the "Risk Factors" section of our Form 10K for the year ended December 31, 2002. This presentation may contain information such as "revenues prior to adjustment to estimated tissue recall

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returns" and pro forma net loss per share that are deemed to be non-GAAP measures pursuant to Regulation G promulgated by the SEC. A reconciliation of these measures to the most closely applicable GAAP measure is contained in the Company's press release issued this morning which has been posted on the Company's website.

This morning, CryoLife reported financial results for the second quarter and six months ended June 30, 2003.

Revenues, as recorded for the three- and six-months periods, were 15.7 and 31.6 million compared to 23.3 and 48.7 million

in the corresponding periods in the prior year.

Revenues as reported for the six months ended June 30, 2003 include \$848,000 in favorable adjustments related to estimated tissue recall returns. Revenues as reported for the six months ended June 30, 2002 include 2.4 million in estimated tissue recall returns. Revenues excluding these items increased 4% in the second quarter of 2003 compared to the third quarter of 2003. Reported net loss for the three and six months ended June 30, 2003 are 22.3 million or a \$1.14 per share and 22.8 million or a \$1.16 per share. This compares to losses of 5.5 million or \$.28 per share and 2.4 million or \$.13 per share in the corresponding periods in the prior year.

The above amounts include the following items recorded in 2002: one, a recall reserve of 2.4 million recorded in the second quarter of 2002; and two, the write-off of a net of 8.9 million of tissues associated with the recall in the second quarter of 2002. The numbers also include the following items recorded in 2003: one, an adjustment to the recall reserve of \$848,000, which effectively increased revenue in the first quarter of 2003; two, the effects of the shipment of tissues previously written off in 2002 of \$3.4 million; three, the personal-injury loss accrual of 12.5 million in the second quarter of 2003; and four, the valuation allowance against deferred tax assets of 11.4 million in the second quarter of 2003. Reported cost of human tissue preservation services as a percentage of reported human tissue preservation service revenues were 60% for the three months ended June 30, 2003 compared to 98.8% for the three months ended June 30, 2002 and were 43% for the six months ended June 30, 2003 as compared to 67% for the six months ended June 30, 2002. Cost of human tissue preservation services as reported for the three and six months ended June 30, 2003 include an increase to cost of preservation services related to lower-of-cost-or-market write-downs of \$1.1 million and \$1.4 million respectively, and includes the favorable effect of shipments of tissue with a zero cost-basis of 1.0 million and 3.4 million respectively. Cost of human tissue preservation services revenues as reported for the three and six months ended June 30, 2002 include a \$10.0 million write-down of deferred preservation costs offset by a \$1.1 million decrease in cost of preservation services due to estimated tissue returns. Cost of preservation services as a percentage of revenues increased over historical levels primarily due to changes in processing methods and higher overhead-cost allocations

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associated with the decreased volume of tissues processed. We believe that once the issues with the FDA are resolved, cost of human tissue preservation as a percentage of revenues will decrease as compared to current levels. BioGlue revenues were 6.8 million and 13.3 million for the three and six months ended June 30, 2003 compared to 5.3 and 10.1 million in the corresponding periods of 2002. BioGlue revenues in the second quarter of 2003 increased 30% over the second quarter of 2002 and 5% over the first quarter in 2003. Total tissue processing revenues were 8.6 million in the second quarter of 2003 compared to 8.3 million in the first quarter of 2003 excluding \$848,000 in favorable adjustments to the recall reserve and compares to 6.3 million in the fourth quarter of 2002. Cardiac revenues were 5.0 million for the second quarter of 2003 compared to 4.6 million in the first quarter of 2003 excluding \$92,000 in favorable adjustments to the estimated tissue recall returns and compared to 3.3 million in the fourth quarter of 2002. Vascular revenues were 3.3 million for the second quarter of 2003 compared to 3.5 million in the first quarter of 2003, excluding \$711,000 in favorable adjustments to the estimated tissue recall returns and compared to 2.9 million in the

fourth quarter of 2002. Orthopedic revenues were \$280,000 for the second quarter of 2003 compared to \$150,000 in the first quarter of 2003 which includes \$45,000 in favorable adjustments to the estimated tissue recall returns and compared to 108,000 in the fourth quarter of 2002. General administrative and marketing expenses increased 23.5 million for the three months ended June 30, 2003 compared to 11.4 million for the three months ended June 30, 2002. This also compares to 11.6 million in the first quarter of 2003 and 15.4 million in the fourth quarter of 2002. The increase from the prior year was primarily due to an accrual of \$9 million for the potential expense to resolve ongoing product liability claims in excess of insurance coverage, and 3.9 million for unreported product liability claims related to services performed and products sold prior to June 30, 2003, and \$150,000 for deductibles under our prior year policies. Additional increases in general and administrative expenses were due to an increase of approximately 1.3 million and 3.3 million respectively in professional fees due to increased litigation, litigation settlement costs and issues surrounding the FDA order and an increase of approximately 179,000 and 488,000, respectively, in insurance premiums.

We periodically assess the recoverability of deferred tax assets and provide evaluation allowance when management believes it is more likely than not that it's deferred tax assets would not be realized. We evaluated several factors to determine its evaluation allowance relative to our deferred tax assets as necessary. Based on the results of this analysis, the Company has determined that it is more likely than not that the Company's deferred tax assets will not be realized and recorded evaluation allowance of \$11.4 million against deferred tax assets as of June 30, 2003. The Company was notified by its bank that it intends to require the Company to enter into a forbearance agreement which would increase the interest rate charged on our \$4.5 million term loan - the LIBOR plus 4% - and accelerate the principal payments on the term loan by requiring a balloon payment to pay off the outstanding balance by October 31, 2003. The

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Company has sufficient cash and cash equivalents to pay the remaining outstanding balance of the term loan. Based on the analysis of the product liability cases now pending against the Company, the Company recorded a liability of 9 million for the estimated potential expense of resolving these cases reflecting the estimated uninsured portion of the liability. These amounts do not reflect actual settlement arrangements or judgments against the Company, nor do they represent a cash reserve. The Company engaged an independent actuarial firm to estimate the loss for product liability claims incurred and not recorded during the 2002/2003 policy year. Based on the review of the actuarial analysis, the Company recorded an additional liability of \$3.9 million to increase the total accrual to \$7.5 million for estimated costs for unreported product claims related to services performed and products sold prior to June 30, 2003. The Company also engaged an independent actuarial firm to estimate the loss for product liability claims incurred and not reported during the 2003/2004 policy year. Based on the review of the actuarial analysis, the Company believes that its 2003/2004 insurance coverage is adequate to defend against claims incurred and reported during the 2003/2004 insurance year. Now, I'll turn it over to Clint Richardson for a summary of ongoing litigation.

Steve Anderson: Thanks Ashley. Clinton Richardson, the Company's legal counsel, will now comment on various legal and insurance matters.

ClintRichardson: As of August 1, 2003, approximately twenty-one personal injury lawsuits were opened. Of the twenty-one opened cases, two lawsuits were filed in the 2000/2001 insurance policy

year, four were filed in the 2001/2002 insurance policy year, fourteen were filed in the 2002/2003 insurance policy year, and one was filed in the 2003/2004 policy year. For the 2000/2001 and 2001/2002 insurance policy years, the Company maintained claims-made insurance policies which management believes to be adequate to defend against the suits filed during those periods. For the 2002/2003 insurance policy year, the Company maintains that claims made insurance policies with three carriers. Two of the three insurance companies who issue policies for the 2002/2003 year have confirmed coverage for the first two layers of coverage totaling \$15 million. However, most of this coverage has already been used to defend and settle lawsuits. A third insurance company covering the last \$10 million of the remaining insurance have indicated that it intends to exclude eleven matters under its policy. The Company is evaluating its alternatives in regards to resolving the issues with the third carrier. The Company filed a motion to dismiss the consolidated shareholders lawsuit which the U.S. District Court denied in part and granted in part. The discovery phase of the case commenced on July 16, 2003. The Company carries directors and officers liability insurance policies which the Company believes to be adequate to defend its action. As you know, two lawsuits against the individual officers and directors have been filed by shareholders derivatively on behalf of the Company. Last year, the Company's board of directors established an independent committee to investigate and report on the allegations made in those two lawsuits. The independent

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committee, which engaged independent experts and legal counsel to assist in its study, has now completed its extensive investigation and reported to the board of directors. The report concludes that no officer or director breached any fiduciary duty and recommends that the board of directors seek to have the lawsuits dismissed.

Steve Anderson:

The Company's total BioGlue revenues were 13.3 million for the first six months of 2003, up 32% over the first six months of last year. The majority of our international sales are BioGlue sales and international sales of BioGlue are up 35% year-to-year. BioGlue is approved in international markets for all vascular sealing and for the sealing of air leaks in lungs. It is also being increasingly used in Europe and Canada where it is approved for the sealing of dura mater in both spinal surgery and brain surgery. A number of papers have been accepted for publication on the various uses of BioGlue and the papers are positive. Particularly positive is a paper co-authored by Professor Andrew Kaye of Melbourne, Australia documenting the successful use of BioGlue on 216 patients in a clinical study on dura sealing. There was also a recent paper published of our six center IDE study of the use of BioGlue on 151 patients for the reduction of anastomotic bleeding an approved indication in the U.S. and internationally. The study concluded that BioGlue is a safe and effective adjunct to standard repair methods and reduces anastomotic site bleeding in cardiac and vascular repair patients.

Domestic BioGlue sales are up 31% year to year and we continue our development efforts for other forms of BioGlue and BioGlue products. The foam version of the product is currently being evaluated as a means of controlling endoleaks in endovascular adominal aortic grafts. We are also investigating the use of BioGlue in hernia repair, and this hernia repair application, IDE application, is scheduled to be submitted to the FDA in late 2004.

Our Japanese distributor has completed the clinical trial of BioGlue and the Japanese Ministry of Health continues to evaluate post-clinical studies and the follow-up of the

clinical trial. We don't know when BioGlue might be approved in Japan.

A number of papers have been published recently on the SynerGraft bovine ureter vascular graft for AV access that is approved in the European Union. We have now implanted about a hundred Model 100 vascular grafts in humans with promising results. We are planning to submit an IDE for the Model 100 vascular graft to the FDA in the second half of 2004.

Cardiovascular allograft tissues, both allograft valves and vascular grafts, continue their recovery from the effects of the August '02 recall. Excluding the \$92,000 adjustment to the recall reserve in the first quarter of 2003, second quarter revenues for cardiovascular allograft preservation are up 9% over the first quarter of '03, and 53% over the fourth quarter of '02.

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We are still discussing SynerGraft process allografts with the FDA. While they have not made their final decision it appears that we will have to file either a 510K or an IDE for the SynerGraft processed allograft heart valves. It appears to us right now that the SynerGraft processed allograft vascular grafts will be classified as banked human tissue. Both of these assumptions may prove to be incorrect, however.

Dr. Hawkins of Salt Lake City recently published a paper in the Journal of Thoracic and Cardiovascular Surgery that discussed his experience with 14 SynerGraft processed allografts, both heart valves and conduits, and compared the SynerGraft process allografts to a historical control group of twenty standard processed allografts. The results show at one year that patients with standard processed allografts had average PRA levels. Now, PRA stands for Panel Reactive Antibodies. They had an average PRA level of 73% while patients receiving SynerGraft process allograft had PRA levels of only 8%. The significance of this data is that it appears that SynerGraft processed allografts have a reduced antigenic response in comparison to standard processed allografts.

As you'll recollect we began shipping non-boned ligaments and tendons to a limited number of our accounts in late February and early March of '03. I'm pleased to announce that we notified our customers that we would begin shipping boned orthopedic tissue on August 1st. Although it is too soon to comment on our effectiveness in reentering the orthopedic allograft market, we remain optimistic. Our orthopedic technical and support management is in place and we have about 105 independent orthopedic technical representatives who will be contacting accounts in the near future.

We also continue to restaff the Company since last year's recall and subsequent 105 person layoff in September of '02. During the first half of '03 we have restaffed 30 positions throughout the Company. Many of whom were re-hires of people employed prior to the layoff. We expect this trend to continue for the foreseeable future. We now have a total of 305 people working at CyroLife both in the United States and in international markets.

Procurement of tissues remain strong and is continuing to increase month to month. In the fourth quarter of '02 we averaged 286 hearts per month and 214 vascular tissues per month. During that quarter we were not accepting any orthopedic tissues for processing.

During the second quarter of '03 we averaged 307 hearts per month, and in the second quarter of '03 we averaged 411

vascular grafts per month. Our orthopedic procurement during the second quarter averaged 201 tissues per month. At this time Ashley will give some guidance for the rest of the year.

Ashley Lee: We believe that we will be able to generate approximately 65 to 67 million in revenues during 2003. This is a revision from our previous forecast of approximately 70 million. The

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change is necessary due to delays in the resumption of shipping our four lines of orthopedic tissues, delays in getting SynerGraft processing issues resolved with the FDA, and yield issues. Gross margins, in large part, will be determined by allograft processing levels for the remainder of the year, future tissue yields, the number of shipments of tissues previously written off, and the percentage of revenues generated from the sale of BioGlue surgical adhesive. Currently, we are not able to project gross margins with a great degree of accuracy, although we expect that they will be less than the gross margin percentages posted at the first half of the year. Consistent with our previous guidance, we believe that SG&A expenses will be at the high end of the \$42 to \$46 million range that was communicated in previous conference calls, excluding the charges in the second quarter of 12.5 million related to product liability accruals. The ultimate level of G&A expenses is highly dependent upon the timing of the resolution of regulatory issues, legal issues and other items. That concludes my comments and I'll turn it back over to Steve.

Steve Anderson: At this time we'd like to open up the conference call for questions.

Conference call coordinator: Thank you, the floor is now open for questions. If you do have a question, please press 1 followed by 4 on your touch tone telephone at this time. If at any point your question has been answered you may remove yourself from the cube by pressing the pound key. Once again, that's 1 followed by 4 on your touch tone telephone at this time. Your first question is coming from Tom Gunderson of Piper Jaffrey, please state your question.

Tom Gunderson: Hi, good morning. Just a little bit more on the vascular sales and the changes in guidance. You did have some guidance for Q2 that fell a little short and it looks like it was mostly in vascular sales. Would you comment on that were there any assumptions on demand or procurement that proved to be wrong in Q2 or was there something else going on?

Ashley Lee: There were two issues, Tom, that lead to the short fall on vascular and the decrease compared to the first quarter of this year. First of all in the first quarter of this year we still had available a lot of prescription tissue. Those are tissues processed between October of '01 and August of '02 that were still available for us to ship and by and large we were depending upon those tissues to drive first quarter revenues. On the surface if you look at vascular procurement which increased 53% during the second quarter it would lead one to believe that the revenues would have increased sequentially. However, there were a couple of issues there. First of all, it takes us approximately sixty days to get tissues through our system so some of the increase that you saw on our vascular procurement will really help us in the third quarter of this year. The other issue which is just a little bit beyond - out of - our control at this time was the yield issue related to how much implantable tissue we are able to get out of the procurement. We expect that once we get these issues resolved with the FDA that the yields will increase on all of our tissues across the board so that



we will be able to hopefully meet the projections that we set forth for the remainder of the year.

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Tom Gunderson: Are you able to explain a little bit more about yield and FDA?

Ashley Lee: I will say that we are working on several things with the FDA right now a lot of which will probably affect yields going forward and I really don't want to comment in much detail about specifically what we're working on with the FDA.

Tom Gunderson: Okay. And then as a bridge to the FDA there's a lot of update here but there is also a lot of people that you've got there that might be able to answer. Is there any new news as far as the February '03 notice with the FDA?

Steve Anderson: I don't have any new news on that Tom. We have a meeting with FDA on those issues on August 7, and we continue to work our way through those issues. And, I would expect that some time in the fall we will be reinspected by them as regards the 483 from February but we never know when they're going to inspect us and they never tell us in advance. So, it - I can't be more definite than that.

Tom Gunderson: Okay. And just clarification - the meeting on 8/7 that's in Washington or Atlanta?

Steve Anderson: It's in Atlanta at the district office.

Tom Gunderson: Okay, and then the last question BioGlue guidance is basically just doubling the first half, is that a matter of being conservative or is there a certain supply/demand wall that we've hit for this year and it will go up again next year?

Ashley Lee: I think that the third quarter is typically very slow in Europe. And Europe accounts for up to 20% of our sales right now. But there are so many people on vacation. I think if you look at historically over the last year or two revenues have not increased much sequentially in the third over the second quarter because of that very issue. And then seasonally just with the holidays and everything coming up in the fourth quarter we hopefully are just being a little bit conservative. We don't really think its any reflection on any slow down in demand at all.

Tom Gunderson: Okay, good, thank you.

Conference call coordinator: Thank you. Your next question is coming from Bob Holacy of Black Rock Capital, please state your question.

Bob Holacy: Yes, thank you. I just have a couple of questions on the liabilities. Do you have any idea -- has it been indicated at all -- how many more lawsuits might be pending against the Company or soon to be filed?

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Clint Richardson: No. This is Clint Richardson, we don't have any particular information we can share about that. We try to be inclusive in our original comments.

Bob Holacy: The comments of one filed in '03 to '04 year. When does that year start? Is it in mid-year?

Ashley Lee: It started on April 1st.

Bob Holacy: April 1st. So there's been one filed since April 1st?

Ashley Lee: Yes. I will say that we have settled approximately five cases at this time and four have been dismissed. And of the five that we have settled it is our opinion that three of those five were some of the more serious cases that were facing the Company.

Bob Holacy: So if you've settled five cases and the insurance coverage so far has taken up about \$12.5 million dollars - are those the right numbers to use? As we think about kind of the magnitude.

Ashley Lee: That is correct.

Clint Richardson: Those numbers also include the cost of defense.

Bob Holacy: It does include the cost of defense.

Ashley Lee: Yes.

Bob Holacy: In one of the questions you mentioned sixty days to work through your process. You expect some of those vascular tissues that were procured in the second quarter and hopefully into the third quarter, do you normally see a seasonal slow down in tissue sales in the third quarter with vacations and stuff?

Ashley Lee: No. You actually see the opposite especially as it relates to cardiac tissues because a lot of the congenital surgery, pediatric surgery, is done during the summer months when kids are out of school. So you would typically expect to see cardiac revenues increase. We really don't see much seasonality as it relates to vascular tissues and orthopedic tissues.

Bob Holacy: And one final question, which is actually escaping me right now, I'll get back in queue if I think of it. Thanks.

Conference call coordinator: We have time left for one last question from Sung Yi of Jenny Montgomery Scott.

Sung Yi: Yes, on July 25th of this year, California's Court of Appeals court. Appeal Court favors ruling to you, and on page 12 of the Court's decision it mentioned about the possible National law may be concerned with that and my question to you is what kind of precedent can this ruling apply to the other jurisdictions?

Clint Richardson: I don't have that in front of me, but I think what you are referring to is the reference to an appellate court case in another jurisdiction other than California that cited a general, what that court found is a general statement of law around the country which is that the issue of strict liability would not apply to a service Company, instead service companies are measured against the standard of negligence, you know doctors are measured against a negligence standard called malpractice. So I think that's what you're referring to. With the statement of that court, that's a general rule throughout the country and that certainly, from our perspective is good news, it's not unexpected, but good news.

Sung Yi: Thank you.

Conference call coordinator: I'm sorry. We do not have any time left. I'd like to turn the floor back to the speakers.

Steve Anderson: Thank you very much for joining us and we will talk to you in about ninety days.

Conference call Coordinator: Thank you. This does conclude today's teleconference. You may disconnect your lines at this time and have a wonderful day.

