

TRANS1 INC

FORM 8-K

(Current report filing)

Filed 10/09/09 for the Period Ending 10/06/09

Address	411 LANDMARK DRIVE WILMINGTON, NC 28412-6303
Telephone	910-509-3100
CIK	0001230355
Symbol	TSON
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment & Supplies
Sector	Healthcare

**UNITED STATES
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): October 6, 2009

TRANS1 INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-33744
(Commission File Number)

33-0909022
(IRS Employer Identification No.)

**411 Landmark Drive
Wilmington, NC 28412-6303**
(Address of principal executive offices)
(Zip Code)

(910) 332-1700
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition.

On October 6, 2009, TranS1 Inc. (the "Company") issued a press release to report its preliminary revenue results for its third fiscal quarter ended September 30, 2009. The release is furnished herewith as Exhibit 99.1 and incorporated herein by this reference.

Also on October 6, 2009, following the issuance of the press release referred to above, the Company conducted a conference call to discuss its preliminary revenue results for its third fiscal quarter ended September 30, 2009. A copy of the transcript of the conference call is furnished herewith as Exhibit 99.2 and incorporated herein by this reference.

The information in this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, are being furnished pursuant to Item 2.02 and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits.**

<i>Exhibit Number</i>	<i>Description</i>
99.1	Press release, dated October 6, 2009.
99.2	Conference call transcript, dated October 6, 2009.

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 hereunto duly authorized.

TRANS1 INC.

October 9, 2009

By: /s/ Michael Luetkemeyer
Michael Luetkemeyer
Chief Financial Officer

EXHIBIT INDEX

<i>Exhibit Number</i>	<i>Description</i>
99.1	Press release, dated October 6, 2009.
99.2	Conference call transcript, dated October 6, 2009.

TranS1 Inc. Announces Preliminary Revenue Results for Third Quarter

WILMINGTON, N.C. — October 6, 2009 (GLOBE NEWSWIRE) — TranS1 Inc. (Nasdaq:TSON) a medical device company focused on designing, developing and marketing products that implement its proprietary minimally invasive surgical approach to treat degenerative disc disease and instability affecting the lower lumbar region of the spine, announced today that revenues for the third quarter of 2009 are expected to be approximately \$6.8 to \$6.9 million. While this represents growth of approximately 15% over the prior year period, the expected revenues are less than the Company's previously announced guidance of \$7.4 to \$7.9 million for the quarter.

"Our results this quarter were impacted by continuing concerns and uncertainty in the marketplace surrounding reimbursement for our AxiaLIF procedure, which we are addressing with increased education and support resources for our current and prospective surgeon users," said Rick Randall, President and CEO of TranS1. "While we are disappointed that our third quarter revenues are below previously issued guidance we remain confident in our products, clinical benefits and prospects for future growth as the market for minimally invasive spine surgery continues to expand."

The Company will provide more information when it releases its full third quarter results, which is expected to occur after the close of trading on October 29, 2009.

Conference Call

TranS1 will host a conference call to further discuss this announcement today at 4:30 pm ET. To listen to the conference call on your telephone, please dial 888-695-0608 for domestic callers and 719-325-2352 for international callers approximately ten minutes prior to the start time. The call will be concurrently webcast. To access the live audio broadcast, use the following link at <http://ir.trans1.com/eventdetail.cfm?eventid=73221>. To access the subsequent archived recording, visit the TranS1 web site at www.trans1.com under the investor relations section.

About TranS1 Inc.

TranS1 is a medical device company focused on designing, developing and marketing products that implement its proprietary minimally invasive surgical approach to treat degenerative disc disease and instability affecting the lower lumbar region of the spine. TranS1 currently markets two single-level fusion products, the AxiaLIF[®] and the AxiaLIF 360^o™, and a two-level fusion product, the AxiaLIF 2L™, in the US and Europe. TranS1 was founded in May 2000 and is headquartered in Wilmington, North Carolina. For more information, visit www.trans1.com.

Forward-Looking Statements

This press release includes forward-looking statements, the accuracy of which is necessarily subject to risks and uncertainties. These risks and uncertainties include, among other things, risks associated with the adoption of a new technology by spine surgeons, product development efforts, regulatory requirements, maintenance and prosecution of adequate intellectual property protection and other economic and competitive factors. These forward looking statements are based on the company's expectations as of the date of this press release and the company undertakes no obligation to update information provided in this press release. For a discussion of risks and uncertainties associated with TranS1's business, please review the company's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2008.

CONTACT:

Investors:

TranS1 Inc.

Michael Luetkemeyer, 910-332-1700

Chief Financial Officer

or

Westwicke Partners

Mark Klausner, 443-213-0501

mark.klausner@westwicke.com

Source: TranS1 Inc.

TRANS1, INC.
October 6, 2009
4:30 pm ET

Operator: Good day and welcome to the TranS1 Investor Conference call. Today's conference is being recorded.

At this time for opening remarks, I would like to turn the conference over to Mr. Mark Klausner. Please go ahead.

Mark Klausner: Thanks, operator. Joining us on today's call are TranS1's President and CEO, Rick Randall, and the company's Chief Financial Officer, Mike Luetkemeyer.

Before we begin, I would like to caution listeners that certain information discussed by management during this conference call will include forward-looking statements covered under the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995.

Actual results could differ materially from those stated or implied by our forward-looking statements due to risks and uncertainties associated with the company's business. The company undertakes no obligation to update information provided on this call. For a discussion of risks and uncertainties associated with TranS1's business, I encourage you to review the company's filings with the Securities and Exchange Commission including its annual report on Form 10-K for the year ended December 31, 2008.

With that, it's my pleasure to turn the call over to TranS1's President and CEO, Rick Randall.

Rick Randall: Thanks, Mark. This afternoon, we announced that we expect revenues for the third quarter of 2009 to be in the range of \$6.8 to 6.9 million. These revenues are below our previously issued guidance of \$7.4 to 7.9 million.

We remained disappointed by the continued impact that reimbursement uncertainty is having on our business and wanted to provide you with some additional insight into the shortfall. U.S. revenues of \$6.4 to 6.5 million and U.S. case volume of approximately 605 in the quarter declined compared to the second quarter of 2009. International revenue of approximately \$400,000 increased approximately \$160,000 from the second quarter of 2009. While the third quarter is always a seasonally slow quarter in the orthopedics and spine arena, our U.S. revenue continues to be negatively impacted by lower-than-expected case volume as a direct result of continued concerns and uncertainty in the market place surrounding AxiaLIF reimbursement.

As we mentioned in our last call, this change most greatly impacts our AxiaLIF 360 procedure where ours is the only procedure being performed. In cases where our procedure is being performed in conjunction with other techniques or in complex cases, we have seen a less-pronounced impact on volumes.

As we discussed after the end of the second quarter, the challenge in reimbursement for our procedure has centered around the CPT code that the physician uses to get paid for performing the AxiaLIF surgery. In 2008, most of our surgeons billed their payer based on an existing ALIF access code.

Beginning in January 2009, physicians transitioned billing for our procedure to a Category III tracking code. This change has increased the difficulty for physicians to get reimbursed for our procedure. In particular, many commercial payers view a Category III code as experimental and

thus will not pre-approve the procedure or will decline to pay for that code. This uncertainty around availability or amount of reimbursement has caused some physicians to revert to other fusion surgeries where reimbursement is more certain. We continue to be focused on both short and long-term strategies to address the uncertainty around reimbursement.

Our first line of defense is our sales force and reimbursement team who work with our surgeons addressing preauthorization denials or non-coverage decisions as they arise. We partner with our surgeons and help them work through payer's appeals process to try and secure coverage. These small victories are important as each positive coverage decision makes it easier to secure payment for the next case. However, they will not resolve the overall issue. In addition, we have proactively identified our most important local payers who have denied coverage and are attempting to educate them on our procedure and secure a positive coverage decision.

In these cases, we have sent the medical director at the payer a letter and binder that contains information about our procedure including our FDA clearance, our 8000 case experience, the strong body of clinical evidence that supports our procedure, and data on our procedure's very favorable safety profile. We then seek to schedule a meeting with the medical director in conjunction with our local surgeons to reinforce our belief that our procedure is not experimental and therefore should be reimbursed. We have made some progress in these discussions and our goal is to meet with our most important local payers over the next several months.

Longer term, we are working with the various societies including NASS, SRS, AAOS and AANS/CNS to garner their support for a Category I code for our procedure. Once we have the support of the societies, we will submit to the AMA for Category I code. As you know, this is a process that takes time and it is uncertain when we will apply for or receive a Category I code.

Separately, we have continued to see real success and increasing interest in utilizing our procedure in complex multilevel spine cases like scoliosis and adult deformity where any single CPT code has little impact on what the surgeon is actually paid for this complex procedure.

At the recent annual meeting of the Scoliosis Research Society or SRS which emphasizes education and research in the surgical treatment of scoliosis and deformity, our AxiaLIF procedure was highlighted in podium presentations and in a workshop as a means of providing anterior column stability for long complex fusion cases in the treatment of patients suffering from adult idiopathic scoliosis. We view recent adoption and rising interest among thought leaders in complex spine as encouraging incremental evidence of the company's unique approach and effective technology. However, complex spine has not been a focus of our sales or marketing efforts.

Based on the recent uptake in interest, we have educated our sales force on this unmet clinical need and directed them to increase their focus on the surgeons who perform these multilevel procedures. We remain convince that the key advantages for our procedure including a favorable safety profile, robust clinical results, reduced OR time, and faster recovery for patients will ultimately make this successful procedure in the market. We continue to believe that reimbursement is not insurmountable problem for the continued adoption of our procedure. However, it will take time to work through the reimbursement challenges that we currently face.

With that, I'd like to close my prepared remarks and answer questions that you may have. Thank for your time and continued interest in TranS1.

Operator, I'd like to open the line to any questions.

Operator: Thank you. Ladies and gentlemen, if you'd like to ask a question at this time, you may do so by pressing the star key followed by the digit 1 on your telephone keypad. If you are joining us by

a speakerphone, please ensure your mute function is off to allow your signal to reach our equipment. And again, that is star 1 for questions at this time and we'll pause for a moment.

And we'll take a question from Matt Miksic with Piper Jaffray.

Matt Miksic: Hi, Rick. Thanks for taking the questions.

Rick Randall: Hi, Matt.

Matt Miksic: So, I guess the one question I wanted to ask just around this process that you're going through, you described — you described some aspects of it. Is there anything that you can tell us as it pertains to whether it's the number of doctors or the number of payers or sort of you know, as you go through this process of educating payers and sort of how far along you think you are into this? I mean, is it — how many doctors you know you've either been able to convert back on or you know, how many you think that you know you've lost or any metrics you could give us that would help us understand where you are and maybe how far out you are from being able to turn the corner and advance to getting a Category I code?

Rick Randall: Yes, Matt. I don't have any particular metrics but I do feel that we have stabilized in terms of the number of surgeons who — and cases that are affected by this.

Now, what did happen this last quarter was, you know, just as we worked with surgeons to educate them as we talked before — educate them on proper preauthorization and proper coding of the procedure, and we stabilized some of these surgeons, then we had other cases denied or other insurance companies take a position on the Category III code that they had not yet taken a position. So, I equate this to kind of a series of grass fires that have occurred and we — you know, as we're dealing in putting out a fire and stabilize, then we find another.

Now, I do feel as we move to the summer months, my sense is that that has stabilized and we have been working our way through the appeal process and as we work our way through the appeal process, we've actually been able to get some of these surgeons with successful appeals to start putting cases back on and because they know they're going to get paid. Actually in some cases due to a kind of an unusual idiosyncrasy with Category III codes, they're getting paid at a higher level than they were getting paid even before with the ALIF code.

And I think more importantly, Matt, as you know a lot of this process is also the education through our — or the execution through our sales force that like any other product as you get comfortable in having these discussions with the coders and the surgeons and you have successes, you become more bullish that you can work through this and you will get paid.

So, as we have these successes, I see our sales force not universally but as we work in pockets and gain more successes, our sales force is getting more comfortable at addressing this head on and working with our surgeons especially in cases where really the only option or based on their own — their current experience with this operation, the clear best option for the patient is an AxiaLIF, they're more willing to work through the appeal process on those patients. So, what's important at the local level is the stabilization, working with the surgeons to appeal the cases, gain confidence in the sales force and their surgeon base that they will and can get paid as we appeal and then obviously moving to the higher ground where we deal directly with the medical directors.

Matt Miksic: OK. So, when you said stabilized, is it — you know, can you say that you're not losing any further docs at this point? The docs aren't taking cases off? Or as you say with these grass fires, are you still finding additional docs that are — you know, that are sort of backing off and need to be — you know, need to be helped back on?

Rick Randall: I wouldn't say at this point that we're not losing docs that you know, there may be a doc who's really not been affected by this. As I mentioned on the last call, we still have areas in the country where when you speak to our representative or regional managers, they're just not seeing much of this at all and so that could pop up and cause a particular problem with a surgeon who did not have a problem in the past. So, I wouldn't say we're not losing docs but I think where the issues is is not as pronounced as we saw it as we worked through the second and third quarter, and we're starting to get some of these surgeons back in doing more cases as they are comfortable that there are payers who do pay, it's not a universal issue, and that they're willing based on prior experience to appeal more cases because the appeal process works and with every appeal, the process gets a little bit faster.

Matt Miksic: When you said so looking forward and I jumped on just I think after you'd started your prepared remarks but if you're still — sounds like you're still kind of playing defense here. You're still chasing down new incidents of doctors having a problem and taking cases off. Maybe the question is, you know, when do you feel like you're going to be able to stop playing defense and you know if this is a level that you're at, you know, when do you start actually — is this the level that you remain at or does it — do we take a step down from here in terms of sort of revenues and caseload and when do you think you start turning the corner to start growing again sequentially?

Rick Randall: Well, I think we'll — when we get to the quarterly call in a few weeks, I think we'll be able to fill in more details there but I believe that I think it's a good — it's the right question. It's the key question.

Playing defense is really the ground war that's going on every day in the market place, with the coders, with our surgeon customers, with new surgeon customers, and our sales force. When I will feel most comfortable that we get back on a trajectory we were on early in the year is when we start having — it's kind of the air war when we start having some of these victories at the larger medical director level.

Case in point, this last quarter we had two — we had two medical director's reviews where TranS1 personnel with surgeon users visited with the medical director in North Carolina and another in Arizona. The Arizona case is fresh and still pending. We're waiting a decision. But in the case of the North Carolina medical director, they went from a basic Category III we-do-not-pay position to a position where now what they're doing is they're reviewing every AxiaLIF case based on medical necessity.

Now, that's a common review process for fusion cases. So, we need to do more of that and I mentioned earlier in the call that the letters and binders have gone out to the medical directors. We also learned from those two experiences that really kind of, I'd say, the positive side of having these discussions is that the medical directors get direct evidence of the financial implication of this minimally invasive approach. When they see that we have a demonstrated 1% complication rate over 8000 patients treated with no permanent complications, that's or more — or just as importantly things like deep wound infections which every medical director or every employee at an insurance company understands, that's where the real costs lie in when these patients have complications that require second surgeries or longer-term care and they don't get back to work, that's a very expensive process.

What we saw in these meetings was that caught their attention, I think helped us at least in the case of North Carolina move to the position we're now in.

We're now working with two separate consulting firms that are focused on and their expertise is access to the medical directors and helping us put together meaningful meetings where we can deliver that type of information and work with them on an overall cost basis in gaining if not a full coverage decision, at least the ability to have these reviewed without a denial just based on Category III status. So, as we move over the next few weeks and months, we hope to have more of these meetings and that process has started.

Matt Miksic: And just two quick ones and I'll hop off here. This is helpful color. Again, on this idea of sort of playing offense and defense, I think it — given that the folks in the field have their hands full with this reimbursement issue, are they able to spend any time at this point moving the ball sort of down the field in terms of new docs or new opportunities, and maybe within the areas we have been able to make some headway on coverage or do you feel like you're — are they, you know, 100% preoccupied with just playing defense?

Rick Randall: No, I don't think they're 100% preoccupied with just playing defense. I did — I was concerned, I'd say, at the end of last quarter early in the third quarter with the number of new surgeons coming on board — I don't have a finite number here but we did see — I saw less first cases but over the last month to 2 months, I'm starting to see more new surgeons who've never performed AxiaLIF. They seem to be coming on at a higher rate now. So, I think — I think that the sales force has responded. You know, they've kind of gotten over their shock of having to learn how to dialogue reimbursement and now that's just part of what they do every day but they still have time to talk to new surgeons and bring new surgeons on board.

So, again, as the sales force gains more confidence, not only does this apply to the existing customers that we have and getting their cases back but it applies equally to going back to the basics of selling new customers on this approach and getting them engaged in this treatment.

Matt Miksic: And finally, just — you'd mentioned last quarter that you were sort of tightening down on some of the spending given that this was going to be — this was going to sort of be an extended process to educate the payer community on the procedure, we'd love to hear, you know, where your confidence is here, you know, that this is something that you'll be able to weather, you know, with the cash on the balance sheet and you know, won't put you in a position, you know, where you're sort of running out of gas or in the market place.

Rick Randall: Yes, Matt. I'll let — I've got Mike Luetkemeyer here. I'll let him take that question.

Mike Luetkemeyer: Matt, we are looking very closely at all of our expenditures. I wouldn't characterize that as we're in the process of absolutely cutting expenditures but what we are doing is looking very carefully at any growth in expenditures. We ended this quarter with a little more than 61 — call it close to 61 and a half million in cash. We burned just over 5 million in cash. So, you know, we've got at the current burn rate about 12 quarters of cash in the bank, and Rick Randall and I are committed to manage that resource very carefully and to have that resource see us through this.

Rick Randall: Matt, I would just..

Matt Miksic: OK. Well, thanks for taking the — oh, go ahead, Rick.

Rick Randall: Matt, I would just add to that that when we embarked on 2009, we were managing this company largely from the perspective that the value creation is going to be driven through, you know, revenue growth. Obviously, we still believe that but right now given the reimbursement issues at hand and the things we have underway to deal with that and get it back on that ramp.

We've modified that position. We're pulling this in as a business, a business that we want to bring profitable and we're looking at managing this business to profitability and making sure that cash gets us there. So, we may see some of the nice things to invest in to drive revenue growth. We're pulling back on those things and looking more at the fundamentals to obviously continue revenue growth but to make sure we're doing it in a sensible fashion that is matched up against the challenges we now have, you know, that we're facing. Obviously, as we work our way through this, we'll continue to open up the first strings when we feel this is no longer a major issue.

Matt Miksic: Thanks, Rick and good luck.

Rick Randall: OK. Thank you.

Operator: And once again, ladies and gentlemen, that is star 1 for questions at this time. We'll take a question from Michael Matson.

Michael Matson: Hi, thanks for taking my question. I guess first of all, just — with regards to getting the Category I code, it seemed like when you originally kind of had the issues with the — or pushed away from using the ALIF code, you seemed to be a bit more confident around the timing and the ability to get that in 2010 and it sounds like there's this amount of uncertainty now. So, I was just wondering what really changed and why is it going to be so much more difficult to get the Category I code than you previously thought?

Rick Randall: Well, Michael, as you know, we are I think uniquely faced with the fact that the spine arena from a coding standpoint is managed by three different societies. You have the NASS coding committee as well as the joint sections or the neurosurgery groups and the orthopedic group, the AAOS. We feel given kind of the political nature of all of this and the multiple entities that we want to do this the right way and we think doing it the right way is having all of these societies endorsing our movement toward a Category I code.

Our caution is basically tied to the reality that we're now working with all three of these groups reaching out through our customers with all three of these groups to aim toward a unified notion that they are going to support this.

The last thing we want to do is go to an AMA meeting and have the support of one or two of those groups and then not have the support or not have ready the other groups. So, we're working through that now. It's a little more difficult because it is three different coding groups and three

different kind of specialties or groups of surgeons but we're doing it as fast as we can with the goal of doing it in a unified fashion.

Michael Matson: OK. And just from a timing standpoint, is it accurate? Do you really just have sort of once-a-year opportunity there and that if you're not able to — I mean, not so much in terms of getting these societies on board but in terms of actually going in front of the AMA, getting the Category I, is that just like an early-in-the-year type of thing and if you missed it in 2010 then it's — do you kind of have to write it off until early 2011?

Rick Randall: My understanding is they meet a couple of times a year and you've got a couple of shots at this process but it's still going to take time because they have to vote on it then they need to rocket all of that business. So, it could take up to a year or more to get it done that's why we still believe given the nature of — what's interesting, Michael, is that since we've had the Category III code, we've had quite a bit of success with our Medicare patients in getting paid.

So again, the real issue is that, you know, how the Category III code is viewed by the private payers. So, I still feel the most important and most manageable process for this company to undertake is the process through which we approach these medical directors on this single code and manage that process so we can get some kind of a coverage decision or even an agreement to review it on medical necessity and we're pretty much back where we were as we entered the year.

Michael Matson: OK. And then just to update on the sales force, I mean, given the coding challenges, is that leading to additional disruption there, frustration, turnover, things like that? Maybe just give us the number if you're OK with that of where you're at with your direct sales force right now?

Rick Randall: Sure. Since the last call, we've only lost really a couple of reps and they were basically managed — that was turnover managed by the company. They were not folks who left us due to any frustration.

Now, obviously, we're very concerned about that and we're watching it very closely and you know, we're trying to make sure that the incentives are aligned with the business condition that we have today in stabilizing and growing the business but so far, we haven't really had much turnover due to this issue but obviously, you know, we're sensitive to it. We recognize what could happen and we're trying to stay on top of it and do the right things.

Michael Matson: OK. And then, I mean, I understand the reimbursement issues and everything but I guess, how do we — how do we get comfortable that there isn't something more going on here, I guess that there's not some, you know, physicians out there kind of having problems with the procedure, be it because they're maybe not doing it the right way or following your recommendations but you know, in terms of biologic use or what have you or you know, not necessarily that it's something wrong with the procedure per se but I mean, I guess, how do we know that there's not just more going on here?

Rick Randall: Well, it's a good question. I don't know how to make you feel there's not more going on. I mean we know like with any spine procedure, any fusion procedure that if surgeons don't perform the technique exactly the way it should be performed or the way it should be performed, then you could get lesser results. We continue to build a growing database of clinical results with this procedure. I know of a paper now that's being put together multi-center well over 100 to 150 patients with 2-year data that underlines the clinical results one should get.

So I don't think — I think if we felt we're losing a lot of cases due to that reason, we would mention it, and there's always surgeons — there always have been surgeons that would prefer a faster rate of fusion or maybe they don't see their fusion results that some of our other surgeons are able to

achieve. We feel that most of that is attributable if that happens, the technique, which is why we go so far as to really you know working with our reps to properly manage those cases and we continue to iterate the devices to even allow you know less than stellar technique to achieve great results but I don't know any other way to assure you that that's — that there's something else going on here but I would never say that every surgeon is getting you know fantastic results. That's just not the case with I think any type of procedure, especially minimally invasive procedures.

Michael Matson: OK. All right, that's all I have. I appreciate it. Thank you.

Rick Randall: Thank you.

Operator: And as a final reminder, ladies and gentlemen, that is star 1 for questions at this time. We'll pause for a moment.

Rick Randall: Well, with no further questions, I thank everyone again for joining us on this call and look forward to giving you a further update later on in the month at the planned quarterly call. Thank you and have a good afternoon.

Operator: And that does conclude today's presentation. Thank you for your attendance. Have a nice day.

END